7.0 Getting Help

7.1 How to Get Help

Datascope maintains a network of service representative and factory-trained distributors. Prior to requesting service, perform a complete operational check of the instrument to verify proper control settings. If operational problems continue to exist, contact the appropriate Datascope Service Department, listed below, for assistance in determining the nearest field service location.

Please include the instrument model number, the serial number, and a description of the problem with all requests for service. Any questions regarding the warranty should be directed to:

Service Manager
Datascope Corp., US, Canada & Latin America
Patient Monitoring
Worldwide Headquarters
800 MacArthur Blvd.
Mahwah, NJ 07430 USA
US Customer Service: 1.800.288.2121
US Fax: 1.800.926.4275
Intl. Customer Service: 201.995.8237
Intl. Fax: 201.995.8659
E-Mail Address: pm_sales@datascope.com

Service Manager
Datascope GmbH
Fabrikstrasse 35
64625 Bensheim
Germany
Tel: 06251.17050
Fax: 06251.67877

Service Manager
Europe & Africa
Drs. van W Royenstraat 8
P.O. Box 26, 3870 CA Hoevelaken
The Netherlands
Tel: +31.33.2544911
Fax: +31.33.2537621

Service Manager
Datascope Medical Co., Ltd.
Lakeview Court
Ermine Business Park
Huntingdon
Cambs
England
PE29 6XR
Tel: 01480.423600
Fax: 01480.423638

Service Manager
Datascope SARL
Z. I. Athelia 1
13705 La Ciotat
Cedex France
Tel: 04.42.08.77.08
Fax: 04.42.08.57.08

Service Manager
Datascope Middle East Office
37 Ahmed El-Sawy Street
Area No.6, Nasr City Cairo
Egypt
Tel: +20.2.274.8330
Fax: +20.2.274.7471

Service Manager
Datascope Corp Asia-Pacific Office
Unit A 30/F, Morrison Plaza
31 Hung To Road
9 Morrison Hill Rd
Wanchai, Hong Kong
Tel: 852.2793.5596
Fax: 852.2344.8824

8.0 *Glossary*

8.1 Terms and Definitions

TERM	DEFINITION
Alarm Level:	Specifies the user selectable severity level. For non-technical alarms a different alarm sound is associated with each of the 3 levels.
Amp (amplitude):	Vertical gain.
Auto Return From Standby:	This is a state where the system automatically restores ViewPoint Central Station monitoring functions to a channel when it detects good waveform and digital data, without an indication of bedside standby status, on a channel for a period of 30 seconds. The monitoring functions are restored to the channel as they were last set. They are set to the system default values for auto admit if no patient is currently admitted. They will resume the existing values for the patient, if one is currently admitted.
Cluster:	An indicator that is assigned to one or more patients on a system to identify by department or caregiver. Patients assigned to a cluster are indicated by color coded bars that appear between the view button and the digital parameter.

TERM	DEFINITION
Holter Print Format:	The Holter Print Format is condensed ECG waveforms presented one minute per line with heart rate for each minute displayed at the beginning of each minute.
Interactive Screen:	This is a screen format where the patient information tiles are painted to the display in a smaller vertical format at the top of the screen and another rectangular area is painted below the patient information tiles for management activities. There are various types of interactive screens, which vary according to the management activities (i.e.: admit, discharge, etc.).
Hub:	A central device that connects several patient monitors to the ViewPoint Central Station.
Latching Alarm:	An alarm that provides continuous audio and visual notification until it is acknowledged by the user.
Monitoring Equipment:	This is instrumentation that recovers and transmits patient data from the patient to the system. This applies to any ViewPoint system compatible bedside unit.
Normal Screen:	This is a screen format where the patient information tiles are painted to the screen. The only other display components painted during this screen are menu selections to take the display into the interactive screen mode.
Parameter:	A vital sign measurement obtained from a patient monitor or other device.
Standby:	This is a state of the monitoring function of the ViewPoint Central Station for a patient. This state clears the waveforms and digital parameters for a patient tile and discontinues the monitoring of waveforms and data for that patient, including alarm processing and data collection. This state is indicated with the "**Standby**" message in the patient's digital tile.
Switch:	A networking device which directs information to other network devices (i.e., other ViewPoint Central Stations, network laser printers, etc.).
Tile:	This refers to a rectangular area on the display screen. There are two types of tiles, digital parameter tiles and waveform tiles. Digital parameter tiles are used to display selected digital parameters, per user preference. The waveform tiles display one or two patient waveforms, as selected by the user. Each patient has a digital parameter tile and a waveform tile.
Restore Factory Settings:	Settings defined in System Setup, Installation Setup, Unit Priorities and Unit Choices.
Restore Previous Settings:	Restore values to that which were present upon initiation of that menu. New settings are established upon exiting that menu and will be utilized the next time "**Restore Previous Settings**" is selected.
Uninterruptible Power Supply (UPS):	Backup power supply that works when electrical power to a computer is interrupted. A UPS supplies power during short power interruptions so that the system can continue to operate until emergency power systems are on line.

TERM	Definition
CI:	Cardiac Index
CO:	Cardiac Output
LAN:	Local Area Network
LVSW:	Left Ventricular Stroke Work
LVSWI:	Left Ventricular Stroke Work Index
LVW:	Left Ventricular Work
LVWI:	Left Ventricular Work Index
PAP:	Pulmonary Artery Pressure
PVR:	Pulmonary Vascular Resistance
PVRI:	Pulmonary Vascular Resistance Index

PWP:	Pulmonary Wedge Pressure
RA:	Right Atrial Pressure
RCWI:	Right Ventricular Work Index
RVSW:	Right Ventricular Stroke Work
RVSWI:	Right Ventricular Stroke Work Index
RVW:	Right Ventricular Work
SV:	Stroke Volume
SVI:	Stroke Volume Index
SVR:	Systemic Vascular Resistance
SVRI:	Systemic Vascular Resistance Index

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9.0 *Specifications*

9.1 ViewPoint Proprietary Software

9.1.1 Performance

Specifications that ViewPoint meets are described below:

9.1.1.1 Display of ECG Performance Requirements

Three Lead Displayable Leads:	I, II, III (one vector at a time)
Five Lead Displayable Leads:	I, II, III, aVR, aVL, aVF, V
Standardizing Voltage:	The ECG size is indicated by a scale bar displayed on the left of the waveform window with a scale indicating the height of the bar in mV. Printed output to have standardizing pulse printed at beginning of strip ANSI/AAMI EC13-1992, 3.2.9.9
Time base selection (Non -permanent display)	25 mm/s ANSI/AAMI EC13-1992, 3.2.9.6 (b).
Time base error (Non-permanent display)	±10% ANSI/AAMI EC13-1992, 3.2.9.6 (b).
Impulse Response	0.1 mV max 0.3 mV/sec max slope ANSI/AAMI EC13-1992, 3.2.9.8 (c)
Aspect Ratio	0.4 ± 0.08 sec/mV (met by 25 mm/s) ANSI/AAMI EC13-1992 3.2.9.7 (f)

Overall System Error	Greater of 5% or 4 cuv ANSI/AAMI EC13-1992-3.2.9.8 a
ECG Input dynamic range	+/- 5mV max ANSI/AAMI EC13-1992-3.2.9.1
Channel Width	30 mm. min ANSI/AAMI EC13-1992-3.2.9.7 a
Waveform Displays	Each waveform in the All Strips, Event List Zoom-In, Full Disclosure Zoom-In and ST reports will be displayed on a calibrated grid (5mm x 5mm) that conforms to ANSI/AAMI EC13: 1992.4.2.9.7d. Each second of the waveforms in the All Strips, Event List Zoom-In, Full Disclosure Zoom-In and ST reports will be marked with a time annotation marker that conforms to ANSI/AAMI EC13: 1992.4.2.9.7e.

