PHILIPS

ST80i Stress Test System

Release A.03

English

Instructions for Use

ST80i Stress Test System

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Release A.03

Revision H
April 2024

Notice

PN 453564396631

April 2024, Revision H, applies to software version A.03.04 and higher.

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Proprietary Notice

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Authorized EU Representative
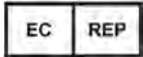
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Germany

Australia Sponsor

Philips Electronics Australia Ltd.
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Australia

Warranty

Be advised that the product warranty could be voided by:

– service performed by an unauthorized service provider;

– use of the device outside of its intended purpose;

– any unauthorized device modifications;

– use non-Philips accessories or consumables.

For specific warranty details, contact your Philips representative or Response Center.

Responsibility of Manufacturer

Philips only considers itself responsible for any effects on safety, reliability and performance of the product if:

- assembly operations, extensions, readjustments, modifications or repairs are done by persons authorized by Philips, and
- the electrical installation of the relevant room or vehicle complies with the IEC or national requirements, and
- the instrument is used according to the instructions for use presented in this manual.

Responsibility of Customer

The user of this product is responsible for ensuring the implementation of a satisfactory maintenance schedule. Failure to do so may cause undue failure and possible health hazards.

Instructions for Use

This Philips product is intended to be operated only in accordance with the safety procedures and operating instructions provided in this *Instructions for Use*, and in accordance with the purposes for which it was designed. Installation, use, and operation of this product is subject to the laws in effect in the jurisdiction(s) in which the product is being used.

Users must only install, use, and operate this product in such a manner that does not conflict with applicable laws or regulations that have the force of law.

Use of this product for purposes other than the express intended purpose provided by the manufacturer, or incorrect use and operation, may relieve the manufacturer (or agent) from all or some responsibility for resultant non-compliance, damage, or injury.

Training

Users of this product must receive adequate clinical training on its safe and effective use before attempting to operate the product as described in this *Instructions for Use*.

Training requirements vary by country. Users must ensure that they receive adequate clinical training in accordance with local laws or regulations.

For further information on available training on the use of this product, please contact a Philips representative.

Trademarks

Product and company names mentioned herein may be the trademarks or registered trademarks of their respective owners.

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ST80i Stress Test System Instructions for Use

Safety Summary

This chapter provides important safety information related to the use of the ST80i Stress Test System.

Conventions Used in the Instructions for Use

The following conventions are used in the *ST80i Stress Test System Instructions for Use*:.

Typeface	Usage	Example
Bold	User interface items and system keys	Click **Settings**. Press **CTRL+F**.
Italic	Variables and document titles	• *<product name>-<hardware configuration>-<software version>*.cfg • *ST80i Stress Test System Instructions for Use*
URL	Website URLs	www.healthcare.philips.com

WARNING

Warning statements describe conditions or actions that may result in personal injury or loss of life.

Caution

Caution statements describe conditions or actions that may result in damage to equipment or software.

Note:

Notes contain additional important information about a topic.

Medical Device Directive

The ST80i Stress Test System complies with the requirements of Medical Device Directive 93/42/EEC and carries the following mark accordingly:

CE 0123

Global Medical Device Nomenclature (GMDN)
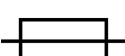
The 5-digit GMDN code adjacent to the symbol is defined in the EN ISO 15225 standard.
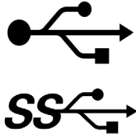
| GMDN | 16231 |

REACH

The EU REACH Regulation 1907/2006 requires Philips to provide chemical content information for Substances of Very High Concern (SVHC), if they are present in the relevant article above a concentration of 0.1% weight by weight. Information on substances contained in the Philips products can be found on the Philips REACH website (www.philips.com/REACH).

Symbols Marked on the ST80i Device ID Label and System

Symbol	Description	Standard/Reference
	Follow the *Instructions for Use* and other product documentation for information.	ISO 7010¥ M002
	Consult electronic instructions for use at www.philips.com/eIFU	ISO 15223-1* 5.4.3
	Attention. Consult accompanying documents.	ISO 15223-1* 5.4.4
	ECG physio isolation is type CF, defibrillator proof. Suitable for all patient applications including direct cardiac application. System is in continuous operation.	IEC 60417+ 5336
	Indicates that the equipment is suitable for AC current only.	IEC 60417+ 5032
	Fuse	IEC 60417+ 5016
	The connector near this symbol receives an incoming signal.	NA

* ISO 15223-1 Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements

+ IEC 60417 Graphical symbols for use on equipment

¥ ISO 7010 Graphical symbols – Safety colours and safety signs – Registered safety signs
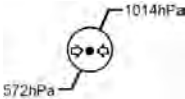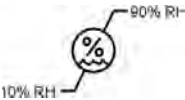
Symbol	Description	Standard/Reference
	USB2 or USB3 connector or port.	NA
IPX0	Indicates an International Protection Rating of IPX0. The equipment has no special protection against moisture ingress. The ST80i System carries this rating.	IEC 60529, Ed. 2.2 Degrees of protection provided by enclosures (IP Code), section 6
	Interference may occur in the vicinity of equipment marked with this symbol.	IEC 60417[†] 5140
	Dispose of in accordance with the requirements of your country.	Waste Electrical and Electronic Equipment directive 2012/19/EU, Article 14.4
GMDN 16231	Global Medical Device Nomenclature (GMDN). A five-digit code that is used to create a single general naming system for medical devices.	ISO 15225
CE 0123	CE marking accompanied by the Notified Body number 0123.	European Medical Device Directive 93/42/EEC
SGS 710412	The product has been certified by SGS (Société Générale de Surveillance)	Société Générale de Surveillance
	Identifies the date and country of manufacture.	ISO 15223-1* 5.1.3
	Packaging unit, To indicate the number of pieces in the package.	ISO 7000* 2794
UDI	Universal Device Identification information	ISO 15223-1* 5.7.10
MD	Indicates that the product is classified as a Medical Device.	ISO 15223-1* 5.7.7

* ISO 15223-1 Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements

† IEC 60417 Graphical symbols for use on equipment

¥ ISO 7010 Graphical symbols – Safety colours and safety signs – Registered safety signs

Symbol	Description	Standard/Reference
SN	The number next to this symbol is the serial number of the device.	ISO 15223-1* 5.1.7
REF	The number next to this symbol is the catalogue number of the device.	ISO 15223-1* 5.1.6
T	The number next to this symbol is the token number of the device.	NA – Philips symbol
Rx Only	CAUTION: In the U.S., Federal law restricts this device to sale on or by the order of a physician.	21 CFR 801.109

* ISO 15223-1 Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements

† IEC 60417 Graphical symbols for use on equipment

¥ ISO 7010 Graphical symbols – Safety colours and safety signs – Registered safety signs

Symbols Marked on the ST80i System Packaging
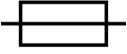
Symbol	Description	Standard/Reference
	Keep dry.	ISO 15223-1* 5.3.4
	Keep upright.	International Air Transport Association, 405B
	Fragile	ISO 15223-1* 5.3.1
	Ambient temperature range of –20 °C (–4° F) to 50 °C (122° F) (non-condensing) for transport and storage.	ISO 15223-1* 5.3.5

* ISO 15223-1 Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements

¥ ISO 7000 Graphical symbols for use on equipment – Registered symbols

Symbol	Description	Standard/Reference
CE	Product meets the requirements of European Medical Device Directive (EU) 2017/745 **Note:** *Refers to lead set.*	European Medical Device Directive (EU) 2017/745
	Battery complies with Taiwan National Communication Commission requirements (accompanied by certification number)	DGT LP00002 Low-power Radio-frequency Devices Technical Specifications
1014hPa / 572hPa	Atmospheric pressure range of 0 to 4572 meters (15,000 feet), 572 hPA above sea level for transport and storage.	ISO 15223-1* 5.3.9
90% RH / 10% RH	Relative humidity range of 10% to 90% (non-condensing) for transport and storage.	ISO 15223-1* 5.3.8
CFB	Recycle as corrugated fiberboard.	GB 18455-2001 National Standard of the People's Republic of China – Packaging recycle mark
* ISO 15223-1 Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements ¥ ISO 7000 Graphical symbols for use on equipment – Registered symbols		

Symbols Marked on the ST80i Thermal Printer

Symbol	Description	Standard/Reference
	Follow the Instructions for Use and other product documentation for information. For information about the Advanced Interface Module, see "Important Notes about the Advanced Interface Module" on page xxx.	ISO 7010¥ M002
	Consult electronic instructions for use at www.philips.com/eIFU	ISO 15223-1* 5.4.3
	Identifies the name and address of the manufacturer.	ISO 15223-1* 5.1.1
† IEC 60417 Graphical symbols for use on equipment ¥ ISO 7010 Graphical symbols – Safety colours and safety signs – Registered safety signs		

Symbol	Description	Standard/Reference
	Fuse	IEC 60417[†] 5016
	USB2 or USB3 connector or port.	NA
	Dispose of in accordance with the requirements of your country.	Waste Electrical and Electronic Equipment directive 2012/19/EU, Article 14.4
CE 0123	CE marking accompanied by the Notified Body number 0123.	European Medical Device Directive 93/42/EEC
SGS 710412	The product has been certified by SGS (Société Générale de Surveillance)	Société Générale de Surveillance

[†] IEC 60417 Graphical symbols for use on equipment

¥ ISO 7010 Graphical symbols – Safety colours and safety signs – Registered safety signs

Symbols Marked on the ST80i PIM and AIM
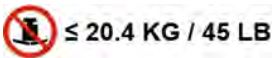
Symbol	Description	Standard/Reference
	Follow the Instructions for Use and other product documentation for information. For information about the Advanced Interface Module, see "Important Notes about the Advanced Interface Module" on page xxx.	ISO 7010[¥] M002
CE 0123	Product meets the requirements of 93/42/EEC for Medical Devices distributed in the European Economic Area (EEA).	European Medical Device Directive 93/42/EEC
	Consult electronic instructions for use at www.philips.com/eIFU	ISO 15223-1* 5.4.3
	Identifies the name and address of the manufacturer.	ISO 15223-1* 5.1.1

* ISO 15223-1 Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements

[†] IEC 60417 Graphical symbols for use on equipment

¥ ISO 7010 Graphical symbols – Safety colours and safety signs – Registered safety signs

Symbol	Description	Standard/Reference
MD	Indicates that the product is classified as a Medical Device.	ISO 15223-1* 5.7.7
R_X **Only**	CAUTION: In the U.S., Federal law restricts this device to sale on or by the order of a physician. **Note:** *PIM only.*	21 CFR 801.109
	Indicates conformity with South Korean EMC regulations	KRRA Radio Waves Act, Article 58-2
	Battery complies with Taiwan National Communication Commission requirements	DGT LP00002 Low-power Radio-frequency Devices Technical Specifications
	Dispose of in accordance with the requirements of your country.	Waste Electrical and Electronic Equipment directive 2012/19/EU, Article 14.4
	Indicates compliance with electrical safety, EMC, EME and telecommunications requirements.	Australian Communications and Media Authority AS/NZS 4417
SGS 710412	The product has been certified by SGS (Société Générale de Surveillance)	Société Générale de Surveillance
	ECG physio isolation is type CF, defibrillator proof. Suitable for all patient applications including direct cardiac application. System is in continuous operation. **Note:** *PIM only.*	IEC 60417[†] 5336
IPX4	Indicates an International Protection Rating of IPX4. The equipment is protected against splashing water from any angle. **Note:** *PIM only.*	IEC 60529, Ed. 2.2 Degrees of protection provided by enclosures (IP Code), section 6
+ 1.5V AA	Indicates that the ST80i PIM requires a single AA battery, inserted in the orientation shown. **Note:** *PIM only.*	NA

* ISO 15223-1 Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements

[†] IEC 60417 Graphical symbols for use on equipment

¥ ISO 7010 Graphical symbols – Safety colours and safety signs – Registered safety signs

Symbol	Description	Standard/Reference
☀	Power and status indicator button. Press this button to illuminate lights for all leads (green = connected; amber = not connected) as well as the lights reflecting the wireless signal strength and battery strength. **Note:** *PIM only.*	IEC 60417[†] 5012
⊤	Wireless signal strength indicator. One to four lights illuminate, depending on wireless signal strength. **Note:** *PIM only.*	IEC 60417[†] 6330B-4
▭	Battery strength indicator. Every five seconds, one to four lights blink, depending on battery strength. Low battery strength is indicated by continuous illumination of only one light. **Note:** *PIM only.*	IEC 60417[†] 5001B

* ISO 15223-1 Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements

[†] IEC 60417 Graphical symbols for use on equipment

¥ ISO 7010 Graphical symbols – Safety colours and safety signs – Registered safety signs

Symbols Marked on the ST80i Trolley

Symbol	Description	Standard/ Reference
≤ 3.6 KG / 8 LB	Do not place more than 3.6 kg (8 lb) of weight on the wire hook.	ISO 7010, P012*
≤ 1.0 KG / 2.2 LB	Do not place more than 1 kg (2.2 lb) on the paper tray.	ISO 7010, P012*
≤ 20.4 KG / 45 LB	Do not place more than 20.4 kg (45 lb) on the laser printer shelf.	ISO 7010, P012*
≤ 4.5 KG / 10 LB	Do not place more than 4.5 kg (10 lb) into the wire basket.	IISO 7010, P012*

* ISO 7010:2011 Graphical symbols – Safety colours and safety signs – Registered safety signs

Disposal Information

This product consists of devices that may contain mercury, which must be recycled or disposed of in accordance with local, state, or federal laws. (Within this system the backlight lamps in the monitor display may contain mercury.)

Remove all batteries prior to disposing of any system components. Properly dispose of or recycle depleted batteries according to local regulations. Then dispose of the device in accordance with local, state, or federal regulations for equipment containing electronic parts.

Important Patient and Safety Information

Patient and safety information is divided into several sections:

- ST80i Stress Test System (next section)
- Medical isolation transformer (page xxviii)
- Philips Advanced Interface Module (AIM) (page xxix)
- Philips wireless Patient Interface Module (PIM) (page xxxii)

For information about electromagnetic compatibility (EMC) with surrounding devices, see "Electromagnetic Compatibility (EMC)" on page E-9 of Appendix E, "Specifications and Requirements".

Compliance

The ST80i Stress Test System complies with all relevant international and national standards and laws. Information on compliance will be supplied on request by a local Philips representative, or by the manufacturer.

The Philips ST80i Stress Test System, when operated with the ST80i AIM, AIM data cable, ST80i PIM, and lead wires, meets all of the requirements specified in the following standards:

- IEC 60601-1:2005+A1:2012+A2:2020 Medical Electrical Equipment-Part 1: General Requirements for basic safety and essential performance
- IEC 60601-2-25: 2011 Medical electrical equipment - Part 2: Particular requirements for the safety of electrocardiographs
- AAMI EC53: 2020 — ECG cables and lead wires

When using the Philips-supplied PC, the ST80i Stress Test System also meets the requirements specified in IEC 60601-1-2:2014+A1:2020 and IEC 60601-1-2: 2020.

The ST80i Stress Test System also meets the following radio requirements:

- EN 300 328 V.2.2.2
- EN 301 489-1 V2.2.3 /EN 301 489-17 V3.2.4
- EN 62311:2020

EU Declaration of Conformity

Philips declares that the ST80i Stress Test System is in compliance with Directive 2014/53/EU. The full text of the EU declaration of conformity is available at the following internet address: https://www.incenter.medical.philips.com

Packaging

Caution

In the event that any of the following has occurred, do not attempt to use the ST80i Stress Test System:

- The packaging is damaged, or

- The packaging has been unintentionally opened before use, or

- The packaging has been exposed to environmental conditions outside the specified parameters (see page xxvi).

If any of these conditions has occurred, please contact your Philips Response Center for assistance.

Safety Information for the ST80i Stress Test System

Warning Statements for the ST80i System

WARNING

Failure to follow these warnings could affect both patient and operator safety.

- As with all electronic equipment, Radio Frequency (RF) interference between the ST80i Stress Test System system and any existing RF transmitting or receiving equipment at the installation site, including electrosurgical equipment, should be evaluated carefully and any limitations noted before the equipment is placed in service.

- Radio frequency generation from electrosurgical equipment and close proximity transmitters may seriously degrade performance.

- Philips assumes no liability for failure resulting from RF interference between Philips medical electronics and any radio frequency generating equipment at levels exceeding those established by applicable standards.

- Do not use the ST80i System in the presence of flammable anesthetics or flammable mixtures of air, oxygen, or nitrous oxide.

- Do not use the ST80i System in Magnetic Resonance Imaging (MRI) applications.

- Do not use the ST80i System in the presence of explosive gases. AC power connection/disconnection or electrostatic discharge (ESD) may result in a spark occurring in an environment where explosive gases are used.

- Submersion and/or conditions that subject the ST80i System to liquid ingress create a shock hazard.

- When operating the ST80i System, ensure that the system and all other electrical equipment connected to or near the patient are effectively grounded.

- To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.

- Do not touch accessible connector pins and the patient simultaneously.

- To maintain designed operator and patient safety when assembling a medical electrical system for use in the patient environment, the responsible organization shall ensure that peripheral equipment and accessories used that can come in direct patient contact must comply with IEC 60601-1 Medical Electrical Equipment-Part 1: General Requirements for basic safety and essential performance.

- Connecting multiple medical electrical instruments to the same patient may pose a safety hazard due to the summation of leakage currents. Any combination of medical electrical instruments should be evaluated by local safety personnel before being put into service. For equipment not certified to medical electrical equipment standards that may be used within the patient vicinity, an appropriately rated isolation transformer is required.

- Do not connect to the system any items that are not specified as part of the system.

- The All-in-One PC, thermal printer, and desk light (powered by AC), purchased as part of a complete system, must be plugged into the medical-grade isolation transformer provided with the ST80i trolley.

- Plug all accessories used with ST80i into the medical-grade isolation transformer provided as part of the trolley or as supplied by the customer.

- Do not connect additional Multiple Port Socket Outlets (MPSOs) or extension cords to the system. Use only the provided isolation transformer outlets.

- The ST80i RS-232 ports should be connected only to treadmills, ergometers, and NIBP monitors that are certified to meet IEC 60601-1 and are listed as supported devices in the Instructions for Use. See "Supported Treadmills and Ergometers" on page E-8 of Appendix E, "Specifications and Requirements". Use of USB cables for these devices is not recommended and may result in abnormal operation of ST80i due to electromagnetic noise interference.

- The performance and safety of the ST80i System cannot be guaranteed if you use non-compatible accessories.

- Only computers, monitors, and printers approved by a National Certification Body (NCB) or a Nationally Recognized Testing Laboratory (NRTL) to IEC 62368-1 shall be connected to the ST80i system. All computer, monitor, and printer outputs shall comply with IEC 62368-1 limited power source requirements. The PC used with the ST80i system must comply with IEC/UL 62368-1 Safety Standard for IT Equipment. Customers are responsible for ensuring their final system configuration and integration meets their local safety and EMC compliance regulations as well as meeting AAMI ES 60601-1, IEC 60601-1 and IEC 60601-2-25.

- The use of ST80i with equipment (electrosurgical equipment and some respiration transducers) that applies high frequency voltage to a patient is not supported and may produce undesired outputs.

- To prevent burns to the patient, remove all ECG electrodes and lead wires prior to the use of high frequency surgical equipment (including electrosurgical equipment and some respiration transducers).

- The installation or use of software, security patches, or updates not approved by Philips for use with the ST80i System is strictly prohibited and is likely to affect system safety and performance.

- Use only the specified Philips-approved lead wires with defibrillator protection resistors. See "Optional Parts and Accessories" on page D-1 for a list of approved lead wire sets.

- To avoid the possibility of serious injury or death during patient defibrillation, do not come into contact with the wireless PIM or lead wires. Additionally, proper placement of defibrillator paddles in relation to the electrodes is required to minimize harm to the patient.

- Do not contact floating electrodes during defibrillation, and avoid touching the lead wires or conductive surfaces on the trolley during defibrillation.

- Conductive parts of the patient lead wires, electrodes, and associated Type CF connections should not come into contact with other conductive parts, including earth ground.

- Electrodes of dissimilar metals should not be used.

- Check lead wires, the cable between the PC and the treadmill, the cable between the PC and the NIBP module, the AC adapter, and power cords daily for any worn or cracked insulation to ensure that no inner conductive material is exposed. Discard worn accessories and replace them only with Philips accessories.

- The following cables should be restricted to less than 3 meters in length:
  - USB AIM cable
  - BNC Sync AIM cable
  - USB printer cable
  - USB PC cable (to serial adapter)
  - RS-232 Tango® NIBP device serial cable

- The ST80i System should only use grounded power cords (three-wire power cords with grounded plugs) and connect to grounded electrical outlets that are labeled as "Hospital Only" or "Hospital Grade." **Never** adapt a grounded plug to fit an ungrounded outlet by removing the ground prong.

- EMI generated by the ST80i System may cause nearby equipment to fail. See "Electromagnetic Compatibility (EMC)" on page E-9 for more information.

- The ST80i System may be interfered with by other equipment even if that other equipment complies with CISPR Emission requirements. For RF transceiver specifications, see Table E-2, "ST80i System Specifications," on page E-3.

- Short-range radio connections are subject to interruption due to interference from other radio sources in the vicinity, including microwaves, Bluetooth devices, and DECT phones. Outside the frequency band and 5% above and below—in other words, the exclusion band according to IEC 60601-1-2—the short-range radio connection is immune up to 3V/m in the frequency range from 80 MHz to 2.5 GHz. Depending on the strength and duration of the interference, the interruption may occur for an extended period. Any interruption of the signal due to interference, moving out of range, or for other reasons is indicated via an RF signal status indicator on both the PIM as well as on the Main screen.

- If your system includes the trolley, ensure that components are installed securely and that no items are placed on the trolley that could cause the trolley to become unstable.

- The maximum weight to be placed in the trolley drawer is 15 lb (6.8 kg).

- The maximum weight to be placed on the shelf beneath the trolley drawer is 10 lb (4.5 kg).

- The maximum weight to be placed on the optional shelf for a laser printer is 45 lb (20.4 kg).

- If your system includes the trolley, always lock the wheel brake when the trolley is not in motion. Press down on the brake tab to set the brake and lift up on the tab to release the brake.

- Safe removal of an All-in-One display from the trolley requires two people.

- Placing or spilling liquids on the trolley may cause electrical safety hazards and/or system malfunction.

- Allow the patient to move freely by:
  - Taking care when dressing the ECG cables so as to minimize the potential tripping hazard during the stress ECG study process.
  - Securing the patient lead set, power cable, treadmill cable, echo cable, NIBP cable, and SpO$_2$ cable away from patient's feet before beginning the exercise stage.

- If a treadmill is being used, instruct the patient to rest his/her hands on the handrails while on the treadmill.

- ST80i captures and presents data reflecting a patient's physiological condition that, when reviewed by a trained physician or clinician, can be useful in determining a diagnosis. However, the data should not be used as a sole means for determining a patient's diagnosis.

- Both analog ECG output and TTL sync output are considered real-time, with a delay (latency) of no more than 25 ms between the patient's physiological activity and the appearance of its representative signal at the external port. This signal should not be used for analysis.

- To get the most accurate interpretation during resting ECG, use traditional limb lead placement.

- For the user's convenience only, rhythm change notifications are provided when specific rhythm changes are detected; however, it is the responsibility of the trained healthcare professional to determine the type of rhythm

change and take appropriate action. Additionally, the healthcare professional should not assume that all rhythm changes will be detected, and they are responsible for taking action when rhythm changes are observed on the displayed waveforms and the system fails to provide a notification. It is expected that only properly trained healthcare professionals working directly under the supervision of a qualified physician will be operating the ST80i System during testing.

- ST80i cannot import ECGs from another vendor's stress system.

- Demo mode must be turned off when testing patients.

- If the Stop Treadmill button on the ST80i interface does not respond for any reason, immediately press the red Emergency button on the treadmill handrail or, if available, pull the safety tether.

- The interpretive algorithm has been validated only with "standard" lead placement.

- Incorrect blood pressure measurement can cause errors for BP-related parameters in reports.

Caution Statements for the ST80i System

Caution

Caution statements describe conditions or actions that may result in damage to equipment or software.

- This product is not intended for home use.

- **Rx Only**: In the U.S., Federal law restricts this device to sale on or by the order of a physician.

- Philips Medical Systems strongly recommends that your site not use patient identification numbers that are related to any other forms of identity, such as social security number or driver's license number. Using unique patient identification numbers is part of best practices for any information technology system as a way to help health care providers and patients avoid identity theft.

- The Multiple Portable Socket-Outlet (MPSO) provided with the system—also referred to as the isolation transformer outlets—shall only be used for powering equipment that forms part of the system.

- Do not pull or stretch patient lead wires as this could result in mechanical and/or electrical failures. Store patient lead wires after forming them into a loose loop.

- Do not attempt to clean the device or patient lead wires by submersion, autoclaving, or steam cleaning.

- Wipe the exterior surface of the device and patient lead wires with a compatible non-alcohol sterilizing disinfectant, then dry with a clean cloth. See "Cleaning the ST80i System" on page 6-2 in the "Maintaining the ST80i System" chapter for a list of approved disinfectants.

- Be careful not to damage the display when moving the trolley or when moving other equipment near trolley.

- To prevent possible damage to the device during transport and storage (while in original packaging), the following environmental conditions must be adhered to:

  Storage Temperature Range:

  –20°C to 50°C (–4°F to 122°F)

  Storage Humidity Range:

  10% to 90% (non-condensing)

  Storage Pressure (altitude):

  Up to 4,572 m (15,000 ft) altitude

- Allow the device to stabilize within its intended operating environment for a minimum of two hours prior to use. The allowable operating environment is as follows:

  Operating Temperature Range:

  10°C to 40°C (50°F to 104°F)

  Operating Humidity Range:

  10% to 90% (non-condensing)

  Operating Pressure (altitude):

  0 to 3,048 m (10,000 ft) altitude (697 mbar)

Note:

The environmental conditions listed above are only applicable to ST80i system parts that acquire and print ECG data, including the AIM, PIM and thermal printer. Off-the-shelf parts such as PC, desk light, and NIBP/SpO$_2$ module have their own operating and storage environment conditions and are not required to meet the condition listed above.

Important Notes about the ST80i System

- The ST80i System is suitable for use in the professional healthcare facility, except in the emergency medical services environment. The system cannot be used in the home healthcare environment.

- The ST80i System has been safety tested with the recommended accessories, peripherals, and leads, and no hazard was found when the system is operated with cardiac pacemakers or other stimulators.

- ST80i may become inoperative when the front-end (PIM) signal acquisition is interrupted due to low PIM battery power, loss of wireless communication between the PIM and the receiver (AIM), and/or loss of USB communication between the AIM and the host PC. ST80i displays a lead-off condition for all leads when signal acquisition is lost and absence of signal strength bars when wireless communication is lost. These inoperative conditions are saved in the logs.

- Power off the system and remove the input AC power cord before installing, repairing, or servicing any hardware.

- Proper patient preparation is important for proper application of ECG electrodes and operation of the device. Use medical tape to fix the lead wires to the chest in order to help minimize the strain applied to the electrode connections, thus reducing noise and the possibility of a leads-off condition.

- ST80i automatically prevents connection to a LAN or WLAN while the treadmill is running.

- As defined by IEC 60601-1 and IEC 60601-2-25, the ST80i system is classified as follows:

  – Class I equipment

  – IPX0

  – Not suitable for use in the presence of flammable anesthetics or flammable mixtures of air, oxygen, or nitrous oxide

  – Continuous operation

- Because of its sampling characteristics and the asynchronism between sample rate and signal rate, ST80i may produce a noticeable modulating effect from one cycle to the next, particularly in pediatric recordings.

- ST80i can download study data to the TraceMasterVue/IntelliSpace ECG Management System server for review.

- ECGs captured with the Resting ECG Workflow product option can be downloaded to IntelliSpace ECG.

- In order to install and configure ST80i in a way that optimizes the user's experience, refer to the *ST80i Stress Test System Installation and Configuration Guide*.

- If the LCD is smashed accidentally by force, its sharp and broken parts may fly out to persons nearby.

Safety Information for the Medical Isolation Transformer

Warning Statements about the Medical Isolation Transformer

WARNING

Failure to follow these warnings could affect both patient and operator safety.

- Use of this isolation transformer with equipment other than originally supplied, or surpassing the ratings, may cause damage, fire, or injury.

- Plugging into the isolation transformer any electrical equipment that has not been supplied as part of the ST80i System could introduce unwanted leakage currents.

- When using additional peripheral equipment powered from an electrical source other than the isolation transformer, the combination is considered to be a medical system. It is the responsibility of the operator to comply with IEC 60601-1 and test the medical system according to the requirements.

- The PC, thermal printer, monitor, and optional blood pressure monitor, must be plugged into a medical isolation transformer to ensure the user/patient is properly protected from leakage current. Do not plug any of these devices directly into a wall outlet or unwanted leakage currents may be produced.

- Do not plug a laser printer, treadmill, or ergometer into the isolation transformer provided with ST80i. Power for the laser printer, treadmill, or ergometer must be provided from another source that complies with your facility's safety requirements or IEC 60601-1.

- Do not place the isolation transformer on the floor.

Caution Statements about the Medical Isolation Transformer

Caution

Caution statements describe conditions or actions that may result in damage to equipment or software.

Before connecting your equipment to the isolation transformer, ensure that:

– The voltage selector switch (visible through the rectangular hole on the right rear side of the transformer) matches your line voltage.

– The correct fuse value (located above the power cord) is selected.

Refer to Figure E-1, "Medical Isolation Transformer Provided with ST80i," on page E-6.

Important Notes about the Medical Isolation Transformer

It is important that the treadmill or ergometer has its own source of unshared power to avoid an interruption to the power supply to the ST80i System. The treadmill and ergometer should have its own circuit and fuse/breaker in a local power distribution box.

Safety Information for the Advanced Interface Module

Warning Statements about the Advanced Interface Module

WARNING

Failure to follow these warnings could affect both patient and operator safety.

- FCC Warning: Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

- This radio transmitter has been approved by Industry Canada to operate with the antenna types listed below with the maximum permissible gain and required antenna impedance for each antenna type indicated. Antenna types not included in this list, having a gain greater than the maximum gain indicated for that type, are strictly prohibited for use with this device.

  Le présent émetteur radio a été approuvé par Industrie Canada pour fonctionner avec les types d'antenne énumérés ci-dessous et ayant un gain admissible maximal et l'impédance requise pour chaque type d'antenne. Les types d'antenne non inclus dans cette liste, ou dont le gain est supérieur au gain maximal indiqué, sont strictement interdits pour l'exploitation de l'émetteur.

Antenna/Antenne	Gain	Impedance
Omnidirectional/SMA connector Omnidirectionnel/connection SMA	2 dBi	50 Ohm

Caution Statements for the Advanced Interface Module

Caution

Failure to heed these caution statements may result in damage to equipment or software.

- The advanced interface module complies with FCC radiation exposure limits set forth for an uncontrolled environment.

- Connect the AIM cable only to the ST80i Stress Test System and only to the proper receptacle.

- The maximum length of the AIM USB cable is 1 meter. The cable should include ferrite beads for EMC purposes.

Important Notes about the Advanced Interface Module

This equipment complies with FCC& RSS-102 radiation exposure limits set forth for an uncontrolled environment. This equipment should be installed and operated with minimum distance 20cm between the radiator & your body.

Ce matériel est conforme aux limites de dose d'exposition aux rayonnements, FCC / CNR-102 énoncée dans un autre environnement.cette eqipment devrait être installé et exploité avec distance minimale de 20 entre le radiateur et votre corps.

- Use Conditions: This device complies with Part 15 of the FCC rules. Operation is subject to the following two conditions:

  – This device may not cause harmful interference.

- This device must accept any interference received, including interference that may cause undesired operation.

- The manufacturer is not responsible for any radio or TV interference caused by unauthorized modifications to this equipment. Such modifications could void the user's authority to operate the equipment.

- FCC Note: This device has been tested and found to comply with the limits for a Class B digital device pursuant to Part 15 of the FCC rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This device generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications.

  However, there is no guarantee that interference will not occur in a particular installation. If this device does cause harmful interference to radio or television reception, which can be determined by turning the device off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

  - Reorient or relocate the receiving antenna.

  - Increase the separation between the device and receiver.

  - Connect the device to an outlet on a circuit different from the circuit to which the receiver is connected.

  - Consult the dealer or an experienced radio/television technician for help.

- The radio device used in this product is in compliance with the essential requirements and other relevant provisions of Directive 2014/53/EC (Radio Equipment and Telecommunications Terminal Equipment Directive). Class 1 radio equipment. Member states may apply restrictions on putting this device into service or placing it on the market.

- Industry Canada Statement:

  This device complies with RSS-210 of the Industry Canada rules. Operation is subject to the following two conditions:

  - This device may not cause harmful interference, and

  - This device must accept any interference received, including interference that may cause undesired operation.

  Ce dispositif est conforme à la norme CNR-210 d'Industrie Canada applicable aux appareils radio exempts de licence. Son fonctionnement est sujet aux deux conditions suivantes:

  - Le dispositif ne doit pas produire de brouillage préjudiciable, et

  - Ce dispositif doit accepter tout brouillage reçu, y compris un brouillage susceptible de provoquer un fonctionnement indésirable.

- This Class B digital apparatus complies with Canadian ICES-003.

  Cet appareil numérique de la classe B est conforme à la norme NMB-003 du Canada.

- The 5-pin connector port on the back of the AIM is non-functional.

- Do not connect PageWriter TC-Series cardiograph patient interface modules to the 5-pin connector port on the back of the AIM.

Safety Information for the Wireless Patient Interface Module

For information about electromagnetic compatibility (EMC) with surrounding devices, see "Electromagnetic Compatibility (EMC)" on page E-9 of Appendix E, "Specifications and Requirements".

Warnings about the Wireless Patient Interface Module

WARNING

Failure to follow these warnings could affect both patient and operator safety.

- The wireless patient interface module transmits data reflecting a patient's physiological condition to a properly equipped system and when reviewed by a trained physician or clinician can be useful in determining a diagnosis. However, the data should not be used as a sole means for determining a patient's diagnosis.

- To maintain designed operator and patient safety when assembling a medical electrical system for use in the patient environment, the responsible organization shall ensure that peripheral equipment and accessories used that can come in direct patient contact must comply with IEC 60601-1:2005+A1:2012+A2:2020 Medical Electrical Equipment-Part 1: General Requirements for basic safety and essential performance.

- Any combination of medical electrical instruments should be evaluated by local safety personnel before being put into service. For equipment not certified to medical electrical equipment standards that may be used within the patient vicinity, an appropriately rated isolation transformer is required.

- The wireless patient interface module transfers ECG data uniformly at 1000 samples-per-second, with the amplitude resolution of 1?V/least-significant-bit over the dynamic range of +/− 32 millivolt (16 bits), and with the frequency response of 0.02 to 300 Hertz. Operation of the equipment or system below this amplitude or threshold may cause inaccurate results.

- FCC Warning: Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

- To avoid the possibility of serious injury or death during patient defibrillation, do not come into contact with the device or lead sets. Additionally, proper placement of defibrillator paddles in relation to the electrodes is required to minimize harm to the patient.

- Defibrillation protection is guaranteed only if the original lead set is used.

- Ensure that the electrodes or lead wires do not come in contact with any other conductive materials (including earth-grounded materials), especially when connecting or disconnecting electrodes to or from a patient.

- If your facility is using more than one PIM, each one must be added to the ST80i application under **Settings** > **System Settings** > **I/O Devices**. When you connect the patient to one of the PIM devices, you also need to verify the address on the device with the address that shows up on the **Prepare** screen.

- A possible explosion hazard exists. Do not use the device in the presence of flammable anesthetics, or flammable mixtures with air, oxygen, or nitrous oxide.

- Some stimulators may cause interference with the signal.

Caution Statements for the Wireless Patient Interface Module

Caution

Failure to heed these caution statements may result in damage to equipment or software.

- The wireless patient interface module complies with FCC radiation exposure limits set forth for an uncontrolled environment. If the low battery message appears after the test has started, there is sufficient power left to finish the test without pausing to replace the battery.

- The wireless PIM supports 1.5V AA alkaline batteries only. Replace the battery if the low-battery alert appears before the stress test starts.

- The wireless PIM uses an off-the-shelf disposable AA alkaline battery for power. The use of rechargeable batteries is not recommended, as the remaining capacity indication may be inaccurate, resulting in the possibility of the PIM powering down during a stress test.

- Minimum operating time of the wireless PIM with new, fully charged batteries: 6 tests per day, 30 minutes average per test, for 5 days. Performance may vary depending on the brand of batteries used. Powering off the PIM when not in use and/or configuring the PIM Power Save feature to 3 minutes helps lengthen battery life.

- Other than the replaceable battery and battery terminals, there are no user-serviceable parts inside. Any modification of this device may alter defibrillator protection. Any modification to any part of this device is to be performed by qualified service personnel only.

- Follow the correct procedure to select the wireless PIM when multiple modules are detected. See "Select the Wireless PIM" on page 3-15.

- To prevent possible damage to the keypad, do not use sharp or hard objects to depress keys; only use fingertips.

- The wireless PIM and patient lead set should be cleaned between each use.

- Do not attempt to clean the wireless PIM or patient lead set by submersion, autoclaving, or steam cleaning. Wipe the exterior surface of the device and patient cables with a non-alcohol sterilizing disinfectant, then dry with a clean cloth. See "Cleaning the ST80i System" on page 6-2 in the "Maintaining the ST80i System" chapter for a list of approved disinfectants.

- Conductive parts of the patient lead sets, electrodes, and associated Type CF connections, including the neutral conductor of the patient cable and electrode, should not come into contact with other conductive parts, including earth ground.

- Do not pull or stretch patient lead sets as this could result in mechanical and/or electrical failures. Store lead sets after forming them into a loose loop.

- The following equipment may cause interference with the RF channel: microwave ovens, diathermy units with LANs (spread spectrum), amateur radios, and government radar.

Important Notes about the Wireless Patient Interface Module

- Wireless Patient Interface Module leakage currents are 100% safety tested in production.

- The wireless Patient Interface Module supports reliable RF transmission within a 3-meter range. With no structures blocking the path to the receiver, the transmission frame error rate is no more than 1% and error frames can be re-transmitted automatically. The wireless transmission stability is 100% tested during manufacturing.

- Use Conditions: This device complies with Part 15 of the FCC rules. Operation is subject to the following two conditions:

  – This device may not cause harmful interference.

  – This device must accept any interference received, including interference that may cause undesired operation.

- The manufacturer is not responsible for any radio or TV interference caused by unauthorized modifications to this equipment. Such modifications could void the user's authority to operate the equipment.

- FCC Note: This device has been tested and found to comply with the limits for a Class B digital device pursuant to Part 15 of the FCC rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This device generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications.

  However, there is no guarantee that interference will not occur in a particular installation. If this device does cause harmful interference to radio or television reception, which can be determined by turning the device off and on, the user is encouraged to try to correct the interference by taking one or more of the following measures:

  – Reorient or relocate the receiving antenna

  – Increase the separation between the device and receiver

  – Connect the device into an outlet on a circuit different from that to which the receiver is connected

  – Consult the dealer or an experienced radio/television technician for help

- The radio device used in this product is in compliance with the essential requirements and other relevant provisions of Directive 2014/53/EC (Radio Equipment and Telecommunications Terminal Equipment Directive). Class 1 radio equipment. Member states may apply restrictions on putting this device into service or placing it on the market.

- Industry Canada Statement:

  This device complies with RSS-210 of the Industry Canada rules. Operation is subject to the following two conditions:

  – This device may not cause harmful interference, and

  – This device must accept any interference received, including interference that may cause undesired operation.

  Ce dispositif est conforme à la norme CNR-210 d'Industrie Canada applicable aux appareils radio exempts de licence. Son fonctionnement est sujet aux deux conditions suivantes:

  – Le dispositif ne doit pas produire de brouillage préjudiciable, et

  – Ce dispositif doit accepter tout brouillage reçu, y compris un brouillage susceptible de provoquer un fonctionnement indésirable.

- This ISM device complies with Canadian ICES-001.

  Cet appareil ISM est conforme à la norme NMB-001 du Canada.

- Proper patient preparation is important for proper application of ECG electrodes and operation of the device.

- Use a wireless PIM belt. Adjust the PIM belt appropriately for the patient and use NIBP cuffs that are appropriate for the patient's size.

- Patient lead sets should be checked for cracks or breakage in its exterior properties prior to use.

- The wireless PIM includes LEDs that indicate battery power level, wireless signal quality, and lead contact status. When the wireless PIM is powered on, the battery power level LED is lit. You can click the power button anytime to check the status of the battery, wireless signal, or lead contacts.

Note:

Wireless status is displayed only when there is communication between a PIM and the AIM, which begins when a test is started.

- As defined by IEC 60601-1 and IEC 60601-2-25, the ST80i PIM is classified as follows:

  – Internally powered

  – Type CF applied part

  – IPX4

  – Not suitable for use in the presence of flammable anesthetics or flammable mixtures of air, oxygen, or nitrous oxide

  – Continuous operation

- The wireless patient module may be warm to the touch but should not cause a burn.

Security Recommendations

As more patient health information is collected, stored, and transmitted electronically on a global basis, the concern for patient privacy grows. We consider the security and confidentiality of patient data to be of paramount importance. We adhere to the highest professional standards focused on providing you with resources aimed at your regulatory compliance needs and allowing you to fully manage the safety, effectiveness, and security risks of medical devices, including your ST80i System.

Protecting Personal Information

It is essential that policies and procedures for the proper handling of personal or sensitive data, consider the confidentiality, integrity, and the availability of these types of data. Each organization using this product must provide the protective means necessary to safeguard personal information consistent with each country law, code and regulation, and consistent with the company policies for managing this information. While handling personal information is outside the scope of this document, in general, each organization is responsible for identifying:

- Who has access to personal data and under what conditions an individual has authorization to use that data.

- How the data is stored and the conditions by which it is stored.

- How the data is transmitted and the conditions under which that data is transmitted.

The US Department of Veterans Affairs has developed a widely used Medical Device Isolation Architecture to minimize the risk of a security breach when medical devices are connected to information networks. Such perimeter and network defenses are essential elements in a comprehensive medical device security strategy.

Additional security and privacy information can be found on the Philips product security website. Visit www.healthcare. philips.com, choose your country and language, navigate to the Response Center page, and locate the Product Security link.

About HIPAA Rules

If applicable, your facility's security strategy should include the standards set forth in the Health Insurance Portability and Accountability Act of 1996 (HIPAA), introduced by the United States Department of Health and Human Services. You should consider both the security and the privacy rules and the HITECH Act when designing policies and procedures. For more information, please visit www.hhs.gov/ocr/privacy/.

Security Controls and Safety Measures

The following controls and safety measures may further strengthen the security and confidentiality of your patient records and system in general:

- Install ST80i in a secure location and use a privacy filter on the ST80i System monitor that shields the visibility of the screen contents from angled viewing.

- In case of a power supply disruption, backup options should be handled by an appropriate power failover system.

- Implement "best practices" Windows security measures to minimize unauthorized system access. These measures include making passwords complex, regularly changing passwords, short auto logout intervals when the system is idle, and training your users to log off or shut down the computer when they leave the ST80i system.

- Install anti-virus software such as McAfee® VirusScan® Enterprise or Symantec™ Norton 360™ software.

- Apply Windows-recommended network security and user privilege policies to prevent:

  – The installation of any software other than Philips-approved software intended for installation on ST80i.

  – The transmission of viruses via removable storage devices (for example, USB sticks).

- Do not load or download to the computer any software, security patches, or updates not authorized by Philips. Unauthorized software may compromise the operation of the system and is strictly prohibited.

- Remember that the ST80i System contains confidential patient health information (PHI) that should be safeguarded. Avoid copying patient health information to removable media. If you do, maintain physical security of the media at all times. Deleting data from rewritable/erasable media does not make the data inaccessible to a determined individual. Dispose of removable media containing patient health information in accordance with your institution's policies.

- Communication of unencrypted PHI should only occur across a secured intranet.

- Upon returning the equipment to Philips, eliminate all patient health information or other confidential data, unless otherwise directed by Philips for problem investigation. Retain only the information necessary for the investigation with full agreement from both parties.

- Configure the system to not run executables (.exe files) automatically when connecting external drives. See the *ST80i Stress Test System Installation and Configuration Guide* for more information.

- Rename the built-in Windows Administrator account.

- Disable the Guest account. Every user should have a unique identity.

- Set up a BIOS password to prevent unauthorized access to the computer setting.

- Although security safeguards to protect the system against the intrusion of malware (viruses, trojans, worms, and so on) are recommended, a possibility remains that a system can become infected. In all circumstances, the system safety mechanisms are designed to remain intact, even when you might notice unfamiliar system behavior and performance. If this happens repeatedly, such as after the system has been switched off and on again, contact Philips customer support to have the system checked and, if needed, cleansed of malware.

- Malware prevention software should be configured to receive automatic updates. If the virus scanning software has detected infection by malware, do not use automatic repair utilities because the integrity of the repaired software cannot be guaranteed. Contact Philips service to assess and repair the system. Additionally, please be sure to adhere to local procedures regarding malware infection, which may include disconnecting from the network until the situation is resolved.

- Perform regular backups of system data and store in a secure location. ST80i allows you to back up the stored ECG report and the configuration setting. Users with administrator accounts can back up and restore ECG reports from the **Archive** screen; administrators can also back up the configuration setting on the **Settings** screen.

- The exported configuration setting can be imported on the **Settings** screen to restore the ST80i configuration.

- User must maintain physical security of the media that stores the backup files at all times.

- You risk losing ePHI if you transfer it to unsupported and/or obsolete backup media (for example, floppy disks).

- Limit Web browsing to the downloading of Philips-authorized security patches or updates. Web browsing dramatically increases the chance of the system being infected by malicious software.

- ST80i is not generally used in situations where emergency access is required. If this is important to your organization, it is recommended that you establish administrative procedures to permit emergency access to the device when normal login and authentication credentials are not available.

- For the latest security updates from Philips, visit www.healthcare.philips.com, choose your country and language, navigate to the Response Center page, and locate the Product Security link.

The Philips ST80i Stress Test System

Intended Use/Intended Purpose

The Philips ST80i Stress Test System is a PC-based diagnostic tool intended to acquire, process, and store ECG data of patients undergoing stress exercise testing. The software records ECG, heart rate, and ST data; creates summary tables and trends; and produces a final report regarding a variety of cardiac data indices. The cardiac data provided by the Stress system is intended to be

reviewed, confirmed, and used by trained medical personnel to assist in the evaluation of the patient's cardiovascular condition and the patient's physiological condition during stress exercise testing. The arrhythmia detection portion of the ST80i Stress Test System is provided to the user for the convenience of automatic detection of arrhythmias but does not provide alarms.

Indications for Use

The Philips ST80i Stress Test System is indicated for use in exercise ECG testing, where the clinician decides to evaluate the electrocardiogram of patients at 10 years or older, as part of decisions regarding possible diagnosis, potential treatment, effectiveness of treatment or to rule out causes for symptoms of cardiovascular disease. The Philips ST80i Stress Test System is not intended to be used as a physiological monitor.

Contraindications

None known.

Operating Principle

As a PC-based diagnostic tool, ST80i Stress Test System acquires electrical ECG signal through body surface electrodes attached to patient. The acquired electrical ECG signals are amplified, digitalized, and processed in digital domain. The system records, displays, analyzes, and prints the processed ECG signals for trained medical personnel to evaluate patient's cardiovascular and physiological condition.

Intended Users

The resting ECG function can be performed by a trained clinician, and for performing exercise ECG testing the trained clinician should be under the supervision of an appropriately trained physician.

Intended Patient Population

The intended patient population are patients 10 years or older.

Medical Conditions

Clinician use resting ECG testing or exercise ECG testing to evaluate the electrocardiogram of patients at 10 years or older, as part of a decision making process regarding possible diagnosis, potential treatment, or effectiveness of treatment, or to rule out causes for symptoms of cardiovascular disease.

Environment for Use

The ST80i Stress Test System is intended to be used in hospital and physician office environments. It is not intended for home use.

Clinical Benefits

The indirect clinical benefits of the ST80i Stress Test System include:

- Supports trained healthcare professionals in preliminary diagnosis through its intended use
- Has a positive impact on clinical outcomes through its intended use

The Philips DXL ECG Algorithm

Intended Use

To analyze multi-channel ECG signals from adult and pediatric patients with algorithms that provide measurements, data presentations, graphical presentations and interpretations for review by the user. The interpreted ECG with measurements and interpretive statements is offered to the clinician on an advisory basis only. It is to be used in conjunction with the clinician's knowledge of the patient, the results of the physical examination, the ECG tracings, and other clinical findings. A qualified physician is asked to over read and validate (or change) the computer generated EGG interpretation.

Indications for Use

Where the clinician decides to evaluate the electrocardiogram of adult and pediatric patients as part of decisions regarding possible diagnosis, potential treatment, effectiveness of treatment or to rule-out causes for symptoms.

The CAlg-STR Exercise ECG Analysis Algorithm

Intended Use

The intended use of the CAlg-STR Exercise ECG analysis algorithm is to analyze multi-channel ECG waveforms acquired from a patient and produce measurements such as heart rate, detect ventricular arrhythmias, form representative beats, and calculate ST segment deviation (elevation or depression) and ST slope for review by a trained physician or clinician in determining a diagnosis. The measurements should not be used as a sole means for determining a patient's diagnosis.

Indications for Use

The analysis algorithm is indicated for use in exercise ECG testing where the clinician decides to evaluate the electrocardiogram of patients at 10 years or older, as part of a decision-making process regarding possible diagnosis, potential treatment, or effectiveness of treatment, or to rule out causes for symptoms. The analysis algorithm is not intended for use as a physiological monitor.

About the Philips ST80i Stress Test System

The Philips ST80i Stress Test System is a PC-based diagnostic tool for use in the exercise stress-testing laboratory. Electrocardiographic data obtained during stress testing is acquired, processed, recorded, analyzed, archived, and exported. The ST80i software creates summary tables, identifies trends, and generates a final statistical report, which trained clinicians review to assist in the diagnosis of the patient's condition.

The ST80i System interfaces to, and controls, a compatible treadmill or ergometer and an optional non-invasive blood pressure monitor. It can also be used with the pharmacological form of testing. The TTL and analog output options allow a selectable ECG signal to be sent to a non-invasive BP device or to an echo system for synchronization and timing.

Overview

The ST80i System is a PC-based diagnostic tool intended to acquire, process, and store ECG data of patients undergoing stress exercise testing. The software records ECG, heart rate, and ST data; creates summary tables and trends; and produces a final report regarding a variety of cardiac data indices. The cardiac data provided by the stress system is intended to be reviewed, confirmed, and used for diagnostic purposes by trained medical personnel to assist in the diagnosis of coronary artery disease (CAD) and the patient's physiological condition during stress exercise testing.

Note:

The arrhythmia detection portion of ST80i is provided for the convenience of automatic documentation. ST80i does not offer a diagnostic opinion; rather, it provides a high-fidelity instrument recording ECG waveforms during exercise, for the purpose of providing a tool to expedite the documentation of a test for which a clinician renders his or her own medical opinion.

ST80i provides the standard 12-Lead ECG using the 10-lead electrode wireless patient interface module (PIM).

Key features provided by ST80i include the following:

- Continuous ECG acquisition and analysis (ST level, risk scoring, and alerts)
- Optional standalone resting ECG acquisition (Resting ECG Workflow product option)
- Monitoring, display, and trending for heart rate and—optionally—for blood pressure and SpO$_2$.
- Optional ability to integrate with device of Cardiopulmonary Exercise Test (Ultima CPX/BreezeSuite application) for metabolic analysis
- Intuitive user interface
- Wireless connection between wireless PIM and ST80i AIM
- Comprehensive test protocol support
- Comprehensive and customizable reports
- Comprehensive connectivity with Electronic Medical Records (EMR), Hospital Information Systems (HIS), IntelliSpace ECG, IntelliSpace Cardiovascular, and third-party departmental systems
- Customizable display layout
- Support for exercise, stress echo, nuclear stress, and pharmacological studies
- Optional interface to patient demographics via DICOM Modality Worklist, HL7 orders, and/or ADT (Admit-Discharge-Transfer) for patient registration
- Remote access to reports

ST80i is also programmable, allowing you to customize the operational conditions to suit your needs. You can customize:

- Up to 100 different user profiles to meet the needs of individual physicians
- Up to 100 different exercise protocols
- Automatic 12-Lead ECGs
- Multiple final report formats

ST80i is compatible with Windows 7, Windows 8.1, and Windows 10 operating systems, either 32-bit or 64-bit. You control ST80i functions using the keyboard and mouse or touch screen (if available).

ST80i interfaces with a treadmill or ergometer, or supports a pharmacological study. ST80i captures five phases of a patient exercise test:

- Prepare
- Pre Exercise
- Exercise
- Recovery
- Report (Post-Recovery)

With the Resting ECG Workflow product option, ST80i can also capture a standalone resting ECG, either prior to a stress test or as a standalone test.

About ST80i Documentation

Philips provides detailed instructional and reference materials to help you get the most out of your ST80i System.

Available Documentation

The following documentation is available with the ST80i system:

ST80i Stress Test System Instructions for Use (IFU)	Provides detailed information about ST80i functionality. It describes the operation of the product and includes all regulatory-required labeling. This guide also includes troubleshooting and maintenance information. The IFU is written for clinical professionals. They are expected to have a working knowledge of medical procedures and medical terminology as required for monitoring potential cardiac patients.
ST80i Stress Test System Installation and Configuration Guide	Describes how to set up the ST80i System, including hardware and software. Also describes how to set up the trolley and how to perform initial configuration of the software.
ST80i Stress Test System Service Manual	Describes preventive and technical maintenance performed by trained service personnel. Includes information about using the service utility for hardware and software management. Also provides troubleshooting procedures and information about the repair and replacement of ST80i components.
ST80i Stress Test System Product Options Upgrade Instructions	Describes how to upgrade your system with software options purchased after your initial ST80i Stress Test System purchase.
CAlg-STR Exercise ECG Analysis Algorithm Physician's Guide	Describes the ECG analysis program available on the ST80i System, and the available report formats. Includes a high level description of the criteria logic.
Philips DXL ECG Algorithm Physician's Guide	Explains how ECG signals are analyzed by the Philips DXL 16-Lead ECG Algorithm. Used with the ST80i Resting ECG Workflow product option.

Using the Philips InCenter Site

The Philips InCenter site provides frequent updates to Philips product documentation and product software.

The Philips InCenter site requires an active registration and password. To register, go to the InCenter site at incenter.medical.philips.com. Click the **Need help?** link on the main page (located under the user login and password fields). On the page that opens, click the cardiology product link under **Software Updates**. The Cardiac Systems InCenter Registration Form page opens. Complete all of the information fields on the page to receive a login and password for the InCenter site.

Registration for the InCenter site requires the serial number of at least one ST80i system in active use at your facility. The serial number is to the right of the **SN** symbol on the product identification label. The product identification label is located on the Advanced Interface Module (AIM).

Figure 1-1   ST80i Product Identification Label

About Adobe Acrobat Versions and InCenter

Adobe Acrobat Reader version 9.0 or higher must be installed on the PC that is used to access the Philips InCenter site. Previous versions of Acrobat Reader are not compatible with Philips InCenter, and attempting to access InCenter with a previous version of Acrobat Reader will result in error messages when opening documents. Uninstall all previous versions of Acrobat Reader, and download a free version of Acrobat Reader at: www.adobe.com.

Any version of Adobe Acrobat Professional or Acrobat Elements is also not compatible with the Philips InCenter site, and error messages will appear when opening documents with these applications. Acrobat Reader must be installed

To access documents on the Philips InCenter site

1. Exit Acrobat Professional or Acrobat Elements (if open).

2. Start Acrobat Reader.

3. Open Internet Explorer, and go to the Philips InCenter site. Keep Acrobat Reader open the entire time while accessing the InCenter site.

How to Use this Guide

This guide is intended to help you use the ST80i system. It also provides maintenance and troubleshooting information, as well as product specifications.

This guide is organized as follows:

Safety Summary. Lists the warnings, caution statements, and important notes that apply to using the ST80i system, the patient modules, and the isolation transformer. Read this chapter before operating any of the equipment.

1 **About the Philips ST80i Stress Test System.** Provides a high-level overview of the ST80i System.

2 **An Overview of the ST80i Stress Test System.** Provides a general overview of the ST80i graphical user interface, features, and functionality. It also provides basic information about changing specific default settings during a patient session.

3 **The Patient Session.** Describes all phases of the patient session, from Prepare through Report.

4 **Working with Reports.** Describes how to configure, view, edit, save, and print the final stress test report.

5 **Resting ECG.** Describes the Resting ECG Workflow product option.

6 **Maintaining the ST80i System.** Describes how to clean and maintain the system.

A **Troubleshooting and Contacting the Response Center.** Describes some issues you might encounter and what to do about them. Also describes how to contact the Philips Response Center.

B **Protocol Reference.** Provides an example of the settings for each of the protocols provided with ST80i.

C **Configuring and Using the Printer.** Provides information about the ST80i thermal printer.

D **Ordering Options and Parts.** Provides a list of parts (including support parts) and options you can order.

E **Specifications and Requirements.** Lists the product specifications.

Getting Help Using ST80i

[?] To view an online version of this *ST80i Stress Test System Instructions for Use*, click the question mark at the upper right of the **Main** screen.

For detailed troubleshooting information, as well as details about contacting the Philips Response Center, see Appendix A, "Contacting Your Philips Response Center."

An Overview of the ST80i Stress Test System

The ST80i Stress Test System is used for the acquisition, analysis, and presentation of stress test data during the patient session. The application also controls the peripheral devices such as the treadmill, ergometer, and blood pressure equipment.

A patient session is the period of time when the exercise stress test is performed and waveforms are acquired and processed for a single patient. Patient information is linked with all waveform data acquired during the patient session. The session starts when you begin to gather exercise data for a new exam and lasts through the generation and review of the final report.

During the patient session, you can change certain default settings as you proceed through each phase using the toolbar icons, so that you can view or gather more specific ECG data. Other changes can be made directly on the screen as you proceed through the various stages of the exam. This may involve changing the default protocol, manually inserting a blood pressure measurement, or manually taking control of the exercise device. In addition, you can select from various print options during the patient session.

If you have the Resting ECG Workflow product option, you can also capture a resting ECG either prior to a stress test or as a standalone test. See Chapter 5, "Resting ECG Workflow."

User Accounts

ST80i supports at least 100 user accounts, which are created with specific access privileges based on function. ST80i user accounts are categorized as follows:

- Administrators — Administrators are allowed to perform all operations on the system.

- Clinicians — Clinicians are allowed to perform all operations on the system, except for system configuration operations and creating and deleting users. Clinicians can create and edit protocols, edit their user profile settings, and edit the final report.

- Technicians — Technicians are allowed to edit their user profile settings and edit the final report.

Technicians cannot confirm reports using their own log-in credentials; however, they can confirm reports on behalf of users with Administrator permissions.

Starting the Application

Your user account enables you to access the application. When you log on to ST80i, you are logging on to your preconfigured user profile.

To log on

1. Double-click the ST80i icon on your desktop. The ST80i window opens.

2. Type your user ID and password.

3. Click **OK**. The **Main** screen opens.

The Main Screen

The **Main** screen is where you begin all tasks for the application.

Figure 2-1   ST80i Main Screen
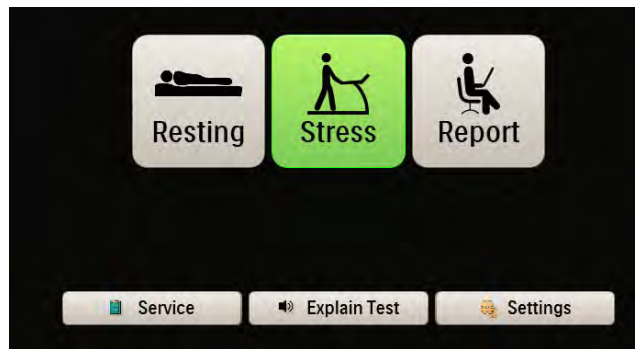
Table 2-1   ST80i Main Screen

Main Screen Button	Description
Resting	Click to conduct a resting ECG **Note:** *This button is present only if you have the Resting ECG Workflow product option installed.*
Stress	Click to conduct a stress test, **Note:** *If the Stress button is dimmed, you may be running ST80i on a remote review PC where patient tests are not performed. If you are not running on a remote review PC, see Appendix A, "Troubleshooting and Contacting the Philips Response Center" for a possible explanation and solution.*
Report	Click to enter the stress system database to review and retrieve archived reports, or to replay, delete, or export a selected stress test.

Main Screen Button	Description
Service	Click to review, update, or test software and firmware configurations. **Note:** *This button is active only to Administrator users.* **CAUTION:** To avoid the potential of altering system parameters, the Service feature should be accessed only by trained service personnel or under the direction of the Philips Response Center.
Explain Test	Click to hear an audio explanation of the exercise stress test. **Note:** *ST80i ships with a default audio file that explains the exercise stress test; however, you can record your own audio file and configure ST80i to play this file when the user clicks the Explain Test button. For more information, see the* ST80i Stress Test System Installation and Configuration Guide*.*
Settings	Click to preconfigure or change system settings, user profiles, exercise protocols, and user accounts.

User Profile

The system ships with a default user profile that cannot be deleted. The user profile contains preconfigured settings that are used to determine how the test runs and how the test results are displayed, printed, saved, and exported. Some settings are fixed and cannot be changed; some settings represent a default view that can be changed during the exercise stress test.

The preconfigured parameters of the user profile include:

- Exercise protocol and equipment
- Display settings
- Report settings
- Filter settings
- Algorithm settings
- Notifications
- Audio alerts

See "Using the Toolbar Icons" on page 2-15 for an explanation of the settings that can be changed during the patient session. See also "Side Panel" on page 2-9 for an explanation of the display features that are continuously updated during the patient session. On this panel you can manually enter blood pressure and SpO_2, as well as equipment settings that are preconfigured as part of the user profile and/or protocol.

Refer to the *ST80i Stress Test System Installation and Configuration Guide* for an explanation of how user profiles are preconfigured and to learn how to modify your user profile (**Settings** > **User Profile**).

Before beginning an exercise stress test, it is important to understand the key features of the ST80i user interface along with the toolbar icons, since you will be using them during the patient session.

ST80i Stress Screen

The ST80i **Stress** screen displays:

- All key procedural information including the protocol being used.
- Menus, windows, and notes pages that can be viewed, then hidden, so that the leads can be viewed in their entirety.
- Time of Day for correct time stamp on the start-up screen for every stress test.
- Real-time ECG as well as NIBP and SpO$_2$, trends, and other numeric displays that include ST values, ST slope, Double Product, and ST/HR index.

On the **Stress** screen, you have command of several functions during a patient session. You can adjust the speed and elevation of a treadmill and insert manual blood pressure data. You can also exit the exam at any point without losing any patient demographics or order information. However, exercise data will be lost.

Figure 2-2   ST80i Stress Screen
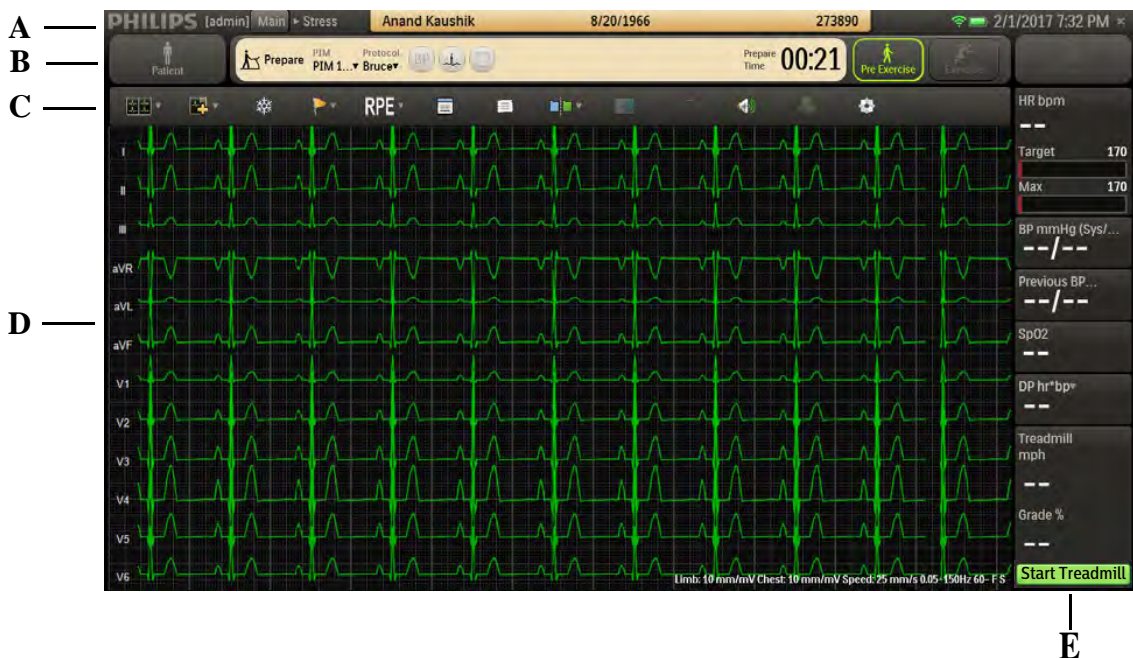
Table 2-1   ST80i Stress Screen Features

Feature	Description
A	Title Bar — Displays patient name, date of birth, and ID, along with current date and time. During the Prepare or Pre Exercise phase of a patient session, you can click the patient name to update patient information. The title bar also displays the PIM battery status and RF signal strength indicators.
B	Procedure Bar — Used to control the exercise stress test process. Displays exercise stage; selected patient interface device; protocol; BP, ECG Print, and Start Rhythm Printing buttons; and stage time.
C	Toolbar — Displays icons that provide quick access to frequently used commands throughout the exercise stress test.
D	Waveform Screen — Provides real-time ECG waveforms during the exercise stress test.
E	Side Panel — Provides real-time updates during the stress test, as well as target heart rate, NIBP, SpO$_2$, and exercise equipment data (speed, grade, stop, and start).

Title Bar

At any time during the Pre Exercise or Report phases of the patient session, you can use the title bar to manually input and edit patient information with data that will be centrally stored in the stress database. The title bar includes the features shown and described below.

Figure 2-3   Title Bar
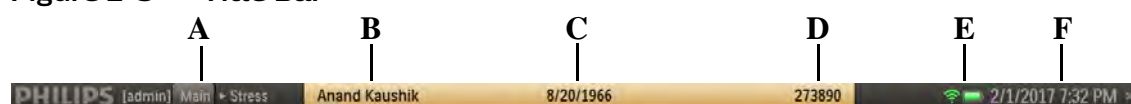
Table 2-2   Title Bar Features

Feature	Description
A	Navigation Keys (**Main** > **Stress**) — Click **Main** to leave the exercise test and return to the **Main** screen.
B	Patient name — Click the patient name to update patient information and add notes on the **Patient Information** tab of the **Patient Demographics** window.
C	Patient's date of birth — DOB formatting is determined by operating system.
D	Patient ID

Feature	Description
E	Indicators for the RF transmitter and PIM battery status.
F	Current date and time — Date formatting is determined by operating system.

To add or update patient information

1. Click the patient name in the title bar.

   The **Patient Demographics** window appears.

2. Enter new information for the patient, or update the fields as needed during the Prepare or Pre Exercise phase of the stress test. Mandatory fields are displayed in blue text.

Note:

You cannot access patient information from the title bar during the Exercise or Recovery phases.

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3. Click **OK** when finished to save the data. The changes are saved and will be visible next time you access this patient's information from the worklist.

If you manually update patient information—for example, by entering Notes—during the Exercise or Recovery phase, or on the **Report** screen, the changes appear only as part of the final report. The changes are not saved to the patient data in the worklist.

Procedure Bar

By default, the procedure bar is at the top of the screen. You can change the location of the procedure bar to the bottom of the screen. See the *ST80i Stress Test System Installation and Configuration Guide* to change the default setting (**Settings** > **User Profile** > **Display**).

Figure 2–4   Procedure Bar
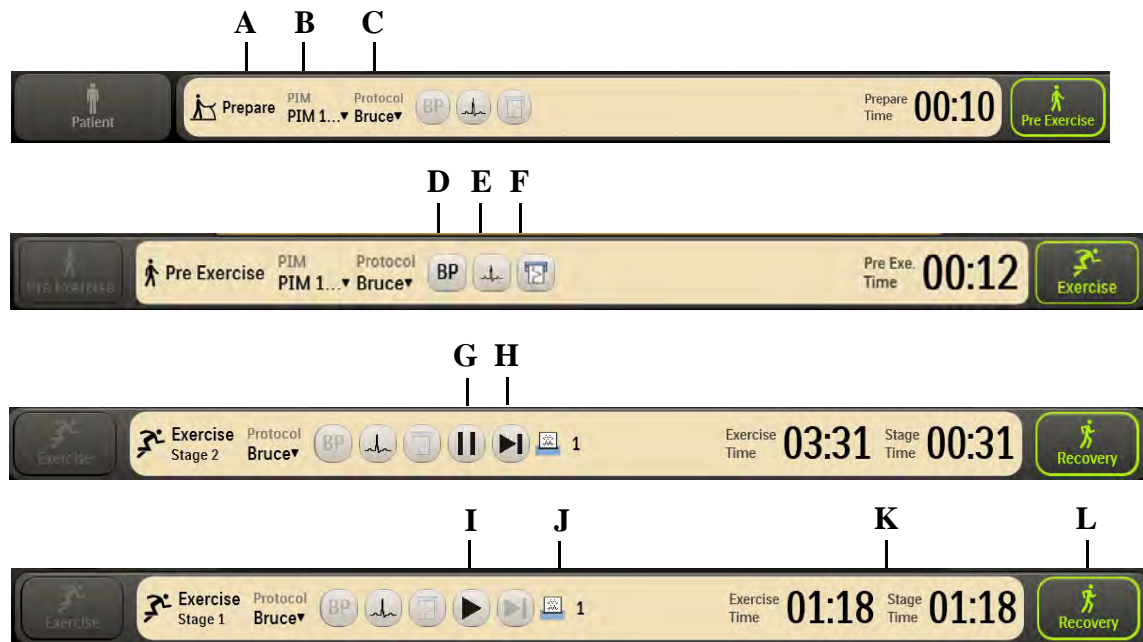
Table 2–3   Procedure Bar Features

Feature	Description
A	Current study phase — **Prepare**, **Pre Exercise**, **Exercise**, **Recovery**, or **Report**.
B	PIM device — Click to display a list of available PIM devices during the Prepare and Pre Exercise phases.
C	Protocol — Click to display a list of available protocols.
D	**BP** button — Click to initiate a manual blood pressure measurement with the optional automatic blood pressure (NIBP) device. You can also use the F3 hot key to initiate a Tango® BP or to open the **BP mm Hg** field to enter a manual BP.
E	**ECG Print** button — Click to print a 10-second ECG.
F	**Start/Stop Rhythm Printing** button — Click to start or stop continuous printing.
G	**Hold Stage** button — Click to keep the stress test in the current stage, overriding automatic stage changes.
H	**Go to Next Stage** button — Click to manually advance the stress test to the next stage.
I	**Unhold Stage** button — Click to remove the hold on stage changes. Even if the duration of the hold spans what would have been multiple stages, the removal of the hold returns the stress test to the stage following the one during which the hold was placed.

Feature	Description
J	Print count — Displays the number of print requests currently in the print queue. **Note:** *If printing is disabled—for example, if the printer is on a network that is disabled during a test—the number of print jobs accumulates until the printer again becomes active.*
K	Elapsed time for exercise and stage. Stage time restarts as each new stage begins.
L	Study phase buttons (**Prepare**, **Pre Exercise**, **Exercise**, **Recovery**, **Report**) — The next phase is always illuminated in green.

Toolbar

The toolbar contains the icons that are used during the patient session. The icons provide quick access to frequently used commands.

During the patient session, the waveform screen is displayed. You can use the toolbar icons during the patient session to view or hide specific exercise stress test data, which appear as an overlay on the waveform screen.

Some of the icons allow you to change specific default settings as you proceed through each phase of the patient session, while others give you a magnified view of various data in relation to the ECG.

When you hover over each icon, a Tool Tip is displayed.

See "Using the Toolbar Icons" on page 2-15 for a complete description of the icons and their functionality.

The default setting for the toolbar is at the top of the screen. You can change the location of the toolbar to the bottom of the screen. See the *ST80i Stress Test System Installation and Configuration Guide* to change the default setting (**Settings** > **User Profile** > **Display**).

Waveform Screen

Real-time ECG waveforms appear on the waveform screen. The default setting is 12-Lead.

Note:

When viewing 6 or 3 leads in the default waveform layout, you can change a lead by clicking the lead label on the left side of the display.

With the customizable options of ST80i, you can use the toolbar icons do the following:

- Change the default waveform layout you want to view (12, 6x2, 6, 3).

- Display the magnified beat (Zoom ST).
- Display the average complexes for each lead.
- Show or remove magnified beat, trends, anatomical representations (ST map), and average complexes from the ECG display.

On the bottom of the screen, the current settings appear for the following:

- Limb Lead amplitude
- Chest Lead amplitude
- Speed of trace display
- Filter (low and high pass)
- AC Filter setting in Hz (50 or 60)
- Indicator that the Artifact Filter is on (F)
- Indicator that the Smart Filter is on (S)

Figure 2-5   Limb Lead, Chest Lead, Speed, and Filter Settings

Limb: 10mm/mV Chest: 10mm/mV Speed: 25mm/s 0.05–150Hz 60~ F S

When you change these default settings using the toolbar icons, they appear in this location.

Side Panel

The side panel shows a continuous display of all relevant physiological parameters as well as visual indicators for current heart rate and a dynamic change in heart rate. From the side panel, you can enter NIBP and SpO_2 values. In addition, you can start, stop, and manually control the exercise device.

Figure 2-6   Side Panel
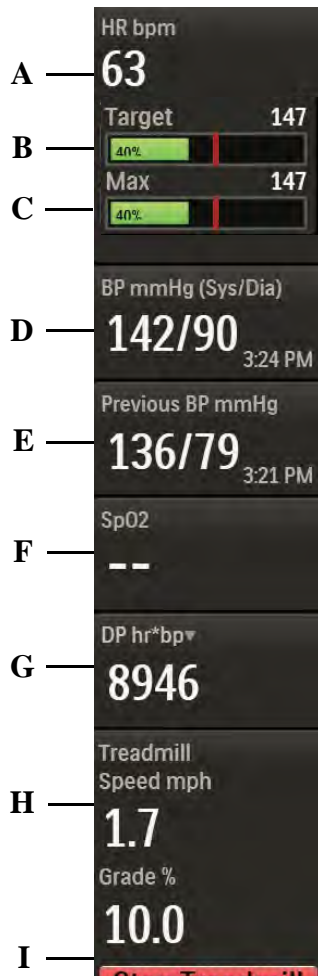
Table 2-4   Side Panel Features

Feature	Description
A	Heart rate beats per minute
B	Percent of target heart rate — Displays visual and audible indicators when target heart rate is achieved. A red vertical bar indicates the highest percentage of target rate achieved during the test.
C	Percent of maximum predicted heart rate. A red vertical bar indicates the highest heart rate achieved during the test.
D	BP mmHg (Sys/Dia) — Displays current blood pressure. Also used to manually insert current BP measurement.
E	Previous BP mmHg — When BP is taken as preconfigured by stage, previous BP is shown. Previous BP is also shown when you manually insert current BP measurement.
F	SpO$_2$ numeric data with appropriate stage. You can manually insert SpO$_2$ data.

Feature	Description
G	DP hr*bp — Double Product (DP) is the current heart rate multiplied by the current systolic measurement.
	DP is the default displayed in this field. You can also select METS or ST.
	METS — Establishes metabolic equivalent (algorithm calculation of HR, speed of treadmill, and so on).
	ST X mm (or mV) — X can be either of the following:
	· The default ST lead configured in **Settings** or selected from the **Zoom ST** window during a test
	· The lead with the Max ST Level or Max ST Slope configured in **Settings**.
H	Treadmill speed (mph) and grade percentage or ergometer power in watts.
I	Treadmill (**Start Treadmill**/**Stop Treadmill**) or Ergometer (**Load Ergometer**/**Unload...**) button — The button displays "Unavailable" when the treadmill or ergometer is unavailable.

Heart Rate bpm

This field shows the current heart rate of the patient.

Target Heart Rate

There are visual and audible indicators when the target heart rate is achieved.

This field shows the percent (%) of the Target Heart Rate achieved. Target Heart Rate is xx% (typically 85%) of maximum heart rate, as established in User Profile.

For more information regarding Target Heart Rate, see the *ST80i Stress Test System Installation and Configuration Guide.*

Max Predicted Heart Rate

This field shows the percent (%) of the maximum predicted heart rate achieved by the patient.

For more information regarding Max Heart Rate, see the *ST80i Stress Test System Installation and Configuration Guide.*

BP mmHg (Sys/Dia)

When the patient's NIBP is collected automatically during the exercise stress test based on the defined interval in the Exercise Protocol (Off, Begin, End, Every), the **BP mmHg** (Sys/Dia) field displays the measurement.

This field is also used to manually enter a blood pressure measurement, if an NIBP monitor is not being used. To manually enter a blood pressure, click the **BP mmHg** field or press F3.

With this interface, there are visual and audio prompts (if enabled) for NIBP acquisition.

To enable audio alerts, see the *ST80i Stress Test System Installation and Configuration Guide*.

To manually enter the blood pressure measurement

Note:

ST80i continues to update the real-time value from the NIBP monitor even when the BP is manually entered.

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1. Click the dashed lines or current BP value in the **BP mmHg** (Sys/Dia) field, or press F3.

2. Type the blood pressure measurement using the following guidelines:

   - Use only numbers 1 through 400 for the systolic and diastolic values.

   - It is not necessary to type the slash (/) between the systolic and diastolic values; ST80i will place the slash after you click **OK**.

   - The following table provides examples of how ST80i accepts manual blood pressure entries.

Table 2-5   Methods of Manually Entering Manual Blood Pressure Measurements

If you enter	Example(s)	ST80i assumes that
5 or 6 digits with no slash (/) between the systolic and diastolic values	12080	the first 3 digits are the systolic value and the last 2 or 3 digits are the diastolic value
2 or 3 digits followed by a slash (/) and then another 2 or 3 digits	120/80	the digits before the slash (/) are the systolic value and the digits after the slash (/) are the diastolic value
4 digits with no slash (/) between the systolic and diastolic values	9880	the first 2 digits are the systolic value and the last 2 digits are the diastolic value

If you enter	Example(s)	ST80i assumes that
2 or 3 digits (with or without the slash (/) after the digits)	120 120/ 98 98/	you have entered only a systolic value (ST80i will place dashes representing the missing diastolic value after you click **OK)**
a slash (/) followed by 2 or 3 digits	/98 /120	you have entered only a diastolic value (ST80i will place dashes representing the missing systolic value after you click **OK**)

3. Click **OK**. The blood pressure measurement is displayed, along with a timestamp for the entry.

Previous BP mmHg

When the blood pressure monitor records the current blood pressure measurement, the **Previous BP mmHg** field displays the previous measurement and a timestamp for that entry. When you click the **BP** button on the procedure bar to trigger a BP measurement or type a BP value, the **Previous BP mmHg** field is not updated until the new BP value is available.

SpO$_2$

The patient's SpO$_2$ is collected in real time through a sensor placed on the patient's finger or ear. During the stress test, SpO$_2$ is measured automatically and is continuously displayed on the screen if the SpO$_2$ is coming from the Tango® NIBP device; otherwise you must manually enter it.

You can override the NIBP and SpO$_2$ values. Depending on the NIBP monitor being used, you may need to manually enter the SpO$_2$ data.

To override or manually enter the SpO$_2$

1. Click the dashed lines or value.

2. Type the latest SpO$_2$ value, from 0 to 100.

3. Click **OK**.

Double Product/METS/ST

You can use the drop-down arrow in this field to select the measurement you want to display.

DP hr*bp

Double Product (DP) is the current heart rate times the current systolic measurement. This is the measurement shown in this field by default.

METS

The METS calculation establishes a metabolic equivalent based on the algorithm calculation of the treadmill time, speed, and elevation or the ergometer power. The METS calculation follows a linear progression up to the 2 minute mark. If the stage reaches 2 minutes, the Max Mets for the stage is displayed.

ST X mm (or mV)

X can be either of the following:

- The default ST lead configured in **Settings** or selected from the **Zoom ST** window during a test
- The lead with the Max ST Level or Max ST Slope configured in **Settings**.

You can change the lead displayed in this field by selecting a new lead from the **Lead** list in the **Zoom ST** window.

To change the lead that is in view

1. Click the **Hide/Show View** icon in the toolbar.
2. Select **Show Zoom ST**.
3. In the **Zoom ST** window, click the **Lead** drop-down arrow.
4. Select the lead you want to view.

Treadmill Speed and Grade Percent or Ergometer RPM and Power

These two fields capture the treadmill speed and elevation, or the ergometer RPM and power, by stage.

You can also use these fields to manually change the treadmill speed and elevation or ergometer power. To do this, see "Controlling the Treadmill or Ergometer" on page 3-38.

During the entire stress test, the host-side application validates the response between the treadmill or ergometer and the PC to ensure that the communication is successful.

Treadmill/Ergometer Buttons

The Start Treadmill/Stop Treadmill buttons are used to start and stop the treadmill during a patient session.

The Load Ergometer/Unload... buttons are used to load and unload the ergometer during a patient session.

Notes:

- *Alternatively, you can press F4 to start the treadmill or load the ergometer, or press F6 to stop the treadmill or unload the ergometer.*

If you have two devices configured, an option is available in the **Select Patient from Worklist** *window to select the device to use for the current patient.*

WARNING

The ST80i RS-232 ports should be connected only to treadmills, ergometers, and NIBP monitors that are certified to meet IEC 60601-1 and are listed as supported devices in the Instructions for Use. See "Supported Treadmills and Ergometers" on page E-8 of Appendix E, "Specifications and Requirements".

Use of USB cables for these devices is not recommended and may result in abnormal operation of ST80i due to electromagnetic noise interference.

Caution

If the Stop Treadmill button does not respond for any reason, immediately press the red Emergency button on the treadmill handrail.

Using the Toolbar Icons

Generally, you do not change the settings associated with a selected profile and protocol during an exercise stress test. However, there may be instances when you wish to change specific display settings. You can change display settings by using the toolbar icons.

Figure 2-7   Toolbar Icons
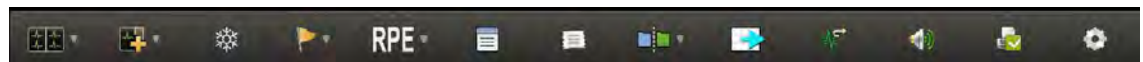
When you hover over each icon, a tool tip is displayed.
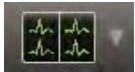
Using the toolbar icons, you can do the following:
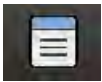
- Change the default setting of the waveforms on the waveform screen.
- Use the lead map diagram to check the lead wire connection integrity with a predefined, color-coded indicator to show any leads that are off.
- Display a zoomed view of an average complex for either a specified lead or for the lead that shows the most significant change in ST level.

- Compare the current averages with a referenced event (resting, supine, hyperventilation, chest pain, and so on) and with the worst case of ST elevation or ST slope for all twelve leads (by selecting Max ST Level or Max ST Slope from the Lead drop-down in the **Zoom ST** window).

- View magnified ST and morphological changes (including ST morphology changes, T wave morphology changes, QRS morphology changes) in the various leads.

- View trend graphs for Heart Rate, METS, BP, SpO_2, and ST values at any time.

- Hide or show the magnified beat, trends, anatomical representations (ST Map) and average complexes that appear over the real-time waveform display.

- View a two-dimensional, color-coded anatomical representation of ischemic area/segments (ST Map); 2D real-time updates anatomical representation (ST Map) every 1 second.

- Freeze the ECG.

- Create events during the test with associated notes.

- Record Rate of Perceived Exertion scores.

- Add notes about the patient's progress during the stress test.

- Add narrative information about the patient and the stress test.

- Advance the thermal paper so that the printing starts at the top of the page.

- Reset the CAlg-STR algorithm in order to relearn the normal morphology of the patient's ECG.

- Turn audible alerts on or off for the current stage; alerts re-initialize with each stage.

- Change specific default settings for Filter, Display, Rhythm Print, Sync Out, Events, and Pacer Detection.

The following table provides an overview of each icon.

Table 2-6   Toolbar Icons

Icon	Description
Waveform	The default is 12 leads; you can select from the following: • 12 Leads • 6x2 Leads • 6 Leads • 3 Leads

Icon	Description
Hide/Show View	Select from the following: • Show Lead Map • Show Zoom ST • Show ST Map • Show Trend View (HR/METS; BP; ST Level, SpO$_2$) • Show Average
Freeze	Captures the most recent 10 seconds of ECG and displays it in a dialog box. You can save and print the freeze ECG.
Event	Select an event from the drop-down list. The events include: • Supine • Stand • Mason-Likar • Hyperventilation • Chest Pain • Shortness of Breath • Sitting • Add New Event — Type the name of the event in the **Add New Event** window and click **OK**.
RPE	Rate of Perceived Exertion — From preconfigured setting in the user profile.
Note	Insert comments about patient and/or test. This information is time-stamped with the current date and time and is printed in the final report.
Narrative	Use to type assessments about the patient and/or test. This information is displayed on the **Report** screen and printed in the final report.
Compare	Compares the current zoomed lead with a previous moment in time; shows the delta. Also compares the averages if they are being displayed.
Paper Advance	Form-feed adjustment for thermal paper.

Icon	Description
Algorithm Relearn	Allows the CAlg-STR algorithm to relearn the normal morphology of the patient's ECG.
Silent	Indicates that alerts in the current stage will be audible. Click to silence audible alerts in the current stage. Indicates that alerts in the current stage will not be audible. Click to turn on audible alerts.
Notification Printing	Events that are preconfigured to print in **Settings** > **User Profile** > **Notifications** are printed automatically when they occur during a patient session. This is called notification printing. At the beginning of each session, notification printing is on by default. Clicking the **Notification Printing** icon once toggles it off and a red symbol appears on the icon to indicate that notification printing is disabled. Clicking the icon again turns notification printing back on. Only events that are preconfigured to print under Notifications are affected by the status of the **Notification Printing** icon. The printer itself is not disabled; You can still print stage ECGs, 12-Lead ECGs, rhythm prints, and events. Up to 100 events are saved, even when notification printing is disabled. Subsequent events are not saved, but if preconfigured, display notifications still appear for these events.
Quick Settings	Quick Settings: · Filter (LP, HP, AC, Artifact, Smart) · Display (Limb Gain, Chest Gain, Speed) · Rhythm Print (Leads, Limb Gain, Chest Gain, Speed) · Sync Out (Analog Out 1/Amplify Ratio, Analog Out 2/Amplify Ratio, TTL Out/Polarity, Duration) · Events (PVC, V Couplet, VRun) · Pacer Detection (Paced Unknown, Paced, Non-paced, Paced (magnet))

Waveform

Real-time ECG analysis employs the latest CAlg-STR analysis to calculate an adult patient's ECG for ST segment (elevation or depression) and to produce events and notifications simultaneously for all supported ECG leads.