9.1.1.2 Display of ECG Derived Heart Rate Meter Performance Requirements

Range:	30 to 300 BPM ADULT/PEDIATRIC ANSI/AAMI EC13–1992, 3.2.7 30 to 350 BPM NEONATAL ANSI/AAMI EC13–1992, 3.2.7
Resolution:	1 BPM

9.1.1.2.1 Alarm Response

High HR alarm Range	60-250 BPM Adult 100-300 BPM Ped. 100-350 BPM Neo. (ANSI/AAMI EC13-1992, 3.2.8.1)
Low HR alarm Range	30-120 BPM Adult 30-150 BPM Ped. 30-200 BPM Neo (ANSI/AAMI EC13-1992, 3.2.8.1)
Resolution	5 BPM max. (ANSI/AAMI EC13-1992, 3.2.8.2)
Accuracy	± 5 BPM or ± 10% (ANSI/AAMI EC13-1992, 3.2.8.3)

Time to alarm Step Change Response Time	Less than 10 seconds for 60 BPM low limit alarm to sound when stepping from heart rate of 80 to 0 BPM and 80 to 40 BPM (ANSI/AAMI EC13-1992, 3.2.8.4 & 3.2.8.5). Less than 10 seconds for 100 BPM high limit alarm to sound when stepping from a heart rate of 80 to 120 BPM (ANSI/AAMI EC13-1992, 3.2.8.6)

9.1.1.3 Display of ST Segment Analysis

Enabling:	Enabled in ADULT and PEDIATRIC modes only
Default ST Measurement Point:	80 ms after J point for heart rates <120 BPM 60 ms after the J point for heart rates >120 BPM

9.1.1.3.1 User Selectable ST

Measurement Points:	40, 60 and 80 ms after J point (heart rate independent) Or 60/80 Heart Rate Dependent

9.1.1.4 Display of Arrhythmia Analysis

- Arrhythmia analysis is disabled in neonatal mode. Arrhythmia analysis will identify ventricular arrhythmia
- The following arrhythmia calls will be displayed

Asystole	Triplets	PVCs per minute
Missed Beat	Runs	Ventricular Tachycardia
Irregular Heart Rate	Bigeminy	Ventricular Fibrillation
Couplets	Trigeminy	

9.1.1.5 Display of NIBP Performance Characteristics

Systolic Pressure Measurement

Range:	55 to 235 mmHg in Adult mode 55 to 160 mmHg in Pediatric mode 45 to 120 mmHg in Neonatal mode
Resolution:	1 mmHg

9.1.1.5.1 Diastolic Pressure Measurement

Range:	30 to 200 mmHg in Adult mode 30 to 150 mmHg in Pediatric mode 20 to 100 mmHg in Neonatal mode
Resolution:	1 mmHg

9.1.1.5.2 Pulse Rate

Range:	35-245 BPM, for Adults/Ped
	70– 245 BPM, for Neonate
Resolution:	1 BPM

9.1.1.6 Display of IBP Pressure Range

Range:	30 to 300 mmHg after zeroing at the *Passport 2®*

9.1.1.7 Display of IBP Heart Rate Meter

Range:	30 to 300 BPM ADULT/PEDIATRIC 30 to 333 BPM NEONATAL
Resolution:	1 BPM

9.1.1.8 Display of Temperature Performance Requirements

Scale:	Selectable Celsius or Fahrenheit
Range:	15 °C to 45°C 59 °F to 113 °F
Resolution:	0.1 °C 0.1 °F

9.1.1.9 Display of ECG Respiration Performance Requirements

Range:	4 to 199 breaths per minute
Resp. Scale:	1, 2, 3, 4, or 5 with standard ECG cable

9.1.1.10 Display of SpO_2

SpO_2 Range:	70% to 100%
Pulse Rate Range:	30 to 235

9.1.1.11 Display of CO_2 Performance Requirements

Range:	0 - 13%s
Respiration Rate Range:	0 - 150 breaths/minute

9.1.1.11.1 Display of CO_2 Alarm

ET CO_2 High Alarm Range:	2 – 10%

ET CO_2 Low Alarm Range:	1 – 6%
Insp. CO_2 High Alarm Range:	1-4%

9.2 ViewPoint Central Station

ViewPoint Central Station hardware consists of a computer, hard drives, Ethernet, display controllers, case, and a power supply.

There is one basic hardware platform for ViewPoint Central Station computer system. It is populated with:

1. One 333MHz Pentium II processor
2. 512 MB of RAM
3. 1280 x 1024 dpi 65535 color display controller
4. 20.5 GB removable system hard drive
5. Two 45 GB fixed full disclosure hard drive
6. Four channel serial interface for touch screen input
7. 100 Mbit/sec Ethernet board

9.2.1 Real Time Clock

- This is used for various time-related functions in ViewPoint Central Station. This function is Y2K compliant.

9.2.2 Power Supply

9.2.2.1 Voltage

- 100-240 VAC (±10%)

9.2.2.2 Frequency

- 60/50 Hz (±3Hz)

9.2.2.3 ViewPoint Central Station Power Consumption Maximum

- 115 VAC @ 1.4 A + 20%
- 230 VAC @ 0.6 A + 20%

9.2.2.4 Operating Temperature

- +5 to +40 degrees centigrade

9.2.2.5 Operating Humidity

- 20% to 80% Relative Humidity Maximum, non-condensing, maximum wet bulb 29 degrees C

9.2.2.6 Operating Altitude

- 1060 to 700 hPa (-1250 to 9889 feet ASL) (-380 - 3014 m) (795 to 525 mm Hg)

9.2.2.7 Shipping

- Meet ISTA Test procedure 1A

9.2.2.8 Storage Temperature

- -20 to +60 degrees centigrade

9.2.2.9 Storage Humidity

- 5% to 80% Relative Humidity Maximum, non-condensing, maximum wet bulb 35 degrees C

9.2.2.10 Storage Altitude

- 1060 to 700 hPa (-1250 to 9889 feet ASL) (-380 - 3014 m) (795 to 525 mm Hg)

9.2.2.11 Surface Temperature

- Temperature does not exceed the values shown in table 16, parts 1 and 2 of EN 60950: 1992

9.2.2.12 Tip Over

- EN 60950:1992, section 4.1.1: Unit does not overbalance when tilted to an angle of 10° from normal upright position

9.2.2.13 Rigidity and Strength of Enclosure

- External enclosures to meet steady force of 250 N ± 10 N for a period of 5 s. Parts of enclosure located in operator access area to meet steady force of 30 N ± 3 N for a period of 5 s.