All ECG data from the start of Pre Exercise through the end of Recovery is saved.

The real-time waveform default is the 12-Lead. You can choose from four display formats for the real-time ECG:

· 12 Leads

· 6 x 2 Leads

· 6 Leads

· 3 Leads

Note:

In 6 Leads or 3 Leads display format, you can click on the lead label on the display to change the lead quickly.

To change the real-time ECG format

1. Click the **Waveform** icon in the toolbar.

2. Select the lead configuration you want to display:

    – 12 Leads

    – 6 x 2 Leads

    – 6 Leads

    – 3 Leads

   The waveform screen display changes to the new setting.

Hide/Show View

To allow maximum viewing of the waveforms, some views are hidden. Use the **Hide/Show View** icon to display the following:

· Show Lead Map

· Show Zoom ST

· Show ST Map

· Show Trend View (HR/METS; ST Level; BP)

· Show Average

About the Lead Map View

The Lead Map diagram shows the status of each lead. Red indicates lead-off, and green indicates good contact.

To view the Lead Map

1. Click the **Hide/Show View** icon.

2. Select **Show Lead Map**.

   The **Lead Map** window appears to the right of the waveform. All connections must be green.

   Figure 2-8   Lead Map Window
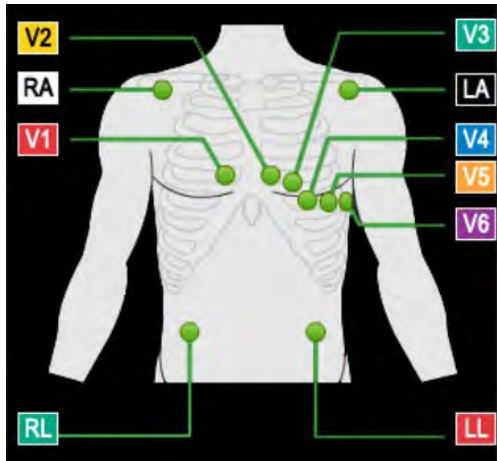
   If a lead is off, a red X on the lead map and a red dashed flat line is displayed in the real-time ECG view. On the PIM, this condition is verified by a yellow LED light.

3. To close the Lead Map, click the **X** in the upper-right corner.

Note:

A leads-off condition is displayed as a dashed line on the display and on printed ECG reports.

About the Zoom ST View

The **Zoom ST** window shows one expanded average ECG complex, which is an averaged ECG enlarged to four times the normal size.

The absolute ST segment values and slope values, as well as the delta values for ST level and slope, are displayed for the expanded lead. This function enables you to better visualize the ST segment changes during the test.

The default ST lead is shown in the **Zoom ST** window during the exercise stress test. When you begin a test, the default ST lead that is shown in the zoomed display is preconfigured in the user profile. You can select any lead as the zoomed lead from the Lead drop-down arrow.

You can also select a lead for the default setting. For default settings, see the *ST80i Stress Test System Installation and Configuration Guide*.

Note:

The Trend view displays the ST change trend for the lead that is elected as the Zoom ST lead. See "About Trend View" on page 2-23.

In the **Zoom ST** window, the following are displayed:

- ST Level (mm or mV) and Delta
- ST Slope (mV/s or mm/s) and Delta
- J+ Point (default is 60 mm)
- Lead (menu)
- Reference (menu)

Delta values for ST Level and ST Slope are calculated in relation to the selected Reference event.

You can change the J+ Point in the **Zoom ST** window by clicking the value. This can be done only during Prepare or Pre Exercise or at the end of the exam on the **Report** screen.

Note:

ST80i can display the lead with the maximum absolute value of the ST level or ST slope if you select **Max ST Level** *or* **Max ST Slope** *using the drop-down arrow for the default lead.*

When you use the Compare feature, the reference QRS (in white) is superimposed on the current QRS to provide a visual comparison of ST change.

The viewing options for Zoom ST are:

Table 2-7   Zoom ST Options

Zoom ST Option	Description
Any individual lead	Any of the twelve leads. This selection remains in force until you change it.
Max ST Level Max ST Slope	The system monitors all twelve leads and displays the one with the most significant ST change. The lead shown changes automatically during the stress test; the changes are reflected on printed reports as well.

To view the Zoom ST

1. Click the **Hide/Show View** icon.

2. Select **Show Zoom ST**.

The default Zoom ST appears as one expanded average ECG complex to the right of the waveform.

3. Click the **X** in the upper-right corner to close the **Zoom ST** window.

To change the Zoom ST lead

1. While viewing the **Zoom ST** window, use the **Lead** menu in the **Zoom ST** window to change to another lead or to Max ST Level or Max ST Slope.

2. Click the **X** in the upper-right corner to close the **Zoom ST** window.

About the ST Map View

The two-dimensional, color-coded ST map, which can help to identify ischemic areas in the myocardium, is based on both the ST deviation and ST slope. It updates every 1 second and can be displayed on the waveform screen.

To view the ST Map

1. Click the **Hide/Show View** icon.

2. Select **Show ST Map**.

The **ST Map** window appears to the right of the waveform.

Figure 2-9   ST Map Window
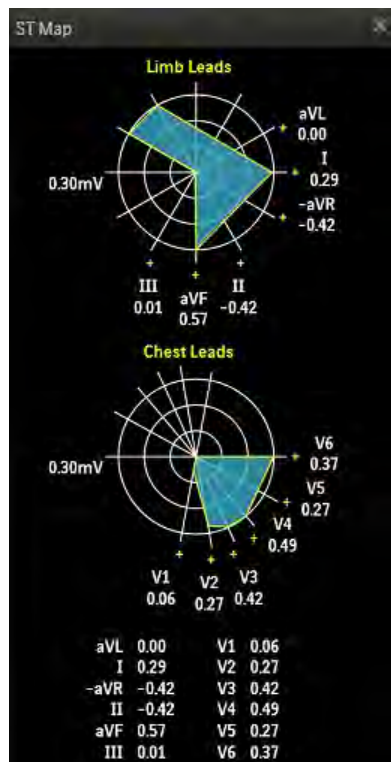
3. Click the **X** in the upper-right corner to close the ST Map.

About Trend View

The Trend graphs show a visual indicator for the current heart rate as well as the dynamic change in heart rate. The Trend data appears in 4 charts that can be viewed at any time.

Note:

The Trend graphs start updating at the beginning of Pre Exercise. The Trend view displays the ST change trend for the lead that is selected as the Zoom ST lead.

To view trends

1. Click the **Hide/Show View** icon.
2. Select **Show Trend View**. The **Trend** window appears to the right of the waveform.

Figure 2-10   Trend Window
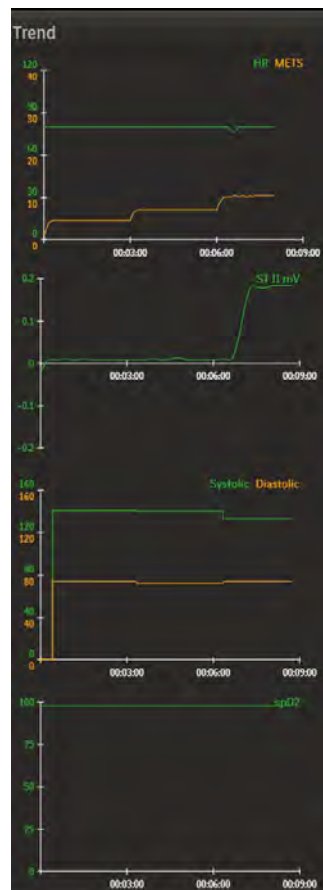
The **Trend** window displays four two-dimensional color-coded charts that show the trend, over time, of the following measurements and clinical information:

- HR/METS
- ST (selected lead) + mV

- BP (Systolic, Diastolic)
- SpO$_2$

3. Click the **X** to close the **Trend** window.

About the Average View

The **Average** window shows one average complex for each of the 12 leads regardless of which lead format is being displayed.

By default, the system displays the ST value in microvolts (mV) for the on-screen average complexes. The ST unit can be configured in **Settings** to be mm. For more information, see the *ST80i Stress Test System Installation and Configuration Guide*.

To view averages

1. Click the **Hide/Show View** icon.

2. Select the **Show Average** check box. The **Average** window appears to the right of the waveform.

Figure 2-11   Average mV and mV/s for Each Lead
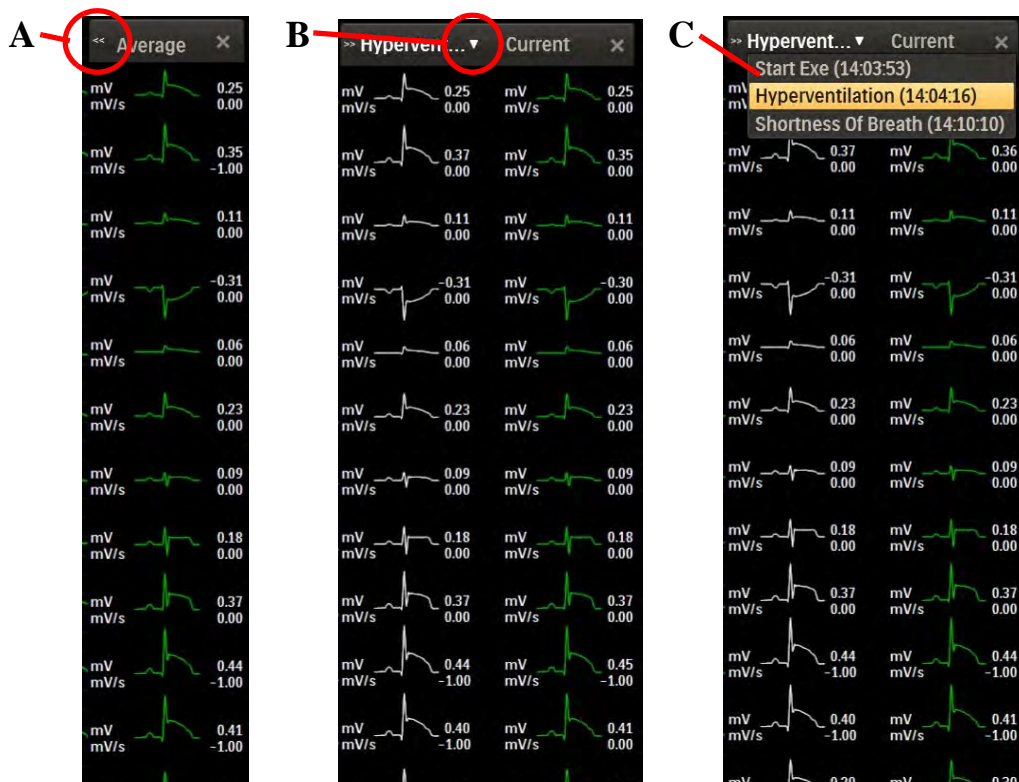
3. To compare the current averages with the averages from an event, click the **<<** button (**A**). Use the down arrow (**B**) to select a different event for comparison from the drop-down list (**C**).

4. Click **X** to close the **Average** window.

Freeze

You can print a 12-Lead ECG at any time by clicking the ECG Print button. During the Exercise phase, when you select the **Freeze** icon, it freezes the most recent 10 seconds of ECG data so that you can view a specific event. A dialog box displays a Freeze image of all leads captured at the moment you clicked the **Freeze** icon.

A scroll bar at the base of the Freeze image allows you to scroll to view any part of the frozen ECG.

To freeze the ECG

1. Click the **Freeze** icon. The **Freeze** dialog box appears to the right of the waveform.

   Figure 2-12   Freeze Dialog Box
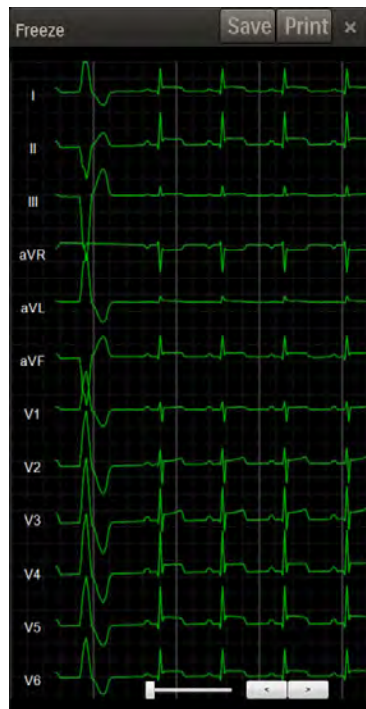
2. Use the slide bar or the arrow buttons to scroll through the ECG.
3. Click the **Save** button to save the frozen ECG as an event.
4. Click the **Print** button to print and save the frozen ECG.
5. To close the **Freeze** dialog box, click the **X** in the upper-right corner.

Recording an Event

Events are associated with the user profile. You can add events to and delete events from the list of event labels when you create a user profile; however, factory-loaded events cannot be deleted. As the test progresses, you can record events, if and when they occur, and you can also add events to the list by clicking the **Event** icon on the toolbar. New events added from the list

during an exam are not saved as new Event labels; they are active only for that particular ECG.

When you record an event, ST80i generates a 12-Lead ECG and documents the event name on the ECG. The system also stores the event in memory and prints it in the Events portion of the final report. User Notes are also associated with the Event, if created. See "Note" on page 2-27 regarding the **Note** icon.

In addition, ST80i automatically detects an arrhythmia event, if this is enabled. To enable arrhythmia detection, see the *ST80i Stress Test System Installation and Configuration Guide*. See also "Notifications and Alerts" on page 3-39.

The default events include:

- Supine
- Mason-Likar
- Standing
- Hyperventilation
- Chest Pain
- Shortness of breath
- Sitting

To record an event

1. Click the **Event** icon to display the following list:

   - Supine
   - Mason-Likar
   - Standing
   - Hyperventilation
   - Chest Pain
   - Shortness of Breath
   - Sitting
   - Add New Event

2. Select the event you want to record.

   The system prints an ECG and records the event for the final report.

To add an event

1. Click the **Event** icon.

2. Click **Add New Event** to open the **Add New Event** dialog box.

3. Type a name for the new event.

4. Click **OK**.

   The system prints an ECG with the new event label and records the new event for the final report.

Note:

New events added from the list during an exam are not saved as new Event labels; they are active only for that particular ECG.

Recording RPE
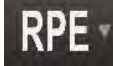
The Rate of Perceived Exertion (RPE) scale provides an indication of the patient's perceived rate of exertion. It subjectively rates work (physical exertion) as stated by the exercising patient. It provides a means to quantify a patient's level of exertion.

RPE scales can be expressed in two ways, 0 to 10 or 6 to 20. The scale used is associated with the selected user profile. To set the RPE scale, see the *ST80i Stress Test System Installation and Configuration Guide*.

When you want to record an RPE score, ask the patient to state which number or statement represents their perceived level of work. Then select the corresponding number from the RPE drop-down list. Once the number is selected, the system prints an ECG report, noting the RPE.

Figure 2-13   RPE List (Showing 0–10 Scale and 6–20 Scale)
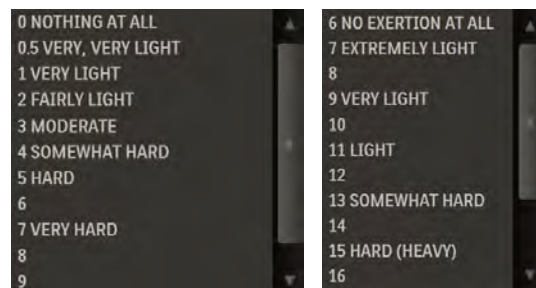
To record the patient's RPE

1. Click the **RPE** icon.

2. From the **RPE** list, select the statement that matches what the patient reports.

3. Click **OK**.

    The system prints an ECG with the RPE statement.

4. Continue this process throughout the Exercise phase.

The RPE ECG is printed in the Events section of the final report.

Note
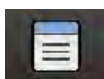
During the patient session, you can add notes about the patient's progress as well as important information regarding the exercise stress test. These comments are stored in the Notes section of the Patient Demographics

database and they also appear as part of the final stress report.

To add a note

1. Click the **Note** icon. The **Note** dialog box appears. There is no limit to the amount of text you can type in this dialog box. Each note is time-stamped with the current date and time.

2. Click **OK** to save the note.

Narrative
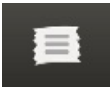
During the patient session, you can add narrative information about the patient and exercise stress test. Narrative text appears in the **Narrative** text box in the Comments section of the **Summary** tab on the **Report** screen. You can also update Narrative information directly from the **Report** screen.

To add narrative information during the patient session

1. Click the **Narrative** icon to open a dialog box in which you can type narrative information.

2. Click **OK** to save the narrative information.

Compare

ST80i can compare the current averages with a selected event (for example, supine or hyperventilation) and with the worst case of ST elevation or ST slope for all 12 leads.

As the heart rate increases and/or morphological changes occur, you can use the Compare function to view the delta between the current QRS morphology and a reference QRS such as a supine event, stage event, or other event.

Note:

ST Segment Analysis must be enabled before you can use the Compare function. See the ST80i Stress Test System Installation and Configuration Guide (**Settings** > **User Profile** > **Algorithm** > **CAlg Templates**).

To use the Compare icon

1. Click the **Compare** icon. A list of current events/compare points allows you to compare the current state to the state when the event occurred or to an earlier point in time.

Note:

*The CAlg-STR Exercise ECG analysis algorithm requires one minute of ECG data in order to generate analysis results. This minute begins when you click the **Pre Exercise** button to start the Pre Exercise phase. If you click the **Compare** icon before CAlg-STR has acquired one minute of ECG data, or before an ST value is displayed, the current lead view cannot be compared with the selected event.*

Figure 2-14   Compare List
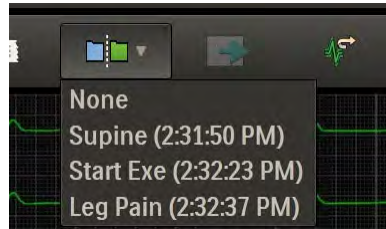
2. Select the event to use as a reference. The **Zoom ST** window appears. In the zoomed lead, the reference ECG is superimposed on the averaged ECG. The white line represents reference data; the current averaged ECG data is green.

Figure 2-15   Compared ECGs
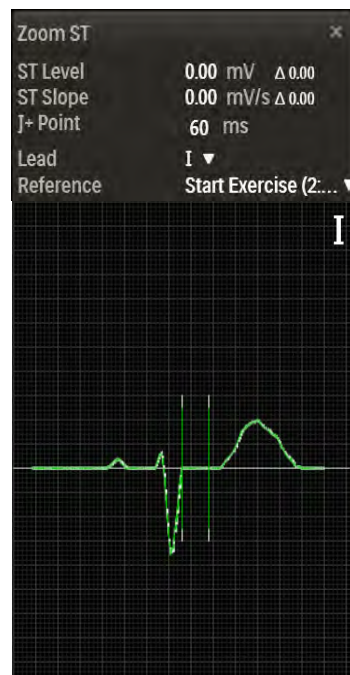
To compare the current averages with the worst case for all 12 leads, select Max ST Level or Max ST Slope from the Lead drop-down arrow.

3. Click the **X** to close the **Zoom ST** window.

Paper Advance

 Use the **Paper Advance** icon to advance the thermal paper so that the printing starts at the top of the page (at the perforation). This form-feed function for the thermal printer returns the paper to "top of form." You can also use the **Paper Advance** icon to advance the paper if there is a paper jam or after installing a new package of paper.

Algorithm Relearn
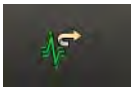
 The **Algorithm Relearn** icon allows the CAlg-STR algorithm to reset in order to relearn the normal morphology of the patient's ECG. You can use the **Algorithm Relearn** icon to recalibrate the algorithm if the ECG becomes noisy, seems to be reporting false-positive rhythm events, or when the ST values or average beats cannot be calculated for several minutes. When you click the **Algorithm Relearn** icon, current ST values and average beats are cleared and recalculated.

The Algorithm Relearn feature may be useful during the Pre Exercise phase if a lead comes off or requires repositioning or during the Recovery phase if many rhythm events are being reported. It is recommended that the Algorithm Relearn feature not be used during the Exercise phase, as important information may be lost.

Silent
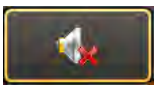
 The **Silent** icon allows you to turn off—for the current stage only—any audible alerts that may be configured. By default, audible alerts are played. Clicking the **Silent** icon turns off audible alerts, and the icon toggles to an image showing that audible alerts are not played. If you click on this image, audible alerts are turned back on. Otherwise, the button automatically changes when the next stage begins, resuming audible alerts.

Notification Printing

 Events that are configured to print under **Settings** > **User Profile** > **Notifications** are printed automatically when they occur during a patient session. You can click the **Notification Printing** icon to toggle notification printing off or on during the session. When notification printing is turned off, a red symbol appears on the icon. You can also check whether notification printing is turned off or on by hovering over the icon.

Turning notification printing off does not disable the printer. You can still print stage ECGs, 12-Lead ECGs, rhythm prints, and events.

Quick Settings

Click the **Quick Settings** icon to open the **Quick Settings** dialog box from which you can change specific default settings (for this study only) that relate to the following:

- Filter
- Display
- Rhythm Print
- Sync Out
- Events
- Pacer Detection

Figure 2-16   Quick Settings Dialog Box

Filter

The Filters are preconfigured in the Settings section of the application. When you log on to ST80i, the active settings of the filters are set to a stored default set that is associated with your user profile.

The ECG data is stored in its recorded state (0.02–300Hz, all filters off) and user-selected settings are stored with the ECG.

Note:

The ECG data is filtered at 0.05–150 Hz and by an AC notch filter before being analyzed by the algorithm. This filter is called the algorithm filter and cannot be turned off by the user. The algorithm filter is independent from other filters, is not controlled by the user, and does not affect the saved ECG data.

All filters can be turned on or off as needed to improve displayed and printed waveform quality except for the algorithm filter (as described above) and minimum filters (0.02Hz high pass filter and 300Hz low pass filter).

Using the **Filter** tab in Quick Settings, you can change the default settings.

The options include:

- Low Pass (LP) Filter: 40Hz, 100Hz, 150Hz, 300Hz
- High Pass (HP) Filter: 0.02Hz, 0.05Hz, 0.15Hz
- AC Filter: 50Hz, 60Hz, Disable
- Artifact Filter: On, Off
- Smart Filter: On, Off

The same filter settings apply to both displayed and printed waveforms. The filter settings are printed with the report.

To change the Filter settings

1. Click the **Quick Settings** icon.
2. Click the **Filter** tab.
3. Change or modify each filter, as required.
4. Click **OK** to save your settings.

Note:

Enabling the Artifact Filter and/or Smart Filter causes a brief data loss represented by red dashed lines on the display due to initialization of filtering algorithms. Disabling the Artifact Filter and/or Smart Filter causes a brief data loss represented by a sudden change in waveform morphology.

For more information, see "Filtering" on page 3-22.

Display

On the **Display** tab, you can change the Limb Gain, Chest Gain, and Speed.

To change the Display settings

1. Click the **Quick Settings** icon.
2. Click the **Display** tab.
3. Use the drop-down arrow to adjust the Limb Gain setting.
4. Select a different Chest Gain setting:
   - Full
   - Half
5. Select a different speed:
   - 25 mm/s
   - 50 mm/s
6. Click **OK** to save your settings.

Rhythm Print

Before you click the **Rhythm Print** button from the procedure bar to print a continuous strip, you can modify your settings based on the following:

· Leads

· Limb Gain

· Chest Gain

· Speed

To change the Rhythm Print settings

1. Click the **Quick Settings** icon.

2. Click the **Rhythm Print** tab.

3. Select the check box for each lead you want to print.

Note:

You cannot select the aVR lead and the –aVR lead at the same time.

---

4. Use the drop-down arrow to adjust the Limb Gain setting to 2.5, 5, 10, or 20 mm/mV.

5. Select a different Chest Gain setting:

   – Full

   – Half

6. Use the drop-down arrow to adjust the Speed to 5, 10, 25, or 50 mm/sec.

7. Click **OK** to save your settings.

Sync Out

ST80i supports two analog ECG output signals and one TTL ECG Sync Output on the Advanced Interface Module (AIM).

· Use Analog ECG Output for synchronization with ECHO device for Stress-Echo procedures. This signal is not to be considered as diagnostic quality.

· Use TTL Sync Output for QRS gating required by the Tango® NIBP device.

Caution

Analog ECG output signals are not diagnostic quality and should not be used for analysis.

The sync outputs are preconfigured as part of the user profile. However, they can be changed during the patient session.

See the *ST80i Stress Test System Installation and Configuration Guide* for how to configure Sync Out settings in the user profile.

To change Sync Out settings

1. Click the **Quick Settings** icon.
2. Click the **Sync Out** tab.
3. Use the drop-down arrows to modify the following:
   – Analog Out 1; Scale
      – *Example*: Analog Out: I; Scale: 3 mV/V
      – *Options*: None, Leads I–V6
   – Analog Out 2; Scale
      – *Example*: Analog Out 2: None; Scale: 1 mV/V
      – *Options*: None, Leads I–V6
   – TTL Out; Polarity; Duration (ms)
      – *Example*: TTL Out: None; Polarity: Positive; Duration: 50 ms
      – *Options*: None, Leads I–V6; Positive, Negative
4. Click **OK**.

Events

You can set the number of events saved per minute for the following events:

- PVC
- VCouplet
- VRun

To change Event settings

1. Click the **Quick Settings** icon.
2. Click the **Events** tab.
3. Adjust the number of events per minute for each event you want to reset.
4. Click **OK**.

Pacer Detection

To change Pacer Detection settings

1. Click the **Quick Settings** icon.
2. Click the **Pacer Detection** tab.
3. Select a new Pacer Detection setting.
4. Click **OK**.

The Patient Session

Overview

A patient session is the period of time when the exercise stress test is performed and waveforms are acquired and processed for a single patient. Patient information is linked with all waveform data acquired during the patient session. The session starts when you begin a new exam by entering the Prepare phase, and lasts through the generation of the final report.

In ST80i, the exercise stress test begins with the Prepare phase and ends with the Report phase:

- Prepare
- Pre Exercise
- Exercise
- Recovery
- Report (including Post-Recovery)

Note:

For information about the patient session when using the Resting ECG Workflow product option, see Chapter 5, "Resting ECG Workflow."

Caution

Do not run any other applications, including screen savers, when performing an exercise stress test. Once the test has begun, the ST80i application does not allow you to access other system functions.

Using the Patient Worklist

When you click **Stress** on the **Main** screen, you are taken to the **Select Patient from Worklist** screen, where you begin a patient session by selecting the patient for the exam.

The **Select Patient from Worklist** screen includes two tabs:

- Worklist

- Remote Find

Use the **Worklist** tab to manage patient information. The worklist enables you to pre-register up to 200 patients. Once the 200 patient limit has been reached, you must delete some patients from the worklist before you can add more. The worklist database is populated by downloading patient orders or ADT data from a Hospital Information System (HIS), or by manually entering information using the **Worklist** tab.

Use the **Remote Find** tab to do a remote search for a patient using several data points. ST80i provides an interface with IntelliBridge (IBE) so that you can do the following before conducting an exercise stress test:

- Download a patient's data from DICOM server.

- Download a patient's orders or ADT data from the hospital HIS system (via IBE).

The **Select Patient from Worklist** screen also includes two menus to enable you to select the appropriate exercise and blood pressure devices:

- **Exercise Device** menu — Select the treadmill or ergometer to be used for the test. If you are using an exercise device that is not physically connected to the PC on which ST80i is installed, select Virtual Treadmill or Virtual Ergometer. ST80i uses standard protocol values for these virtual devices.

- **BP Configuration** menu — Select the blood pressure device to be used for the test. The content of this menu depends on the device selected in the Exercise Device menu. For most exercise devices, only SunTech Blood Pressure is supported. However, for the Ergoline Ergometer, you can select either SunTech Blood Pressure or Ergoline BP. For the Lode Ergometer, you can select either SunTech Blood Pressure or Lode BP.

Worklist Tab

The **Worklist** tab of the **Select Patient from Worklist** screen is used to manage the patient information list, including:

- Adding a new patient

- Finding a patient

- Editing a patient profile

- Deleting one or more patient information records

- Downloading orders or pre-registered patient information

- Selecting a patient to begin the exercise stress test

On the **Worklist** tab, you can change the placement of each column by clicking and dragging the column headings. You can also click the column headings to sort each list.

Figure 3-1   Worklist Tab
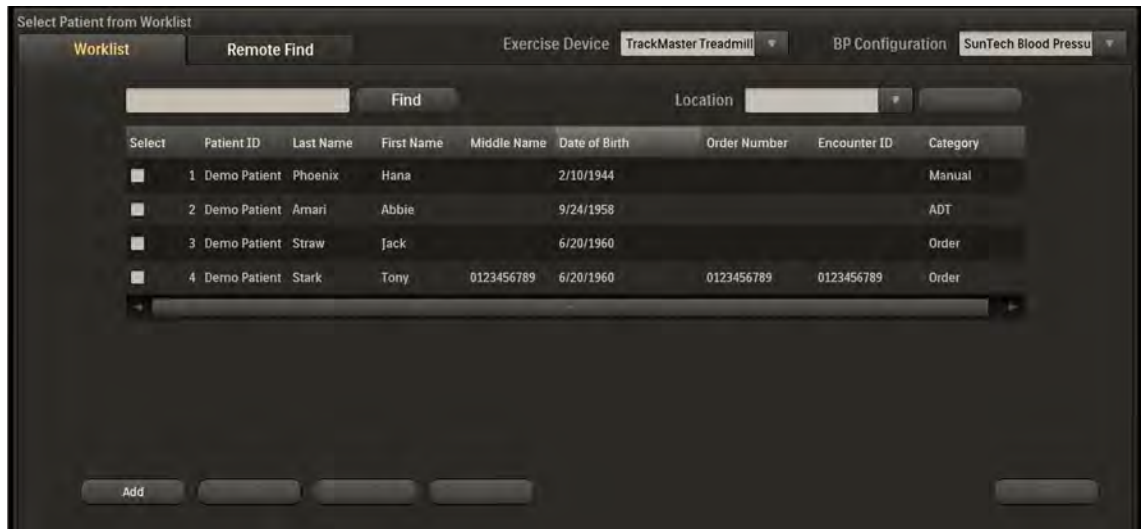
Patient Information Management

ST80i displays and reports key patient demographic information such as the patient name, patient ID number, and so on. Some settings are mandatory and configurable. Some settings are set to ON or OFF.

There are three ways to access patient demographic information:

- From the **Worklist** tab before the test:

    – Click the patient's worklist entry to select the patient.

    – Click **Edit** to open the **Edit Patient Information** window. Patient demographic information is displayed.

- From the **Stress** screen during a patient session (only during the Prepare and Pre Exercise phases):

    – Click the patient's name in the title bar. Patient demographic information is displayed.

- From the **Report** screen after a patient session:

    – Click the patient's name in the title bar. Patient demographic information is displayed.

Figure 3-2   Patient Demographic Information

Patient Information Fields

ST80i supports predefined and user-defined patient information fields. The predefined patient information fields are shown on the **Patient Information** tab of the **Edit Patient Information** window. The patient information fields are configured as mandatory or not. Mandatory fields must be populated before you can move to the Prepare phase. Mandatory fields are displayed in blue text. By default, mandatory fields include the following:

- Patient ID
- Last Name
- First Name
- DOB (MM/DD/YYYY)
- Age
- Gender
- Height
- Weight

Caution

To support optimal algorithm output, ensure that the DOB/Age and Gender fields are enabled and complete.

To configure or change mandatory patient information fields, see the *ST80i Stress Test System Installation and Configuration Guide.*

Add a New Patient to the Worklist

To manually add a new patient name to the worklist

1. Click **Add**.

2. In the **Add New Patient** window, complete the required fields for each of the following tabs:

   – **Patient Information**

Note:

- *When you complete the DOB (MM/DD/YYYY) field, the Age field is automatically populated.*

- *If you complete the Age field when the DOB (MM/DD/YYYY) field is empty, ST80i populates the DOB (MM/DD/YYYY) field with the calculated year, but uses the current month and day.*

- *If you delete either the DOB (MM/DD/YYYY) or Age, ST80i also removes the contents of the other field.*

- *If you change the Age while the DOB (MM/DD/YYYY) is populated, ST80i recalculates the DOB year but uses the current month and day.*

- *The Indications field is limited to 8 lines with 70 characters per line.*

- *The Symptoms field is limited to 5 lines with 70 characters per line.*

   – **History**

   – **Medications/Dosages**

Note:

- *The **Medications** field is limited to eight lines with 30 characters per line.*

- *The **Dosages** field is limited to six lines with 30 characters per line.*

- *The **Frequency** field is limited to six lines with 20 characters per line.*

- *When the maximum number of items in a field has been reached, a red exclamation point appears to the right of the field, Hover over the exclamation point for information about the field's limitation.*

   – **Physician/Order**

   – **Custom Fields**

3. If you want to:

   – Save the information and return to the worklist, click **Save**.

   – Save the information and begin the stress test, click **OK**.

Note:

If mandatory fields are missing, the Patient Info message indicates "Missing Required Fields." You cannot move beyond this point without supplying the missing information.

Find a Patient

You can find a patient already listed in the worklist by using specific demographic information as search criteria.

To find a patient in the worklist

1. Type one of the following into the search field: patient ID, last name, first name, or order number.

2. Click **Find**. The worklist displays only the patient(s) matching the search criteria.

3. Click **Back** to restore the full list of names.

Edit Patient Information

In the worklist, you can edit or review patient information by clicking the **Edit** button.

The Edit button becomes active when you select a patient name.

To edit patient information in the worklist

1. Click the patient's worklist entry to select the patient.

2. Click **Edit** to open the **Edit Patient Information** window.

Figure 3-3   Edit Patient Information Window

3. Update or edit the patient information in each of the following tabs, as required:

- **Patient Information** (See "Add a New Patient to the Worklist" on page 3-5 for more information on using the DOB (MM/DD/YYYY) and Age fields.)
- **History**
- **Medications/Dosages**
- **Physician/Order**
- **Custom Fields**

Note:

*You cannot edit the information in the **DICOM Fields** tab. It is presented only for informational purposes.*

4. If you want to:

- Save the information and return to the worklist, click **Save**.
- Save the information and begin the stress test, click **OK**.

Note:

*If a **Race** field is configured in Settings, a menu for race selection is included in the **Edit Patient Information** window.*

Delete a Patient Name

You can delete one or many patients from the worklist. In Settings, you can also configure the **Remove from Worklist after the final report is saved** option for automatic patient deletion.

To delete a patient name from the worklist

1. Click the patient's worklist entry to select the patient. You can select more than one patient name to delete.

2. Click **Delete**. A confirmation dialog box appears.

3. Click **Yes**.

Download Preregistered Patient Information

With ST80i, you can download preregistered patient information by accessing the order or ADT server via the network. The local patient information that you download from a remote server or manually add is stored in a local database. This optional feature permits the creation of a preregistered patient list.

Before downloading orders, you must connect to the preconfigured remote site.

Preconfigured IBE or DICOM remote sites are displayed in the **Location** list.

To download orders

1. Click the **Location** list.

2. Select the server on which the order is stored.

3. Click **Download**. The requested orders are downloaded and displayed in the worklist.

Review a Previous Study

Note:

This feature is only available if you have IECG/TraceMasterVue.

To review a patient's previous study

1. Click the patient's worklist entry to select the patient.

2. Click **Previous Study**. The **Previous Study Report List** screen opens.

Figure 3-4   Previous Study Report List Screen
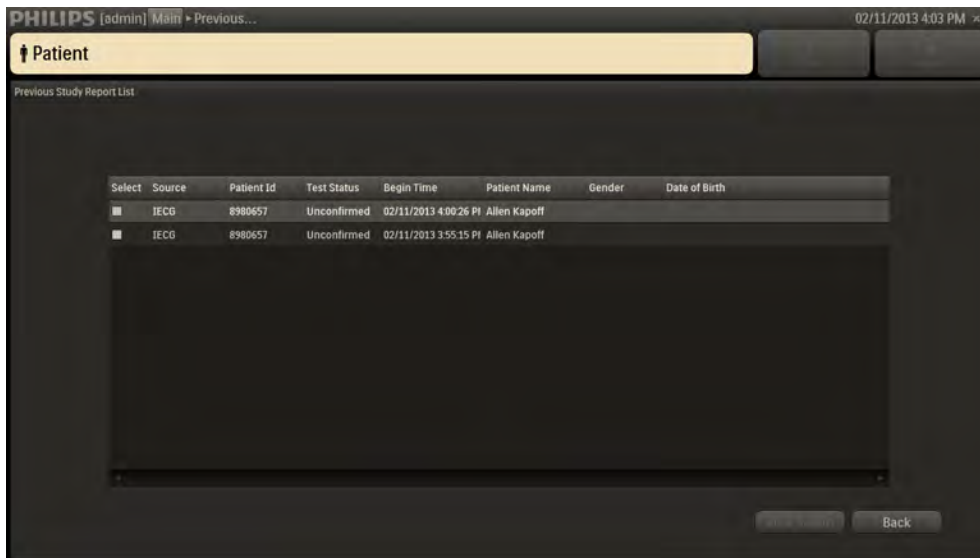
3. Click on the study you want to review.

4. Click **View**. The report opens in PDF format in the **Previous Study** viewer window. Note that the report contains multiple pages.

Figure 3-5   ECG Report in PDF Format

5. Click **X** in the upper-right corner of the **Previous Study** viewer window to close it.

6. Click **Back** to return to the **Select Patient from Worklist** window.

Select a Patient

When you are ready to begin the patient session for a patient, select his or her name from the worklist.

To select a patient to begin the patient session, click the patient's worklist entry to select the patient and click **OK**, or double-click the patient's name. This opens the first phase of the test—Prepare.

Remote Find Tab

The **Remote Find** tab of the **Select Patient from Worklist** window enables you to do a remote search for a patient using several data points. With this feature, you can select one or more entries from the search results list and save them to the worklist.

Figure 3-6   Remote Find Tab
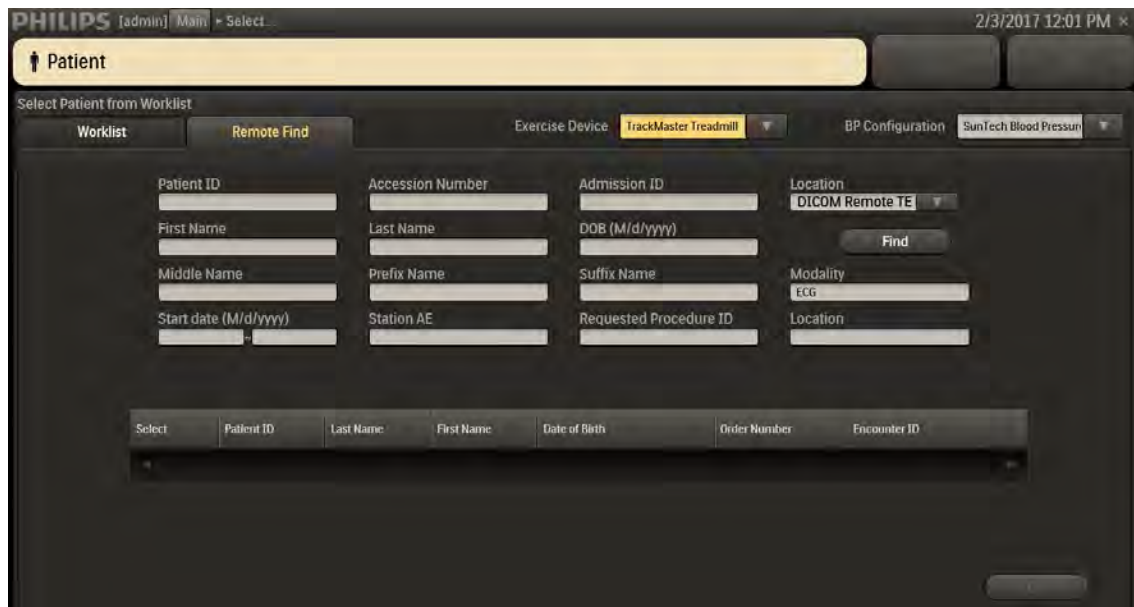
Figure 3-6 shows the **Remote Find** tab for a DICOM remote site. For other remote site types, fewer fields are available for entering search data.

To do a remote find

1. Select the location from the **Location** list.

2. Complete one or more of the following fields:

    -   Patient ID

    -   Last Name

    -   First Name

    -   DOB (MM/DD/YYYY)

    -   Order Number

    -   Encounter ID

3. Click **Find**. The patient's name appears in the **Remote Find** list.

4. Click the patient's entry to select the patient and click **OK**, or double-click the patient's name. This opens the first phase of the test—Prepare.

Before the Patient Session

The exercise stress test process requires some advance preparation before running the patient session. Advance preparation includes the following:

•   Checking the wireless Patient Interface Module (PIM)

•   Checking the equipment connection (treadmill or ergometer), if used

•   Setting up a Pharma test, if ordered, according to hospital protocol

Once advance preparation is complete, the patient session follows a series of typical steps, from preparing the patient to the final review of the exam.

Wireless Patient Interface Module (PIM)

The wireless PIM is a small data acquisition device that samples patient ECG signals and sends the processed signals to ST80i. The wireless PIM assembly contains the signal acquisition electronics, patient isolation circuits, and system interface circuits. The patient lead set connects to the patient electrodes on one end and plugs in to the wireless PIM on the other.

Figure 3-7   Wireless PIM and Lead Set

The wireless PIM digitizes the ECG signal and downsamples the ECG data before transmitting ECG data to ST80i. The wireless PIM uses high-pass and low-pass filters to produce filtered ECG data within certain bands.

The wireless PIM performs lead signal quality detection to determine if a lead is not connected to the patient or if electrode/patient contact impedance is excessively high.

Before each patient session, inspect the PIM and lead wires for any visible damage, including worn or cracked insulation on the lead wires.

The wireless PIM displays the following information:

· Wireless signal strength indicator:

  The wireless signal strength indicator appears once the PIM and AIM are synchronized, when the real-time ECG screen is displayed. This occurs when the exam moves to the Prepare phase or when you have clicked **Resting** from the **Main** screen.

  Wireless performance and signal strength are monitored on the currently used RF channel. The wireless PIM's signal quality icon indicates the connection status. If a channel has excessive interference, the wireless PIM automatically determines a clearer channel with higher signal strength and

coordinates with the Advanced Interface Module (AIM) to switch to the new channel.

- Lead-off indication for every lead:

  ST80i recognizes when an electrode is not connected and displays that information on the graphic of a human torso on both the wireless PIM and ST80i interface.

- Power indication for battery:

  The wireless PIM is battery-powered, and the battery voltage is monitored to ensure that the battery is not overly discharged. The remaining battery capacity is displayed in the wireless PIM's power indicator lights within the battery icon. These lights blink every 5 seconds when the PIM is in use.