9.2.2.14 External Connector Compatibility

- Clause 4.3.17 of the CAN/CSA standard C22 no 950-95, third edition, and UL 1950 third edition

9.2.2.15 Alarms: Audio and Visual

- EN 475:1995

9.2.2.16 Electromagnetic Compatibility

- The electromagnetic compatibility (EMC) requirements are summarized below:

9.2.2.16.1 Radiated Emissions

- EN55022: 1998

  Class A Radiated

9.2.2.16.2 (RF) Conducted Emissions

- EN55022: 1998

  Class A Conducted

9.2.2.16.3 Radiated Susceptibility

- EN 61000-4-3:1998:

  3 V/M: 26 MHz – 1 GHz

80% AM

9.2.2.16.4 Conducted Susceptibility

- EN 61000-4-6:1996

  0.15-80 MHz
  3V, 80% AM

9.2.2.16.5 Electro-Static Discharge (ESD)

- EN55024: 1998
- EN 61000-4-2; 2 and 4 contact, and 2,4,6, and 8 kV air

9.2.2.16.6 Electrical Fast Transient (EFT/B)

- EN 50024:1998
- EN 61000-4-4:1995 2kV supply and control 1kV data and signal

9.2.2.16.7 Surge Immunity

- EN55024:1998
- EN 61000-4-5:1995 2kV common mode; 1kV differential to AC line

9.2.2.16.8 Magnetic Emissions

- MIL-STD-461D
- RES101 30 Hz to 100KHz @ 7cm

9.2.2.16.9 Magnetic Immunity

- EN55024:1998
- EN 61000-4-8: 1994

  50 HZ, 1 A/m

9.2.2.16.10 Voltage Dips, Short Interruptions and Voltage Variations

- EN 55024:1998
- EN 61000-4-11:1994

9.2.2.16.11 Harmonics

- EN 61000-3-2: 1995

  Amendment A1: 1998 & A2: 1998

9.2.2.16.12 Voltage Fluctuations and Flicker

- EN 61000-3-3:1995

9.2.2.16.13 Steady State Voltage

- FDA Reviewer Guidance 1993. App A (m) 7 (c) (1)

9.2.2.16.14 Enclosure Risk Current:

- 3.5 mA max. per EN 60950

9.2.2.16.15 Dielectric Withstand

- Central Monitoring System does withstand and operate as specified after application of 1500 V RMS at 50 or 60 Hz for 1 minute from AC mains hot or neutral to chassis

9.2.2.16.16 AC Dropout

- Draft IEC 601-1-2: 1996
- FDA Reviewer Guidance 1993 App A (m) 7 (c) (2)

9.2.2.16.17 AC Slow Sags and Surges

- FDA Reviewer Guidance 1993 App A (m) 7 (c) (3)

9.2.2.16.18 Quasi-Static

- FDA Reviewer Guidance 1993 App A (m) 7 (f)

9.2.2.16.19 Ground Resistance

- For items that have a connection to AC mains power:
- ViewPoint Central Station does have a ground resistance of ≤0.1 ohm from the AC mains power inlet module's ground contact pin to any exposed metal part, which may become energized when, measured per IEC 950. A ground resistance of up to 0.2 ohm is allowed when measured from the U blade of the supplied AC line cord to any exposed metal part which may become energized.

9.2.2.17 Physical Characteristics

9.2.2.17.1 Maximum Size:

- Depth: 18.87" (479 mm)
- Height: 17.18" (436 mm)
- Width: 7.44" (189 mm)

9.2.2.17.2 Maximum Weight:

- 36.5 lbs (16.56 kg)

9.3 Keyboard

- Keyboard is supported for system diagnostics only.
- This keyboard is offered in English language only, and is not be required for normal operation, but may be required for non-application system maintenance.
- The System will not require a keyboard to boot up and enter ViewPoint Central Station application software.

9.4 Mouse

- The mouse is supported for system diagnostics and user interface.
- Supported as an interface control device.
- The mouse operates independent of a touch screen interface.
- The mouse/touch screen is used together with the display to make selections from various menus and screens.

9.5 Displays

9.5.1 21" CRT Display

This is an integrated monitor that includes an internal touch screen controller and has the following features:

- SXGA
- 1280 x 1024 dpi capability
- 0.27mm dot pitch
- 19" viewable image measured diagonally

9.5.2 20" CRT Display

This is an integrated monitor that includes an internal touch screen controller and has the following features:

- SXGA
- 1280 x 1024 dpi capability
- 0.27mm dot pitch
- 18.9" viewable image measured diagonally

9.5.3 18.1" Flat Panel

This is an integrated monitor that includes an internal touch screen controller and has the following features:

- SXGA
- 1280 x 1024 dpi capability
- 0.28mm dot pitch
- 18.1" viewable image measured diagonally

WARNING: The 18.1" flat panel may tip over, if the display head is inclined to an angle greater than 45°, backward tilt. If the user elects to have the display head inclined to an angle greater than 45°, backward tilt, the flat panel must be attached to a secure mounting surface via three screw locations on the bottom of the base.

9.5.4 Touch Screen

- A Surface Acoustical Wave (SAW) touch screen is supported as the standard input device on 18" flat panel and 20" or 21" display.
- The touch screen operates independent of a mouse interface.
- The actual touch screen and its controller are integrated into the display.
- The touch screen communication is accepted by ViewPoint Central Station via a serial port.
- Use of the touch screen does not preclude the use of a mouse.

9.6 Network Printer

- The network printer is the standard hard copy output device for the output of ViewPoint Central Station waveform strip-charts and reports.
- There is no provision to support a printer mounted within ViewPoint Central Station CPU enclosure.
- The printer connects to the system via the ViewPoint Central Network.
- Two network laser printers are supported per ViewPoint Central Station.

For additional information see the Printer Configuration Manual (0070-00-0561).

9.6.1 Requirements:

- **Communications connection:** 10/100Base-TX Ethernet with internal print server
- **Speed:** 17 pages per minute printing at full resolution
- **Resolution:** 1200-dpi output
- **Media:** Plain paper sheets
- **Media sizes:** 8.5 in. by 11 in. and A4 standard

NOTE: Please refer to the manufacturer's printer manual for specific instructions regarding the printer.

10.0 *Appendix: Definitions, Default Values and Report Formats*

10.1 Arrhythmia Alarms

Arrhythmia detection is automatically assigned to the patient.

Arrhythmia calls are classified as critical (life-threatening) and non-critical. The critical arrhythmias include: Asystole, Ventricular Tachycardia and Ventricular Fibrillation.

Asystole - QRS waves are not detected for 4 seconds or longer in the absence of ventricular fibrillation.

Bigeminy - Two or more cycles of one PVC coupled to one normal beat.

Couplets - Two consecutive PVCs between normal beats Irregular Heart Rate - Consistently irregular R-R intervals.

Pause or Missed Beat - Two normal beats separated by an R-R interval that is twice the current average interval.

PVC/minute - Rate of PVC's per minute exceeds the value set by user for PVC rate alarm.

Run - Number of consecutive PVCs at a rate between 100 and 150 bpm exceeds user selected number (default 8).

Trigeminy - Two or more cycles of one PVC coupled to two normal beats.

Triplets - Three consecutive PVCs.