  If the battery is discharged to the point where the PIM is expected to shut down shortly:

  - The PIM battery indicator blinks once every second.

  - The ST80i battery indicator turns red and blinks once every second.

  - ST80i displays one of the following Low Battery messages, depending on the current phase of the exam:

    - When you enter the Prepare phase: "Battery capacity is too low to perform a new test. Please replace battery."

    - During an exam: "Remaining battery capacity will provide approximately 1 hour of operation. Replace at your discretion."

The wireless PIM uses off-the-shelf (OTS) disposable AA alkaline batteries for its power source. For the disposable AA battery, the system has been designed to provide approximately one week of battery service life for a typical user environment.

Caution

- **ST80i supports only 1.5V AA alkaline batteries for the PIM. Replace the battery before the stress test starts if you receive the "Battery capacity is too low to perform a new test" message. The message that indicates estimated battery life is at least 1 hour should enable an exam to be completed before you replace the battery.**

- **The use of rechargeable batteries is not recommended, as the remaining capacity indication may be inaccurate, resulting in the possibility of the PIM powering down during a stress test or a low-battery alert shortly after replacing the battery.**

If your facility is using more than one PIM, each one must be added to the ST80i application under Settings (**System Settings** > **I/O Devices**). When you connect the patient to one of the PIM devices, you also need to verify that the address on the device matches the address displayed on the **Prepare** screen.

To preconfigure multiple PIM addresses, see the *ST80i Stress Test System Installation and Configuration Guide.*

Checking the Treadmill/Ergometer Connection

During the entire stress test, the ST80i software validates the response from treadmill/ergometer to ensure the communication between PC and treadmill/ergometer is successful.

If there is a connection issue, a communication error message appears across the waveform area.

During the Prepare phase, successful connection to the exercise device is indicated the presence of the **Start Treadmill** or **Load Ergometer** button at lower right of screen. In later phases, after the exercise device has been started, the buttons are named **Stop Treadmill** and **Unload Ergometer**. If the device loses communication with the ST80i system during any exercise phase, these buttons disappear.

Setting Up a Pharma Test

To set up a Pharma test, follow hospital protocol.

Starting a Patient Session

When you start a patient session by clicking **Stress** on the **Main** screen, you move through the following phases:

- Prepare
- Pre Exercise
- Exercise
- Recovery
- Reports

Note:

If you have the Resting ECG Workflow product option installed, you can also start a patient session by clicking **Resting** *on the* **Main** *screen. Once you have performed the resting ECG, you can move directly to the Prepare phase of the stress test. For more information, see Chapter 5, "Resting ECG Workflow."*

When you select a patient from the worklist for the stress test, you are immediately brought to the **Prepare** screen. Based on your user account settings at login, a preconfigured profile is loaded for the stress test. During the Prepare phase, the patient is connected to the electrodes so that the proper placement and ECG quality can be confirmed.

Select the Patient

To select a patient from the worklist

1. Click **Stress** on the **Main** screen.

2. Click the patient's worklist entry to select the patient and click **OK**, or double-click the patient's name.

   The **Prepare** screen appears. The patient's name and date of birth appear on the title bar along with the patient ID. The predefined protocol is shown on the procedure bar.

Note:

*If communication with the BreezeSuite™ application is enabled, but BreezeSuite is not ready to receive data, a message opens to ask whether you want to proceed without BreezeSuite. Click **Yes** to continue or **No** to cancel.*

Figure 3-8   Prepare Screen
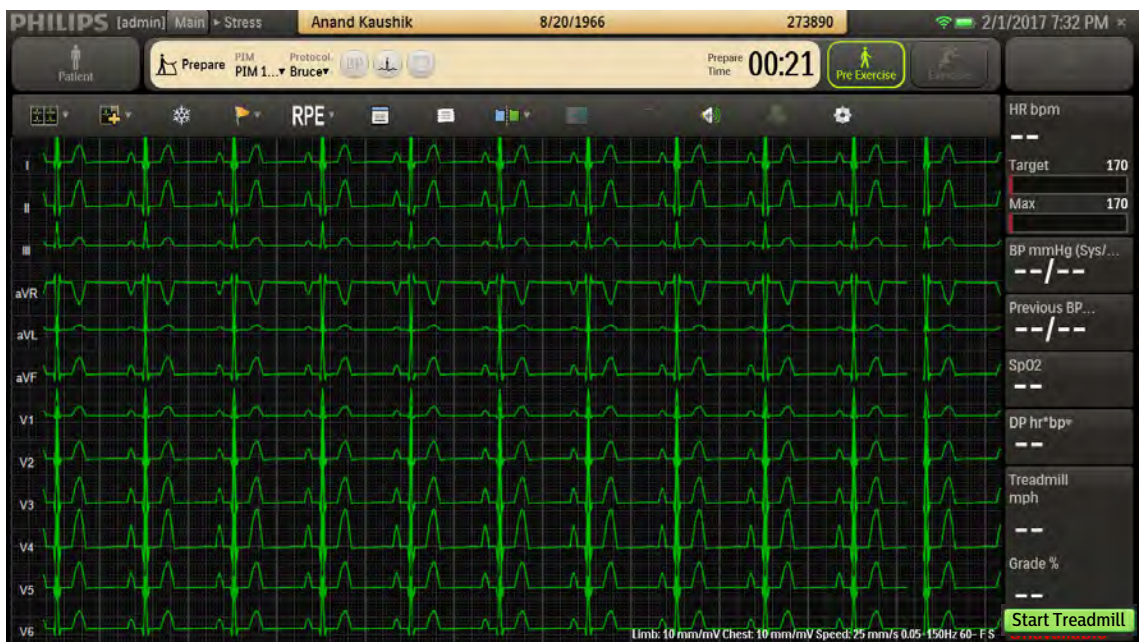
By default, the application displays the real-time ECG waveforms in the format specified in the selected user profile.

To change the real-time ECG display, see "Using the Toolbar Icons" on page 2-15.

When the treadmill is configured in the protocol or selected from the **Exercise Device** list in the **Select Patient from Worklist** window, the **Start Treadmill** button appears in the side panel.

If you select Cycle as the protocol for the patient or select an ergometer from the **Exercise Device** list on the **Select Patient from Worklist** window, the **Load Ergometer** button appears instead.

Select the Wireless PIM

Make sure the PIM is powered on and that it shows at least two bars of battery power. In a multiple-PIM environment, make sure that you select the correct PIM once the exam enters the Prepare phase.

By default, the last PIM used appears as the current PIM on the **Prepare** screen. When you click on the device name, a unique address appears, which is used to identify that specific PIM. If there are multiple PIMs registered, they appear as they were named during configuration.

To select the wireless PIM

1. Click the **PIM** menu in the procedure bar.

2. Click the name of the PIM device to be used.

3. Press the PIM button on the device to power it on (if it is powered off). The PIM wireless status provides feedback that the PIM is selected to communicate with the application.

Caution

Follow the correct procedure to select the PIM when multiple PIMs are detected.

To ensure proper wireless function of the PIM, press the PIM's light button to display battery strength.

If the battery is discharged to the point where the PIM is expected to shut down shortly:

• The PIM battery indicator blinks once every second.

• The ST80i battery indicator turns red and blinks once every second.

• ST80i displays this message: "Battery capacity is too low to perform a new test. Please replace battery."

Note:

To save the battery power, the PIM is preconfigured to power off automatically when there is no action on the PIM for a predefined period. This period of inactivity can be configured from 3 to 15 minutes.

To configure PIM Power Saving, see the *ST80i Stress Test System Installation and Configuration Guide*.

Prepare Phase

When you select the patient name, the **Prepare** screen appears. In the Prepare phase, you ensure that everything is ready, including the patient, the PIM, and the exercise device, before the actual test begins.

During the Prepare phase, you perform the following tasks:

- Instruct the patient about the stress test.
- Prepare the patient's skin.
- Attach the electrodes/lead wires.

Note:

You cannot enter the Pre Exercise phase without, at minimum, all limb leads connected. Good ECG technique is very important to achieve the best quality results.

- Connect the wireless PIM.
- Check the lead map.
- Check signal quality (filtering and sync output).
- Verify a clean ECG.
- Attach the BP cuff and/or the SpO$_2$ sensor.
- Click the **Pre Exercise** button or press F7 to move to the Pre Exercise phase.

Note:

If you attempt to start the exercise device during the Prepare phase, you receive the "Cannot start equipment in the Prepare Phase" message.

Instructing the Patient about the Test

Before attaching the electrodes, greet the patient and explain the procedure. Explaining the procedure decreases anxiety and informs the patient about what to expect. You can also click the **Explain Test** button on the **Main** screen to play an audio file that explains the test to the patient. Make sure that the PC's audio is enabled (in other words, that the speakers are not muted).
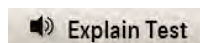
Note:

*ST80i ships with a default audio file that explains the exercise stress test; however, you can record your own audio file and configure ST80i to play this file when the user clicks the **Explain Test** button. For more information, see the ST80i Stress Test System Installation and Configuration Guide.*

- Privacy is important to relaxation. When possible, prepare the patient in a quiet room or area where others cannot see the patient.
- Reassure the patient that the procedure is painless.

- Make sure the patient is comfortable. The patient's arms and hands must be relaxed.
- If a treadmill is being used, instruct the patient to rest his or her hands on the handrails and not grasp the handrails tightly.

The more relaxed the patient is, the less the ECG is affected by noise or muscle artifacts.

Preparing the Skin

Thorough skin preparation is very important. The skin is a poor conductor of electricity and frequently creates artifact that distorts the ECG signal. By performing methodical skin preparation, you greatly reduce the potential for myographic noise and baseline wander, ensuring high-quality printouts and displayed data. There is a natural resistance on the skin surface due to dry or dead epidermal cells, oils, and dirt.

To prepare the skin

1. Shave hair from electrode sites, if necessary. Excessive hair prevents a good connection.

2. Wash the area thoroughly with mild soap and warm water.

Note:

Do not use alcohol to clean the skin.

3. Dry the skin vigorously with a gauze pad to increase capillary blood flow to the tissues and to remove dead or dry skin cells and oil.

4. Use an abrading pad to lightly scratch an X pattern into the skin, taking care to avoid excessive abrading.

Attaching the Electrodes/Lead Wires

Be sure to place the snap connectors on the electrodes before placing the electrodes on the patient.

Ensure that the leadset is long enough to connect limb leads to the patient's wrist and ankle if you plan to capture a resting/supine ECG during Pre Exercise.

Placement of the electrodes may need to be changed according to the stage of the test:

- When performing a supine/resting ECG to capture a baseline during Pre Exercise, place the limb leads on the limb extremities. This provides the most accurate results,

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Note:

You must also place limb leads on the limb extremities if you use the Resting ECG Workflow product option to capture a resting ECG. See Chapter 5, "Resting ECG Workflow," for more information.

- When performing a standing or Mason-Likar ECG, place the limb leads on the torso in the Mason-Likar positions.

ST80i supports the use of 12-lead wireless PIMs. The 12-lead wireless PIMs connect to the AIM and support 10 electrodes. Using AAMI/IEC labeling, these electrodes are:

- Right Leg [RL/N]
- Left Leg [LL/F]
- Right Arm [RA/R]
- Left Arm [LA/L]
- Chest leads [V1/C1, V2/C2, V3/C3, V4/C4, V5/C5, and V6/C6]

All leads are acquired simultaneously. Review the following lead wire labeling and electrode placement information in Figure 3-9 to ensure a quality ECG.

Figure 3-9   Mason-Likar Electrode Placement (AAMI/IEC)
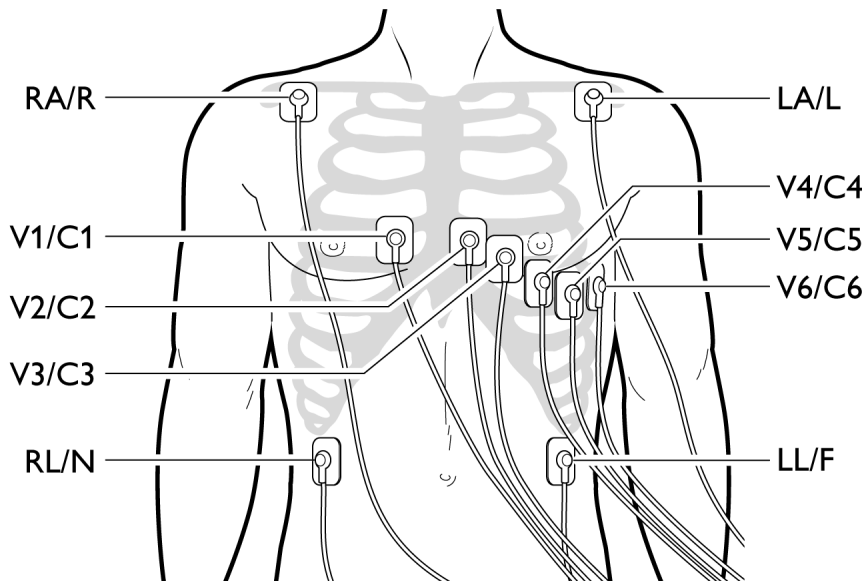
AAMI Lead	IEC Lead	Electrode Position
V1	C1	Right side of the sternum in the 4th intercostal space
V2	C2	Left side of the sternum in the 4th intercostal space

AAMI Lead	IEC Lead	Electrode Position
V3	C3	Midway between V2 and V4
V4	C4	Left midclavicular line in the 5th intercostal space
V5	C5	Between V4 and V6
V6	C6	5th intercostal space, left midaxillary
LA	L	Place the limb electrodes for the arm directly on the clavicle bones (away from major muscles)
RA	R	
LL	F	Below V6 on the lower edge of the ribcage
RL	N	On the lower edge of the ribcage

To attach the electrodes to the patient

1. Place the gel area of the electrode over the center of the prepared area, using the positioning shown in Figure 3-9; then press the adhesive ring into place.
   - Avoid pressing the center of the gel area; this might hinder conduction.
   - Place the electrodes on the soft tissue of the arms, avoiding muscle. See limb lead placements notes next.

   Lead placement is similar to standard 12-Lead ECG placement; however, limb leads are modified, as follows:
   - Right Arm and Left Arm leads should be placed close to the shoulders on the clavicle bone, away from the muscular areas to avoid muscle interference.
   - The Right Leg lead should be placed on the lower edge of the rib cage, in the lower right area of the patient's chest (avoiding flabby areas and the belt). This may need adjustment depending on body habits.
   - The Left Leg lead should be placed on the lower edge of the rib cage, below V6, in the lower left area of the patient's chest (avoiding flabby areas and the belt). This may need adjustment depending on body habits.

2. Ensure the electrodes are firmly attached.

   A good test for firm electrode contact is to try to move it. If it moves easily, the electrode connection is too loose. Do not allow electrodes to move in any way.

3. Have the patient raise his or her arms over the head. This helps verify good lead placement and no strain on the electrodes.

Connecting the Patient to the Wireless PIM

All of the ST80i lead sets are designed to share the same connector that plugs into the mating connector on the wireless PIM.

To connect the patient to the wireless PIM

1. Plug the lead set connector into the mating connector on the wireless PIM.

   Ensure that lead wires do not bump or rub against anything.

2. Place the wireless PIM into the PIM holder. The PIM holder and belt are designed to keep the PIM steady, thereby minimizing movement of the lead wires and ECG signal artifacts. The PIM holder/belt is adjustable up to a patient waist size of 57".

Wireless PIM Button Functions

The wireless PIM has one button that you can use to:

- Power the PIM on or off
- Check PIM battery status, wireless link quality, and lead contact quality.

  - When requested to check battery status, the wireless PIM provides an indication of estimated battery power remaining.

  - When requested to check lead/electrode connections, the wireless PIM indicates a poor lead signal quality condition by showing a yellow LED light for any patient electrode connection where the measured impedance is considered excessively high for good quality, low–noise ECG measurements. You can check the lead signal quality of lead connections while hooking up and preparing the patient in an area outside of the range of the system's radio connection.

Checking the Lead Map

To check the Lead Map

1. Click the **Hide/Show View** icon in the toolbar on the **Prepare** or **Pre Exercise** screen.

2. Select **Show Lead Map**. A color-coded anatomical diagram displays the lead connections.

Figure 3-10   Lead Connections
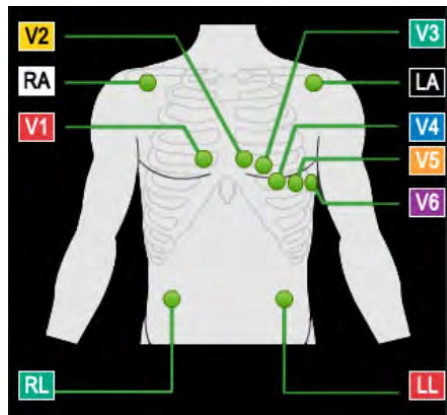
If a lead is off, a red X is displayed on the lead map to indicate the affected lead. Red dashed lines are displayed in the real-time ECG view. For the chest leads, the lost lead location is indicated by red dashed lines. If a limb lead is lost, all leads or all but one limb lead display as dashed red lines.

For more details on checking the lead quality connection, see "About the Lead Map View" on page 2-20.

For more details about adjusting the filter, see "Quick Settings" on page 2-31.

Note:

Using medical tape to fix the lead wires to the chest may help to minimize strain applied to electrode connections, thus reducing noise and the possibility of a leads-off condition occurring.

Checking Signal Quality to Verify a Clean ECG

ST80i can recognize when an electrode is not connected and display that information on both the wireless PIM and the **Exercise** screen. As you adjust the electrodes, the display is updated to reflect changes in the connectivity of the signal. The leads-off condition is saved with the data and is indicated on any printed reports that contain that data.

You can set the color of the ECG (waveform) to be green on black or black on red. For green waveforms, a lead-off condition is indicated on the real-time display as a red dashed line; for black waveforms, a lead-off condition is indicated as a black dashed line. When printed, the lead-off condition also appears as a dashed line.

Figure 3-11   Red Dashed Line Showing Leads-off Condition for V4
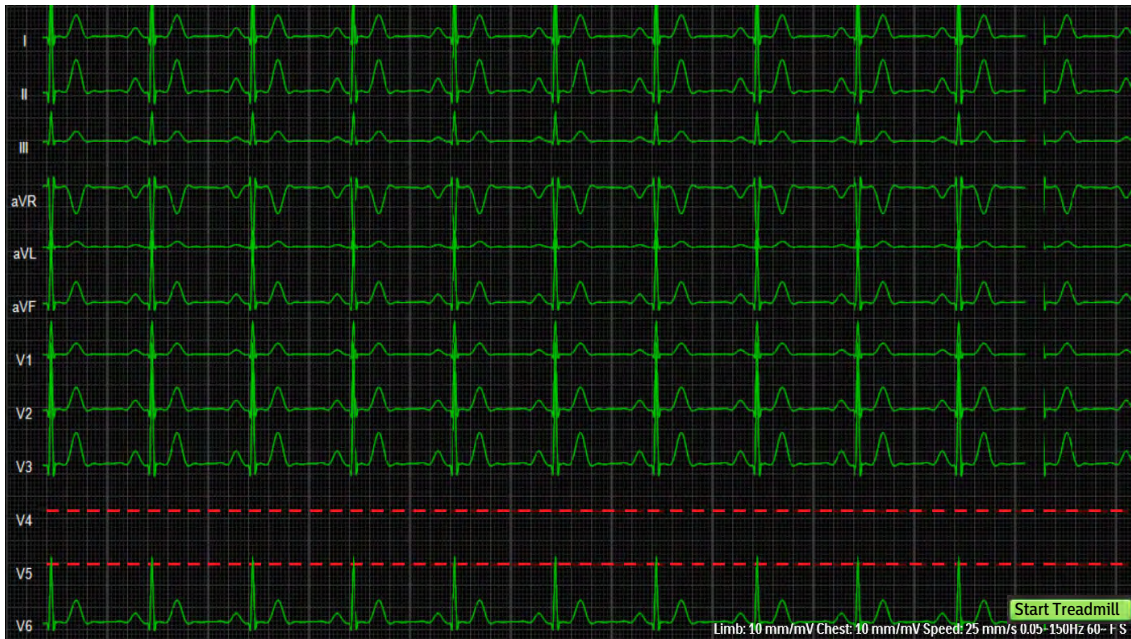
ST80i also provides an indication to the operator when the front-end is inoperative and cannot acquire a signal. If the PIM is off or cannot acquire a signal, then the ST80i display does not show the wireless signal indicator or battery status indicator. If the AIM can find the PIM but no ECG is displayed, then all leads are shown as red dashed lines, but the wireless signal and battery status indicators are displayed. These conditions are saved with the data and are indicated on any printed reports that contain that data.

Filtering

When you open the ST80i application, the active settings of the filters are associated with your user profile. The same filter settings apply to both displayed and printed waveforms. The filter settings are printed with the report.

Note:

Enabling the Artifact Filter and/or Smart Filter during a test causes a brief data loss represented by red dashed lines on the display due to initialization of filtering algorithms. Disabling the Artifact Filter and/or Smart Filter causes a brief data loss represented by a sudden change in waveform morphology.

The filtering techniques developed for ST80i permit the user to identify any clinically significant ST deviation and do not degrade the integrity of the relevant ECG signal content, specifically the ST segment (deviation and slope). This capability is especially important during stages of exercise (stage three and later) where more motion and muscle artifact is present, which could otherwise obscure the ST deviation.

The ECG data is stored in its recorded state (0.02–300Hz, all filters off) and user-selected settings are stored with the ECG.

Note:

· *The ECG data is filtered at 0.05–150 Hz before being analyzed by the algorithm. This filter is called the algorithm filter and cannot be turned off by the user. The algorithm filter is independent from other filters, is not controlled by the user, and does not affect the saved ECG data.*

· *All filters can be turned on or off as needed to improve displayed and printed waveform quality except for the algorithm filter (as described above) and minimum filters (0.02Hz high pass filter and 300Hz low pass filter).*

· *If the AC Filter is enabled, it is applied at a user-specified 50Hz or 60Hz to ECG data sent to the algorithm. If the Smart Filter is enabled, it automatically detects the frequency of the AC Filter, rather than using the specified 50/60 Hz.*

If needed, you can change the default filter settings. For details on filter settings, see "Quick Settings" on page 2-31.

Sync Output

ST80i supports two analog ECG output signals and one TTL ECG Sync output on the AIM. The AIM accepts real-time ECG data from the wireless PIM and dispatches the data to the PC and output channels. This signal serves as a synchronization signal for coordination of timing between ST80i and another device, such as imaging devices. The analog-out signals are amplified.

TTL/Analog Output Option:

You can specify the ECG lead used for syncing the TTL/Analog Output.

The source signal of the analog ECG and TTL Sync for each output channel can be selected by software from any of the available ECG leads separately. The amplify ratio for the Analog ECG Output can also be configured independently.

To change Analog and/or TTL Output settings during a patient session, see "Quick Settings" on page 2-31.

To configure Analog and TTL Output, see the *ST80i Stress Test System Installation and Configuration Guide.*

WARNING

Both analog ECG output and TTL sync output are considered real-time, with a delay (latency) of no more than 25 ms between the patient's physiological activity and the appearance of its representative signal at the external port. This signal should not be used for analysis.

Note:

- *ST80i monitors drop-out (interference) and signal strength and automatically selects a clearer frequency band when excessive drop-out exists. The drop-out level threshold is configurable from **Settings** > **System Settings** > **I/O Devices**. For more information, see the ST80i Stress Test System Installation and Configuration Guide.*

- *Software design also ensures that the waveform or lead label can be correctly displayed, stored, and printed, to avoid data conversion or lead combination errors.*

Attaching the BP Cuff

Note:

If using the SunTech Tango® NIBP device, follow the manufacturer's recommendations to attach the cuff. It is important that the microphone be placed in the correct position to ensure accurate BP measurements. There is excellent information on the SunTech Medical website, www.suntechmedical.com, related to Tango® and the proper positioning of the cuff.

To attach the BP cuff

1. Place the cuff on the patient.

2. Take a pre-stress NIBP connection test to determine whether the cuff is correctly placed on the patient and to ensure NIBP measurements throughout the stress test.

Attaching the SpO$_2$ Sensor

To attach the SpO$_2$ sensor, attach the SpO$_2$ sensor to the patient's finger and verify that the screen displays an SpO$_2$ value.

Interpretive Settings

In **Settings** > **User Profile** > **Algorithm**, you can preconfigure interpretive settings for the DXL Algorithm and CAlg templates. This must be done before you begin a patient session. For details on configuring interpretive settings, see the *ST80i Stress Test System Installation and Configuration Guide*.

The settings are listed here for reference only, with the exception of Pacer Detection, which you can access from the Quick Settings menu during a stress test.

DXL Algorithm

- Borderline Statement Suppression

- Pacer Detection — The pacer detection algorithm detects both atrial and ventricular pacing. Pacemaker detection is preset in the user profile, but can be changed using the **Quick Settings** icon. The options include:

  - Paced Unknown

  - Paced

  - Non-paced

  - Paced (magnet)

  Paced Unknown is the default mode, in which the detector uses its default sensitivity setting to determine if pacemaker pulses are present.

  The pacer detection setting in effect at the time an event is recorded is used for the analysis of that event. If the pace-pulse program is enabled and it detects the presence of pace-pulses, it provides output in textual and graphical formats:

  - The interpretive report contains textual statements about the findings for the pace-pulse program.

  - Tick marks appear on the printed ECG at locations where pulses are detected. The interpretive report contains textual statements about findings.

  - Only one set of tick marks is printed for any given period of acquisition, regardless of the number of channels presented.

- Adult Bradycardia Limit (BPM)

- Enable DXL Algorithm for Stress

- Report Confirmation Label

- Lead Check

- Critical Values

- RR Measurement

- STEMI-CA

- LHS Upper Case

CAlg Templates

- Enable ST Segment Analysis

- Enable Arrhythmia Analysis

- J-ST (msec)

Note:

ST Segment analysis must be enabled for ST values to be analyzed and displayed. The same applies to Arrhythmia analysis. There is no printing or saving of arrhythmia ECGs; however, PVCs are counted.

Entering the Pre Exercise Phase

The Pre Exercise phase does not start automatically. To enter the Pre Exercise phase, click the **Pre Exercise** button or press F7.

Pre Exercise Phase

The Pre Exercise phase does not start automatically. Once the leads are in place and the patient has been prepared (during the Prepare phase), you must click the **Pre Exercise** button or press F7 to move to the Pre Exercise phase.

Once you have clicked the **Pre Exercise** button, the ST template starts and the Max and Target heart rates show real values. During the Pre Exercise phase, you create a baseline for the patient by taking a resting blood pressure and a resting ECG.

Note:

To have Pre Exercise averages available in reports, Pre Exercise must run for approximately 40 seconds before entering the Exercise phase.

The Pre Exercise phase consists of the following tasks:

1. Wait 40 to 50 seconds for the ST template to be built. The template is complete when an ST value is displayed. This is required if you want to compare the final test results with the resting results.

2. Take a resting/baseline BP to be used as the Reference BP in the final report.

Note:

The BP must be taken before the ECG.

---

3. Take a resting/baseline ECG.

Note:

The type of baseline ECG (Supine or Standing) to be used as the Reference ECG is preconfigured in Settings.

4. After the Pre Exercise data is gathered, have the patient move to the treadmill or ergometer to begin monitoring.

    –   If you are using a treadmill, have the patient straddle the belt. Then start the treadmill and give the patient time to become accustomed to using it.

    –   If you are using an ergometer, seat the patient and instruct the patient to begin pedaling. The patient encounters the initial resistance configured for the protocol.

5. When the patient is accustomed to the device, click the **Exercise** button or press F7 to begin the Exercise phase.

During Pre Exercise, you can adjust the J+ Point value. With the **Zoom ST** window open, hover the cursor over the current value, then click and type the new value. Finally, click **OK**.

The Pre Exercise phase is preset for treadmill speed and grade or for ergometer power based on the protocol selected.

Figure 3-12   Treadmill Speed and Grade

Note that the Pre Exercise time is separate from the Exercise time.

Note:

If you manually update patient information in the **Edit Patient Information** *window during the Pre Exercise phase, patient information is also updated in the* **Report** *screen.*

Baseline/Reference BP and SpO$_2$

ST80i supports optional SpO$_2$ and motion-tolerant Non-Invasive Blood Pressure (NIBP) devices. ST80i automatically collects the NIBP through a cuff. The patient's SpO$_2$ is collected in real-time through a sensor.

BP and SpO$_2$ are real-time numeric displays for the NIBP and SpO$_2$ values for an entire study or for a single instance. They can be manually measured and the values can be overridden.

During the stress test, NIBP is measured according to the intervals defined in the exercise protocol and is continually displayed on the screen. This is recorded in the **BP mmHg** field in the side panel and also on the ECG. The SpO$_2$ measurement is continuously updated and is recorded in the side panel in the **SpO$_2$** field.

If enabled, there are also audible prompts for NIBP. To enable audio prompts, see the *ST80i Stress Test System Installation and Configuration Guide*.

To connect the patient to the NIBP device and to the SpO$_2$ sensor, see "Attaching the BP Cuff" on page 3-24 and "Attaching the SpO2 Sensor" on page 3-24.

Manually Enter BP and SpO$_2$

When you enter or acquire blood pressure values according to the pre-programmed automatic prompts or at any other times during the test, for each recording, the blood pressure value, phase, and total time of the phase at the time of the acquisition are captured.

The automatic timing of blood pressure measurements is established in the exercise protocol. You can, however, take blood pressure measurements with an NIBP device at any time during each stage by using the BP button. Or you can enter the measurement manually, after taking the patient's blood pressure.

When you manually enter the values of BP and SpO$_2$, the value of BP and SpO$_2$ are displayed in the stage report and the final stress report.

Note:

ST80i continues to update the real-time NIBP or SpO$_2$ values from the NIBP monitor even when or if the values are manually entered.

To take a blood pressure measurement (if the patient is connected to an automatic blood pressure monitor) other than a timed BP, click the **BP** button in the procedure bar.

- The current blood pressure measurement displays in the **BP mmHg** (Sys/Dia) field.

- The previous blood pressure measurement displays in the **Previous BP mmHg** field.

To manually enter the blood pressure measurement when no NIBP device is connected

1. After you take the patient's blood pressure, click the **BP mmHg(Sys/Dia)** field in the side panel.

2. Type the latest blood pressure measurements in this field using the following guidelines:

    - Use only numbers 1 through 400. There is no need to type the slash (/) between the systolic and diastolic values.

- Type a minimum of five digits. The systolic value must include three digits, so if the systolic measurement is below 100, type a zero as the first digit (for example, type 097).

3. Click **OK** in the **BP mmHg** (Sys/Dia) field. The display shows the manually entered measurements.

   The previous blood pressure measurement displays in the **Previous BP mmHg** field.

To override the SpO$_2$

1. Click the **SpO$_2$** field in the side panel.

2. Type the latest measurement in this field using numbers between 0 and 100.

3. Click **OK** in the **SpO$_2$** field. The display shows the manually entered measurement.

Note:

ST80i software validates the input values of BP and SpO$_2$ before they take effect to ensure that the numbers fall within an expected physiological range.

For details about how this information is displayed in the final report, see Chapter 4, "Working with Reports."

Resting ECG with Interpretation

Wait 40 to 50 seconds for the ST template to be built. The template is complete when an ST value is displayed. This is required if you want to compare the final test results with the resting results.

Note:

This section describes how to capture resting ECGs during the Pre Exercise phase of a stress test. This information does not apply to using the Resting ECG Workflow product option. See Chapter 5, "Resting ECG Workflow," for information about the Resting ECG option.

Once the waveforms are satisfactory, you are ready to acquire a resting (supine) or standing baseline ECG.

Note:

If you plan to use the Compare feature with the baseline ECG as a reference, be sure to wait 40 to 50 seconds after the start of Pre Exercise before you capture the ECG. This allows the template to be built. The template is complete when an ST value is displayed.

ST80i allows you to acquire and print a 12-Lead resting ECG with or without interpretation when the patient is supine. DXL must be enabled in Settings to

have interpretation appear on the ECG. This data appears as part of the final ECG report.

ST80i provides resting ECG interpretation using the latest Philips DXL algorithm for traditional limb lead placement. To get interpretation, you must first configure "Enable DXL Algorithm" in **Settings** > **User Profile** > **Algorithm**. For details, see the *ST80i Stress Test System Installation and Configuration Guide*.

WARNING

To get the most accurate interpretation during resting ECG, use traditional limb lead placement. Using "Mason-Likar" electrode placement may result in deviation in interpretation. Interpretations and analysis results provided by the Philips DXL 12-lead Analysis Algorithm for 12-lead ECG captures are intended for use with traditional limb lead placement and are not validated for use with other lead placements

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When the algorithm finds excessive artifact or AC noise, it gives a related warning/error string. The string is printed on the report and is saved when saving the report. The algorithm also reports wrong lead placement.

See "Filtering" on page 3-22 regarding artifact or AC noise.

To obtain a 12-Lead resting ECG with interpretation during the Pre Exercise phase

1. Click the **Event** icon in the toolbar.

2. Select **Supine**.

After a few seconds, if printing is enabled, the ST80i system prints a full 12-Lead resting ECG with measurements and interpretation text. If printing is not enabled, ST80i saves the ECG.

To obtain a 12-Lead ECG without interpretation (during any phase of the stress test)

- If you do not want the printed ECG to have a label, click the **ECG Print** button.
- If you want the printed ECG to have a label, click the **Event** icon and select the appropriate label from the menu.

After a few seconds, the ST80i system prints a full 12-Lead resting ECG.

After taking the baseline measurements, you are ready to instruct the patient in the proper use of the equipment.

Starting the Patient on the Treadmill or Ergometer

The start and stop control for the treadmill or ergometer appears in the ST80i side panel. There is also an emergency stop button on the treadmill. Depending on the treadmill model, there might also be a safety tether.

You can manually control the speed and grade of the treadmill or the power (wattage) of the ergometer during any stage in the Exercise test. See "Controlling the Treadmill or Ergometer" on page 3-38.

To start the patient on the treadmill

1. Have the patient straddle the belt.

2. In the ST80i application, click **Start Treadmill.** The button changes to **Stop Treadmill**. The treadmill starts at the preselected speed and grade set for the protocol.

Note:

Alternatively, you can press F4 to start the treadmill or load the ergometer, or press F6 to stop the treadmill or unload the ergometer.

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3. Allow the patient to become acclimated to the movement of the belt, and then provide the patient with the following instructions:

   - Keep your body straight and head up.

   - Walk in a normal walking position with arms at your sides, or place your hands lightly on the handrails for stability but do not bear down with too much gripping force.

   - Use as little upper-body motion as possible and stay near the front of the treadmill.

You are now ready to begin the Exercise phase.

To start the patient on the ergometer, instruct the patient to begin pedaling. The patient encounters the preselected resistance set for the protocol.

You are now ready to begin the Exercise phase.

To begin the Exercise phase, click the **Exercise** button on the procedure bar or press F7. The **Exercise** screen appears.

Exercise Phase

CAlg has a "learning phase" during which it automatically selects the initial 12-lead dominant QRS complex. CAlg removes baseline wander and aligns successive non-noisy complexes of similar shape and then averages them together to form a noise-reduced representative beat. As new, similar complexes arrive, they are added to the representative beat, and old complexes are removed from it. When CAlg stops finding good matches for the representative beat and all old complexes have been removed, it automatically detects a new dominant morphology and builds a new representative beat. CAlg makes ST measurements on the noise-reduced representative beat.

During the test, you can print 12-Lead ECGs automatically or manually. You can choose any of the following display choices:

- 12 leads
- 6x2 leads
- 6 leads
- 3 leads

You can start the Exercise phase of the test at any time; however, a warning message pops up if the algorithm has not obtained an ST value from all 12 leads. Because baseline ST values, which are used to calculate ST elevation and depression, are recorded at the beginning of the Exercise phase, it is important to make sure there are valid ST values when beginning the Exercise phase.

Conducting the Exercise Stress Test

When you move into the Exercise phase of the test, the treadmill loads the settings associated with the first stage of the test, and the stage and phase clocks start counting.

Figure 3-13 Exercise Screen
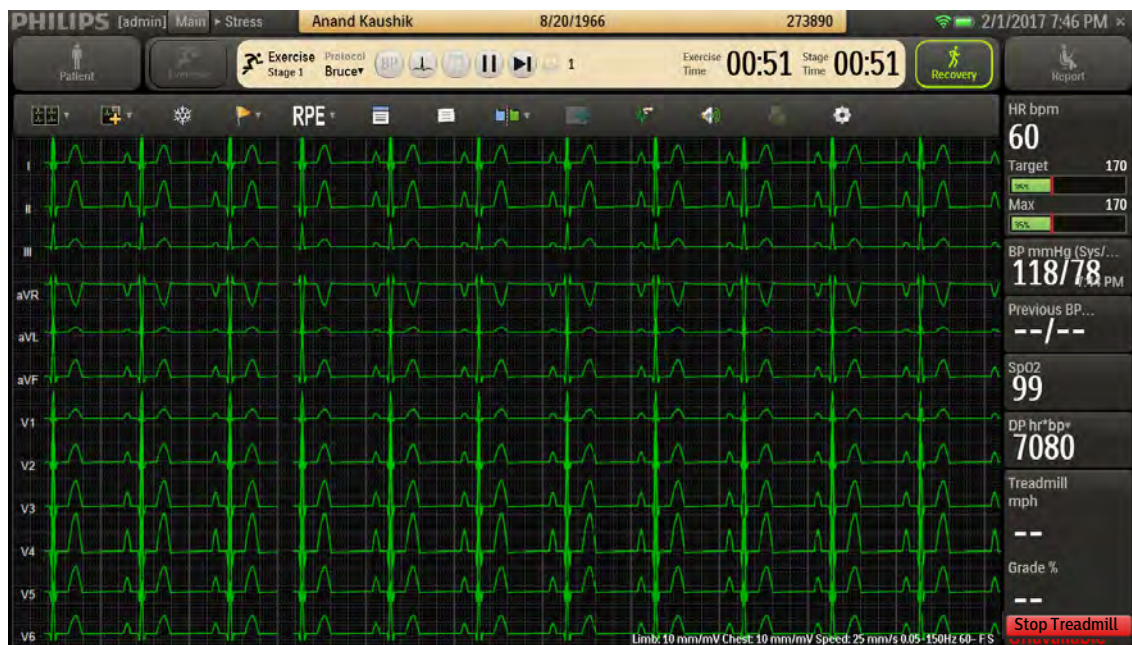
The exercise time builds cumulatively as the patient completes each stage. However, with each new stage, the stage clock restarts at 00:00. The stage time, speed, and elevation for each stage are defined by the protocol.

If you want to move to the next stage, without waiting for the system to automatically change, you can click the **Go to Next Stage** button on the procedure bar. This starts a new stage and a new stage time, but the exercise time continues to build.

If you want to keep the stress test in the current stage, overriding automatic stage changes, you can click the **Hold Stage** button.

To remove the hold on stage changes, click the **Unhold Stage** button. Even if the duration of the hold spans what would have been multiple stages, the removal of the hold returns the stress test to the stage following the one during which the hold was placed.

If the patient can no longer continue exercising, you can end the Exercise phase of the stress test by clicking the **Recovery** button, or by clicking the **Stop Treadmill** button, if necessary, and then clicking **Recovery**. The Recovery phase is preset to slow down the treadmill and lower the elevation.

Monitoring the Patient

During the Exercise phase:

- The patient walks on the treadmill or peddles the ergometer, unless the patient is unable to exercise or is not using an exercise device.

- You record blood pressure/SpO$_2$, observe events, and record RPE, while closely monitoring the patient.

- You can switch from an automated protocol to manual operation, giving you full control over the treadmill. To switch to manual control, see "Controlling the Treadmill or Ergometer" on page 3-38.

- You can change the display parameters, as needed during the Exercise phase. For details, see "Using the Toolbar Icons" on page 2-15.

- The Exercise phase comprises several stages, which are defined by the selected protocol. For a breakdown, see Appendix B, "Protocol Reference".

Figure 3-14   Exercise Stage and Protocol
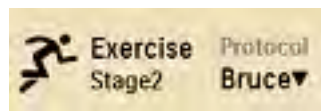
In general, you will most likely use the standard settings as specified by the profile and protocol selected.

Changing to Another Protocol

If you need to switch to a different protocol at any time during the Exercise phase of the test click the drop-down arrow next to the current protocol to select a new protocol from the list that was configured in Settings. The phases and stage settings associated with the newly selected protocol are loaded into ST80i.

See the *ST80i Stress Test System Installation and Configuration Guide* for setting default protocols.

To change to another protocol

1. On the procedure bar, click the drop-down arrow next to the current protocol to display the list of preconfigured protocols:

- Bruce
- Modified Bruce
- Balke
- Ellestad
- Naughton
- Pharma
- Low Ramp
- Med Ramp
- High Ramp
- USAF/SAM 2.0
- USAF/SAM 3.3

2. Select a new protocol from the list. The time on the stage clock resets to 00:00 for the next stage.

When you change the protocol, the test advances to the beginning of the next stage. The speed and grade settings (for treadmill) or RPM and power settings (for ergometer) change to reflect the new protocol.

Printing During the Stress Test

At any time during the stress test, you can trigger real-time ECG (a real-time ECG is defined as 10 seconds of ECG data) and continuous Rhythm printing using the icons displayed on the **Exercise** screen or using hot keys. The time latency should be less than 7 seconds. You can also capture and store events and notes for later review and reporting.

Arrhythmia events can trigger automatic printing with the context ECG, if configured. In addition, you can also turn off the continuous printing both on the configuration and during the test.

Hot Keys for Printing

The following hot keys can be used in place of the ST80i icons and buttons:

- F10 — Starts the printing of a rhythm report. Pressing again stops the printing.
- F11 — Prints a 12-Lead ECG.
- CTRL+P — Prints a selected Event during the Report phase.

Printer Settings

During the patient session, you can change the Rhythm Print settings using the **Quick Settings** icon. See "Using the Toolbar Icons" on page 2-15 for details.

See the *ST80i Stress Test System Installation and Configuration Guide* for information about preconfiguring default printer settings.

Print Options

ST80i supports the following print options during the stress test:

- Resting ECG with interpretation — Interpretation is printed only during Pre Exercise phase when a Supine event is selected.
- Real-time ECG
- Continuous rhythm strip
- RPE statement printout
- Event printout
- Freeze printout
- Stage printout

Resting ECG with Interpretation

During the Pre Exercise phase of the stress test, you can print a resting ECG with interpretation by selecting a Supine event.

Note:
- *You can also print a resting ECG with interpretation using the Resting ECG Workflow product option. See Chapter 5, "Resting ECG Workflow," for more information.*
- *The DXL setting must be enabled in Settings to include interpretation on the ECG. See "Interpretive Settings" on page 3-24.*

To print a resting ECG with interpretation

1. Click the **Event** icon on the toolbar to display the **Event** list.
2. Select **Supine**. The system prints a resting ECG.

Real-Time ECG

Any time during the testing, you can print a real-time ECG using the **ECG Print** button. The time latency should be less than 7 seconds.

To print a real-time ECG, click the **ECG Print** button on the procedure bar. The system prints a real-time ECG.

Continuous Rhythm Strip

You can trigger continuous rhythm printing using the **Start Rhythm Printing** button on the **Exercise** screen. You can also turn off continuous printing by using the same **Start Rhythm Printing** button.

Before using the rhythm printing option, be aware that:

- ST80i software automatically advances the paper to the page header.
- You can adjust Rhythm Print settings using the **Quick Settings** icon.

To print a continuous rhythm strip

1. Click the **Quick Settings** icon on the toolbar.

2. Click the **Rhythm Print** tab.

3. Adjust the settings, if applicable, for:

    - Leads — Select the leads you want to print.

    - Limb Gain — Options include 2.5 mm/mV, 5 mm/mV, 10 mm/mV, and 20 mm/mV.

    - Chest Gain — Options include Full and Half.

    - Speed — Options include 5 mm/s, 10 mm/s, 25 mm/s, and 50 mm/s.

4. Click the **Start Rhythm Printing** button.

5. To end the printing, click the **Start Rhythm Printing** button again.

RPE Statement Printouts

When you want to print an ECG with an RPE statement, ask the patient to state which number or statement represents their perceived level of exertion. Then select the corresponding number from the **RPE** list. Once the number is selected, the system prints an ECG report, noting the RPE.

To print an ECG with an RPE statement

1. Click the **RPE** icon on the toolbar.

2. From the list, select the RPE statement that matches what the patient reports.

3. Click **OK**. The system prints an ECG with the RPE statement.

Event Printouts

An Event printout is triggered when you document patient events and symptoms using the **Event** icon.

The Supine, Mason-Likar, and Standing events are typically selected to provide baseline information. Events such as Hyperventilation, Chest Pain, and so on are used to document patient symptoms as they occur.

Note:

If enabled, Arrhythmia events can trigger automatic printing with the context ECG. This can be enabled in the user profile.

See the *ST80i Stress Test System Installation and Configuration Guide* for how to enable Arrhythmia events.

To print an event

1. Click the **Event** icon on the toolbar.

2. From the **Event** list, select the event to record. The system prints an ECG and records the event for the final report.

For more information, see "Recording an Event" on page 2-25.

Freeze Printouts

When you click the **Freeze** icon on the procedure bar, the most recent 10 seconds of ECG data is frozen. A dialog box opens to display an image of all leads captured at the moment you click the **Freeze** icon.

To print a freeze

1. Click the **Freeze** icon on the toolbar. The **Freeze** dialog box appears to the right of the waveform.

2. Click the **Print** button to print and save the frozen ECG.

For more information, see "Freeze" on page 2-25.

Stage Printouts

Stage printouts can be configured in the exercise protocol to print automatically (or to not print at all) during each stage of the Exercise phase of the stress test. A 12-Lead ECG can be printed at the beginning or end, or at some other specified time interval of each stage. However, the stage printout/schedule time is also affected by how the printer type is configured. If the printer type is set to Off in Settings, the stage does not print even if it is configured in the protocol to print. However, the ECGs are saved.

The stage printout can also be configured to include the 12-Lead average beats and/or the zoomed lead. These settings are defined for each stage of the exercise protocol when an ECG is automatically generated for the stage.

Both Event and Stage printouts include the following:

· Report title

· Protocol name, phase, stage number, and so on

· Patient demographics (mandatory)

· Heart rate, blood pressure, and speed and grade (when using a treadmill) or Load (when using an ergometer)

· ECG Waveform

· ECG acquisition time and Stage time

· Average beat (if configured)

· Event name (for Event printout only)

· Maximum ST changes in this stage (for Stage printout only and only if a zoomed lead or averages are configured to print)

For more information on printing reports, see Chapter 4, "Working with Reports."

Controlling the Treadmill or Ergometer

At any point during the Exercise phase of the stress test, you can switch to manual mode and change the speed and/or elevation grade of the treadmill or the power setting of the ergometer. This change overrides the protocol settings for the current stage. Once you enter manual mode, there is no next stage, and you cannot return to the protocol.

Caution

Be sure to inform the patient of the changes.

If the treadmill or ergometer is unavailable, ST80i displays **Unavailable** where the **Start Treadmill** or **Load Ergometer** button would be.

To control the treadmill or ergometer manually

1. Click in the field that shows the current speed or current elevation of the treadmill or the current power setting of the ergometer. The Manual Mode confirmation appears.

2. Click **OK** to enter manual mode so that you can override the protocol settings and operate the treadmill or ergometer manually.

Note:

The protocol selection on the procedure bar now shows Manual Mode.

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3. Boxes with minus (−) signs to the left and plus (+) signs to the right of the current settings are displayed.

   Figure 3-15   Treadmill Speed and Grade Adjustment

4. Make the appropriate adjustment(s), down or up, and click **OK** to make each change. The maximum change in treadmill grade you can make at one time is 5%. The minimum change in treadmill speed you can make at one time is one-tenth (0.1 mph or 0.1 km/h).

 To stop the treadmill or unload the ergometer during the Exercise phase, click the **Stop Treadmill** button to stop the treadmill (or press the red emergency

stop button).

Click the **Unload Ergometer** button to unload the ergometer.

Note:

Alternatively, you can press F4 to start the treadmill or load the ergometer, or press F6 to stop the treadmill or unload the ergometer.

Be aware of the following when restarting the treadmill during the existing patient session:

- Before restarting, inform the patient that the treadmill will quickly ramp up to the speed and elevation that was in use when the treadmill was stopped.
- If you used the Stop Treadmill button, you must use the Start Treadmill button to restart the treadmill.
- If you used the emergency stop button (ESB), you must disengage the ESB before pressing the Start Treadmill button.

See "Maintaining the ST80i System" on page 6-1 for information about inspecting the cables and attachments between the PC and the Treadmill.

Notifications and Alerts

ST80i provides visual indications or alerts in case of dramatic morphology or rhythm changes. All notifications are preconfigured in **Settings** > **User Profile** > **Notifications**. The configuration includes the events to be displayed or printed as well as specific audio alerts.

Configuration must be completed before you begin a patient session. For details on configuring interpretive settings, see the *ST80i Stress Test System Installation and Configuration Guide*.

In **Settings** > **User Profile** > **Notifications**, you can choose to display and/or print the following Arrhythmia events:

- 1 missed beat
- 2 missed beats
- Afib
- Asystole
- High Heart Rate (>=220 bpm is the default, but this limit can be configured)
- Pause >4000 ms
- PVC (Premature Ventricular Contractions) –/+ per minute
- Sudden drop in BP (>=50 mmHg is the default, but this limit can be configured)
- Ventricular Escape Beat
- VFIB

- VRun(>=3PVCs) –/+ per minute
- VTACH (>= 9PVCs and >=120BPM)
- V Bigeminy
- V Couplet –/+ per minute

The preconfigured audio alerts consist of the following:

- NIBP
- Notifications

Note:

If you enable Notifications, all configured arrhythmia events trigger audible alerts; if you disable Notifications, all arrhythmia event audible alerts are off.

- Stage Change

See the *ST80i Stress Test System Installation and Configuration Guide* for more information regarding the setting of notifications.

See also "Interpretive Settings" on page 3-24.

Ending the Exercise Phase

The protocol determines the number of exercise stages as well as their duration. Once the final stage is complete, the application automatically moves into the Recovery phase.

During any stage, you can end the exercise stress test and move directly to Recovery by clicking the **Recovery** button.

Generally, you terminate the Exercise phase when the patient reaches a percentage of their target heart rate. The clinician determines the end point according to patient's status, and many patients never reach 100%. The target heart rate is preconfigured in the user profile.

If the reading reaches 100% of the target heart rate, the graph indicator color changes from green to red.

Recovery Phase

When the last stage of the Exercise phase is complete, ST80i automatically moves into the Recovery phase. For the Recovery phase, the factory-loaded protocols are preset for the number of stages and for speed and grade or power.

See the *ST80i Stress Test System Installation and Configuration Guide* for Exercise Protocol settings.

When the patient has completed the last exercise stage of the protocol or the

test has been discontinued (as documented in "Reason to End" in the Summary), the exercise stress test automatically enters the Recovery phase.

If conditions require it, you can manually move to the Recovery phase.

To manually enter the Recovery phase, click the **Recovery** button. The system moves into the Recovery phase of the test.

You can now acquire a recovery ECG and blood pressure and proceed with the Recovery phase of the test.

During the Recovery phase:

· The system automatically prints a 12-Lead ECG. The 12-Lead ECG is printed at this stage of transition regardless of system settings. This is the Peak Exercise ECG.

· The total exercise time clock freezes and begins displaying the Recovery time instead. If there is more than one Recovery stage, the software displays the stage time and the cumulative Recovery time.

· ST80i advances the treadmill or ergometer to the recovery workloads specified in the protocol.

· Click **Stop Treadmill** or press F6 to stop the treadmill (or press the red emergency stop button).

· Using the **Narrative** icon, you can type comments describing why the patient ended the Exercise phase of the test, the patient's symptoms, and conclusions.

Figure 3-16   Recovery Phase Screen
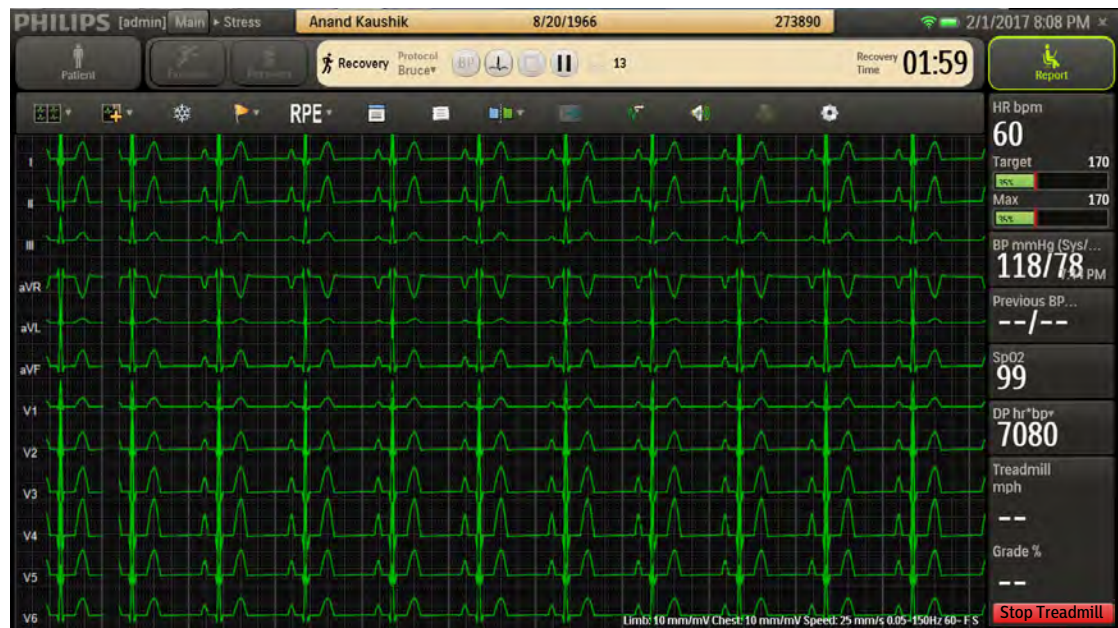
To end the Recovery phase
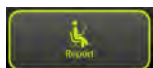
1. Click the **Report** button. The **End Test** confirmation appears.

2. Click **OK** to confirm. You also have the option to cancel. When the report is finished loading, the **Report** screen opens.

Report Phase

The Report phase begins when the Recovery phase ends and the **Report** screen opens.

Post-Recovery

During the Report phase, a period of post-recovery that lasts from 5 to 60 minutes allows ST80i to continue to monitor the ECG, HR arrhythmia alerts, and BP changes. You can manually enter a BP or initiate a Tango NIBP. To include a record of this BP in the final report, type it in the **Narrative** or **Notes** window. If you take a 12-lead ECG in this phase, it is saved as an event and included in the final stress report.

Data is not saved unless an event is triggered. If events are triggered, the event data is saved as part of the final report. During post-recovery, you can click the **Save** button on the **Report** screen as many times as necessary. All saved data is part of the final report. The patient session ends when you exit the **Report** screen. When you exit, monitoring stops and no more ECG data is displayed.

Note:

*ST80i stops streaming test data after the 60-minute post-recovery period. From the **Report** screen, you can review and modify the content of the final test report. You can print the individual reports that are also included in the final report, save the final report, and print it. After you save the report, you can export it to a PDF file for distribution or storage.*

Report Screen

On the **Report** screen, you can review and edit the stress test results to prepare the final stress report. The final report includes:

- Patient ID Report
- Summary Report (including Tabular and ST Analysis)
- Trends Report
- Average QRS Report
- 12-Lead ECG Report (including Interpretation and Measurements)
- Events Report (including manual ECG, manual event, stage report, RPE, arrhythmia, freeze)
- ST Comparison Report
- Max ST Report

The report is then confirmed, saved, exported, archived, and/or printed on preconfigured printers. You have the option to print the whole report or specify which page(s) to be printed.

From the **Report** screen, you can also:

· Review or replay the stress test

· Confirm the final report before export

· Review previous patient studies

See Chapter 4, "Working with Reports," for information on the Report phase and **Report** screen.

Ending the Patient Session

After saving the final stress report, you are ready to close out the patient session.

The patient can now be disconnected from the PIM, if not disconnected already:

· Detach patient from PIM

· Remove the electrodes from the patient

For details about working with the final report, including viewing, editing, printing, and saving reports, see Chapter 4, "Working with Reports."

Starting a New Patient Session

You do not have to exit the application to start a new session, unless you want to use a different user profile. Otherwise, you exit the application only when you are shutting down the system.

Once the data from the previous patient session has been saved, you can begin a new patient session. All user profile settings return to the same as the previous test unless you exit the application and a different user logs in.

Note:

When a new patient session begins, all temporary files are deleted and all patient information and stress study data from the previous patient is automatically cleared from memory.

To start a new patient session

1. Click **Stress** on the **Main** screen.

2. Click the **Worklist** tab.

3. Select the patient's name or add a new patient.

Exiting the Application

You exit the application when you need to use a different profile, when a new user is logging on to the system, or when you are shutting down the system.

To exit the ST80i application, click the **X** in the upper-right corner of the **Main** screen.

If Security Mode is not enabled, the application shuts down.

If Security Mode is enabled, you are presented with four options:

- **Restart Operating System** — Shuts down the application and restarts the operating system.

- **Shut Down Operating System** — Shuts down the application and the operating system.

- **Restart Application** — Restarts the application without shutting down the operating system.

- **Cancel** — Cancels the exit.

<div align="right">4</div>

Working with Reports

Overview

When you enter the Report phase, data from the Pre Exercise through Recovery phases of the test are saved as part of the final stress study that is viewed on the **Report** screen.

From the **Report** screen, you can review and modify the contents of the final stress report, which is displayed in tab format. This includes report summary information, trends, average QRS, events, ST comparison, maximum ST, and resting ECG. You can save the final report, and then print it. In addition, you can print the individual sections that are part of the final report. After you save the report, you can export it for distribution or storage as a PDF file, as XML data, or—if you have IntelliSpace ECG version B.01 or later—as raw data (PDR). If exporting to a DICOM report server, the report can include 12-Lead ECGs and/or PDR, or it can be exported as a DICOM Structured Report (SR). Export settings are preconfigured in **Settings** > **Remote Sites**. See the *ST80i Stress Test System Installation and Configuration Guide* for more information.

Note:

*If you manually update patient information from the **Report** screen, this information is not updated in the patient profile in the worklist. However, updating patient information during Prepare or Pre Exercise does update the patient profile on the **Select Patient from Worklist** screen.*

Report Phase

When stress testing enters the Report phase, you can edit various fields and data and then generate a final stress report. The final report is divided into several pages that include, for example, the report summary, trends, average QRS, events, and resting ECG.

During the Report phase:

- ST80i freezes the Recovery display while the study information is transferred to system storage.

- ST80i loads the **Report** screen, so you can specify the parameters and format of the final report.

- A real-time 11.5-second ECG is displayed in the lower-left section of the screen during Post-Recovery.

Post-Recovery

During Post-Recovery, ST80i continues to monitor the patient's ECG, configured notifications, and HR. Data is not saved unless an event is triggered, in which case the event data is saved as part of the final stress report. You can manually enter a BP or initiate a BP at a Tango NIBP device. To include a record of this BP in the final report, type it in the **Narrative** or **Notes** window. If you take a 12-lead ECG in this phase, it is saved as an event and included in the final stress report.

Report Screen

During the Report phase of the test, you work from the **Report** screen to review, update, and save the data for the final stress report, which you can then save, confirm, export, archive and/or print on preconfigured printers. You have the option to print the whole report or specify which individual sections to print and to change default printer settings.

From the **Report** screen, you can also review or replay the exercise stress test and finalize (or confirm) the final report before export.

As you prepare the final report on the **Report** screen, you can do the following:

- Review the ECG

Note:

If you change the J+ Point, all ST values are recalculated.

- Add or update patient information
- Print the individual events and delete extraneous events
- Review and edit final study data and make any necessary adjustments to the waveforms (for example, adjusting the J+ point)
- Review events
- Review the exam
- Prepare the patient's final stress report
- Save the report and export it, if appropriate
- Archive the patient's stress report

The **Archive** screen provides access to stored stress test results. All reports and study records are stored in the ST80i database and/or exported to servers or stored on the local system based on settings.

Note:

When you click the **Report** *button, the* **Archive** *screen appears. Each report is labeled according to its status:*

- *Confirmed*
- *Unconfirmed*

  For more information regarding archived reports, see "Working with Archived Study Data" on page 4-32.

Figure 4-1   ST80i Report Screen

Table 4-1   ST80i Report Screen Features

Feature	Description
A	Title Bar — Where you enter or update patient information in the **Patient Demographics** window.
B	Procedure Bar — Report Status (Unconfirmed or Confirmed) and buttons: **Change J+**, **Save**, **Export**, **Print**, **Confirm**, and **Replay**
C	Report Tabs — **Summary**, **Tabular**, **Trend Graph**, **Averages**, **Events**, **Resting ECG**, **ST Comparison**, **Max ST**, **Full Disclosure**, and **Previous Study**

Feature	Description
D	Real-time 11.5-second ECG by selected lead — ECG for one lead is displayed in the lower left section of the screen. Click on the lead label to change the selected lead.
E	Two print options for the current ECG lead — **Print 12-Lead ECG Report** and **Start Rhythm Printing**
F	HR (bpm) and BP (mmHg) — Shows the current heart rate of the patient and the patient's last blood pressure taken before moving to the Report phase. You can obtain a current blood pressure by manually initiating a blood pressure reading from the NIBP device or manually entering the BP.

Title Bar

Figure 4-2   Title Bar
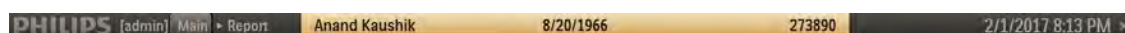
From the **Report** screen, you can enter or update information about the patient by clicking the patient name in the title bar. If you did not fill in or update this information during the Pre Exercise phase, you can open the **Patient Demographics** window to update this information as necessary. For an explanation of the features of the title bar, see "Title Bar" on page 2-5. For instructions on editing patient information, see "Edit Patient Information" on page 3-6.

Procedure Bar

Figure 4-3   Procedure Bar
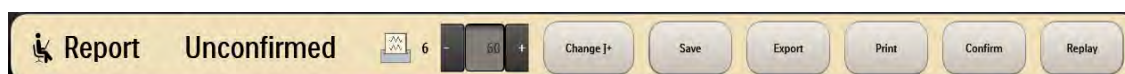
On the procedure bar, you can:

- Adjust the J+ Point
- Save the report
- Export the report
- Print the report
- Confirm the report
- Replay the ECG

The blinking printer icon shows the number of print jobs currently in the queue for the report.

Change J+ Point

The ST Measurement J+ Point is preconfigured in the user profile (**Settings** > **User Profile: Algorithm** > **J–ST (msec)**).

You can adjust the J+ Point value on the **Report** screen to re-analyze the stress test using a different measurement point. Once the J+ms value is modified, ST80i recalculates all related values and updates the corresponding displays on the **Report** screen.

Note:

If you change the J+ Point, all ST values are recalculated.

To modify the J+ Point setting and recalculate all ST values based on the new setting

1. On the procedure bar, click the plus (+) or minus (–) to change the value in milliseconds for J–ST.

2. Click **Change J+** on the procedure bar.

Save

Use the **Save** button or press **CTRL+S** to save the report to the stress system database after you have finished updating and reviewing the report data. The system can be configured to automatically export when you save.

The **Save** button saves an unconfirmed report; however, you can also use the **Save** button if you make changes to a confirmed report. Clicking the **Save** button after modifying a confirmed report makes the report unconfirmed. The report can then be confirmed again.

Once a final stress report is saved, it can be exported. The report can be finalized and signed. The export status and date/time of last export are maintained. The stress study raw data is saved in the local stress study database. You can transfer the raw data:

· To a different database, such as IECG version B.01 and later, for editing.

· To a DICOM Report Server.

· To a remote PC. where the data can be downloaded for review and editing using Remote Review.

 See "Transferring Test Data to a Remote Review Location" on page 4–38 for more information.

Export

Use the **Export** button to export your reports to remote sites that have been preconfigured in the Settings section of the application. When you export from the **Report** screen, the report is exported to all destinations set as defaults in **Settings** > **System Settings** > **Remote Sites**.

If no remote sites have been configured, or if **Set as Default** has not been configured for any remote site, you receive the following error message when you try to export from the **Report** screen: "Error. No destination is selected. Please select a destination in Archive window!" If this error appears, the report can still be exported, but you must go to the **Archive** window (by clicking **Report** from the **Main** screen) and then select a destination from the **Transfer Destination** list. To create remote sites, see the *ST80i Stress Test System Installation and Configuration Guide.*

It is also possible to export a report directly to external media such as a USB flash drive in PDF or XML format. The final stress report in PDF format can be emailed to the referring physician from either the test system or the remote review system. For more information on exporting reports, see "Exporting Reports" on page 4–44.

Print

You can use the **Print** button on the procedure bar to print individual report sections or the final stress report.

Before printing individual reports, you must select a printer type that has previously been configured in Settings. When using a laser printer, the grid can be set to print a grid on standard paper. Individual reports can be printed both before and after you save the report.

The types of individual reports that can be printed include:

- Patient ID
- Summary
- Trend Graphs
- Average QRS
- 12-Lead Resting ECGs
- Events (including manual ECG, manual event, stage report, RPE, arrhythmia, freeze)
- ST Comparison
- Max ST

When printing a final stress report, you can choose which individual sections to include and the number of copies to print for each individual report. You can also print a complete final stress report. Regardless of settings, a patient ID report is always printed on the first page of a final stress report.

Confirm

Once you review and edit the results, you can then confirm the report before exporting.

On the **Archive** screen, the study status is listed as follows:

- Confirmed

- Unconfirmed

Note:

You must save the report before confirming.

For more information regarding patient fields, see the section entitled "Patient Information Management" on page 3-3.

When you confirm the report you are also saving the report.

To confirm the report

1. Click **Confirm** in the procedure bar. The **Confirm Report** dialog box appears, with the current user name displayed in the **User ID** field.

Note:

Technicians cannot confirm reports using their own log-in credentials; however, they can confirm reports on behalf of users with Administrator permissions.

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2. If necessary, select a different user in the **User ID** field.

   For example, if you do not have Administrator access but you are authorized to confirm reports on behalf of an Administrator user, select the Administrator's user name.

3. Type the user password in the **Password** field.

4. Click **OK**.

Replay

When you click the **Replay** button on the **Report** screen, you can review the entire exam, as run. The **Replay** button enables you to review a completed stress report that is either confirmed or unconfirmed.

Note:

The Replay function replays from Pre Exercise through Recovery. Prepare is not included.

You can also print a 12-Lead ECG or print a rhythm strip during the review of the study. This feature is beneficial if you wish to review a specific segment of the test. When replaying a test, you can:

- Pause or stop the ECG stream
- Change the ECG waveform speed from real-time speed to sixteen times faster or half speed
- Move quickly to any point in the replay
- Print or reprint a 12-Lead ECG or rhythm strip for significant episodes

To replay the exercise stress test

1. Click **Replay** on the procedure bar. This brings you to ECG results that were recorded at the start of the Exercise phase. You can then view the exercise stress test by using the floating status bar that appears at the bottom of the ECG. This bar may be hidden.

2. To view the floating status bar, sweep your pointer over the lower part of the waveform area.

Figure 4-4   Floating Status Bar

3. Click the **Play** button on the floating status bar to begin the replay from Pre Exercise.

Each stage change or phase change is color-coded with a dark or light blue. The slider control moves across the status bar to show the replay's progress. As it moves, the time is displayed to the right showing both elapsed and end time. The changing colors along the status bar represent stage and phase changes. You can hover your cursor over the status bar to identify the exact time, phase, and stage of any point in the replay. To move quickly to any point in the replay, click on the desired location on the status bar or drag the slider control to the desired location. These features work in either Play or Pause mode. From Pause mode, click the **Play** button to resume the replay from the desired location.

Figure 4-5   Floating Status Bar Features
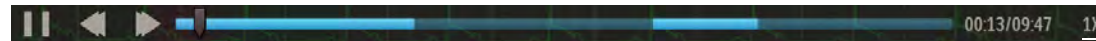
– To pause the replay, click the **Pause** button. The replay remains at the elapsed time that was displayed when it was paused. Click the **Play** button to resume the replay from the moment it was stopped.

– To decrease the speed of the replay, click the **Decrease Speed** button. The default replay speed is 1X. You can decrease the replay speed to 0.5X.

– To increase the speed of the replay, click the **Increase Speed** button. The default replay speed is 1X. You can increase the replay speed to 2X, 4X, 8X, or 16X.

4. To hide the floating status bar, sweep your pointer away from the lower part of the waveform area.

At any time during the Replay of the exercise stress test, you can print an ECG or Rhythm Strip.

· Click the **Print ECG** button for a 12-Lead ECG.

· Click the **Rhythm Print** button for a rhythm strip.

Once you have replayed the ECG, you can return to the **Report** screen.

To return to the Report screen

1. Click the **Report** button in the upper-right corner of the screen.

   The **End Replay** notification appears.

2. Click **OK** to return to the **Report** screen.

Real-Time ECG for One Lead

On the bottom of the **Report** screen, real-time patient data is still captured for one lead. You can change the lead by using the lead label drop-down menu to the left.

Note:

*Real-time ECG for one lead is visible on the **Report** screen immediately after the stress test. If the report is saved and you view it later, this area of the **Report** screen is empty.*

Figure 4-6   Lead Label List

To change the lead

1. Click the lead label. The lead label list appears.

2. Select the lead you want to see. The system redisplays the real-time ECG, showing the lead you selected.

Print Options

At the bottom of the screen, to the right of the real-time ECG, are two print options for the current lead in view:

• **Print 12-Lead ECG Report**

• **Start Rhythm Printing**

When you click the **Print 12-Lead ECG Report** button, you get a printout of that segment of the ECG.

When you click the **Start Rhythm Printing** button, a rhythm strip begins printing. To turn off rhythm printing, click this button again.

Current Heart Rate and Blood Pressure

The current heart rate of the patient and the patient's last blood pressure taken before moving to the Report phase are displayed on the bottom right section of the **Report** screen.

Final Stress Report Overview

The final stress report is based on data gathered during the last four phases of an exercise stress test:

- Pre Exercise
- Exercise
- Recovery
- Report (including Post-Recovery)

The final stress report includes the patient information summary, trends, average QRS, resting ECG results and events. ST80i allows you to choose several individual reports to include in the final stress report.

Along with the Patient ID report, which is included in all reports, the composition of a stress report may or may not include the following:

- Summary Report (including Tabular and ST Analysis)
- Trends Report
- Average QRS Report
- 12-Lead ECG Report (interpretation and measurements are displayed and printed according to user configuration)
- Events Report
- ST Comparison Report
- Max ST Report

After finishing the data acquisition, stress testing enters the report-generating phase. Once signed by a cardiologist or clinician, the report is finalized.

After a stress test procedure, you work from the **Report** screen to review, update, and save the data for the final stress report. When the report is satisfactory, you can print the individual sections on a laser printer or directly to a thermal printer when printing from ST80i.

Data from the Recovery phase is included as part of the final report. In the post-recovery period of the Report phase, the data is not saved unless an event is triggered or a manual ECG is captured. In this case, only the event data or the 12-lead ECG is saved as part of the final report.

WARNING

ECG signals printed on a laser printer should not be used to make time-sensitive measurements directly from the printed page.

Each section is configured to print or not to print in a final stress report except the Patient ID section, which is the minimum printed page in a final stress report. It is printed as the first page of the final stress report.

You can configure the following to be included in or omitted from the final stress report. The setting for each can be changed from the **Report** screen.

- Summary Report
- Trends Report
- Average QRS Report
- Events Report (If Events is configured, you can select which events to include.)
- 12-Lead ECG Report (Resting ECG)
- ST Comparison Report
- Max ST Report

You can reprint each report manually. You can also specify the number of final report copies to print. In addition, you can specify the printer to send the final report copies and whether or not to have the grid visible.

Report Screen Tabs

The sections of the final report are displayed as tabs on the **Report** screen. The tabs contain the patient's ECG data in a variety of formats:

- Summary
- Tabular
- Trend Graph
- Averages
- Events
- Resting ECG
- ST Comparison
- Max ST
- Full Disclosure
- Previous Study

The following sections describe each report tab.

Summary Tab

The **Summary** tab includes:

- Study information including test protocol and exercise time.

- Clinical information including, for example, the reason for the test and the reason to end the test, the number of PVCs, Risk scores, free-text entry of narrative summary notes, and Max values for BP, ST, and METs HR.You can override the clinical values presented. When you change the values, they appear dark red and italic.

On the **Summary** tab, you can include your comments about the test, along with the Reason for End and Symptoms. All values included are based on data captured during each stage of the exercise stress test.

Figure 4-7   Summary Tab

The screen is divided into four sections:

- Summary — The Summary region shows:

  - Total exercise time

  - Maximum treadmill speed and grade (or ergometer power) achieved during test

  - Max grade

  - ECG leads that presented more than 100 uV (or 1 mm) of ST elevation or depression during test

  - PVCs (count)

  - Functional Aerobic Impairment (FAI%)

  - Angina menu enabling you to select Unknown, None, Non-Limiting, or Limiting

  - Duke Score (treadmill only)

Note:

- *Functional Aerobic Impairment, Angina, and Duke Score do not appear unless Risk Score Calculation is enabled in Settings.*

- *If the Event (Standing or Supine) is not configured as the Reference ECG, the Summary Report does not include the reference HR and BP.*

- Max Values — The Max Values region shows:
  - Maximum heart rate
  - Percentage of maximum predicted heart rate attained
  - Maximum metabolic equivalents (METS)
  - Maximum Double Product (HR * BP)
  - Blood pressures for which both the maximum systolic and maximum diastolic blood pressures were achieved
  - Maximum SpO$_2$ percentage
- Max ST Measurements — The Max ST Measurements region shows:
  - Absolute ST Elevation and ST Depression times and leads
  - Amount of ST Elevation and ST Depression change
  - ST/HR Index

Note:

Patients may already have ST elevation or depression before exercise begins. It is important for the clinician to see how much change occurs during exercise.

- Comments — In the Comments section, you can:
  - Update the comment fields:
    - Narrative — Insert final assessments about the patient and/or test. You can either click the down-arrow to access pre-defined narrative templates, or type directly in the comments field. If you select a pre-defined template, click **Insert** to insert the template content into the Narrative field. If you type directly into the Narrative field, there is no limit to the amount of text you can type. If the Narrative text is longer than the printed report area, additional pages are printed for the additional text. For information about creating templates, see the *ST80i Stress Test System Installation and Configuration Guide*.
    - Reason for End — Update the Reason for End using the up and down arrow buttons, as well as the **Del** and **Add** buttons.
      Use the up and down arrows to rearrange the order of the selections in the field.
      Use the drop-down list below **Reason for End** to add selections to the **Reason for End** field. Either type a reason directly in the drop-down box or select a reason from the drop-down list and then click **Add** to add the selection to the **Reason for End** field.
      To remove a selection from the **Reason for End** field, highlight the selection and click **Del**.
      The **Reason for End** field is limited to five items, with 70 characters per line.

Figure 4-8   Reason for End Field
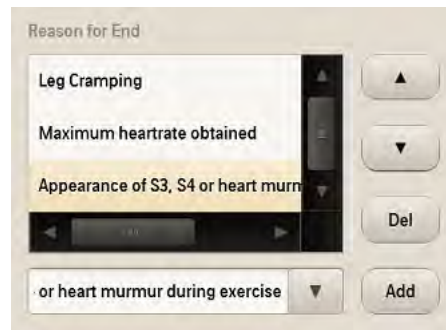
Note:

The system displays vertical and/or horizontal scroll bars in the **Reason for End** *field when necessary.*

    –   Symptoms — Update the Symptoms using the up and down arrows, as well as the **Del** and **Add** buttons.

        Use the up and down arrows to rearrange the order of the selections in the field.

        Use the list below **Symptoms** to add selections to the **Symptoms** field. Either type a symptom directly in the drop-down box or select a symptom from the drop-down list and then click **Add** to add the selection to the **Symptoms** field.

        To remove a selection from the **Symptoms** field, highlight the selection and click **Del**.

        The **Symptoms** field is limited to five items, with 70 characters per line.

Figure 4-9   Symptoms Field

Note:

The system displays vertical and/or horizontal scroll bars in the **Symptoms** *field when necessary.*

To print the Summary Report

1.   Click **Save** on the procedure bar, or press CTRL+S, to save the report.

2. Click **Print** on the procedure bar. The **Quick Print Settings** dialog box appears. See "Print Button (Quick Print Settings Dialog Box)" on page 4-28 for details.

3. Select a printer from the list.

4. Click **Summary**. The Summary Report prints from the selected printer.

Note:

The Tabular Report automatically prints as the Summary Table section of the Summary Report. This section is included in every report.

Tabular Tab

The **Tabular** tab displays the following tabular data for the Pre Exercise phase, the Exercise phase, and the Recovery phase by stage or by minute:

- Time
- Speed/Power
- Grade
- Max HR
- BP (Sys/Dia)
- METs
- HR*BP (Double Product)
- SpO_2
- ST values per lead

Figure 4-10   Tabular Tab

Data from the **Tabular** tab is automatically printed as the Summary Table section of the Summary Report. It cannot be printed as a separate Tabular Report.

Trend Graph Tab

The **Trend Graph** tab displays the following graphs:

- Heart Rate
- Blood Pressure (Systolic, Diastolic, and SpO$_2$)
- Speed/Grade of the Treadmill (or data from the Ergometer)
- METS/Double Product (HR*BP)
- Trends by lead for ST Level and ST Slope (use the right and left arrows to scroll)

To review the leads to the right, use the right arrow button.

Figure 4-11   Trend Graph Tab
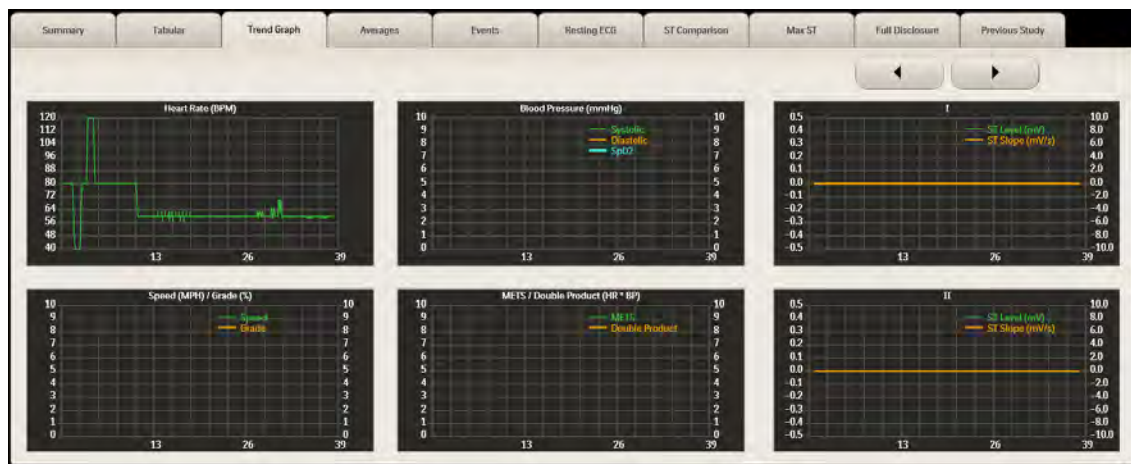
To print the Trend Graph Report

1. Click **Save** on the procedure bar, or press CTRL+S, to save the report.
2. Click **Print** on the procedure bar. The **Quick Print Settings** dialog box appears. See "Print Button (Quick Print Settings Dialog Box)" on page 4-28 for details.
3. Select a printer from the **Printer** list.
4. Click **Trends**. The Trend Graph Report prints from the selected printer.

Averages Tab

The Average Beat Complexes Report is an overview of median morphologies by stage or by minute that are configurable before and after the stress test. For more information, refer to "Configuring Print Settings" in the *ST80i Stress Test System Installation and Configuration Guide*.

This report includes:

- Report title and patient demographic data
- Study information
- Averages and ST values for all twelve leads for each phase, including Pre Exercise and Recovery

Figure 4-12   Averages Tab
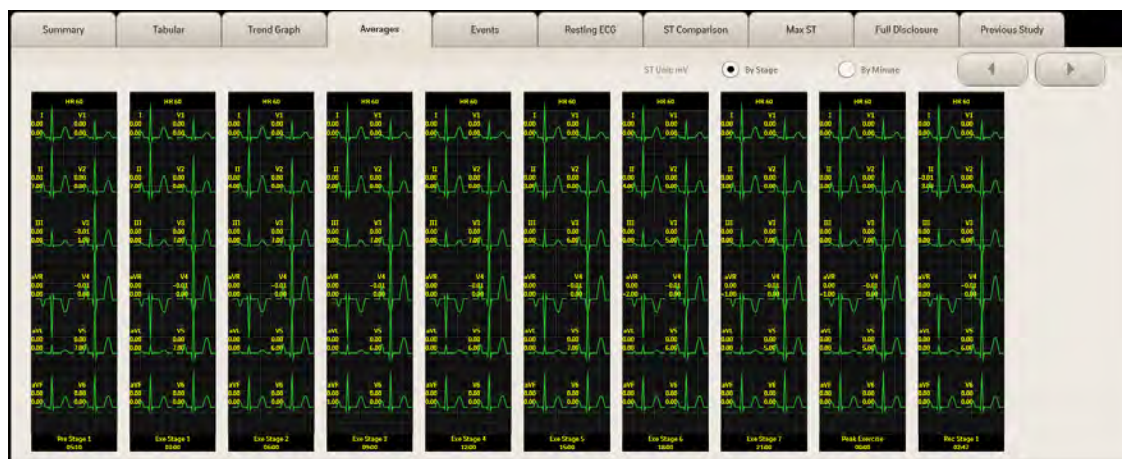
Use the radio buttons on the **Averages** tab to select whether to print the report by stage or by minute.

To print the Averages Report

1. Click **Save** on the procedure bar, or press CTRL+S, to save the report.

2. Click **Print** on the procedure bar. The **Quick Print Settings** dialog box appears. See "Print Button (Quick Print Settings Dialog Box)" on page 4-28 for details.

3. Select a printer from the **Printer** list.

4. Click **Average QRS**. The Averages Report prints from the selected printer.

Events Tab

On the **Events** tab, you can review, relabel, and print rhythm events. You can select the events to include in a printed report. You can also delete events that you do not want to include in the final stress report. Events can be deleted one at a time or in multiples.

The **Events** tab displays snapshots of all events, captured arrhythmias, and RPE scale selections acquired during the stress test, including events manually captured during the stress test by selecting an item from the Events menu. Event snapshots are displayed in groups of up to six events at a time. Use the right and left arrow buttons to display the next and previous sets of six.

Figure 4-13   Events Tab

12-Lead ECGs that are printed during the Pre Exercise, Exercise, and Recovery phases are included with the Events Report. The Start Exe event does not print during the stress test but it does appear on the **Events** tab. The Peak Exe event does print during the stress test.

The **Events** tab includes a **List All** button that opens the **All Events** window. In this window, rhythm events are listed according to type, as defined by six tabs. You can use the **All Events** window to view lists of all events and to select events to include in printed reports.

Figure 4-14   All Events Window
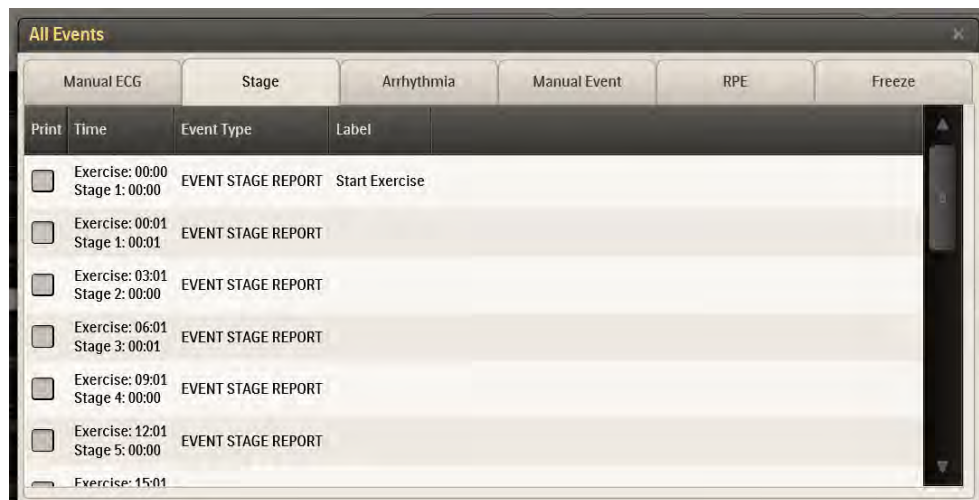
On the **Events** tab, you can:

- Review rhythm events for all captured events (for example, Chest Pain, Hyperventilation, Shortness of Breath, Ventricular Tachycardia, Bigeminy, Trigeminy, and so on), arrhythmias, and RPE scale selections acquired during the entire stress test.

- Review 12-Lead ECGs printed during the Pre Exercise, Exercise, and Recovery phases that are included with the Rhythm Events.

- Print individual events using the **Print** button on the **Events** tab.

- Relabel events.
- Select events to include when you print an entire report using the **Print** button on the procedure bar. These selections do not affect the events configured to be included in the final PDF report. You can select events from the snapshot view or from the **All Events** window.
- Delete one event or multiple events. To delete multiple events, press CTRL and select the events to delete. The **Delete** button displays the number of selected events.

To review rhythm events

1. Click the **Events** tab.

   Alternatively, click the **List All** button to open the **All Events** window, where events are listed by type: Manual ECG, Stage, Arrhythmia, Manual Event, RPE, and Freeze.

2. Double-click anywhere in an event snapshot or on an event in the **All Events** window to display an expanded view of that event.