Ventricular Fibrillation - Fibrillatory waveform (no recognizable P, QRS, or T waves) detected for 4 consecutive seconds.

Ventricular Tachycardia - Eight or more consecutive PVCs at a rate equal or greater than the user selected V-Tach limit.

10.2 Report Layout and Specifications

This section discusses the layout of the reports that are printed from the ViewPoint Central Station. The following information is discussed in this section:

- Standard Header/Footer Information
- Report Format and Specifications (Page Orientation, Header Information, Report Content, and Footer Information)

10.2.1 Standard Report Header/Footer Information

All of the ViewPoint Central Station's reports contain a header and a footer. There are two standard types of headers; a first page header and a header for subsequent pages. The information that is shown in the headers is setup in the patient A/D/T tab.

If a report uses a custom header it is defined in the corresponding report section.

10.2.1.1 Standard 1st Page Report Header

The ViewPoint Central Station's standard 1st page report header includes the following information:

- A Header String section that shows the name of the report.
- A Date/Time section that shows the date and time at which the report was printed. The format of the Date/Time section is based on the system setting, however seconds are not shown in the headers of reports.
- A Last Name section that shows the last name of the patient for whom the report was generated.
- A First Name section that shows the first name of the patient for whom the report was generated.
- An ID section that shows the identification number of the patient for whom the report was generated.
- A Bed section that shows the bed number of the patient for whom the report was generated.
- A Weight section that shows the weight that was entered for the patient for whom the report was generated.
- A Height section that shows the height that was entered for the patient for whom the report was generated.
- A Room section that shows the room number that was assigned to the patient for whom the report was generated.
- A Doctor section that shows the doctor of the patient for whom the report was generated.
- An Other section that shows additional comments for the patient for whom the report was generated.

10.2.1.2 Standard Report Header for Subsequent Pages

The ViewPoint Central Station's standard report header for subsequent pages includes the following information:

- A Header String section that shows the name of the report.
- A Date/Time section that shows the date and time at which the report was generated. The format of the Date/Time section is based on the system setting.
- A Last Name section that shows the last name of the patient for whom the report was generated.
- A First Name section that shows the first name of the patient for whom the report was generated.
- An ID section that shows the identification number of the patient for whom the report was generated.
- A Room section that shows the room number that was assigned to the patient for whom the report was generated.
- A Bed section that shows the bed number that was assigned to the patient for whom the report was generated.

10.2.1.3 Standard Report Footer

All of the ViewPoint Central Station's reports use the same footer information. The standard report footer includes the Page Number and a Device Label.

- A Page # section that shows the number that was assigned to the page of the report.
- A Device label section that shows the label that was assigned to the system that generated the report. If the device does not have a label, the system name (serial number) is used.

10.2.2 Report Format and Specifications

This section details the layout and data that is presented in each report.

10.2.2.1 The All Strips Report Format

Figure 10-1 and Figure 10-2 show the layout of the All Strips Report.

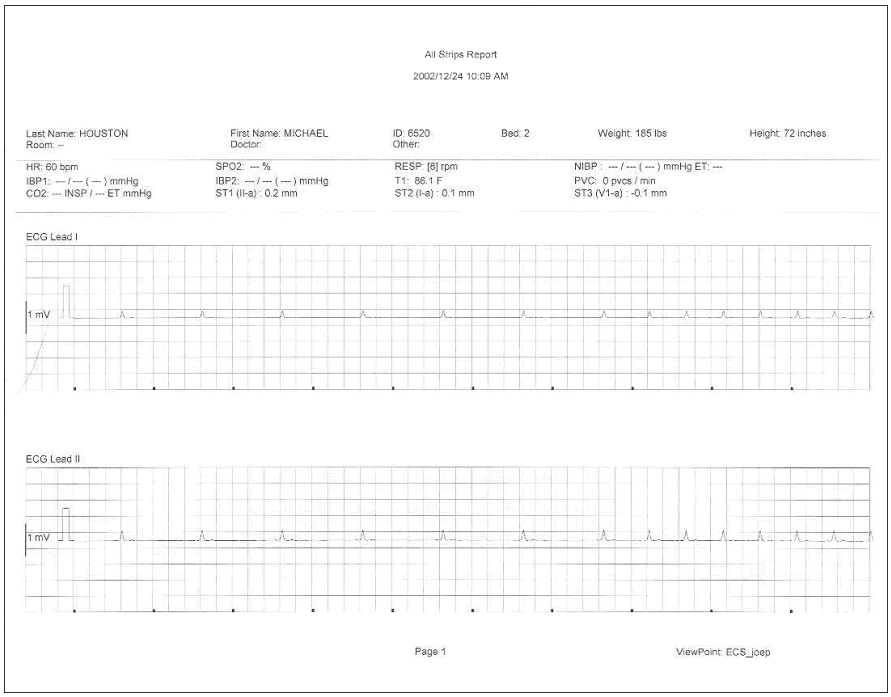


FIGURE 10-1 All Strips Report

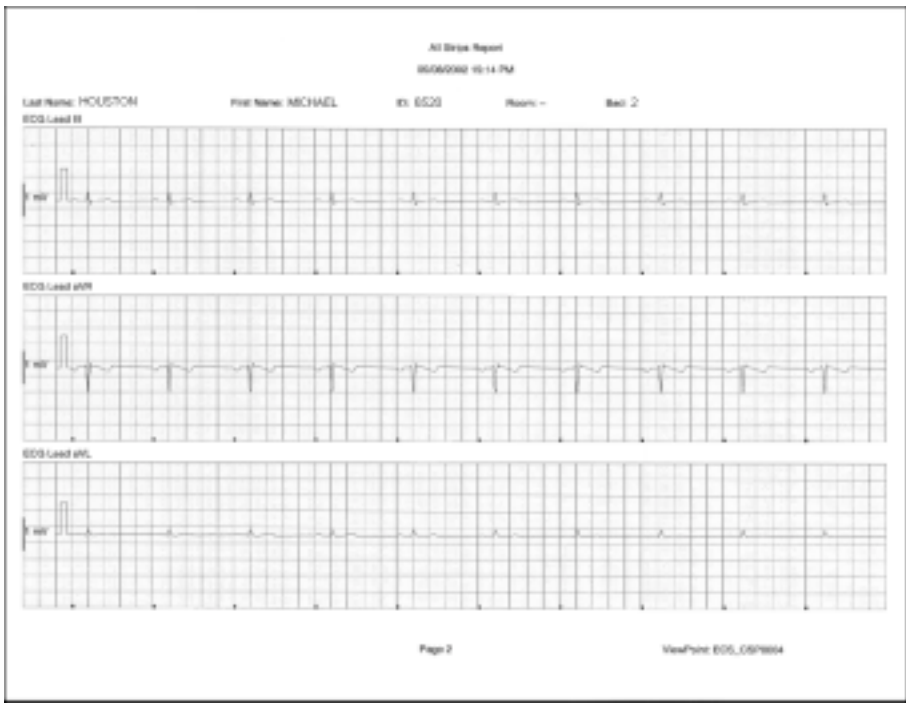


FIGURE 10-2

10.2.2.2 Specifications of the All Strips Report

This section discusses the layout of the All Strips Report and the data that is included in the report.

Paper Orientation

The All Strips Report uses the Landscape paper orientation.

Header Information

The All Strips Report uses the standard report header with the "All Strips Report" header string.

Report Body

The body of the All Strips Report includes sections for Digital and Waveform data.

Digital Data Section

The Digital Data section of the All Strips Report displays data for each parameter that is measured by the ViewPoint Central Station. The report shows unit labels for each piece of data in report.

If multiple units of measurement can be used to measure the data in the report, the report will show the unit of measure for which the patient is configured. For information regarding the types of measurement available for each variable, See "System Alarm Limits and Ranges for Parameters" on page 10-24.

The following information is shown in the digital data section of the All Strips Report:

- HR
- SpO_2
- RESP
- NIBP
- IBP1
- IBP2
- T1
- PVC
- CO_2
- ST1 and ECG lead for ST1

  The Digital Data section of the All Strips Report will include a lead label in parentheses for the lead from which the displayed data is acquired. The labels that are available for ST1 lead include: I, II, III, avL, avR, avF, and V1.

- ST2 and ECG lead for ST2

  The Digital Data section of the All Strips Report will include a lead label in parentheses for the lead from which the displayed data is acquired. The labels that are available for ST2 lead include: I, II, III, avL, avR, avF, and V1.

- ST3 and ECG lead for ST3

  The Digital Data section of the All Strips Report will include a lead label in parentheses for the lead from which the displayed data is acquired. The labels that are available for ST3 lead include: I, II, III, avL, avR, avF, and V1.

- All ST lead labels in the All Strips report include a tag that indicates if the ST measure is seen by the bedside monitor as a delta value (-d) or an absolute values (-a).

The All Strips Report will show dashes for all missing or invalid data and square brackets around alarming parameters.

Digital data is only shown on the first page of an All Strips Report.

Waveform Data Section

The Waveform Data section of the All Strips Report displays a 10-second strip for each waveform in the report. A label is included above each waveform strip to identify the source of the waveform data. Waveforms in the All Strips Report are shown in the wave gain for which the system is configured.

The first page of the All Strips Report contains 2 waveform strips. The middle pages of the All Strips Report contain 3 waveform strips. The last page of the All Strips Report will contain either 1, 2, or 3 waveforms strips depending on the number of waveforms available. The All Strips Report will include either the RESP waveform or CO2 waveform, but not both, depending on which of the parameters is displayed on the patient monitor.

ECG Waveforms

All of the ECG waveforms in the All Strips Report have a calibration pulse and a scale bar indicator.

The All Strips report will show an empty waveform strip for ECG waveform leads that are not connected.

Non-ECG Waveforms

All of the non-ECG waveforms in the All Strips Report have a scale range indicator.

The All Strips report will not include non-ECG waveform leads that are not connected in the report.

Footer Information

The All Strips Report uses the standard report footer.

10.2.2.3 The Equipment Report Format

Figure 10-3 and Figure 10-4 show the layout of the Equipment Report.

Equipment Report

2001/06/19 11:40 AM

Label	Type	Tile	Device ID	Patient Name	Patient ID
aa	Passport2	0	E0004AFX	------	------
------	No Device	------	------	------	------
------	No Device	------	------	------	------
------	No Device	------	------	------	------
------	No Device	------	------	------	------
------	No Device	------	------	------	------
------	No Device	------	------	------	------
------	No Device	------	------	------	------
------	No Device	------	------	System Defaults	IC-994
------	No Device	------	------	------	------
------	No Device	------	------	------	------
------	No Device	------	------	------	------
------	No Device	------	------	------	------
------	No Device	------	------	------	------
------	No Device	------	------	------	------
------	No Device	------	------	------	------
------	No Device	------	------	------	------
------	No Device	------	------	------	------
------	No Device	------	------	------	------
------	No Device	------	------	------	------
------	No Device	------	------	------	------
------	No Device	------	------	------	------
------	No Device	------	------	------	------
------	No Device	------	------	------	------
------	No Device	------	------	------	------
------	No Device	------	------	------	------
------	No Device	------	------	------	------
------	No Device	------	------	------	------
------	No Device	------	------	------	------
------	No Device	------	------	------	------
------	No Device	------	------	------	------
------	No Device	------	------	------	------

Page 1 ViewPoint: S29E4E7X

FIGURE 10-3 Equipment Report

Equipment Report

2001/06/19 11:40 AM

Label	Type	Tile	Device ID	Patient Name	Patient ID
------	No Device	------	------	------	------
------	No Device	------	------	------	------
------	No Device	------	------	------	------
------	No Device	------	------	------	------
------	No Device	------	------	------	------
------	No Device	------	------	------	------
------	No Device	------	------	------	------
------	No Device	------	------	------	------
------	No Device	------	------	------	------
------	No Device	------	------	------	------
------	No Device	------	------	------	------
------	No Device	------	------	------	------
------	No Device	------	------	------	------
------	No Device	------	------	------	------
------	No Device	------	------	------	------
------	No Device	------	------	------	------
------	No Device	------	------	------	------
------	No Device	------	------	------	------
------	No Device	------	------	------	------
------	No Device	------	------	------	------
------	No Device	------	------	------	------
------	No Device	------	------	------	------
------	No Device	------	------	------	------
------	No Device	------	------	------	------
------	No Device	------	------	------	------
------	No Device	------	------	------	------
------	No Device	------	------	------	------
------	No Device	------	------	------	------
------	No Device	------	------	------	------
------	No Device	------	------	------	------
------	No Device	------	------	------	------
------	No Device	------	------	------	------

Page 2 ViewPoint: S29E4E7X

FIGURE 10-4

10.2.2.4 Specifications of the Equipment Report

This section discusses the layout of the Equipment Report and the data that is included in the report.

Paper Orientation

The Equipment Report uses the Landscape paper orientation.

Header Information

The Equipment Report uses a custom report header that includes a Header String and Date/Time. The report uses the "Equipment Report" header string and the Date/Time is shown in the system format.

Report Body

The Equipment Report shows one piece of equipment in each row of the report.

The following information is shown in the columns of the Equipment Report:

- Label

  The Label is assigned from the Equipment List.

- Type

  The Type is assigned from the Equipment List.

  NO DEVICE is shown for an invalid Type.

- Tile #

  The Tile # is assigned from the Equipment List.

- Device ID

  The Device ID is assigned from the Equipment List.

- Patient Name

  The Patient Name is assigned from the Patient A/D/T tab.

- Patient ID

  The Patient ID is assigned from the Patient A/D/T tab.