Figure 4-15   Expanded View of an Event
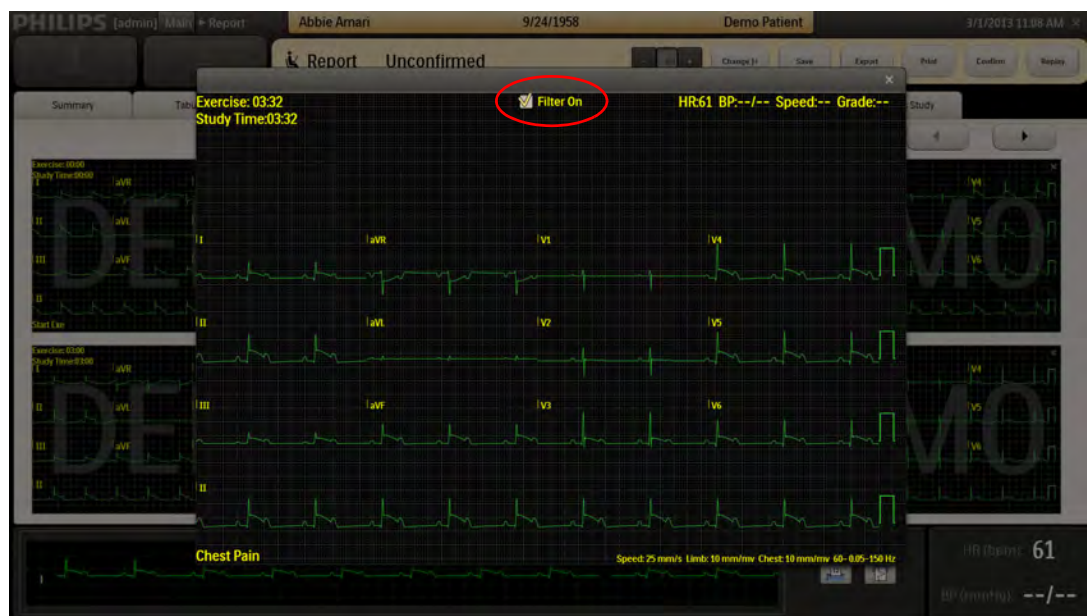
Note:

The expanded view of events shows filtered data by default. To view unfiltered data (only for events created during the Exercise and Recovery phases), click to deselect **Filter On**.

3. Review the event.

4. Click the **X** in the upper-right corner to close the window.

5. If you used the **All Events** window, click the **X** in the upper-right corner to close it.

Note:

Rhythm change notifications are provided when specific rhythm changes are detected; however, it is the responsibility of the trained healthcare professional to determine the type of rhythm change and appropriate action.

Additionally, the healthcare professional should not assume that all rhythm changes will be detected and they are responsible for taking action when rhythm changes are observed on the displayed waveforms and system fails to provide a notification. It is expected that only properly trained health care professionals working directly under the supervision of a qualified physician will be operating the ST80i Stress Test System during testing.

To relabel an event

1. Click anywhere in an event snapshot to highlight the event you want to relabel.

2. Click **Relabel**. The **Event Note** dialog box appears.

3. Type a description of the new label for the event.

4. Click **OK**.

5. The event displays the new label in the lower left corner.

To print an individual event

1. Click anywhere in the Event snapshot to highlight the event you want to print.

2. Click the **Print** button in the **Events** tab.

Note:

*The **Print** button on the procedure bar is used to print the full report or select sections of the final report.*

To select events to include in a printed report, for each event you want to include in the printed report, do either of the following:

- Click the icon in the upper right of the event snapshot: The icon changes to a green check mark.

- Click **List All** to open the **All Events** window, click the tab containing the event you want to select, and select the check box to the left of the event. To select all events on a tab, click **Print** at the top of the check box column.

Note:

*Selecting an event in snapshot view causes the event to also be selected in the **All Events** window, and vice versa.*

To delete one or more events

1. Click anywhere in an event snapshot to highlight the event you want to delete. To select more than one event, press CTRL while you select.

   The **Events** tab displays snapshots of up to six events at a time. Use the right and left arrow buttons to display the next and previous sets of six. When selecting multiple events, you can select only from the six currently displayed events.

   The **Delete** button displays the number of events you have selected.

2. Click the **Delete** button to delete the selected events. A warning appears, asking if you are sure you want to delete the event or events.

3. Click **Yes** to confirm deletion. All deleted events are removed from the list.

Resting ECG Tab

Note:

This information applies to resting/supine ECGs taken during the Pre Exercise phase of a stress test. It does not apply to ECGs captured with the optional Resting ECG Workflow feature. See Chapter 5, "Resting ECG Workflow."

Measurement and interpretation for either Supine or Mason-Likar resting ECGs are included as part of a 12-Lead ECG report only during the Pre Exercise phase when a Supine or Mason-Likar event is selected and the user has selected Enable DXL Algorithm in **Settings** > **User Profile** > **Algorithm**. The 12-Lead ECG is printed according to the user profile settings. A resting ECG can be printed at the beginning of each exercise stress test and is included in the final stress report.

Figure 4-16   Resting ECG Tab
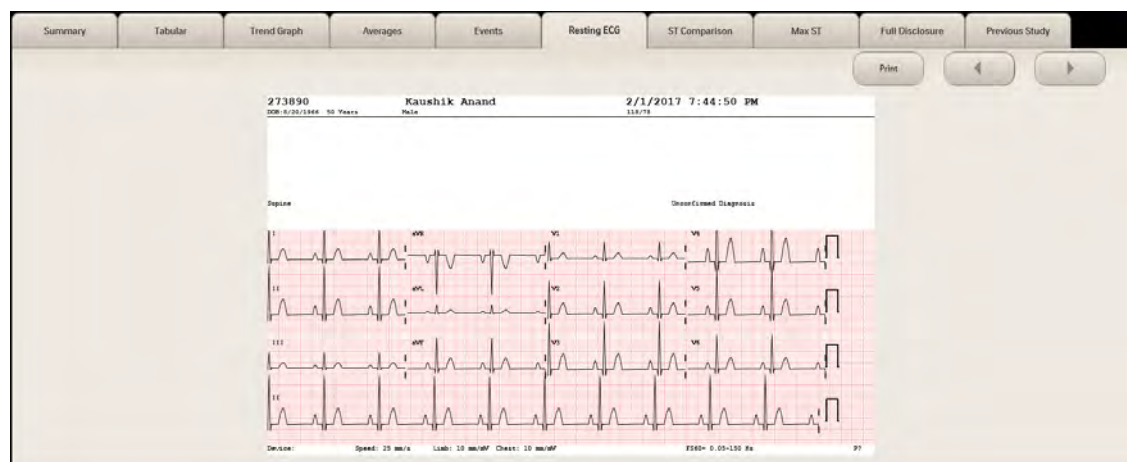
The **Resting ECG** tab shows reports of ECGs of Supine and Mason-Likar events. At the top of the report, patient data as well as ECG data appears with interpretation.

The report includes:

- Patient Demographic Data
- Study Information
- Interpretation of 12-Lead ECG Report
- 12x1, 6x2, 3x4, 3x4 3R display

Caution

Specific patient data is required for each interpretation. If patient data such as DOB or gender is edited, the ECG is reinterpreted and updated based on the new data,

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You can configure mandatory patient information fields in system configuration. When these mandatory fields are missing, you are warned with a pop-up message box. If the values in the age and/or gender fields are changed, a warning message pops up and the resting ECG is re-interpreted.

On this screen, you can scroll through the images on the screen using the right and left arrows. You can also print a resting ECG using the **Print** button on the **Resting** screen.

ST Comparison Tab

The **ST Comparison** tab displays the average ST values captured for all 12 leads at the following points in the test:

- Baseline — Average beats for one baseline. By default, the baseline is the first event during the test. You can specify a different baseline from the menu of events above the Baseline image. All events printed during the test are included in this menu.
- Peak Exercise — Average beats at peak exercise, which is the point at which the test advances from Exercise phase to Recovery phase.
- Worst Case — Average beats when maximum ST is reached. Maximum ST is the greatest ST elevation or ST depression measured during the test.
- Test End — Average beats at the end of the Recovery phase.

Figure 4-17   ST Comparison Tab
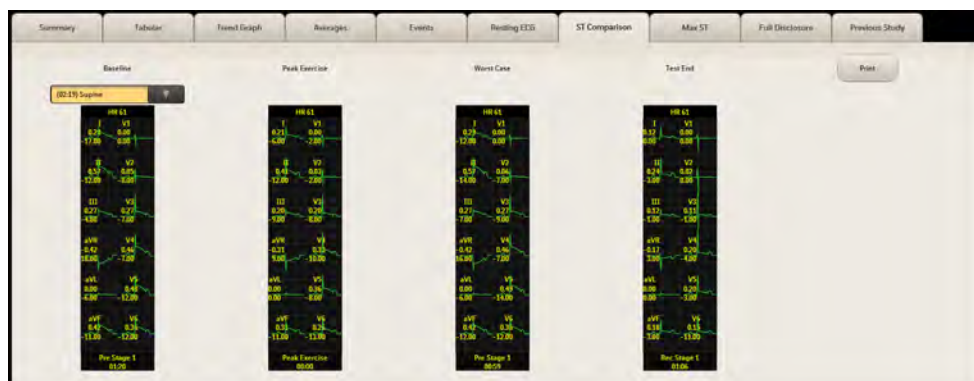
Max ST Tab

The **Max ST** tab displays the 5-second 12-lead ECG at the point in the test when the maximum ST elevation or ST depression was measured. Average beats for each lead are displayed to the right of the ECG.

Figure 4-18   Max ST Tab
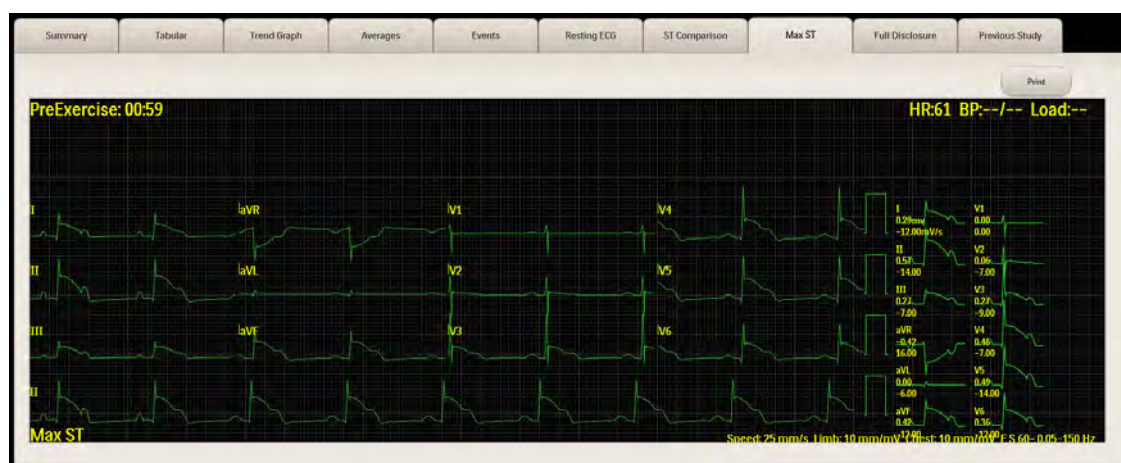
Full Disclosure Tab

On the **Full Disclosure** tab, the entire ECG waveform results of the stored stress tests, from Pre Exercise through Recovery, are loaded for full disclosure review.

Note:

If you are reviewing an exam performed with a software version prior to A.01, the waveform and progress bar begin with the start of the Exercise phase rather than the Pre Exercise phase.

Figure 4-19   Full Disclosure Tab

To view an ECG for the whole exam or a moment in time, use the slide bar and arrow buttons at the bottom of the screen. Each screen holds 18 seconds of data.

Figure 4-20   Full Disclosure Tab Slide Bar and Arrows

The start time of the portion of the ECG being displayed is noted in the bottom left corner of the waveform screen. The end time of the ECG is noted in the bottom right corner.

The changing colors along the status bar represent stage and phase changes. You can hover your cursor over the status bar to identify the exact time, phase, and stage of any point in the exam. To move quickly to any point in the exam, click on the desired location on the status bar or drag the slider control to the desired location.

Clicking and dragging the slider control changes the time frame being reviewed. You can also click the left and right arrow buttons to advance backward and forward in the ECG.

In addition, you can also create new events while reviewing the Full Disclosure Report. To create a new events, you use your mouse to place an event marker. To capture the intended event and make it visible in the ECG report, the marker must be placed a specific number of seconds following the actual event.

The ECG Event format configured in Settings determines the event marker placement delay. The Standard format is 3X4 with one or two rhythm leads. In this format there are four leads groups, each providing 2.5 seconds of ECG. Each leads group requires a different delay, as shown in the following table.

Table 4-2   Event Marker Placement Delay for a 3x4 Layout

Leads Group	Placement Delay
I. II. III	10 to 7.5 seconds
aVR, aVL, aVF	7.5 to 5 seconds
V1, V2, V3	5 to 2.5 seconds
V4, V5, V6	2.5 to 0 seconds

As another example, for 6x2 format, there are two groups of six leads each. Each group in this case displays 5 seconds of ECG for a total of 10 seconds. Therefore, the delay after the event would be 10 to 5 seconds for the first groups and 5 to 0 seconds for the second group.

To create a new event during the review of the Full Disclosure report

1. Press and hold the left mouse button for a few seconds on the intended maker location inside the waveform area of the **Full Disclosure** tab.

   The marker should be placed a specific number of seconds following the event you want to capture. See Table 4-2 on page 4-25 for an example of appropriate event marker placement delays.

   Release the left mouse button. The **Add New Event** dialog box appears.

Note:

If you press and hold the left mouse button anywhere within the first 15 seconds of the waveform area, a pop-up message states, "Cannot add events in the first 15 seconds."

2. Type a description of the event.

3. Click **OK**. The newly created event is added to the **Events** tab and saved to the database.

You can then print the event.

To print the event

1. Click the **Events** tab. The **Events** tab displays up to six events at a time. Use the right and left arrow buttons to display the next and previous sets of six.

2. Click to select the event you created.

3. Click the **Print** button in the **Events** tab.

Saving the Final Stress Report

Typically, the final stress report comprises a summary and/or narrative summary page that includes patient name and ID, date of exam, exercise time, maximum HR/ST/BP values, Duke score, FAI%, reasons for ending the

test, symptoms, conclusions, diagnosis, reviewing physician, and real-time ECG.

The final stress report is created by the reporting application as unconfirmed or confirmed (finalized) by a cardiologist or clinician.

When you finish updating and reviewing the report data, you can save the final stress report to the stress system database. After you save a stress test, the test's status is listed as **Unconfirmed** on the **Archive** screen.

To save the Final Stress Report, click **Save** on the procedure bar, or press CTRL+S. The stress test contains the PDF report and can be exported. The **Report** screen is still displayed.

Note:

If the patient is still being monitored when you save the report, and another event occurs after you save, you must save the report again before you can print it.

You can now print the final report from the **Report** screen.

Printing Reports

On the **Report** screen, there are three options for printing reports:

- **Print** (Quick Print Settings) button on the procedure bar
- **Print** button on the **Resting ECG** tab and the **Events** tab
- Post Recovery ECG (two print buttons to the right of the ECG waveform)

The printers, for printing individual reports or the final stress report, are preconfigured in the Settings section of the application. However, the printer default settings and the **Print Grid** check box (if you are using a laser printer) can be changed on the **Report** screen. You can also preconfigure the print settings to add your facility logo and site information to the final stress report.

The seven main report sections that comprise the final stress report are preconfigured with specific settings as part of the user profile in the Settings section of the application.

- Summary Report
- Trends Report
- 12-Lead ECG Report
- Average QRS Report
- Events Report (including manual ECG, manual event, stage report, RPE, arrhythmia, freeze)
- ST Comparison
- Max ST

"Printer Configuration" on page 4-27 provides a general overview of printer configuration options. "Printer Configuration" on page 4-27 provides basic information about print report settings. See the *ST80i Stress Test System Installation and Configuration Guide* for more information on how to preconfigure printers, add your facility logo, or preconfigure reports for the final stress report.

Printer Configuration

ST80i supports the following printer options:

- Thermal printer — You can print only on the device. The optional thermal printer supports all printing formats, including resting ECG auto/rhythm printing and stress ECG report printing.

- Laser printer — You can print locally on the device to which a laser printer is attached or through the network to a remote laser printer. The laser printer supports all printing formats. If the printer is networked, the network connection is disabled while the treadmill or ergometer is running.

- Remote printers — If ST80i is set up to connect remotely to a default laser printer, this printer path needs to be set up first. The remote printers support all formats except for continuous/real-time printing.

The default printer is configurable in the Settings section of the application. However, you can manually change the settings on the **Report** screen using the **Print** (Quick Print Settings) button.

The grid can also be selected under the Print function on the **Report** screen.

Printed reports provide a calibration pulse on printed waveform reports for an added check on print speed and amplitude accuracy.

WARNING

ECG signals printed on a laser printer should not be used to make time-sensitive or amplitude-sensitive measurements directly from printed page.

You are expected to provide power for the laser printer from a source other than the ST80i isolation transformer in order to be in compliance with your facility's safety requirements or IEC 60601-1.

The All-in-One PC, thermal printer, desk light, and NIBP/SpO$_2$ module must be plugged into medical isolation transformer provided with the stress system.

During the exercise stress test, ST80i supports several kinds of printing, including:

- Resting 12-Lead ECG report (with or without interpretation)

- Manually generated 12-Lead

- Stage printout (without interpretation)

- Event printout (without interpretation)

- Real-time rhythm printing

ST80i produces an interpretive report if DXL is enabled and a Supine Event is selected during Pre Exercise. The interpretive components are printed at the top of an ECG record.

The interpretive report components consist of:

- Global ECG measurements: Heart Rate, PR Interval, QT Interval and QTc, Frontal Plane P, QRS and T axis
- Interpretive statements (left-hand side)
- Reasons (right-hand side)
- Severity label

All the interpretation components are stored in the ECG file.

For information about preconfiguring print report settings, see the *ST80i Stress Test System Installation and Configuration Guide.*

Print Button (Quick Print Settings Dialog Box)

From the **Report** screen you can print individual reports as well as the final stress report. Clicking the **Print** button opens the **Quick Print Settings** dialog box, where you can override some preconfigured settings as follows:,

On the **Report** screen, clicking the **Print** button opens the **Quick Print Settings** dialog box, which you can use to override certain preconfigured print settings and then print individual reports or the final stress report.

Figure 4-21   Quick Print Settings Dialog Box

Print Options

In the Print Options section of the **Quick Print Settings** dialog box. you can override the following preconfigured settings either for individual reports or for the final report:

- Printer
- Print mode (by stage, by minute, or by both)
- Print Grid (selected or cleared)

Quick Print

In the Quick Print section of the **Quick Print Settings** dialog box, you can click to print any of the following individual reports:

- Patient ID
- Summary
- Trends
- Average QRS,
- Resting ECG (for a resting ECG captured during Pre Exercise phase of a stress test, not one captured using the optional Resting ECG Workflow feature)
- Rhythm Events
- ST Comparison

- Max ST

Print Final Report

In the **Print Final Report** section, you can select the number of copies to print for each of the following sections of the final report:

- Summary
- Trends
- Average QRS
- Rhythm Events
- 12-Lead ECGs
- ST Comparison
- Max ST

To exclude a section from the report, select 0 (zero) for that section.

A Patient Data section is always printed at the beginning of each report; you cannot exclude it.

If de-identify is preconfigured in Settings, you can de-identify or hide patient names on all final reports before printing. You can also de-identify individual reports from the **Archive** screen. See "De-Identifying Tests Using the Back Up Function" on page 4-40 for details about how to protect a patient's confidential information when printing individual and final patient reports.

Printing the Final Report

By default, the final stress report includes:

- Summary Report
- Trends Report
- 12-Lead ECG Report (Resting or Supine)
- Average QRS Report
- Events Report
- 12-Lead ECG Report
- ST Comparison Report
- Max ST Report

To print the final stress report

1. On the **Report** screen, click **Print**.

    The **Quick Print Settings** dialog box opens. The **Print Options**.section displays the preconfigured settings for printer, print mode, and grid printing. You can change these settings, as described in steps 2, 3, and 4, or leave the defaults.

2. Select a different printer from the list.

3. Select a different print mode:

   – Stage

   – Minute

   – Both

4. Select or clear the **Print Grid** check box if you want the grid to print or not print on laser paper.

5. In the **Print Final Report** section, select the number of copies to print for each report, using the minus (–) and plus (+) indicators. To deselect a report, make the number of copies zero (0).

6. Click **Print**.

Note:

All timestamps on the final report—except for 12-Lead ECG timestamps— represent the time that has elapsed since the beginning of the Exercise phase. 12-Lead ECG timestamps represent the ECG acquisition time.

For more information on the configuration of printers, see "Printer Configuration" on page 4-27.

Printing Individual Reports

You can print individual reports from the **Report** screen.

To print an individual report

1. On the **Report** screen, click **Print**. The **Quick Print Settings** dialog box opens. The **Print Options**.section displays the preconfigured settings for printer, print mode, and grid printing. You can change these settings, as described in steps 2, 3, and 4, or leave the defaults.

2. Select a different printer from the list.

3. Select a different print mode:

   – Stage

   – Minute

   – Both

4. Select or clear the **Print Grid** check box if you want the grid to print or not print on laser paper.

5. In the **Quick Print** section, click the button for the report you would like to print

   – Patient ID

   – Summary

   – Trends

-   Average QRS

-   Resting ECG (This is for a resting ECG captured during Pre Exercise phase of a stress test, not one captures using the Resting ECG Workflow product option.)

-   Rhythm Events

-   ST Comparison

-   Max ST

Post-Recovery ECG Printing

The two print options at the bottom of the **Report** screen are used to print the current lead (or any lead you select) during Post-Recovery.

·   Print 12-Lead ECG Report

·   Start Rhythm Printing

Figure 4-22   Print Options
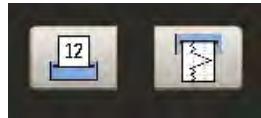
When you click the **Print 12-Lead ECG Report** button, you get a printout of that segment of the ECG.

When you click the **Start Rhythm Printing** button, a rhythm strip begins printing. To turn off Rhythm Printing, click this button again.

Working with Archived Study Data

The test database (archive) is a repository for storage of and access to study data.

All stored studies can be reviewed. Archived studies can be loaded from the local ST80i archive or restored from a local or network share to the ST80i local archive.

For each stress test (and each resting ECG if you have the Resting ECG Workflow product option installed), a database entry is generated to archive patient demographics, reports, and full disclosure data. Together with this study data, also saved into this database are patient information, the events captured during the testing, protocol settings, and the algorithm output.

The final report can be exported and stored.

The study database stores all archived data from stress tests. If you have the Resting ECG Workflow product option installed, it also stores data from resting ECGs captured using that option.

To display the patient test database, click **Report** on the **Main** screen. The **Ar-chive** screen appears.

Figure 4-23   Archive Screen
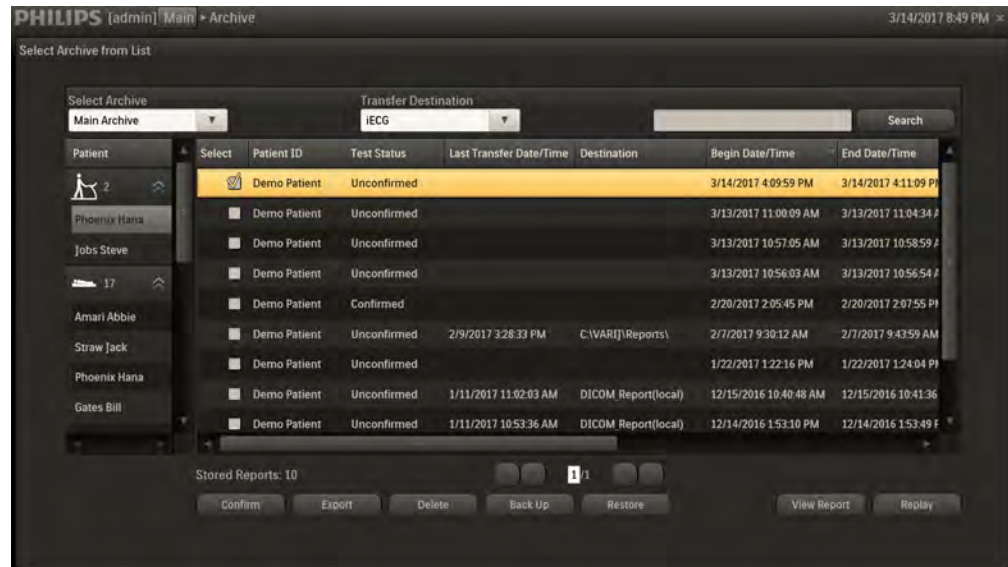
The **Archive** screen provides access to all archived stress studies.

If you have the Resting ECG Workflow product option, the **Archive** screen also provides access to the archived resting ECGs captured with that feature.

On the **Archive** screen, you can:

- Display a list of archived tests according to patient names or date/time categories.
- Search for patient studies.
- Confirm or unconfirm patient studies.
- Export patient study data as a PDF report, XML, SR (DICOM Structured Report), or raw study data (PDR). Export destinations and formats are preconfigured in **Settings** > **Remote Sites**, as described in the *ST80i Stress Test System Installation and Configuration Guide*.
- Transfer patient study data to a remote review location.
- Delete one or more stored patient studies (Administrator users only).
- Back up patient studies to another location (Administrator users only).
- Restore patient studies from another location (Administrator users only).
- View patient studies.
- Download patient studies at a remote review location.
- Replay patient studies.

Note:

- *For archived ECGs captured using the optional Resting ECG Workflow feature, you can do all of the above except:*

- *Confirm and unconfirm.*
- *Export as raw data.*
- *Export to and download at a remote review location.*
- *Replay.*

When you select an archived ECG to view, the ECG opens in a dialog box from which you can update patient data, print, export, or save the report. For details, see Table 5-3, "Resting Procedure Bar Features," on page 5-4.

Displaying the List of Archived Studies

You can display the list of archived studies by patient or by date/time category. The archive list is divided into a left and a right pane.

If you have the Resting ECG Workflow product option, the archive list includes all resting ECGs captured and saved with that feature.

By default, the left pane lists the names of all patients for whom studies have been archived, and the right pane displays all archived studies for the patient selected in the left pane.

Note:

Until you select a patient in the left pane, the right pane lists all studies for the patient with the most recently completed stress test.

Figure 4-24   Archive List Displayed for a Selected Patient

Left Pane   Right Pane
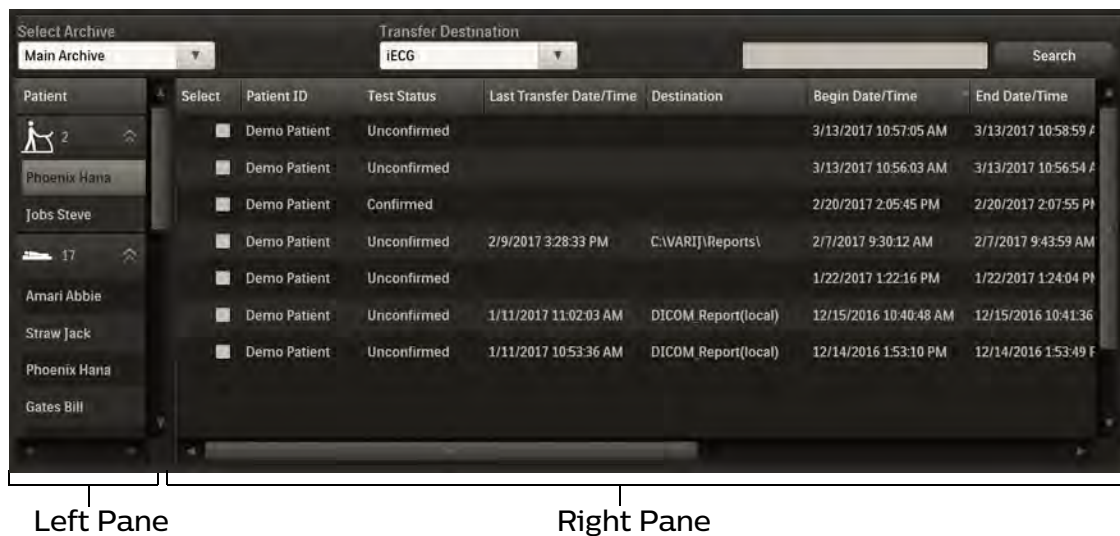
You can change the archive list so that the left pane displays date/time categories. When you do, the right pane lists all studies in that category.

Note:

Until you select a date/time category in the left pane, the right pane lists all studies in the category that contains the most recently archived study.

Figure 4-25   Archive List Displayed for a Selected Date/Time Category

The following table describes the time periods covered by each **Begin Date/Time** category.

Table 4-3   Date/Time Categories

Begin Date/Time	Description
Today	Studies saved today
Yesterday	Studies saved yesterday
This week	Studies saved within the current calendar week (starting on Sunday), including yesterday and today
Last week	Studies saved during the previous calendar week
Earlier this month	Studies saved during the current calendar month, not including this week or last week
Last month	Studies saved during the previous calendar month
Earlier this year	Studies saved during the current calendar year, not including this month and last month
Last year	Studies saved in the previous calendar year
A long time ago	Studies saved before the previous calendar year

The Left Pane of the Archive List

In the left pane of the archive list:

- Items associated with regular Stress tests are grouped under the **Stress** icon.

- Items associated with the optional Resting ECG Workflow feature (if you have it) are grouped under the **Resting** icon

- The lists in the left pane are expanded by default. You can click the **Stress** or **Resting** icon or the double up-arrow to collapse a list.

- The number to the right of the **Stress** and **Resting** icons indicates the number of items (patient names or date/time categories) in that group.

The Right Pane of the Archive List

In the right pane of the archive list:

- You can select the check box to the left of any report to select that report

- You can click **Select** at the top left of the pane to select or deselect all tests.

- You can click any of the following column headings to sort the list by that column:

  - Patient ID

  - Test Status — Confirmed or Unconfirmed

  - Last Transfer Date/Time

  - Destination

  - Begin Time

  - End Time

  - Patient Name

  - Gender

  - Date of Birth

  - Commitment Status

  - Proxy Commitment Status

- You can use the scroll bars to scroll right to view all columns, or down to view all listed tests.

- If the number of listed studies exceeds 50, navigation controls below the archive list become active. You can click the first page, last page, next page, or previous page button, or type a page number you want to display.

Changing How the Archive List Is Displayed

You can display the archive list in a number of different ways.

To change the archive list display from **Patient** to **Begin Date/Time**

1. Click **Patient** at the top of the left pane.

2. In the menu that opens, click **Begin Date/Time**,

The list in the left pane shows date/time categories rather than patient names. The right pane lists all studies archived for the selected date/time category.

To list all archived stress studies for a patient, with the left pane set to display patient names, click a patient name below the **Stress** icon. All archived stress studies for the selected patient are listed in the right pane.

To list all archived resting ECGs for a patient if you have the Resting ECG Workflow product option, with the left pane set to display patient names, click a patient name below the **Resting** icon. All archived ECGs for the selected patient are listed in the right pane,

To list all archived stress studies within a particular date/time category, with the left pane set to display date/time categories, click a category below the **Stress** icon. All archived studies within the selected date/time category are listed in the right pane.

To list all archived resting ECGs within a particular date/time category if you have the Resting ECG Workflow product option, with the left pane set to display date/time categories, click a category below the **Resting** icon. All archived ECGs within the selected date/time category are listed in the right pane.

Searching for Patient Tests

The **Archive** screen enables you to search for patient tests to confirm/ unconfirm, export, transfer to a remote review location, delete, back up, restore, view, download from a remote review location, or replay. You can search for tests using the **Search** text box and button.

Note:

If you have the Resting ECG Workflow product option, the search results will include all resting ECGs captured and saved with that feature.

To search for tests using the Search text box and button

1. Type the search criteria into the text box to the left of the **Search** button. You can use the Patient ID, Patient Last Name, or Patient First Name as search criteria.

2. Click **Search**. The **Archive** screen displays only the results that match the search criteria.

To sort the archived reports using column headings, click a column heading (for example, Test Status) to sort archived patient tests.

- The **Archive** screen sorts the contents of that column in ascending or descending order.

- Click the column heading again to reverse the sorting order.

To search for tests in a different archive, select an archive from the **Select Archive** menu. Test data stored in the selected archive can be searched for by patient ID, first name, or last name. Once you find and download the desired tests, they appear in the archive list.

Confirming a Test

Any user with confirmation privileges can confirm a report,

Note:

Resting ECGs captured with the Resting ECG Workflow product option cannot be confirmed in ST80i.

To confirm a patient test

1. Select one or more patient tests to confirm by selecting the check boxes in the Select column to the left of the Patient ID.

2. Click **Confirm** on the procedure bar. The **Confirm Report** dialog box appears, with the current user name displayed.

3. If necessary, select a different user.

4. Type the user password.

5. Click **OK.**

   The Test Status for the selected test(s) changes to **Confirmed**.

Exporting Test Data

For information about exporting test data, see "Exporting Reports" on page 4-44.

Transferring Test Data to a Remote Review Location

This optional feature allows you to transfer patient stress tests to a location (database) from which they may be downloaded to a PC that is not connected to the ST80i Stress Test System. See "Downloading Test Data at a Remote Review Location" on page 4-43 for details.

Note:

- *ECGs captured with the Resting ECG Workflow product option cannot be transferred to remote review locations.*

- *Transferring test data to a remote review location removes the test data from your stress test database.*

This feature requires the purchase of option D57. In addition, the remote review site must be configured under **Settings** > **System Settings** > **Remote Sites** on both the stress test system and the remote PC. For more information, consult the *ST80i Stress Test System Installation and Configuration Guide*.

Deleting Tests

If you have administrative privileges, you can select single or multiple stress tests to delete. When doing this, you are warned about the potential data loss. When deleting multiple tests, you can also cancel the operation to stop the delete process.

Note:

If you have the Resting ECG Workflow product option, you can delete any ECG captured and saved with that feature.

To delete tests

1. Select one or more patient tests or ECGs to delete. To select all tests, click the **Select** column heading.

2. Click **Delete**. The **Delete Report** dialog box appears.

3. Type your password and click **OK**. The **Delete Selected Reports** confirmation appears.

WARNING

This procedure permanently deletes the tests (raw data and metadata) from the local database.

4. Click **OK** to confirm deletion of the test(s) or click **Cancel** to exit.

Backing Up Tests

If you have administrative privileges, you can select single or multiple stress tests to back up to another location, including an external storage location (such as removable hard disk or USB flash drive). The Back Up function also supports providing data to the factory for troubleshooting.

Note:

If you have the Resting ECG Workflow product option, you can back up ECGs captured and saved with that feature.

Once the stress test data has been backed up, you can delete it from the **Ar-chive** screen.

If you have the Resting ECG Workflow product option, you can back up resting ECGs in the same manner as stress tests.

To back up tests

1. Select one or more patient tests or ECGs to back up.

Note:

*To select ALL tests, click the **Select** column heading.*

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2. Click **Back Up**. The **Back Up Report** dialog box appears.
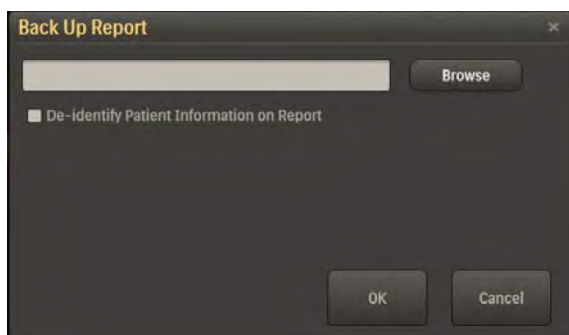
3. Click **Browse**. The **Browse For Folder** window appears.
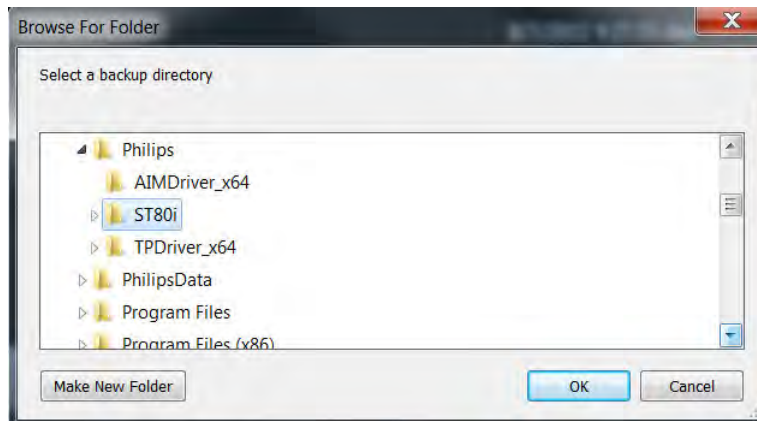
4. Browse to select the location for the backup.

5. Click **OK**. The **Backup Reports** confirmation appears.

6. Click **OK**. The selected test(s) are backed up to the specified location.

De-Identifying Tests Using the Back Up Function

You can use the **Back Up** function in the **Archive** screen to de-identify individual reports on the system. This method is primarily used by Support to get all necessary files for analysis and investigation.

Note:

If you have the Resting ECG Workflow product option, you can de-identify any ECG captured and saved with that feature.

To de-identify individual reports

1. On the **Archive** screen, select one or more reports to back up.
2. Click **Back Up**. The **Back Up Report** dialog box appears.
3. Select the **De-Identify Patient Information on Report** check box to create a support folder.
4. Click **Browse**.
5. Browse to select a location for the support folder.
6. Click **OK**.

The support folder contains one folder for each report that is backed up. Each folder contains five files: one raw data (PDR) file and four audit files (DAT) for Algorithm Engineering.

Restoring Tests

Stress tests that have been backed up to another location and deleted from the **Archive** screen can be restored. If you have administrative privileges, you can select single or multiple stress tests to restore from another location.

Note:

If you have the Resting ECG Workflow product option, archived ECGs captured with that feature can be restored.

To restore tests

1. Click **Restore**. The **Open** window appears.
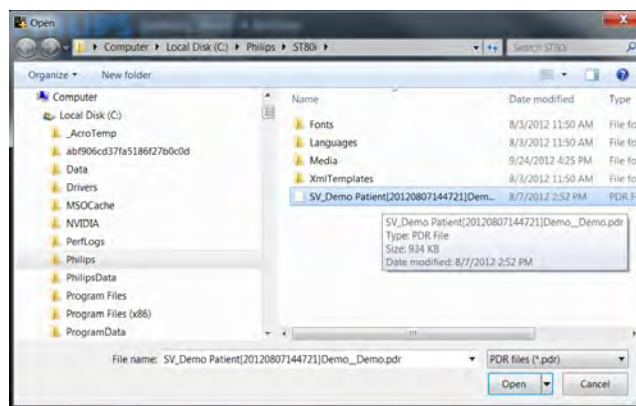
2. Browse to locate the test(s) to restore.
3. Click to select the test(s) to restore.

4. Click **Open**. The **Restore Reports** notification appears, confirming restoration of the test(s).

Note:

If any tests selected to be restored are already listed on the **Archive** *screen, the* **Restore Reports** *notification states, "The following reports already exist in the store: folder location of test(s) that already exist in ST80i".*

---

5. Click **OK**. All restored reports are displayed on the **Archive** screen.

Viewing a Test

When you view an archived stress test, it opens on the **Report** screen, described earlier in this chapter.

When you view an archived ECG captured using the Resting ECG Workflow product option, it opens in the same dialog box as when you click **Resting ECG** on the **Resting** screen, as described in Table 5-3, "Resting Procedure Bar Features," on page 5-4.

To view an archived stress study

1. In the archive list, select the check box to the left of the study you want to view.

2. Click **View Report**. The **Report** screen opens. See "Report Screen" on page 4-2 for details about what you can do on the **Report** screen.

Note:

You can also open the study by double-clicking it in the archive list.

To view an archived ECG (if you have the Resting ECG Workflow product option)

1. In the archive list, select the check box to the left of the ECG you want to view.

2. Click **View Report**. The ECG opens in a dialog box, where you can:

- Print the ECG to the ECG report printer configured in **Settings** > **System Settings** > **System**.

- Export the report to all destinations set as defaults in **Settings** > **System Settings** > **Remote Sites**.

- Double-click the patient name in the dialog box header to modify patient data.

- Save any changes you make.

Note:

You can also open the ECG by double-clicking it in the archive list.

Downloading Test Data at a Remote Review Location

The optional Remote Review feature enables you to download patient stress tests at a PC that is not connected to the ST80i Stress Test System. The test data must first be exported to the remote review location using the procedure "To export exam data to a remote review shared drive" on page 4-48. You can then download and view the tests at the remote PC.

The remote PC must have the Remote Review option installed.

Note:

ECGs captured with the Resting ECG Workflow product option cannot be downloaded at remote sites.

To download test data at a remote review location

1. At the remote PC, select the remote review location from the **Select Archive** list. The **Remote** dialog box appears.
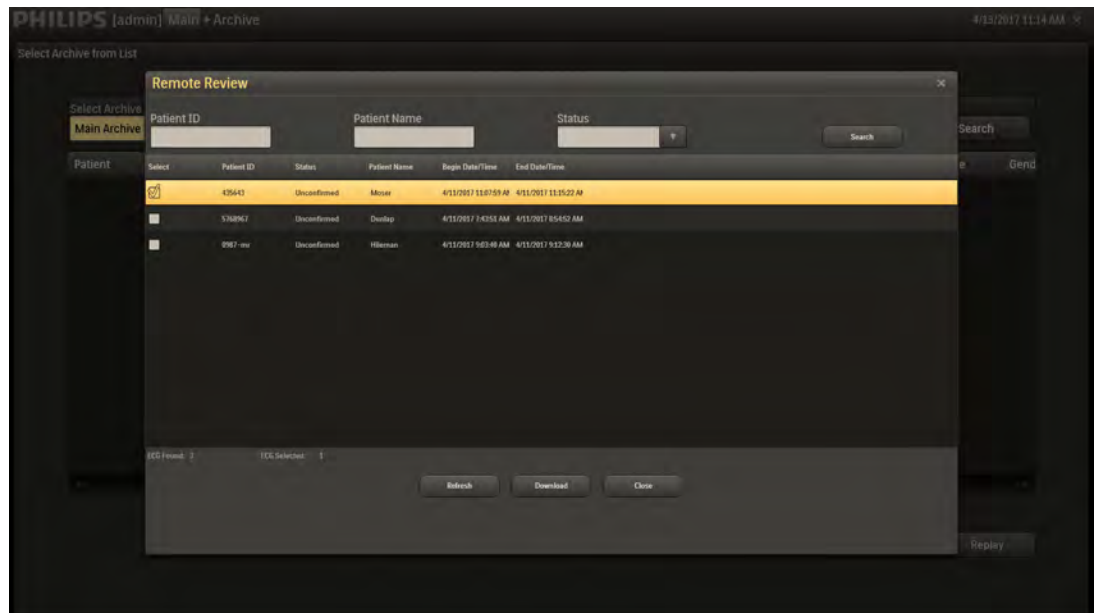
2. Click **Refresh** to get the most updated list of patient tests.

3. Select one or more tests to download. You can select directly from the list or use the Search feature to filter the list as follows:

   a Type in the **Patient ID** and/or **Patient Name** field, and/or select a status from the **Status** list.

   b Click **Search**.

The list is refreshed to match your search criteria

   c Select one or more tests.

4. Click **Download**.

5. Click **Close**.

The selected tests are downloaded to the **Archive** screen. You can now view the tests as described in "Viewing a Test" on page 4-42.

Replaying a Test

This option enables you to scan the entire exam from the beginning of the Pre Exercise stage to the end of the Recovery stage. For details about how to replay a test, see "Replay" on page 4-7.

Note:

You cannot replay ECGs captured using the Resting ECG Workflow product option.

While reviewing the stored stress test, you can change the reference ECG. The stress study data and configuration settings are saved in database.