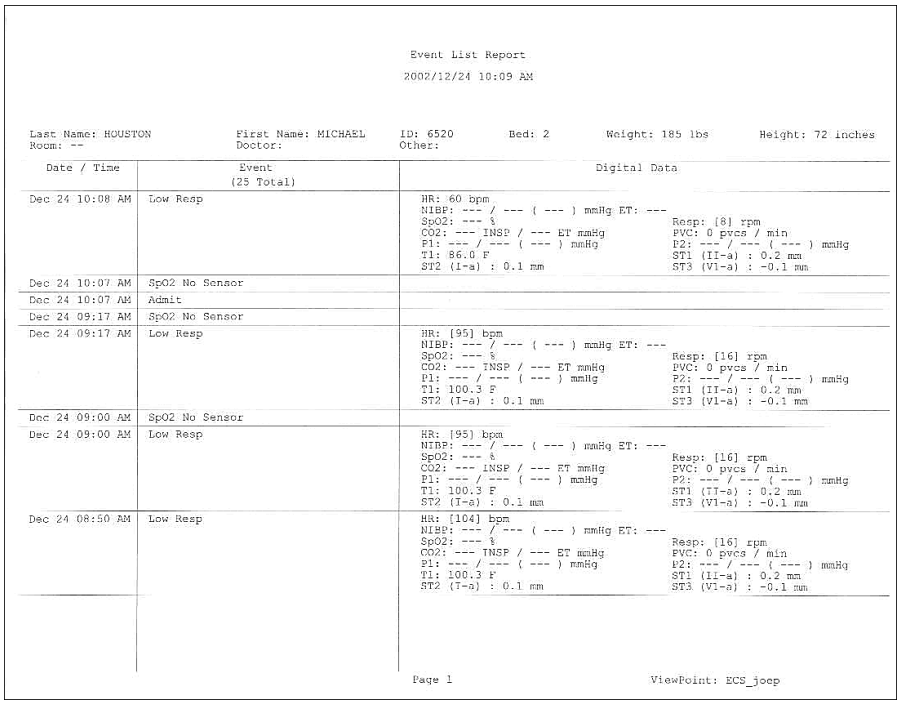
The Equipment Report will show 6 dashes for all invalid data.

Footer Information

The Equipment Report uses the standard report footer.

10.2.2.5 The Event List Report Format

Figure 10-5 shows the layout of the Event List Report.



Event List Report

2002/12/24 10:09 AM

Last Name: HOUSTON First Name: MICHAEL ID: 6520 Bed: 2 Weight: 185 lbs Height: 72 inches
Room: -- Doctor: Other:

Date / Time	Event (25 Total)	Digital Data
Dec 24 10:08 AM	Low Resp	HR: 60 bpm NIBP: --- / --- (---) mmHg ET: --- SpO2: --- % CO2: --- INSP / --- ET mmHg P1: --- / --- (---) mmHg T1: 86.0 F ST2 (I-a) : 0.1 mm Resp: [8] rpm PVC: 0 pvcs / min P2: --- / --- (---) mmHg ST1 (II-a) : 0.2 mm ST3 (V1-a) : -0.1 mm
Dec 24 10:07 AM	SpO2 No Sensor	
Dec 24 10:07 AM	Admit	
Dec 24 09:17 AM	SpO2 No Sensor	
Dec 24 09:17 AM	Low Resp	HR: [95] bpm NIBP: --- / --- (---) mmHg ET: --- SpO2: --- % CO2: --- INSP / --- ET mmHg P1: --- / --- (---) mmHg T1: 100.3 F ST2 (I-a) : 0.1 mm Resp: [16] rpm PVC: 0 pvcs / min P2: --- / --- (---) mmHg ST1 (II-a) : 0.2 mm ST3 (V1-a) : -0.1 mm
Dec 24 09:00 AM	SpO2 No Sensor	
Dec 24 09:00 AM	Low Resp	HR: [95] bpm NIBP: --- / --- (---) mmHg ET: --- SpO2: --- % CO2: --- INSP / --- ET mmHg P1: --- / --- (---) mmHg T1: 100.3 F ST2 (I-a) : 0.1 mm Resp: [16] rpm PVC: 0 pvcs / min P2: --- / --- (---) mmHg ST1 (II-a) : 0.2 mm ST3 (V1-a) : -0.1 mm
Dec 24 08:50 AM	Low Resp	HR: [104] bpm NIBP: --- / --- (---) mmHg ET: --- SpO2: --- % CO2: --- INSP / --- ET mmHg P1: --- / --- (---) mmHg T1: 100.3 F ST2 (I-a) : 0.1 mm Resp: [16] rpm PVC: 0 pvcs / min P2: --- / --- (---) mmHg ST1 (II-a) : 0.2 mm ST3 (V1-a) : -0.1 mm

Page 1 ViewPoint: ECS_joep

FIGURE 10-5 Event List Report

10.2.2.6 Specifications of the Event List Report

This section discusses the layout of the Event List Report and the data that is included in the report.

Paper Orientation

The Event List Report uses the Landscape paper orientation.

Header Information

The Event List Report uses the standard 1st page report header on every page of the report. The Event List Report uses the "Event List Report" header string.

Report Body

The Event List Report shows one event in each row of the report with the newest data at the top of the page.The length of the report is determined by the number of waveforms in the report.

The following information is shown in the columns of the Event List Report:

- Date/Time

  The Date/Time column of the Event List Report uses the Month Abbreviation Day date format (for example, Feb 11) and the system's time format.

- Event

  The Event column of the Event List Report displays a list of all of a patient's events.

The Event column shows the total number of patient events in the system in parentheses under the Event column label (the number of events in the system may differ from the number of events in the report if not all events are printed).

- Digital Data

  The Digital Data column only displays data for Physiological events.

  The Digital Data column includes unit labels for each piece of data in the report.

  If multiple units of measurement can be used to measure the data in the report, the report will show the unit of measure for which the patient is configured., For information regarding the types of measurement available for each variable, See "System Alarm Limits and Ranges for Parameters" on page 10-24.

The following information is shown in the Digital Data column of the Event List Report:

- HR
- NIBP
- SpO2
- RESP
- CO_2
- PVC
- P1
- P2.
- T1
- ST1 and ECG lead for ST1

  The Digital Data section of the Event List Report will include a lead label in parentheses for the lead from which the displayed data is acquired. The labels that are available for ST1 lead include: I, II, III, avL, avR, avF, and V1.

- ST2 and ECG lead for ST2

  The Digital Data section of the Event List Report will include a lead label in parentheses for the lead from which the displayed data is acquired. The labels that are available for ST2 lead include: I, II, III, avL, avR, avF, and V1.

- ST3 and ECG lead for ST3

  The Digital Data section of the Event List Report will include a lead label in parentheses for the lead from which the displayed data is acquired. The labels that are available for ST3 lead include: I, II, III, avL, avR, avF, and V1.All ST lead labels in the Event List Report include a tag that indicates if the ST measure is seen by the bedside monitor as a delta value (-d) or an absolute values (-a).

The Event List Report will show dashes for all invalid data and square brackets around alarming parameters.

Footer Information

The Event List Report uses the standard report footer.

10.2.2.7 The Event Zoom-In Report Format

Figure 10-6 and Figure 10-7 show the layout of the Event Zoom-In Report.