For more information on the Replay function, see "Replay" on page 4-7.

Exporting Reports

After a final stress test is saved, it can be exported to the hospital system and/or to IntelliSpace ECG or to a shared drive. The test can be confirmed on both the device side and the server side (IECG).

The stress study raw data (PDR) is saved in the local stress study database. The export status and date/time of last export are maintained. You can also export raw data to IntelliSpace ECG version B.01 or later.

The final stress study can also be exported in PDF or XML file format to:

- External media such as a USB flash drive
- Remote sites, including:
  - An ECG Management System
  - A hospital system
  - A local or shared drive
  - An email destination
  - A remote review shared drive
  - A PACS server

– An EG Plus DICOM proxy

Note:

If exporting to a DICOM report server, your ST80i administrator will have preconfigured the PDF report either to include 12-Lead ECGs and/or PDR, or to be exported as a DICOM Structured Report (SR).

Archived ECGs captured with the Resting ECG Workflow product option can be exported. to the following destinations and formats:

• External media such as a USB flash drive

• Remote sites, including:

– An email destination (PDF)

– IntelliSpace ECG (XML)

– A shared drive (PDF)

– A DICOM Report Server (DICOM data)

Note:

To export a report, you need the appropriate permission level or network.

You can still print the report from ST80i at any time. The exported report follows all the settings for the final stress report. See "Printing the Final Report" on page 4-30.

You can also view or print the PDF file through Adobe Acrobat. See "Viewing and Printing Reports Saved as PDF Files" on page 4-49.

See the *ST80i Stress Test System Installation and Configuration Guide* for how to create folder permissions to protect data.

PDF Naming Conventions

ST80i uses two naming formats when exporting PDFs, long and short. The long format is used

• if the study includes the order number, and

• when the report is being exported to a shared drive.

Otherwise, the short report format is used.

Report name formats are as follows:

• Short format:

  SV_Patient ID[Acquisition Date/Time]FirstName_LastName.PDF

• Long format:

  SV_Patient ID[Acquisition Date/Time]FirstName_LastName_Gender_DOB_Status_MDSignature_OrderNumber_StudyID.PDF

Export Reports to External Media

You can export reports to external media such as a USB flash drive.

You can export ECGs captured with the Resting ECG Workflow product option in the same manner.

Note:

ST80i does not support exporting directly to a CD or DVD. To save a report to these media, first export the report to a local drive, then transfer the resulting PDF report to the CD or DVD. See "To export reports to a local or shared drive" on page 4-48.

To export reports to external media

1. Insert the USB flash drive into a USB port on the PC.

2. Click **Report** on the **Main** screen. The **Archive** screen appears.

3. From the **Transfer Destination** list, select **Removable Disk** (*drive letter*:).

4. Select the archived report(s) to export.

5. Click **Export**. The progress bar at the bottom of the screen displays the progress of the export.

6. The **Transfer Reports** dialog box appears. Click **OK**.

Export Reports to Remote Sites

You can export reports from the **Report** screen or from the **Archive** screen, as well as by selecting automatic export after saving the report.

To export from the **Report** screen, the destination must already have been configured as a default. See "Export" on page 4-5 for details.

On the **Archive** screen, you can select the remote site from a list of preconfigured sites. The procedures in this section describe export from the **Archive** screen.

You can export ECGs captured with the Resting ECG Workflow product option in the same manner.

For configuration information, see the "Configuring Remote Sites" section in the *ST80i Stress Test System Installation and Configuration Guide*.

Once the connection is established, all selected ECGs are transferred to the remote site. After each ECG has been successfully transmitted, the information is logged.

If the connection fails, the operator is given an alert. No attempt is made to automatically retry the operation.

A maximum of 100 remote sites profiles can be created without noticeable performance degradation when switching screens.

To create remote sites, see the *ST80i Stress Test System Installation and Configuration Guide*.

Export Reports to an ECG Management System

You can export PDF files for import into the Philips IntelliSpace ECG Management System (version A.01 and later) or the Philips TraceMasterVue ECG Management System (version C.01 through C.03).

You can export the raw data (PDR) file for import into Philips IntelliSpace ECG Management System version B.01 or later, if your ST80i administrator has configured it to do so in **Settings** > **Remote Sites**.

You can also export ECGs captured with the Resting ECG Workflow product option to an ECG management system. ECGs are exported in XML format.

To export reports to an ECG management system

1. From the **Transfer Destination** list on the **Archive** screen, select the ECG management system remote site.
2. Select the report(s) to export.
3. Click **Export**. The progress bar at the bottom of the screen displays the progress of the export.
4. The **Transfer Reports** dialog box appears. Click **OK**.

The report(s) should now appear in the ECG Management System.

Export Reports to the Hospital System

You can export reports to the hospital system through an IntelliBridge Enterprise remote site.

To export reports to the hospital system

1. From the **Transfer Destination** list on the **Archive** screen, select the hospital system transfer destination.
2. Select the archived report(s) to export.
3. Click **Export**. The progress bar at the bottom of the screen displays the progress of the export.
4. The **Transfer Reports** dialog box appears. Click **OK**.

The report(s) should now appear in the hospital system.

Export Reports to a Local or Shared Drive

You can export reports to a local PC hard drive or a shared (network) drive. The file format is PDF or XML, depending on how the drive is configured in **Settings** > **Remote Sites**.

You can export ECGs captured with the Resting ECG Workflow product option in the same manner. ECGs are exported as PDF files.

To export reports to a local or shared drive

1. From the **Transfer Destination** list on the **Archive** screen, select the name of the local or shared drive for the export.

2. Select the archived report(s) to export.

3. Click **Export**. The progress bar at the bottom of the screen displays the progress of the export.

4. The **Transfer Reports** dialog box appears. Click **OK**.

The report(s) should now appear in the local or shared drive folder.

Export Reports to an Email Destination

You can export reports to an email destination. Reports are exported as PDF files.

You can export ECGs captured with the Resting ECG Workflow product option in the same manner. ECGs are exported as PDF files.

To export reports to an email destination

1. From the **Transfer Destination** list on the **Archive** screen, select the email group for the export.

2. Select the archived report(s) to export.

3. Click **Export**. The progress bar at the bottom of the screen displays the progress of the export.

4. The **Transfer Reports** dialog box appears. Click **OK**.

The destination email address(es) receive the report(s).

Export Exam Data to a Remote Review Shared Drive

For Remote Review systems to download exams for review, you must first export the study data to a remote review shared drive. This is a drive on a system that is not connected to the ST80i Stress Test System.

To export exam data to a remote review shared drive

1. From the **Transfer Destination** list on the **Archive** screen, select the remote review location.

2. Select the archived exam(s) to export.

3. Click **Export**. The progress bar at the bottom of the screen displays the progress of the export.

4. The **Transfer Reports** dialog box appears. Click **OK**. The remote site receives the exam data.

The remote system must have the optional Remote Review application installed in order to download and view the exported exam data. For information, see "Downloading Test Data at a Remote Review Location" on page 4-43.

Export Reports in DICOM Format to a PACS Server

You can export reports in DICOM format to a PACS server (DICOM Report Server).

When exporting to a DICOM Report Server, your ST80i administrator will have preconfigured the PDF report to either include 12-Lead ECGs and/or PDR, or to be exported as a DICOM Structured Report (SR).

Note:

You can export ECGs captured with the Resting ECG Workflow product option in the same manner. ECGs are exported in DICOM format.

To export reports in DICOM format to a PACS server

1. From the **Transfer Destination** list on the **Archive** screen, select the DICOM server destination for the export.
2. Select the archived report(s) to export.
3. Click **Export**. The progress bar at the bottom of the screen displays the progress of the export.
4. The **Transfer Reports** dialog box appears. Click **OK**.

The selected remote site receives the report(s).

Export Reports to the EG Plus DICOM Proxy

You can export reports in DICOM format to an EG Plus DICOM proxy. The proxy then communicates with the remote DICOM server.

To export reports in DICOM format to an EG Plus DICOM proxy

1. From the **Transfer Destination** list on the **Archive** screen, select the EG Plus destination for the export.
2. Select the archived report(s) to export.
3. Click **Export**. The progress bar at the bottom of the screen displays the progress of the export.
4. The **Transfer Reports** dialog box appears. Click **OK**.

The selected remote site receives the report(s).

Viewing and Printing Reports Saved as PDF Files

To view and print a report saved as a PDF file

1. Exit the ST80i application.
2. From Windows Explorer, locate and select the directory where the file was exported.

3. Locate the file you want to review and double-click it. Adobe Acrobat Reader automatically opens and displays the file.

4. Press **Page Down** and **Page Up** to navigate through the file.

If the PC has access to a local or shared printer, you can print the file by selecting **File**, then **Print**.

Importing Data or Reports

If you have the ST80i Inbound Worklist product option installed, you can import data (orders) from IntelliBridge Enterprise (IBE) or a DICOM MWL server into ST80i.

Import Data from IntelliBridge Enterprise (IBE), a DICOM MWL Server, or an EG Plus DICOM Proxy

You can import data (orders) for a stress test from IntelliBridge Enterprise (IBE), a DICOM MWL server, or an EG Plus DICOM proxy. In all cases, the remote site must already be configured. For more information, refer to the *ST80i Stress Test System Installation and Configuration Guide*.

To import data from IBE or a DICOM server or proxy

1. Click **Stress** on the **Main** screen.

2. On the **Worklist** tab, select the desired remote site from the **Location** list.

3. Click **Download**. The **Worklist** tab is populated with the imported data.

Query a Previous Report

You can query previous reports in ST80i. See "Review a Previous Study" on page 3-8.

Resting ECG Workflow

Resting ECG Workflow is an ST80i product option that enables you to capture a resting ECG. It can be used for the following purposes:

- To capture a standalone resting ECG not associated with a stress test.
- To capture a resting ECG before a stress test. You can advance directly from the resting ECG to the Prepare phase of the stress test.

Note:

The Resting ECG Workflow option uses the same algorithm as Philips cardiograph products, such as the TC Cardiograph series.

This chapter provides the information you need to perform a standalone resting ECG using the Resting ECG Workflow option.

Caution

Do not run any other applications, including screen savers, when performing a resting ECG. Once the ECG has begun, the ST80i application does not allow you to access other system functions.

For information about a patient session for a full stress test, see Chapter 3, "The Patient Session."

WARNING

To get the most accurate interpretation during resting ECG, use traditional limb lead placement. Using "Mason-Likar" electrode placement may result in deviation in interpretation. Interpretations and analysis results provided by the Philips DXL 12-lead Analysis Algorithm for 12-lead ECG captures are intended for use with traditional limb lead placement and are not validated for use with other lead placements

ST80i Resting Screen

If you have the Resting ECG Workflow product option, the ST80i **Main** screen includes a **Resting** icon, which you click to open the **Resting** screen.

On the **Resting** screen, you have command of several functions during a patient session. You can stop the session at any point without losing any patient demographics or order information. However, in this case, the ECG data will be lost.

The **Resting** screen provides:

- All key procedural information.

- Buttons to manage patient information, capture the resting ECG, move to a stress test, and open the **Report** screen.

- Menus to manage the ECG, with windows that can be viewed, then hidden, so that the leads can be viewed in their entirety.

- Time of Day for correct time stamp for every resting ECG.

Figure 5-1   ST80i Resting Screen

Table 5-1   ST80i Resting Screen Features

Feature	Description
A	Title Bar — Initially displays only current date and time. The patient name, DOB, and ID appear after you click the **Patient** button in the procedure bar and do one of the following in the window that opens: • Select a patient from the worklist. • Use the Find button and search field to find a patient. • Add a new patient by clicking **Add**. During the resting ECG, you can click the patient name in the title bar to update patient information.
B	Procedure bar — Displays icons that provide quick access to frequently used commands. Also displays procedure information, such as the selected PIM device and heart rate along with the **Start Rhythm Printing**/**Stop Rhythm Printing** button.
C	Waveform screen — Displays real-time ECG waveforms.

Resting Title Bar

You can use the title bar to manually input and edit patient information that will be stored in the patient worklist. The title bar includes the features shown and described below.

Figure 5-2   Resting Title Bar
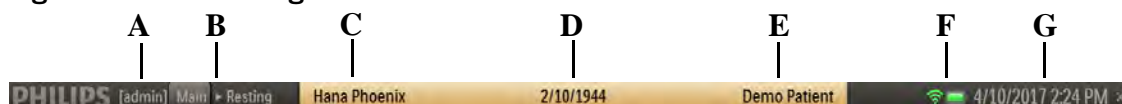
Table 5-2   Title Bar Features

Feature	Description
A	Current user name.
B	Navigation Keys (**Main > Resting**) — Click **Main** to leave the ECG and return to the **Main** screen.
C	Patient name — Click the patient name to update patient information and add notes on the **Patient Information** tab of the **Patient Demographics** window. **Note:** *Patient name, DOB, and ID are not displayed until you click the* **Patient** *button in the procedure bar to select, find, or add a patient.*
D	Patient's date of birth — DOB formatting is determined by operating system.

Feature	Description
E	Patient ID
F	Indicators for the RF transmitter and PIM battery status.
G	Current date and time — Date formatting is determined by operating system.

Resting Procedure Bar

The procedure bar contains the icons and buttons you can use during the patient session to access frequently used commands, change default settings, and view or hide specific ECG data.

Changes you make to default settings are reset to the preconfigured defaults when you start a new patient session.

The procedure bar also displays procedure information, including the selected PIM device and heart rate along with the Start/Stop Rhythm Printing button.

When you hover over each icon or button, a tool tip is displayed.

By default, the procedure bar is at the top of the screen. You can change its location to the bottom of the screen. See the *ST80i Stress Test System Installation and Configuration Guide* to change the default setting (**Settings** > **User Profile** > **Display**).

Figure 5-3   Resting Procedure Bar
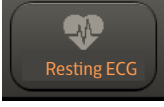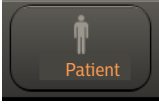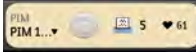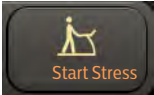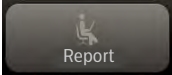
Table 5-3   Resting Procedure Bar Features

Feature	Description
A **Waveform** icon	The default is 12 leads; you can select from the following: • 12 Leads • 6x2 Leads • 6 Leads • 3 Leads
B **Lead Map** icon	Toggle to display or hide the lead map. The lead map is hidden by default. Display the lead map diagram to check lead wire connection integrity with a predefined, color-coded indicator to show any leads that are off.

Feature	Description
C **Paper Advance** icon	Form-feed adjustment for thermal paper.
D **Quick Settings** icon	Opens the **Quick Settings** dialog box, where you can change the following default settings for this ECG only: · Filter (LP, HP, AC, Artifact, Smart) · Display (Limb Gain, Chest Gain, Speed) · Rhythm Print (Leads, Limb Gain, Chest Gain, Speed) · Pacer Detection (Paced Unknown, Paced, Non-paced, Paced (magnet)) For details about these Quick Settings, see the appropriate sections under "Quick Settings" on page 2-31: · "Filter" on page 2-31 · "Display" on page 2-32 · "Rhythm Print" on page 2-33 · "Pacer Detection" on page 2-34

Feature	Description

E **Resting ECG** button	Captures the most recent 10 seconds of ECG and displays it in a dialog box where you can:
	
	• Preview the report. If the report is longer than one page, you can navigate through it using the Prev and Next buttons.
	
	• Click **Print** to print the report to the ECG report printer configured in **Settings** > **System Settings** > **System**.
	
	• Click **Export** to export the report to all destinations set as defaults in **Settings** > **System Settings** > **Remote Sites**. Valid destinations include:
	
	  – Email Address List (exports XML)
	
	  – IntelliSpace ECG (exports XML)
	
	  – Shared Drive (exports PDF)
	
	  – DICOM Report Server (exports DICOM data)
	
	• Click **Save** to save the report to the patient test database (archive).
	
	Once a report is saved, you can access it by clicking the **Report** button on the **Resting** screen or on the **Main** screen to open the **Archive** screen, where you select the report from the list of resting ECG reports, then click **View Report**. The archived report has the same functions described here for 10-second ECG (Print, Export, and so on).
	
	See Chapter 4, "Working with Reports," for details.
	
	• Click **Close** to close the report and return to the **Resting** screen.

F **Patient** button	Opens the worklist so you can select, find, or add a patient. Also enables you to modify patient demographics. See "Using the Patient Worklist" on page 3-1.
G Procedure information	Displays the selected PIM device and enables you to choose a different PIM. Also includes the Start/Stop Rhythm Printing button to start or stop real-time rhythm printing. The number to the right of the **Printer** icon indicates the number of pending print jobs. Heart rate is also displayed.

Feature	Description
H **Start Stress** button Start Stress	Advances the patient from resting ECG to the first phase of a stress test. Opens the **Stress Study Options** dialog box, where you select the exercise device and BP configuration for the test. When you click **OK** in the **Stress Study Options** dialog box, the test advances to the Prepare phase of the stress test.
I **Report** button Report	Ends the current resting ECG session and opens the **Archive** screen, where you can search for and select archived reports. See Chapter 4, "Working with Reports,"for details.

Waveform Screen

Real-time ECG waveforms appear on the waveform screen. The default setting is 12-Lead. You can use the **Waveform** icon on the procedure bar to change the waveform layout.

Note:

When viewing 6 or 3 leads in the default waveform layout, you can change a lead by clicking the lead label on the left side of the display.

At the bottom of the screen, the current settings appear for the following:

- Limb Lead amplitude
- Chest Lead amplitude
- Speed of trace display
- Filter (low and high pass)
- AC Filter setting in Hz (50 or 60)
- Indicator that the Artifact Filter is on (F)
- Indicator that the Smart Filter is on (S)

Figure 5-4   Limb Lead, Chest Lead, Speed, and Filter Settings

Limb: 10mm/mV Chest: 10mm/mV Speed: 25mm/s 0.05-150Hz 60~ F S

You can use the **Quick Settings** icon to change these settings. The changes are immediately reflected at the bottom of the screen.

Maintaining the ST80i System

Daily Maintenance

Every day, check lead wires, the cable between the PC and the treadmill, the cable between the PC and the NIBP module, the AC adapter, and power cords for any worn or cracked insulation to ensure that no inner conductive material is exposed. Discard worn accessories and replace them only with Philips accessories.

Precautions

- Before cleaning any equipment, unplug the AC power cord connecting the equipment to the power source.
- Do not attempt to clean the device or patient cables by submersing into a liquid, autoclaving, or steam cleaning.
- Wipe the exterior surface of the device and patient cables with a non-alcohol sterilizing disinfectant, and then dry with a clean cloth.
- Conductive parts of the patient cable, electrodes, and associated Type CF connections, including the neutral conductor of the patient cable and electrode, should not come into contact with other conductive parts, including earth ground.
- Do not pull or stretch patient cables as this could result in mechanical and/or electrical failures. Patient cables should be stored after use by forming them into a loose loop.
- Patient cable exteriors should be checked for cracks or breakage prior to use.

Caution

Dispose of waste material according to local regulations and laws regarding medical and battery waste.

Cleaning the ST80i System

ST80i system components should withstand cleaning using a cloth dampened with the following solutions.

Important:

This applies only to Philips Healthcare custom-designed components. For all commercial off-the-shelf (COTS) components, including NIBP monitors, laser printers, PCs/monitors, LCD displays, keyboards, and mice, customers must follow the manufacturers' cleaning specifications.

- Isopropyl alcohol, 70% solution
- Mild soap and water
- Chlorine bleach (5.25% sodium hypochlorite content), 3% solution in water
- Steris Coverage Plus NPD, 1/2 fluid ounce per gallon water (one part Coverage Plus NPD to 256 parts water)

To clean the ST80i system, advanced interface module (AIM), and transport cart

- Clean the outside of the computer with a soft cloth lightly moistened with a mild detergent solution. Do not use solvents or abrasive cleaners.
- Clean the display with a soft cloth lightly moistened with a mild detergent approved for use on the display. Do not use solvents or abrasive cleaners. Follow manufacturers' recommendations for all OEM (COTS) components.
- Clean the AIM with a soft cloth lightly moistened with a mild detergent approved for use on the AIM. Do not use solvents or abrasive cleaners.
- Clean the trolley with a cloth dampened with mild soap and water, as necessary.

Cleaning the PIM After Each Use

The wireless patient interface module (PIM), PIM holder, PIM belt, and lead wires must be cleaned after each use with any of the approved solutions described in "Cleaning the ST80i System" on page 6-2.

Caution

Do not:

- **Autoclave the patient module, patient cable/lead wires, or use ultrasonic cleaners**
- **Immerse**
- **Use abrasive materials**

• **Wet the connectors**

To clean the PIM, PIM holder, and belt

1. Dampen a soft cloth with one of the disinfectants or cleaning agents appropriate for the device, as defined in "Cleaning the ST80i System" on page 6-2.

2. Wring excess moisture from the cloth before cleaning.

3. Simply wipe off the exterior of the PIM, PIM holder, and belt.

To clean the patient cable and lead wires, refer to the instructions in the corresponding accessory's Instructions for Use.

Maintaining the ST80i Thermal Printer

You should implement a satisfactory cleaning and inspection schedule for this equipment for proper equipment operation and to reduce the possibility of equipment failure.

Note:

There are no serviceable parts for this printer. Should you experience problems with the printer, it is replaced as a whole.

Inspecting the ST80i Thermal Printer

Inspect the equipment for the following conditions on a regular basis:

• Examine power cable and the USB cable for obvious damage (for example, torn insulation, broken connectors, and so on). Replace cables as necessary.

• All cords and connectors are securely seated in their corresponding connections.

• Examine the equipment for missing screws, cracks or broken areas that might allow unintended access to internal electronics areas.

Cleaning the ST80i Thermal Printer

Note:

If the system is configured with a laser printer, refer to the User Guide provided with the printer for maintenance and cleaning instructions.

To clean the printer

1. Disconnect the power source.

2. Clean the exterior surface of the unit with a damp cloth using a solution of mild dish washing detergent diluted in water.

3. After washing, thoroughly dry the unit with a clean, soft cloth or paper towel.

Clean the print head monthly, as described next.

Note:

Do not let soap or water come into contact with the writer, plugs, jacks, or vents.

To clean the print head

1. Open the printer cover door.

2. Use a cotton swab lightly dampened with isopropyl alcohol to clean the print head.

3. Allow the print head to air dry.

4. Clean the platen by using adhesive tape. Apply the tape and pull it off. Rotate the roller and repeat until the entire roller is clean.

5. Use a cotton swab lightly dampened with isopropyl alcohol to clean the paper sensor.

Testing ST80i Thermal Printer Operation

After inspecting and cleaning the thermal printer, confirm that the printer is working properly.

To test printer operation, using an ECG simulator with the stress testing system, acquire and print ECGs of known amplitude.

A successfully printed ECG report has the following characteristics:

- Printing should be dark and even across the page.

- There should be no evidence of print-head dot failure (for example, breaks in printing forming horizontal streaks).

- Paper motion should be smooth and consistent during printing.

- Waveforms should appear normal, with proper amplitude, and without distortion or excessive noise.

- Paper should stop with perforations near the tear-bar (indicating proper cue sensor operation).

Replacing the ST80i Thermal Printer Fuse

The AC fuse may need to be replaced when the AC power-on indicator light does not illuminate when the printer is plugged into AC power.

Figure 6-1   AC Fuse Location and AC Power-on Indicator Light on ST80i Thermal Printer
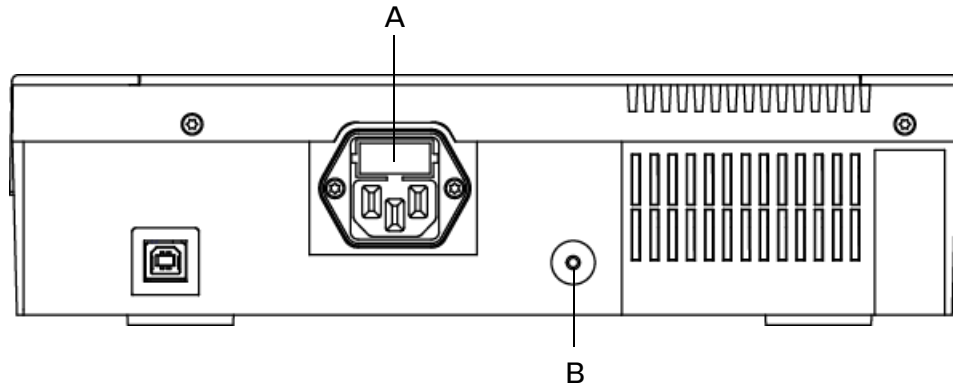
A   AC fuse location
B   AC power-on indicator light

Only use replacement AC fuses with Philips part number 453564131221, or use a 1.6 amp (250V) time-delay fuse the same size and configuration as the original fuse.

To replace the AC fuse

1. Unplug the thermal printer from AC power. Pull out the AC power cord from the AC power connector on the rear of the printer.
2. Locate the AC fuse holder directly above the AC power connector.
3. With a small blade screwdriver or other small blade tool, push on both ends of the fuse and pull out the fuse from the fuse holder slot.
4. Insert the new fuse using the same orientation.
5. Push the fuse all the way into the fuse holder slot. The fuse snaps into place.

A
Troubleshooting and Contacting the Philips Response Center

When you encounter a problem working with ST80i, address the issue in the following order:

1. Review the Troubleshooting chapter to see if your issue is addressed.

2. Contact your ST80i administrator.

3. Contact the Philips Response Center.

The Philips Response Center can assist with product troubleshooting and provide technical expertise to help with any issue with the ST80i system. For details, visit www.healthcare.philips.com, select your country and language, and navigate to the Response Center page.

Troubleshooting ST80i Issues

When you are using ST80i, you may encounter some problems with the system. The following table describes some of the more common symptoms and provides information regarding possible causes and solutions to help you solve potential problems.

Table A-1   Troubleshooting ST80i Issues

Problem	Cause	Solution
Waveform Issues		
Baseline drift	Poor skin-to-electrode contact.	Re-prep skin and replace faulty electrodes.

Problem	Cause	Solution
Waveform Issues *(continued)*		
A red dashed line is displayed on the real–time ECG display No waveform signal on the screen	• Missing or corrupt AIM driver	• In the Windows Device Manager, check for the presence of *Philips ST80i Advanced Input Module* under *Philips Healthcare Device.* In earlier versions of the software, check for the driver *Kernel Mode Driver for Advanced Input Module* under *PMS–PCCI–CDC Device.* If not present, try reseating the USB cable and/or reinstalling the AIM driver
	• Missing RL/N lead	• Check leads. Run the Lead test from the Service Utility. Replace leads if necessary.
	• PIM MAC address incorrect	• Check PIM configuration in **Settings** for correct MAC address. Correct if necessary.
	• Wrong PIM selected	• In multi–PIM setting ensure correct PIM is selected when initiating a test. Correct if necessary.
	• Defective PIM	• Call the CCSC.
	• Defective AIM	• Call the CCSC.

Problem	Cause	Solution
Waveform Issues *(continued)*		
ECG artifact caused by muscle interference.	• Electrode placed over an area of muscle or fatty tissue	• Find a stable electrode site, re-prep the skin, and apply a new electrode away from muscular and fatty areas.
	• Non-stress or monitor type electrodes being used.	• Replace electrodes
	• Dried out or expired electrodes	• Replace electrodes
	• Treadmill handles being gripped to tightly	• Instruct patient not to grip treadmill handles too tightly.
	• Clothing interfering with lead wires	• Adjust clothing.
System Navigation Issues		
For wired keyboard/ mouse: No response to keyboard commands or cursor does not move.	USB cable connection to keyboard or mouse	• Check USB cable connection to the keyboard or mouse.
		• Disconnect and connect the keyboard or mouse to check whether the keyboard or mouse can be identified by the system.
		• Ensure mouse power switch is in the ON position
For wireless keyboard/ mouse: No response to keyboard commands or cursor does not move.	• Wireless USB connection	• Remove and reseat the wireless USB receiver.
		• Press and hold the Connect button on the keyboard or mouse for 10 seconds
	• Dead battery in wireless keyboard or wireless mouse	• Replace the battery in the wireless keyboard or mouse.

Problem	Cause	Solution
Treadmill Issues		
Treadmill does not respond to the On command from ST80i	• Equipment was powered up in the wrong sequence	• Turn the treadmill off by using the treadmill power switch, located at the base of the treadmill hood, on the left side. Wait one minute and turn the power on. Proceed with the test. • Ensure the correct equipment is specified in the Configuration settings.
	• The Treadmill power switch is in the Off position, or the treadmill cable is not properly attached	• Check the treadmill-to-ST80i cable connection. Turn the Treadmill main power switch to the On position. • Ensure the correct COM port is configured.
	• The Emergency Stop button is engaged	• Reset the Emergency Stop button by turning it clockwise one quarter turn.
	• Safety tether not attached	• If so equipped, make sure the safety tether is attached.
System Error Messages		
The Lead Map displays a red X on one or more connections	• One or more leads are not connected.	• Connect the electrodes. Once connected, the red X disappears.
	• One or more leads have failed • Defective lead set	• Replace lead set.
An error occurred during export of selected exams	• Network is down • Remote Site configured incorrectly	• Check remote location. • Try pinging remote location. • Test remote site connection from Settings. If it fails, investigate cause and resolve.
	• Export folder does not exist	• Check Export directory.

Problem	Cause	Solution
System Error Messages		
Information message appears when you attempt to begin the Exercise phase: At least one ST value is invalid. Do you want to proceed the test?	ST80i has not yet learned the normal morphology of the patient's ECG.	Click **Cancel** to allow ST80i more time to learn the normal morphology in the Pre Exercise phase. or Click **OK** to move to the Exercise Phase. This does not affect analysis in any way.
When Compare is selected, the Compare (White) Zoomed ECG is flat-lined with the A.01 version of the software. Earlier versions displayed both the Current and Compare as flat-lined.	The ST80i had not yet learned the normal morphology when selected Compare event was created	Select an Event that was created after the normal morphology has been learned (ST value present).
Printer Issues		
• Thermal printer paper out light is on • Thermal printer is not printing • Uneven printing of ECGs or reports	• Paper jammed • No paper in tray • Open printer door • Print head needs cleaning • Paper door not closed completely • Paper installed incorrectly	• Open writer cover and remove jammed paper. • Insert new pack of paper in tray. • See if writer door is latched. • Verify that the correct printer is specified in the configuration settings. See "Printer Settings" on page 3-34. • Clean the print head as specified in "Cleaning the ST80i Thermal Printer" on page 6-3. • See if paper door is closed completely. • Ensure paper is properly aligned. • Check for correct paper orientation using sensor hole at bottom left of paper.

Problem	Cause	Solution
Uneven printing	• Print head needs cleaning	• Clean the print head as specified in "Cleaning the ST80i Thermal Printer" on page 6-3.
	• Paper roller	• Check the paper roller for uneven wear.
	• Poor or damaged paper (thermal paper that is old or that was improperly stored can cause light or uneven printing. Exposure to heat or chemical vapors can damage the paper)	• Test printer using a fresh pack of properly stored paper.
No printing	• Power cord or USB cable may be disconnected	• Check AC power cord and USB cable connections and confirm that the Power On indicator is illuminated.
	• Printer might not have paper loaded or paper could be loaded incorrectly	• Check to see that paper has been loaded and that it has been loaded correctly. Paper sensor mark is at the bottom right
	• Printer error	• Check device manager to ensure driver is loaded by looking for Device Manager/PMS-PCCI-CDC Device/Kernel Mode Driver for Thermal Printer. If it is not present, call the CCSC.

Problem	Cause	Solution
Printer Issues *(continued)*		
Blood pressure printout and report discrepancy	• Use of **NIBP** field to enter new blood pressure values	• You must enter blood pressure values using the **BP mmHg** (Sys/Dia) field in the side panel. For details on entering blood pressure values, see "Baseline/Reference BP and SpO2" on page 3-27.
	• Cuff/mic not positioned correctly.	• Position cuff and mic correctly.
	• Cuff too large/too small for patient.	• Use properly sized cuff.
	• Tango NIBP device defective.	• Call the CCSC.

Contacting Your Philips Response Center

Your Philips Response Center can assist with product troubleshooting and provide technical expertise to help with any issue with the Cardiac Workstation or any of its accessories.

For more information on how to contact your Philips Response Center, go to https://www.healthcare.philips.com, then select the link for your country or region.

B
Protocol Reference

This appendix provides an example of each of the included protocols. You can define and edit protocols. For details, see the *ST80i Stress Test System Installation and Configuration Guide.*

The following protocols are delivered with every ST80i system. See the indicated page for an example of each of these protocols:

Bruce Protocol

This sample Bruce protocol produces the following operations and conditions:

- A stage change occurs every 3 minutes with an increase in treadmill speed and grade.
- Blood pressure is automatically measured at the end of each stage (by default, but can be changed by the user).

- A 12-lead ECG report is automatically printed at the end of each stage (by default, but can be changed by the user). ECG acquisition begins 10 seconds prior to the end of a stage.

- In the Recovery phase, the treadmill slows to 1.5 mph and the following reports are automatically printed:

  - The final ECG from the last stage

  - Peak exercise ECG

  - Recovery ECGs based on your configuration

- Blood pressure measurement is set to every 2 minutes (2, 4, 6, 8...) until the end of the Recovery phase.

- The following are created and saved as events but are not printed:

  - Start Exercise

Table B-1   Bruce Protocol Settings

	Stage #	Time Duration (mm:ss)	Speed (mph)	Grade (%)	ECG Print	BP Measurement
Bruce						
Pre Exercise						
	1	Unlimited	1.0	0.0	Off	Off
Exercise						
	1	3.00	1.7	10.0	End	End
	2	3.00	2.5	12.0	End	End
	3	3.00	3.4	14.0	End	End
	4	3.00	4.2	16.0	End	End
	5	3.00	5.0	18.0	End	End
	6	3.00	5.5	20.0	End	End
	7	3.00	6.0	22.0	End	End
Recovery						
	1	3.00	1.5	0.0	Every 02:00	Every 02:00

Modified Bruce Protocol

Table B-2   Modified Bruce Protocol Settings

	Stage #	Time Duration (mm:ss)	Speed (mph)	Grade (%)	ECG Print	BP Measurement
Modified Bruce						
Pre Exercise						

Modified Bruce					
1	Unlimited	0.5	0.0	Off	Off
Exercise					
1	3.00	1.7	0.0	End	Begin
2	3.00	1.7	5.0	End	Begin
3	3.00	1.7	10.0	End	Begin
4	3.00	2.5	12.0	End	Begin
5	3.00	3.4	14.0	End	Begin
6	3.00	4.2	16.0	End	Begin
7	3.00	5.0	18.0	End	Begin
8	3.00	5.5	20.0	End	Begin
9	3.00	6.0	22.0	End	Begin
Recovery					
1	3.00	1.0	0.0	Every 02:00	Every 02:00

Balke Protocol

The Pre-Exercise and Recovery phase settings are the same as for the Bruce protocol. See "Bruce Protocol Settings" on page B-2.

Table B-3   Balke Protocol Settings

Balke					
	Stage #	Time Duration (mm:ss)	Speed (mph)	Grade (%)	ECG Print	BP Measurement
Pre Exercise					
	1	Unlimited	1.0	0.0	Off	Off
Exercise					
	1	1.0	3.3	1.0	End	Off
	2	1.0	3.3	2.0	End	Off
	3	1.0	3.3	3.0	End	End
	4	1.0	3.3	4.0	End	Off
	5	1.0	3.3	5.0	End	Off
	6	1.0	3.3	6.0	End	End
	7	1.0	3.3	7.0	End	Off
	8	1.0	3.3	8.0	End	Off
	9	1.0	3.3	9.0	End	End
	10	1.0	3.3	10.0	End	Off
	11	1.0	3.3	11.0	End	Off
	12	1.0	3.3	12.0	End	End

Balke					
13	1.0	3.3	13.0	End	Off
14	1.0	3.3	14.0	End	Off
15	1.0	3.3	15.0	End	End
16	1.0	3.3	16.0	End	Off
17	1.0	3.3	18.0	End	Off
18	1.0	3.3	20.0	End	End
19	1.0	3.3	21.0	End	Off
20	1.0	3.3	22.0	End	Off
21	1.0	3.3	23.0	End	End
22	1.0	3.3	24.0	End	Off
Recovery					
1	3:00	1.0	0.0	Every 02:00	Every 02:00

Ellestad Protocol

The Pre Exercise and Recovery phase settings are the same as for the Bruce protocol. See "Bruce Protocol Settings" on page B-2.

Table B-4   Ellestad Protocol Settings

Ellestad					
	Stage #	Time Duration (mm:ss)	Speed (mph)	Grade (%)	ECG Print	BP Measurement
Pre Exercise					
	1	Unlimited	1.0	0.0	Off	Off
Exercise					
	1	3.00	1.7	10.0	End	End
	2	2.00	3.0	10.0	End	End
	3	2.00	4.0	10.0	End	End
	4	3.00	5.0	10.0	End	End
	5	2.00	6.0	15.0	End	End
	6	2.00	7.0	15.0	End	End
	7	2.00	8.0	15.0	End	End
Recovery					
	1	3.00	1.5	0.0	Every 02:00	Every 02:00

Naughton Protocol

The Pre Exercise and Recovery phase settings are the same as for the Bruce protocol. See "Bruce Protocol Settings" on page B-2.

Table B-5   Naughton Protocol Settings

	Naughton					
	Stage #	Time Duration (mm:ss)	Speed (mph)	Grade (%)	ECG Print	BP Measurement
Pre Exercise						
	1	Unlimited	0.5	0.0	Off	Off
Exercise						
	1	2.00	1.0	0.0	End	Off
	2	2.00	2.0	2.0	End	End
	3	2.00	2.0	3.5	End	Off
	4	2.00	2.0	7.0	End	End
	5	2.00	2.0	10.5	End	Off
	6	2.00	2.0	14.0	End	End
	7	2.00	2.0	17.5	End	Off
Recovery						
	1	3.00	1.0	0.0	Every 02:00	Every 02:00

Pharmacological Protocol

Table B-6   Pharmacological Protocol Settings

	Pharmacological						
	Stage #	Time Duration (mm:ss)	Speed (mph)	Grade (%)	ECG Print	BP Measurement	Dose
Pre Exercise							
	1	Unlimited	0.0	0.0	Off	Off	Off
Infusion							
	1	3.00	0.0	0.0	End	End	Off
	2	3.00	0.0	0.0	End	End	Off
	3	3.00	0.0	0.0	End	End	Off
	4	3.00	0.0	0.0	End	End	Off
	5	3.00	0.0	0.0	End	End	Off
	6	3.00	0.0	0.0	End	End	Off
	7	3.00	0.0	0.0	End	End	Off

Pharmacological						
Post-Infusion						
	1	3.00	0.0	0.0	Every 01:00	Every 02:00	Off

Low Ramp Protocol

The Pre Exercise and Recovery phase settings are the same as for the Bruce protocol. See "Bruce Protocol Settings" on page B-2.

Table B-7   Low Ramp Protocol Settings

Low Ramp					
	Stage #	**Time Duration (mm:ss)**	**Speed (mph)**	**Grade (%)**	**ECG Print**	**BP Measurement**
Pre Exercise						
	1	Unlimited	1.0	0.0	Off	Off
Exercise						
	1	0:30	1.0	0.0	End	End
	2	0:30	1.1	1.0	End	End
	3	0:30	1.2	1.0	End	End
	4	0:30	1.3	2.0	End	End
	5	1:00	1.4	3.0	End	End
	6	0:30	1.5	4.0	End	End
	7	0:30	1.6	4.0	End	End
	8	0:30	1.7	5.0	End	End
	9	0:30	1.8	6.0	End	End
	10	1:00	1.9	7.0	End	End
	11	0:30	2.0	8.0	End	End
	12	0:30	2.1	8.5	End	End
	13	0:30	2.2	9.0	End	End
	14	0:30	2.3	9.5	End	End
	15	1:00	2.4	10.0	End	End
	16	0:30	2.5	10.5	End	End
	17	0:30	2.6	11.0	End	End
	18	1.00	2.7	12.0	End	End
	19	0:30	2.8	13.0	End	End
	20	0:30	2.9	14.0	End	End
	21	1.00	3.0	15.0	End	End
	22	0:30	3.1	16.0	End	End
	23	0:30	3.2	17.0	End	End
	24	1.00	3.4	18.0	End	End
	25	1:00	3.6	19.0	End	End

Low Ramp					
Recovery					
	1	3:00	1.5	0.0	Every 02:00	Every 02:00

Medium Ramp Protocol

The Pre Exercise phase settings are the same as for the Bruce protocol.
See "Bruce Protocol Settings" on page B-2.

Table B-8   Medium Ramp Protocol Settings

Medium Ramp					
	Stage #	**Time Duration (mm:ss)**	**Speed (mph)**	**Grade (%)**	**ECG Print**	**BP Measurement**
Pre Exercise						
	1	Unlimited	1.0			
Exercise						
	1	0:30	1.5	3.0	End	End
	2	0:30	1.6	4.0	End	End
	3	0:30	1.7	5.0	End	End
	4	0:30	1.7	6.0	End	End
	5	1.00	1.8	7.0	End	End
	6	0:30	1.9	8.0	End	End
	7	0:30	2.0	8.5	End	End
	8	0:30	2.1	9.0	End	End
	9	0:30	2.2	9.5	End	End
	10	1.00	2.3	10.0	End	End
	11	0:30	2.4	11.0	End	End
	12	0:30	2.5	11.5	End	End
	13	0:30	2.6	12.0	End	End
	14	0:30	2.7	12.5	End	End
	15	1.00	2.8	13.0	End	End
	16	0:40	3.0	13.5	End	End
	17	0:40	3.2	14.0	End	End
	18	0:40	3.4	14.5	End	End
	19	0:40	3.6	15.0	End	End
	20	0:40	3.8	15.5	End	End
	21	0:40	4.0	16.0	End	End
	22	0:40	4.2	17.0	End	End
	23	0:40	4.5	18.0	End	End
	24	0:40	4.8	19.0	End	End
	25	0:40	5.2	20.0	End	End
Recovery						

					Medium Ramp	
	1	3:00	1.0	0.0	Every 02:00	Every 02:00

High Ramp Protocol

The Pre Exercise phase settings are the same as for the Bruce protocol. See "Bruce Protocol Settings" on page B-2. The Recovery phase settings are the same as for the Medium Ramp protocol. See "Medium Ramp Protocol Settings" on page B-7.