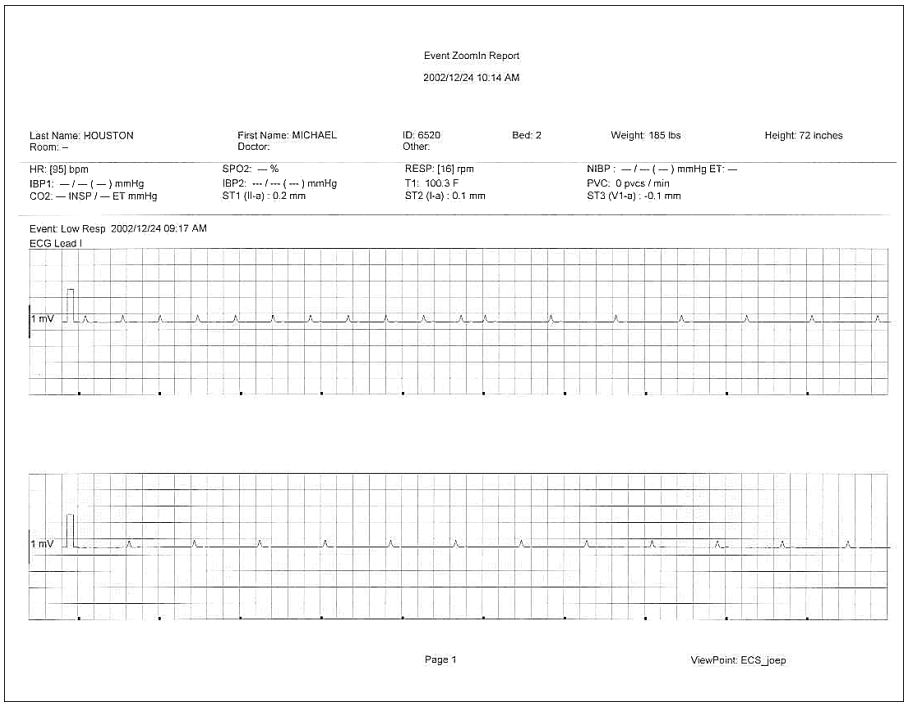


FIGURE 10-6 Event Zoom-In Report

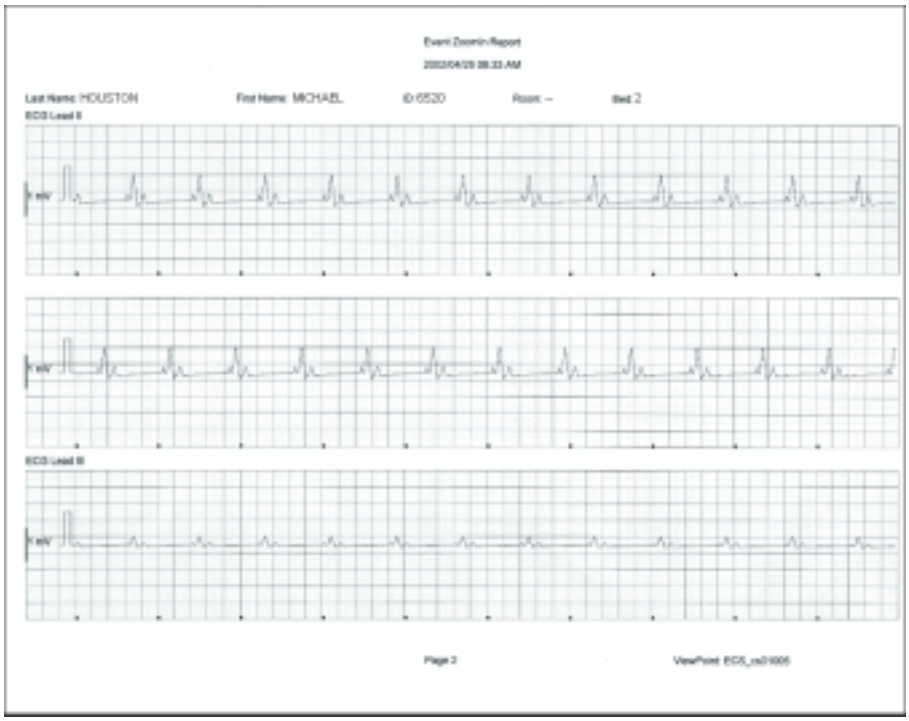


FIGURE 10-7

10.2.2.8 Specifications of the Event Zoom-In Report

This section discusses the layout of the Event Zoom-In Report and the data that is included in the report.

Paper Orientation

The Event Zoom-In Report uses the Landscape paper orientation.

Header Information

The Event Zoom-In Report uses the standard report header with the "Event ZoomIn Report" header string.

Report Body

The Event Zoom-In Report includes sections for Digital and Waveform data.

Digital Data Section

The Display Data section of the Event Zoom-In Report displays data for each parameter that is measured by the ViewPoint Central Station. The report shows units labels for each piece of data in the report.

If multiple units of measurement can be used to measure the data in the report, the report will show the unit of measure for which the patient is configured. For information regarding the types of measurement available for each variable, See "System Alarm Limits and Ranges for Parameters" on page 10-24.

The following information is shown in the Digital Data section of the Event Zoom-In Report:

- HR
- SpO2
- RESP
- NIBP
- IBP1
- IBP2
- T1
- PVC
- CO2
- ST1 and ECG lead for ST1

  The Digital Data section of the Event Zoom-In Report will include a lead label in parentheses for the lead from which the displayed data is acquired. The labels that are available for ST1 lead include: I, II, III, avL, avR, avF, and V1.

- ST2 and ECG lead for ST2

  The Digital Data section of the Event Zoom-In Report will include a lead label in parentheses for the lead from which the displayed data is acquired. The labels that are available for ST2 lead include: I, II, III, avL, avR, avF, and V1.

- ST3 and ECG lead for ST3

  The Digital Data section of the Event Zoom-In Report will include a lead label in parentheses for the lead from which the displayed data is acquired. The labels that are available for ST3 lead include: I, II, III, avL, avR, avF, and V1.

  All ST lead labels in the Event Zoom-In Report include a tag that indicates if the ST measure is seen by the bedside monitor as a delta value (-d) or an absolute values (-a).

The Event Zoom-In Report will show dashes for all missing or invalid data and square brackets around alarming parameters.

Digital data is only shown on the first page of an Event Zoom-In Report.

Waveform Data Section

The Waveform Data section of the Event List Zoom-In Report displays a 20-second strip (10-second pre/10-second post event) for each of the selected event's waveforms. The first page of the Waveform Data section displays an Event label that shows the type of event and the time of the event that occurred in the report (the event time is based on the system time format). A label is shown above each waveform to identify the source of the waveform data. Waveforms in the Event Zoom-In Report are shown in the wave gain for which the system is configured.

The first page of the Event Zoom-In Report contains 2 waveform strips. The middle pages of the Event Zoom-In Report contains 2 or 3 waveform strips. The last page of the Event Zoom-In Report will show either 1 or 3 waveforms strips depending on the amount of waveforms available.

ECG Waveforms

All of the ECG waveforms in the Event Zoom-In Report have a calibration pulse and a scale bar indicator.

The Event Zoom-In Report will show an empty waveform strip for ECG waveform leads that are not connected.

Non-ECG Waveforms

All of the non-ECG waveforms in the Event Zoom-In Report have a scale range indicator.

The Event Zoom-In Report will not include non-ECG waveform leads that are not connected in the report.

Footer Information

The Event Zoom In Report uses the standard report footer.

10.2.2.9 The Full Disclosure Report Format

Figure 10-8 shows the layout of the Full Disclosure Report when it is printed from the Disclosure tab.