Table B-9   High Ramp Protocol Settings

					High Ramp	
	Stage #	Time Duration (mm:ss)	Speed (mph)	Grade (%)	ECG Print	BP Measurement
Pre Exercise						
	1	Unlimited	1.0	0.0	Off	Off
Exercise						
	1	0:30	1.6	5.0	End	End
	2	0:30	1.7	10.0	End	End
	3	0:30	1.7	10.0	End	End
	4	0:30	2.0	10.0	End	End
	5	1.00	2.2	11.0	End	End
	6	0:30	2.4	11.5	End	End
	7	0:30	2.5	12.0	End	End
	8	0:30	2.6	12.5	End	End
	9	0:30	2.8	13.0	End	End
	10	1.00	3.0	13.5	End	End
	11	0:30	3.2	14.0	End	End
	12	0:30	3.4	14.0	End	End
	13	0:30	3.5	14.5	End	End
	14	0:30	3.6	15.0	End	End
	15	1.00	3.7	15.5	End	End
	16	0:40	4.0	16.0	End	End
	17	0:40	4.2	16.0	End	End
	18	0:40	4.4	16.5	End	End
	19	0:40	4.6	17.0	End	End
	20	0:40	4.8	17.5	End	End
	21	0:40	5.0	18.0	End	End
	22	0:40	5.2	19.0	End	End
	23	0:40	5.5	20.0	End	End
	24	0:40	5.8	21.0	End	End
	25	0:40	6.0	22.0	End	End
Recovery						
	1	3:00	1.0	0.0	Every 02:00	Every 02:00

USAF/SAM 2.0 Protocol

Table B-10   USAF/SAM 2.0 Protocol Settings

	Stage #	Time Duration (mm:ss)	Speed (mph)	Grade (%)	ECG Print	BP Measurement
USAF/SAM 2.0						
Pre Exercise						
	1	Unlimited	0.5	0.0	Off	Off
Exercise						
	1	3.00	2.0	0.0	End	Off
	2	3.00	2.0	5.0	End	End
	3	3.00	2.0	10.0	End	Off
	4	3.00	2.0	15.0	End	End
	5	3.00	2.0	20.0	End	Off
	6	3:00	2.0	25.0	End	End
Recovery						
	1	3.00	1.0	0.0	Every 02:00	Every 02:00

USAF/SAM 3.3 Protocol

Table B-11   USAF/SAM 3.3 Protocol Settings

	Stage #	Time Duration (mm:ss)	Speed (mph)	Grade (%)	ECG Print	BP Measurement
USAF/SAM 3.3						
Pre Exercise						
	1	Unlimited	1.2	0.0	Off	Off
Exercise						
	1	3.00	3.3	0.0	End	Off
	2	3.00	3.3	5.0	End	End
	3	3.00	3.3	10.0	End	Off
	4	3.00	3.3	15.0	End	End
	5	3.00	3.3	20.0	End	Off
	6	3:00	3.3	25.0	End	End
Recovery						
	1	3.00	1.2	0.0	Every 02:00	Every 02:00

Cycle (Ergometer) Protocol

Table B-12   Cycle (Ergometer) Protocol Settings

	Stage #	Time Duration (mm:ss)	Power (Watts)	ECG Print	BP Measurement
Cycle (Ergometer)					
Pre Exercise					
	1	Unlimited	10	Off	Off
Exercise					
	1	3.00	25	Begin	End
	2	3.00	50	Begin	End
	3	3.00	75	Begin	End
	4	3.00	100	Begin	End
	5	3.00	125	Begin	End
	6	3.00	150	Begin	End
	7	3.00	175	Begin	End
	8	3.00	200	Begin	End
	9	3.00	225	Begin	End
	10	3:00	250	Begin	End
Recovery					
	1	3.00	25	Every 01:00	Every 02:00

Astrand Protocol

Table B-13   Astrand Protocol Settings

	Stage #	Time Duration (mm:ss)	Power (Watts)	ECG Print	BP Measurement
Astrand					
Pre Exercise					
	1	Unlimited	50	Off	Off
Exercise					
	1	6.00	50	End	End
	2	6.00	100	End	End
	3	6.00	150	End	End
	4	6.00	200	End	End
	5	6.00	250	End	End
	6	6.00	300	End	End
Recovery					
	1	3.00	50	Every 01:00	Every 02:00

Pharma Ergometer Protocol

Table B-14   Pharma Ergometer Protocol Settings

	Stage #	Time Duration (mm:ss)	Power (Watts)	ECG Print	BP Measurement	SpO$_2$ Measurement
Pharma Ergometer						
Pre Exercise						
	1	Unlimited	0	Off	Off	Off
Exercise						
	1	1.00 (configurable)	0	End	End	End
Recovery						
	1	3.00	0	Every 02:00	Every 02:00	Every 02:00

C

Configuring and Using the Printer

The ST80i Stress Test System supports the following different printers:

- ST80i thermal printer
- Network printer and local printer with Windows 7, Windows 8.1, or Windows 10 drivers

For printer troubleshooting, see Appendix A, "Troubleshooting and Contacting the Philips Response Center."

ST80i Thermal Printer

The ST80i thermal printer uses an eight–dot–per–millimeter (dpm) print head to print ECG tracings and report data. Multiple print formats are supported.

The ST80i thermal printer includes:

- Hospital-grade power cord for connection to the isolation transformer
- USB cable for connection to the PC

Thermal Printer Dimensions and Specifications

Figure C–1   ST80i Thermal Printer Dimensions

Back Dimensions
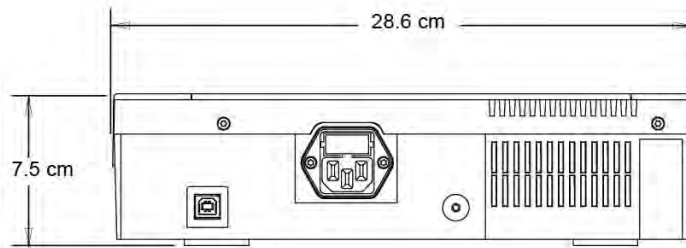
Top Dimensions
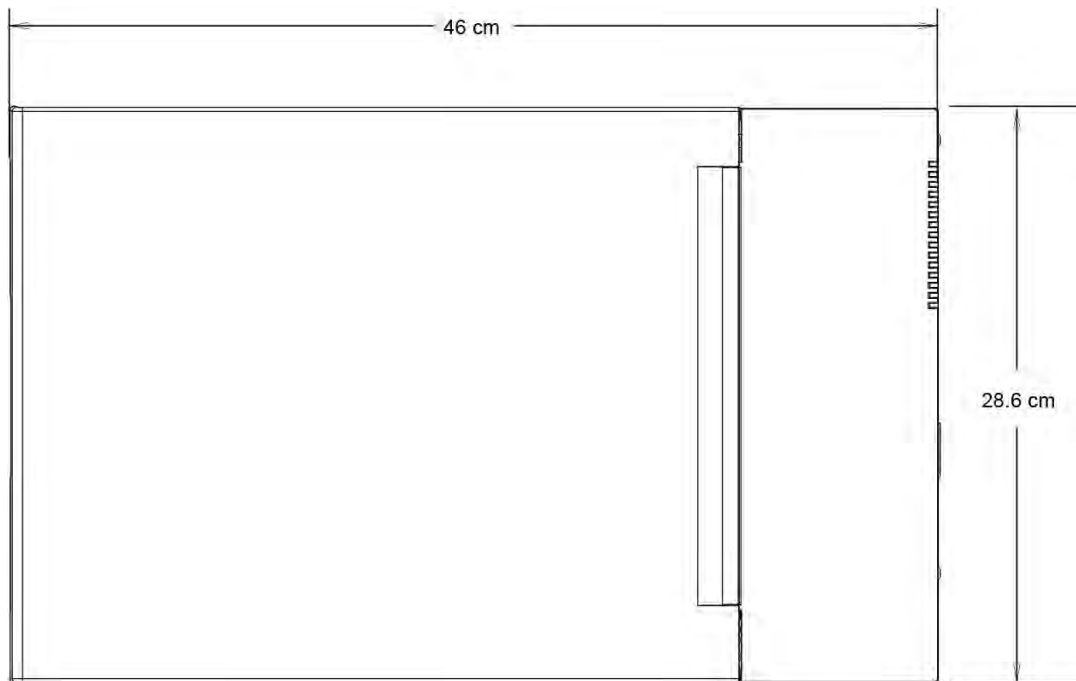
Side Dimensions
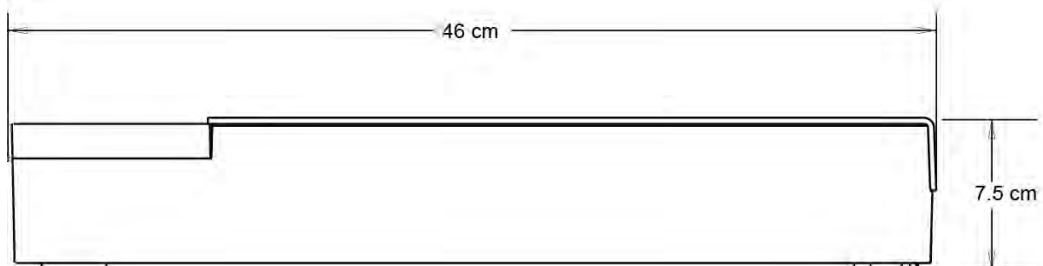
Figure C-2   ST80i Thermal Printer

Table C-1   ST80i Thermal Printer Specifications

Feature	Specification
Instrument type	Thermal printer
Paper type	Supports the use of the following paper types supplied as Z-fold in packages of 100 and 200 sheets: • A-size Normal, Anti-fade, and Easy Tear • A4-size Normal, Anti-fade, thin, and Easy Tear
Recording technique	Computer-controlled, thermal dot array
Print-head width	8.5 inches (216 mm)
Print-head resolution	• Vertical: 200 dots/inch • Horizontal: 5, 10, and 25 mm/sec: 500 dots/inch 50 mm/sec: 250 dots/inch
Writer speeds	• 25 or 50 mm/sec for AUTO report • 5, 10, 25, or 50 mm/sec for rhythm print
External ports and data interfaces	USB 2.0-compliant, type-B socket connector
Chassis leakage current	Meet or exceed requirements of IEC 60601-2-25
Power	100-240 VAC at 50/60 Hz
Weight	9 lb
Dimensions H x W x D	8 cm x 48 cm x 30 cm maximum

Feature	Specification
Fuses	T–Type, 1.6 Amp, 250 V, 5 mm x 20 mm
Special functions	• "Door closed" sensor that detects when paper door is open • "Top–of–form" sensor that positions paper at the edge and detects "paper out" and "paper jam" conditions

Note:

Specifications are subject to change without notice.

Table C–2   Input and Output Descriptions

Feature	Description
AC Power	The ST80i thermal printer operates on 120/240 VAC at 50/60 Hz. Power is supplied to the thermal printer as soon as the AC power cord is connected to an AC power outlet.
Power On Indicator	This indicator illuminates in green when AC power is applied.
Hard Copy Printout	The ST80i thermal printer uses 8 1/2 in x 11 in (21 cm x 27.9 cm) sheets of Z–fold, thermal sensitive paper with cue marks. Printing speeds are 10, 25, and 50 mm per second. Dot density is eight dots per millimeter or 203.2 dpi.

Loading the Thermal Printer Paper

To load the paper

1. Remove the outer packaging from the paper pack (**A**).

2. Facing the front of the unit, use the release latch on the left side and slide the paper tray cover to the left (**B**).

Caution

To avoid damaging the door open switch activation tab, do not pull the tray cover more than half way.

Figure C-3   Loading ST80i Thermal Printer Paper
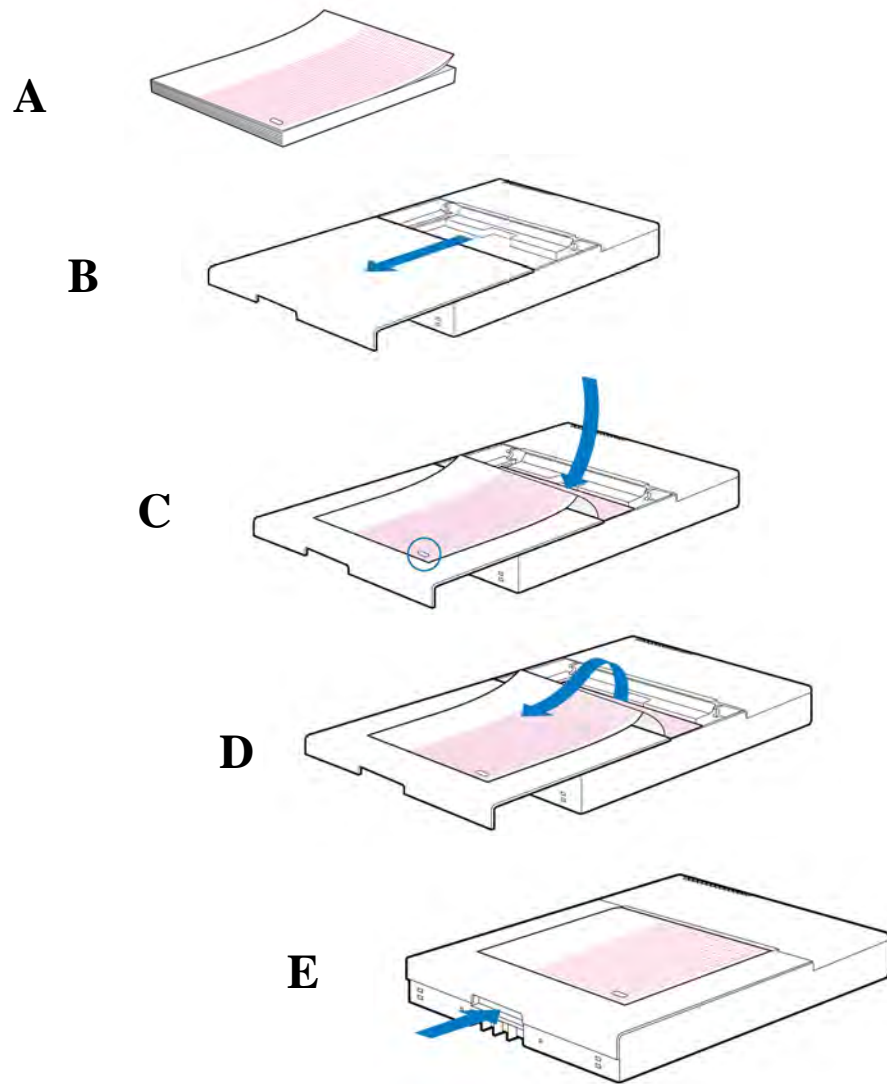
3. Place the pack of thermal paper into the paper tray such that the grid side of the paper is up when it is pulled over the paper tray cover (**C**).

   The paper cue mark (an oval-shaped hole) should be in the lower left corner.

4. Manually advance one page of paper beyond the closure point of the writer (**D**). Make sure the paper lies on the black roller evenly within the channel of the paper door.

5. Slide the paper tray cover to the right until the cover latches in a locked position (**E**).

   You hear a sharp click when the door is properly latched. If the door is not completely closed the result may be uneven printing.

6. Click the **Paper Advance** icon in ST80i to align the cue mark and prepare the paper for printing.

Setting Up the Thermal Printer

To connect the ST80i thermal printer

1   Connect the AC power cord to the AC connector (**B**) on the printer and to the isolation transformer.

2   Connect one end of the USB cable to the USB cable connector (**A**) on the ST80i thermal printer and the other end to a USB port on the back of the ST80i PC, as shown in Figure C–5, below.

Figure C–4   ST80i Thermal Printer Rear Panel
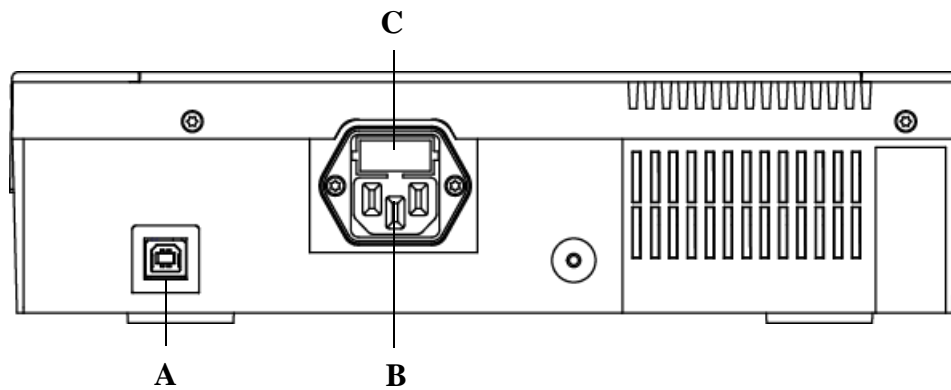
A USB connector	B AC connector (for power cord)
C AC fuse	

Figure C–5   ST80i PC Rear Panel USB Ports
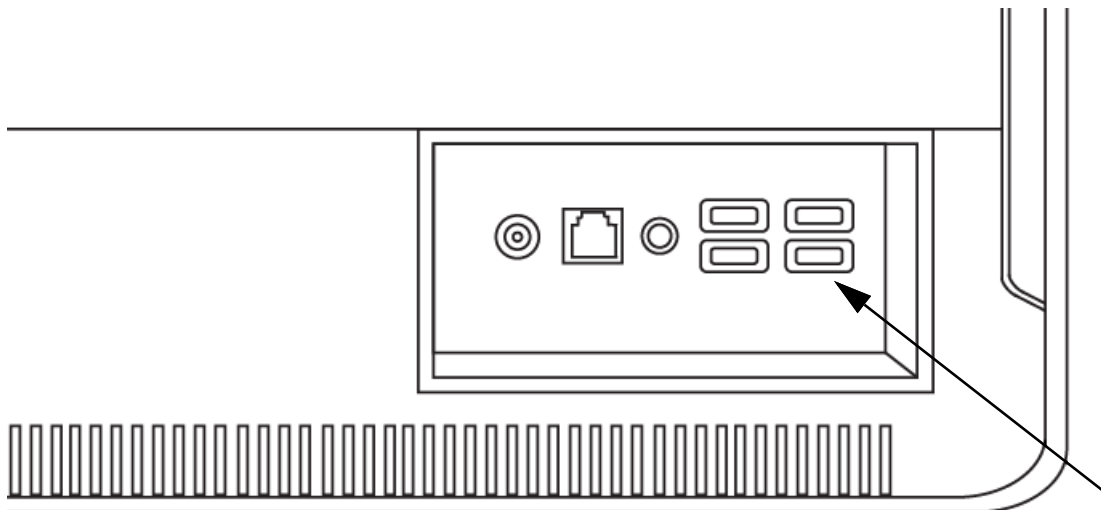
About the Supported LaserJet Printers

ST80i also supports the use of the HP 4250 LaserJet, HP P2055, and HP P4014 PCL5 printers using drivers for the Windows 7, Windows 8.1, or Windows 10 operating system.

It is capable of printing reports, without a grid, at 35 ppm. It prints with a grid at approximately 2 ppm.

Note:

The LaserJet printer must be a local printer, connected directly to the ST80i test system, if it is to be used during testing. It cannot be a network printer, as connection to the network is disabled during a test.

For details about the printers, refer to the HP website (www.hp.com) or to the printer documentation.

D

Ordering Options and Parts

This appendix describes the parts and options available for the ST80i Stress Test System.

Supplies and Ordering Information

The part numbers for all supplies for the ST80i system are listed in this section.

All supplies can be ordered on the web at http://shop.medical.philips.com.

Use the part numbers listed in the following tables for reference to ensure that the correct supplies are ordered.

Optional Parts and Accessories

The following items represent the parts available at the time of this manual's printing. Changes to and deletions from this list are likely to occur over time. Not all accessories may be available in all countries.

For more information on accessories or to place an order, contact the nearest Philips Response Center. See "Contacting Your Philips Response Center" on page A-7.

For available support parts (which can only be ordered by Philips personnel), see "Support Parts" on page D-2.

Part Number	Description
989803180121	12-Lead Complete Lead Set (AAMI), Standard Length, Grabber
989803180131	12-Lead Complete Lead Set (IEC), Standard Length, Grabber
989803180141	12-Lead Complete Lead Set (AAMI), Standard Length, Snaps
989803180151	12-Lead Complete Lead Set (IEC), Standard Length, Snaps
989803180801	STRS, PIM Belt
453564575091	TrackM CBL Treadmill Interface Cable, 7.62M

Part Number	Description
40420A	High-Tack Foam Wet Gel ECG Electrode
40493D	Foam Wet Gel ECG Electrode
40493E	Foam Wet Gel ECG Electrode
M2202A	Adult Radio-Translucent Foam Electrode
M1708A	Thermal paper, z-fold, no header, 8.5 in x 11 in
M1710A	Thermal paper, z-fold, no header, A4 size
M2481A	Thermal paper for PageWriter, 8.5 in x 11 in
M2483A	Thermal paper for PageWriter, A4 size
M3707A	Thermal paper, English
M3708A	Thermal paper, A4
M2485A	Anti-fade paper for PageWriter, 8.5 in x 11 in

Support Parts

For more information on accessories or to place an order, contact the nearest Philips Response Center. See "Contacting Your Philips Response Center" on page A-7.

The parts listed in the following tables can only be ordered by Philips personnel.

New Assembly Part Number	Item
PIM	
453564237251	STRS MECHASY Battery Door Assy
453564277261	STRS ST80i Wireless PIM, AAMI
453564277271	STRS ST80i Wireless PIM, IEC
453564530561	Battery Terminal Repair Kit
AIM	
453564305221	STRS, ST80i Advanced Input Module (AIM)
453564236991	STRS, ANT, AIM Antenna
USB	
453564336341	USB Cable Printer to PC, 1.8M

New Assembly Part Number	Item
Printer Accessories and Thermal Printer Paper	
453564048431	PW, PL, Metric Spacer, A4 paper
453564131221	Fuse (Metric) 1.6A 250V FE IEC
453564305231	STRS ST80i Thermal Printer
Power Cords	
8120-1351	CBL AC POWER CORD OPTION 900, 2.0M
8120-1689	CBL AC POWER CORD OPTION 902, 2.0M
8120-4211	CBL AC POWER CORD OPTION 917, 2.0M
8120-4475	CBL AC POWER CORD OPTION 901, 2.0M
8120-5182	CBL AC POWER CORD OPTION 919, 2.0M
8120-6869	CBL AC POWER CORD OPTION 920, 2.0M
8120-6978	CBL PWR-CORD-921 18-AWG 3-COND OPTION 921, 2.0M
8120-8376	CBL AC POWER CORD OPTION 922, 2.2M
8120-5429	CBL AC 3 WIRE POWER CORD, OPTION 903, 2.4M
Trolley Parts	
453564237601	ST80i Isolation Transformer, 240V
453564237591	ST80i Isolation Transformer, 120V
453564398511	STRS Trolley Light Assembly–AAMI
453564623661	STRS Trolley Light Assembly–IEC
453564604121	STRS Lamp, North America (NA)
453564604131	STRS Lamp Driver, North America (NA)
453564604101	STRS Lamp, European Union (EU)
453564604111	STRS Lamp Driver, European Union (EU)
453564334161	STRS CASTER Roll Stand 4" TENTE Locking
453564334701	STRS BRKT VESA 75 x 75mm Adapter
453564334901	STRS PLAST Trolley Base Cover
453564334981	STRS PLAST Trolley Column Rear Cover
453564539721	Mushroom Mount Support Kit
453564335001	STRS PLAST Trolley Wall Channel Cover

New Assembly Part Number	Item
Trolley Parts *(continued)*	
453564334881	STRS MET Basket Paper Catch
453665085641	USB to RS232 Serial Port Adapter
453564335281	STRS Utility Basket
453564335271	STRS MET Top Shelf Utility Hook
453564337261	STRS 1/2 work surface cover
453564334881	STRS Basket Paper Catch
453564391881	STRS Full cover work surface
453564335301	STRS Tango Arm Kit
Software and Documentation	
453665003611	ST80i Software and Documentation Disk

Compatible Products/Parts

The following items represent compatible parts and options available for the ST80i Stress Test System at the time of this manual's printing. For more information on accessories or to place an order, contact your local Philips sales representative or SunTech Medical for ordering and other information pertaining to accessories and options for the SunTech Tango M2. See "Contacting Your Philips Response Center" on page A-7.

Part Number	Description	Manufacturer
989803197451	Tango® M2 automated blood pressure monitor	SunTech
91–0011–01	RT 58 Coax BNC to BNC cable, 3M	SunTech
91–0013–01	Tango M2 RS232 serial cable, 3M	SunTech
98–0062–22	Orbit–K Adult Cuff with Mic	SunTech
98–0062–25	Orbit–K Adult Plus Cuff with Mic	SunTech
98–0062–23	Orbit–K Large Adult Cuff with Mic	SunTech
989803197221	STRS CBL SpO$_2$ Adult Finger Kit Tango M2	SunTech

Specifications and Requirements

For details about setting up the system, see the *ST80i Stress Test System Installation and Configuration Guide*.

Note:

No user serviceable parts are inside. ANY modification of this device may alter defibrillator protection. Any modification to any part of this device is to be performed only by qualified service personnel. See also Chapter 6, "Maintaining the ST80i System".

Essential Performance Statement

Within the intended use and environment, the performance elements critical to the ST80i Stress ECG system remain to be the accurate, safe acquisition of ECG signal, accurate rendering of acquired ECG information, as well as correct processing, analysis, and printing of the ECG report. These functionalities shall not be degraded or negatively impacted by electromagnetic, electrical interference, or environmental conditions that the system is designed to withstand.

The ST80i system can receive and store blood pressure (BP) and SpO_2 measurements (no waveforms) from a qualified OEM medical device. The BP/SpO_2 product is sold as an option and is not used by all customers. *Failure to successfully store the measurements on the ST80i system is not considered to be an essential performance failure.* The measurement values are available for review on the OEM device and can be manually entered into the ST80i report if persistent data transmission failures occur during the stress ECG exam.

Non-medical equipment in the system has been assessed to determine if failures with that equipment could create an unacceptable level of risk. Specifically, it has been determined that early termination or an interruption of a test protocol does not necessarily preclude the patient from receiving additional therapy in a timely fashion. Inclusion of and failure of the non-medical equipment in the system does not result in creation of an unacceptable risk and, therefore, does not negatively affect the essential performance of the stress system.

Similarly, transmission of the ECG report is not considered an essential performance element under environmental disturbances. The test procedure is observed by a qualified clinician as mandated by hospital protocols. Results from the test are stored in real time. Loss of data due to an interruption in the exam is covered by the previous statement dealing with early termination. A report for the test is generated and stored when the testing has been completed. Failure to transmit the data is a recoverable error and delayed transmission of the data does not result in additional unacceptable risk to the patient.

ST80i System IT Hardware Requirements

For the ST80i System to function properly, the following minimum specified system requirements must be met.

Table E–1   Minimum ST80i System IT Hardware Requirements

Component	Minimum Hardware/Software Specifications
Processor	1.1 GHz, 1 MB L2 cache
Memory	8 GB or more
Hard disk	No less than 160 GB SATA; 7200 RPM
Display	The lowest resolution for each layout: • For 4:3, the lowest resolution is 1280 x 960 • For 16:9, the lowest resolution is 1366 x 768 **Note:** *The display used with* ST80i *must meet UL/IEC 62368–1 Safety Standards for Information Technology Equipment.*
Network	• The PC's LAN interface should support IEEE 802.3 compliant 10M/100M/1000M Base-T(X) Ethernet connections • LAN connection for laser printer is required • Optional LAN card for networking capabilities
Operating system	Microsoft Windows 10 Professional, 32–bit and 64–bit

Component	Minimum Hardware/Software Specifications
External Connectivity	The system must have the following external connections: • Two RS232 on the PC (or via the USB to RS232 Serial Port Adapter) • 100–240V 50/60Hz AC Power input • Display output • LAN • Minimum of five USB ports • ST80i may use an external USB hub to extend the USB ports for easier user access, if required • Speaker output • Printer port

Specifications

ST80i System Specifications

Caution

The system does not contain user-serviceable parts. Any modification of this device may alter defibrillator protection. Only qualified service personnel are authorized to modify any part of this device.

Table E–2   ST80i System Specifications

Function	Specifications
Instrument type	Exercise stress test system
Isolation transformer power	Output Voltage: 120/240 VAC @ 50/60 Hz Output power: 600VA
Input Channels	Simultaneous acquisition of all 12 leads
Standard leads	I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6
Exercise equipment interface	Digital serial interface to treadmill or ergometer
Automatic blood pressure measurement option	Supports SpO_2 and motion tolerant NIBP modules

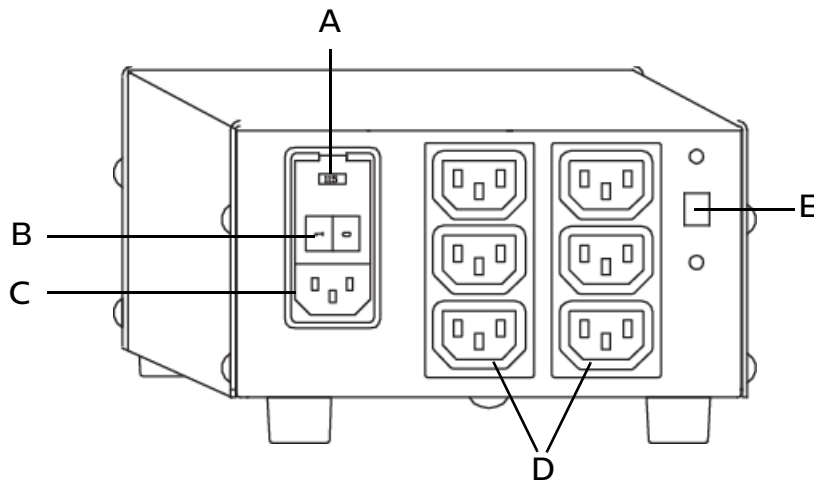| Function	Specifications
Network option	Optional Network interface for data transfer and printing across your local network
Remote Review Workstation option	Optional Remote Review Workstation for review, printing, and editing of patient text data acquired from the ST80i system
Display format	**Sweep speed:** Two supported speeds: 25 mm/s and 50 mm/s **Size:** Range from 19" to 24" **Resolution:** The lowest resolution for each layout: • For 4:3, the lowest resolution is 1280 x 960 • For 16:9, the lowest resolution is 1366 x 768
Display Accuracy	• The accuracy of the ECG signals are within +/– 5% (or +/– 40 μV whichever is greater), over a range of 0 to +/– 5 mV, in the presence of common mode DC offset voltages of +/– 300 mV. The cardiograph performance is tested to comply with the accuracy requirements over the dynamic ranges and frequency ranges specified in the IEC 60601-2-25:2011 standard. • For additional details regarding accuracy and precision, refer to the *Physician's Guide* and the Manufacturer's Disclosure Statement.
ECG input	Simultaneous input from all 12 leads
Patient physiological signal	System transfers ECGs uniformly at 1000 samples-per-second, with the amplitude resolution of 1?V/least-significant-bit over the dynamic range of +/– 32 millivolt (16 bits), and with the frequency response of 0.02 to 300 Hertz. **Note:** *Operation of the equipment or system below this amplitude or threshold may cause inaccurate results.*
RF Transceiver	**RF Type:** IEEE 802.15.4 **RF band:** 2405MHz~2480MHz. **RF channel:** 2405MHz+n*5MHz, n=0,1,2,3...15. **Occupied Bandwidth:** 2MHz **RF Maximum Transmit Power:** 6dBm **Modulation:** Offset-QPSK (O-QPSK). **Effective radiated power:** 5mW **Note:** *The ST80i System may be interfered with by other equipment even if that other equipment complies with CISPR Emission requirements.*
Input impedance	• Meets the requirements of IEC 60601-2-25 • Defibrillator protected when used with specified patient cable

Function	Specifications
Input dynamic range	Meets the requirements of IEC 60601-2-25
Common mode rejection	Meets the requirements of IEC 60601-2-25
Patient leakage current	Meets the requirements of IEC 60601-1
Overall system error	Meets the requirements of IEC 60601-2-25
Frequency response	Meets the requirements of IEC 60601-2-25
Digital sampling rate	1,000 sample/sec/channel, used for recording and analysis
Recording technique	Thermal array printer, 200 dots per inch (dpi)
Paper type	Thermal, perforated, 8.5 in x 11 in Z-fold
Recorder	**Recording speeds:** 5mm/sec, 10mm/sec, 25mm/sec, 50mm/sec **Channels:** User can select any channels to print to thermal printer **Sensitivity:** 2.5mm/mV, 5mm/mV, 10mm/mV, 20mm/mV **Gain:** 2.5mm/mV, 5mm/mV, 10mm/mV, 20mm/mV **Data acquisition:** Direct connect or wireless connection using ST80i wireless patient interface module
Max Power Rate Consumption	**Computer:** 150 W **Monitor:** 50 W **Thermal printer:** 60 W **Desk light:** 6 W **Isolation transformer:**600 Volt Amps
Device Classification	ST80i system classification: · Class I equipment · IPX0 · Not suitable for use in the presence of flammable anesthetics, or flammable mixtures of air, oxygen, or nitrous oxide · Continuous operation ST80i PIM classification: · Internally powered · Type CF applied part · IPX4 · Not suitable for use in the presence of flammable anesthetics, or flammable mixtures of air, oxygen, or nitrous oxide · Continuous operation

Function	Specifications
Data acquisition	Direct connect or wireless connection using ST80i digital transmitter
External output	TTL and analog output

Medical Isolation Transformer Specifications

The medical isolation transformers used with the ST80i system should meet the following specifications: UL 60601-1, CSA C22.2 601.1, EN60601.1, CE (LVD), ROHS compliant.

Figure E-1   Medical Isolation Transformer Provided with ST80i

A   AC fuse holder/Input voltage   B   On/Off switch
    selector

C   AC input   D   AC output

E   Output voltage selector

Table E-3   Medical Isolation Transformer Specifications

Function	Specifications
Input	115 (120)/230 (240) VAC, 50/60 Hz, 5.28/2.64 A
Output	115 (120)/230 (240) VAC 5/2.5 A 600 VA Max
Weight	26.5 lb (12 kg)
Dimensions	**Height:** 4.08" (103.5mm) **Width:** 6.55" (166.4mm) **Depth:** 10.5" (266.7mm)

Function	Specifications
REF: 1404–102	Input 120 VAC – 6.3AT
REF: 1404–003	Input 230 VAC – 3.15AT
Fuses	120 VAC – 6.3AT 230 VAC – 3.15AT Use agency-approved fuses only: 250V. The transformer has an internal thermal resettable fuse.

ST80i Thermal Printer Specifications

Figure E-2   Thermal Printer Provided with ST80i
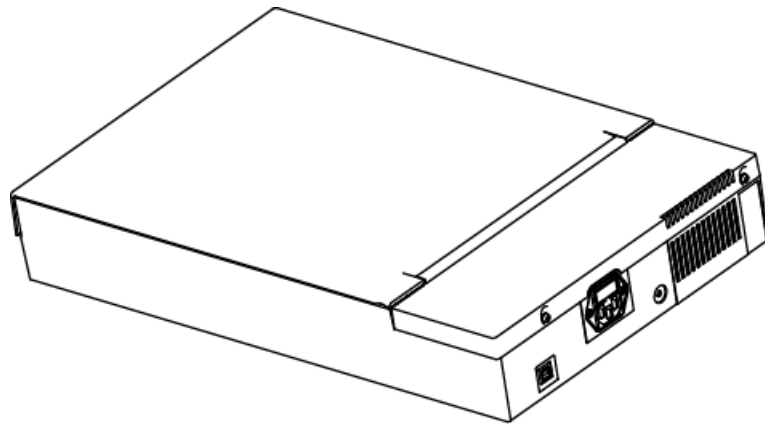
Table E-4   ST80i Thermal Printer Specifications

Feature	Specification
Instrument type	Thermal printer
Paper type	Supports the use of the following paper types supplied as Z-fold in packages of 100 and 200 sheets: • A-size Normal, Anti-fade, and Easy Tear • A4-size Normal, Anti-fade, thin, and Easy Tear
Recording technique	Computer controlled, thermal dot array
Print head width	8.5 inches (216 mm)
Print head resolution	**Vertical:** 200 dots/inch, vertical **Horizontal:** • 5, 10, and 25 mm/sec: 500 dots/inch • 50 mm/sec: 250 dots/inch

Feature	Specification
Printer speeds	• 25 or 50 mm/sec for AUTO report • 5, 10, 25, or 50 mm/sec for rhythm print
External ports and data interfaces	USB 2.0-compliant, type-B socket connector
Chassis leakage current	Meet or exceed requirements of IEC 60601-2-25
Power	100-240 VAC at 50/60 Hz
Weight	9 lb (4.1 kg)
Dimensions H x W x D	8 cm x 48 cm x 30 cm maximum

Supported Treadmills and Ergometers

The ST80i Stress Test System supports the following treadmills and ergometers.

Table E-5   Supported Treadmills and Ergometers

Equipment	Manufacturer	Models
Treadmills	• Trackmaster Treadmills by Full Vision	• TMX425 • TMX425C • TMX425CP • TMX428 • TMX 428C • TMX428CP
	• Lode	• All OEM treadmills manufactured by Lode B.V. with the part number 939907, 939908, 939909, or 939910, with serial number 20150001 or later • All Katana treadmills with serial number 9349XX to 201X0001 • All Valiant 2 treadmills with serial number 9389xx to 20140001
	• Quinton/Mortara/ Cardiac Science	• Quinton TM55
	• h/p/cosmos (Coscom)	• All models with manufacturing date after December 31, 2007
	• GE	• T2100

Equipment	Manufacturer	Models
Ergometers	Ergoline	• ST80i supports all Ergoline ergometers that use the "ergoselect" protocol
	Lode	• Corival (906900)

Electromagnetic Compatibility (EMC)

Electromagnetic compatibility with surrounding devices should be assessed when using the ST80i Stress Test System. The system should be installed and put into service according to the EMC information provided.

An electronic device can either generate or receive electromagnetic interference. Testing for electromagnetic compatibility (EMC) has been performed on the ST80i Stress Test System according to the international standard for EMC for medical devices (IEC 60601-1-2, Editions 4 and 4.1). This IEC standard has been adopted in Europe as the European Norm (EN 60601-1-2, Editions 4 and 4.1).

WARNING

Radio frequency (RF) interference from nearby transmitting devices may degrade performance of the electronic equipment. Electromagnetic compatibility with surrounding devices should be assessed prior to using the equipment.

WARNING

Fixed, portable, and mobile radio frequency communications equipment can also affect the performance of electrical equipment. See your Service Provider for assistance with the minimum recommended separation distance between RF communications equipment and the ST80i Stress Test system.

WARNING

The use of accessories and cables other than those specified in the Philips ST80i Stress Test system service and user documentation can result in increased emissions or decreased immunity of the system.

WARNING

The ST80i Stress Test system should not be used next to or stacked on top of other equipment. If you must stack the product, you must check that normal operation is possible in the necessary configuration before the product is used.

WARNING

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the ST80i system including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Note:

The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential area (for which CISPR 11 class B is normally required), this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or reorienting the equipment.

Accessories and Cables Warning

The use of accessories and cables other than those specified in Appendix D, "Ordering Options and Parts," may result in increased emissions or decreased immunity of the ST80i Stress Test System.

Use only a shielded LAN cable when connecting the cable to the ST80i LAN port.

Use only an RS-232 cable to connect the ST80i system to treadmills, ergometers, or NIBP devices such as the SunTech Tango M2. Use of USB cables for these devices is not recommended and could result in abnormal operation of ST80i due to electromagnetic noise interference

Reducing Electromagnetic Interference

The ST80i Stress Test system and accessories may become sensitive to interference from other RF energy sources including power lines. RF energy sources include other medical devices, wireless devices, information technology equipment, and radio/television transmission. Should interference be encountered, as demonstrated by artifact on the ECG trace, unintended change on operating state, or unit lockup, attempt to locate the source by assessing:

- If the interference is intermittent or constant?
- Does the interference occur only in certain locations?
- Does the interference occur only when in close proximity to certain medical devices?
- Does the ECG signal quality change dramatically when the AC power cord is unplugged?

Once the source of the interference is located, attempt to attenuate the EMC coupling path by distancing the ST80i from the source of the interference as much as possible. If further assistance is needed, contact the Philips Response Center or your certified dealer.

The ST80i Stress Test system has been evaluated in the Electromagnetic Environment listed in tables E-6 to E-11 based on Medical Collateral standard IEC 60601-1-2:2020.

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Table E-6   Electromagnetic Emissions

Phenomenon	Compliance	Electromagnetic Environment
RF Emissions	CISPR 11, Group 1, Class A	Professional healthcare facility environment **Note:** *The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.*
Harmonic distortion	IEC 61000-3-2 Class A	Professional healthcare facility environment
Voltage fluctuations and flicker	IEC 6100-3-3	Professional healthcare facility environment

Note:

According to clause 7.2.1 and 7.2.2 of IEC 60601-1-2:2014 and IEC 60601-1-2:2020, Harmonic Emissions and Voltage Fluctuations/Flickers emissions are not applicable to ST80i Stress Test System when working with treadmill or ergometer which is not qualified to connect to PUBLIC MAINS NETWORK.

Table E-7   Enclosure Port

Phenomenon	Compliance	Immunity Test Levels Professional Healthcare Facility Environment
Electrostatic discharge	IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air
Radiated RF EM field	IEC 61000-4-3	3 V/m 80 MHz – 2.7 GHz 80% AM at 1 kHz
Proximity fields from RF wireless communications equipment	IEC 61000-4-3	Refer to table E-8
Rated power frequency magnetic fields	IEC 61000-4-8	30 A/m 50 Hz or 60 Hz
Proximity magnetic fields	IEC 61000-4-39	Refer to Table E-11

Table E-8   Proximity fields from RF wireless communications equipment

Test Frequency (MHz)	Band (MHz)	Immunity Test Levels Professional Healthcare Facility Environment
385	380 –390	Pulse modulation 18 Hz, 27 V/m
450	430 –470	FM, ±5 kHz deviation, 1 kHz sine, 28 V/m

Table E-8   Proximity fields from RF wireless communications equipment *(continued)*

Test Frequency (MHz)	Band (MHz)	Immunity Test Levels Professional Healthcare Facility Environment
710	704–787	Pulse modulation 217 Hz, 9 V/m
745		
780		
810	800–960	Pulse modulation 18 Hz, 28 V/m
870		
930		
1720	1700–1990	Pulse modulation 21 Hz, 28 V/m
1845		
1970		
2450	2400–2570	Pulse modulation 217 Hz, 28 V/m
5240	5100–5800	Pulse modulation 217 Hz, 9 V/m
5500		
5785		

Table E-9   Input AC Port

Phenomenon	Basic EMC Standard	Immunity Test Levels Professional Healthcare Facility Environment
Electrical fast transients/ burst	IEC 61000-4-4	±2 kV 100 kHz repetition frequency
Surges line-to-line	IEC 61000-4-5	±0.5 kV, ±1 kV
Surges line-to-ground	IEC 61000-4-5	±0.5 kV, ±1 kV, ±2 kV

Table E-9   Input AC Port *(continued)*

Phenomenon	Basic EMC Standard	Immunity Test Levels Professional Healthcare Facility Environment
Conducted disturbances induced by RF fields	IEC 61000-4-6	3 V, 0.15–80 MHz 6 V in ISM bands between 0.15 and 80 MHz 80% AM at 1 kHz
Voltage dips	IEC 61000-4-11	0% U_T; 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315°
		0% U_T; 1 cycle and 70% U_T; 25/30 cycles Single phase at 0°
Voltage interruptions	IEC 61000-4-11	0% U_T; 250/300 cycles

Table E-10   Signal Input/Output Parts Port

Phenomenon	Basic EMC Standard	Immunity Test Levels Professional Healthcare Facility Environment
Electrostatic discharge	IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air
Conducted disturbances induced by RF fields	IEC 61000-4-6	3 V, 0.15–80 MHz 6 V in ISM bands between 0.15 and 80 MHz 80% AM at 1 kHz
Electrical fast transients/bursts	IEC 61000-4-4	±1 kV 100 kHz repetition frequency

Table E-11   Proximity Magnetic Fields

Test Frequency	Modulation	Immunity Test Levels Professional Healthcare Facility Environment
134.2 kHz	Pulse modulation 2.1 kHz	65 A/m
13.56 MHz	Pulse modulation 50 kHz	7.5 A/m

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Instructions for Use