When the Full Disclosure Report is printed from the Disclosure tab it will print the report for the lead that is selected. When the Full Disclosure Report is printed from the Report menu button it will only print the report for ECG Lead 2.

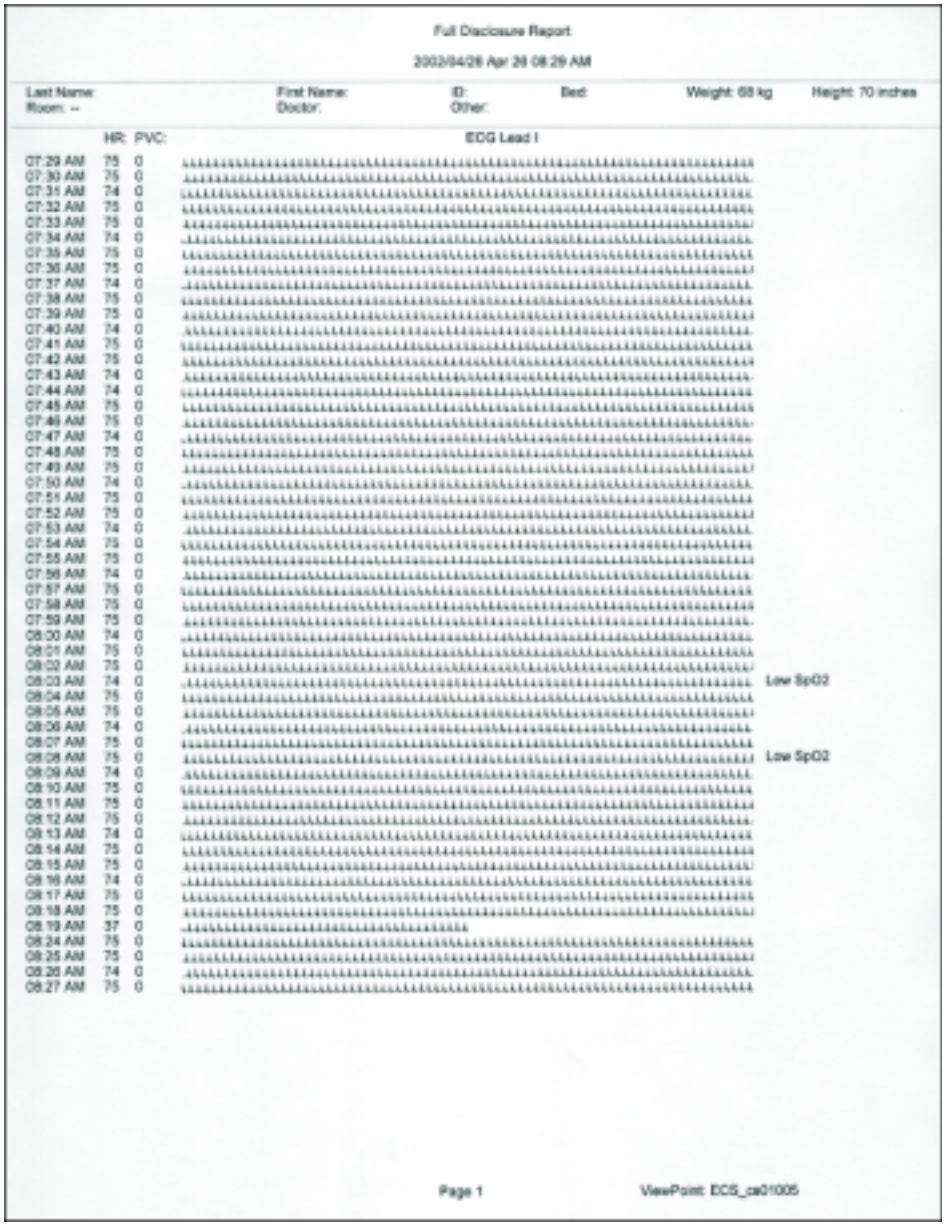


FIGURE 10-8 Full Disclosure Report

10.2.2.10 Specifications of the Full Disclosure Report

This section discusses the layout of the Full Disclosure Report and the data that is included in the report.

Paper Orientation

The Full Disclosure Report uses the Portrait paper orientation.

Header Information

The Full Disclosure Report uses the standard report header with the "Full Disclosure Report" header string.

Report Body

The Full Disclosure Report shows 60 minutes worth of data in each page of the report and one minute of data in each row. The newest data is shown at the bottom of the report.

The report uses 2 different formats (one for ECG data and one for all other disclosure information).

ECG Format

The following information is shown in the ECG format of the Full Disclosure Report:

- A Time column which follows the system time format.
- A HR column that shows the heart rate for the minute specified.
- A PVC column that shows the PVC for the minute specified.
- A Waveform Data column that shows the Waveform specified by the waveform label.
- An Event column that uses the Event Algorithm to select an event for each minute in the report.

The Event Algorithm selects the event to display for each minute of a report. The algorithm looks at the severity of an alarm and the time at which it occurred. The process of the algorithm is as follows:

1. The Event Algorithm searches the specified minute for a Priority 1 event. If the algorithm finds a priority 1 event, the event is listed for the minute specified and the algorithm stops.
2. If no Priority 1 event is found, the algorithm searches the specified minute for a Priority 2 event. If the algorithm finds a Priority 2 event, the event is listed for the minute specified and the algorithm stops.
3. If no Priority 2 event is found, the algorithm searches the specified minute for a Priority 3 event. If the algorithm finds a Priority 3 event, the event is listed for the minute specified and the algorithm stops.
4. If no Priority 3 event is found, the algorithm searches the specified minute for a System/Technical event. If the algorithm finds a System/Technical event, the event is listed for the minute specified and the algorithm stops.
5. If no System/Technical event is found, then no event is displayed for the specified minute.

Non-ECG Format

The following information is shown in the Non-ECG format of the Full Disclosure Report:

- A Time column which follows the system time format.
- A HR column that shows the average heart rate for the first second of the minute specified.
- A Waveform Data column that shows the Waveform specified by the waveform label.
- An Event column that uses the Event Algorithm to select an event for each minute in the report.

The Event Algorithm selects one event to display for each minute of a report. The algorithm looks at the severity of an alarm and the time at which it occurred. The process of the algorithm is as follows:

1. The Event Algorithm searches the specified minute for a Priority 1 event. If the algorithm finds a priority 1 event, the event is listed for the minute specified and the algorithm stops.
2. If no Priority 1 event is found, the algorithm searches the specified minute for a Priority 2 event. If the algorithm finds a Priority 2 event, the event is listed for the minute specified and the algorithm stops.
3. If no Priority 2 event is found, the algorithm searches the specified minute for a Priority 3 event. If the algorithm finds a Priority 3 event, the event is listed for the minute specified and the algorithm stops.
4. If no Priority 3 event is found, the algorithm searches the specified minute for a System/Technical event. If the algorithm finds a System/Technical event, the event is listed for the minute specified and the algorithm stops.
5. If no System/Technical event is found, then no event is displayed for the specified minute.

Footer Information

The Full Disclosure Report uses the standard report footer.

10.2.2.11 The Full Disclosure Zoom-In Report Format

Figure 10-9 and Figure 10-10 show the layout of the Full Disclosure Zoom-In Report.

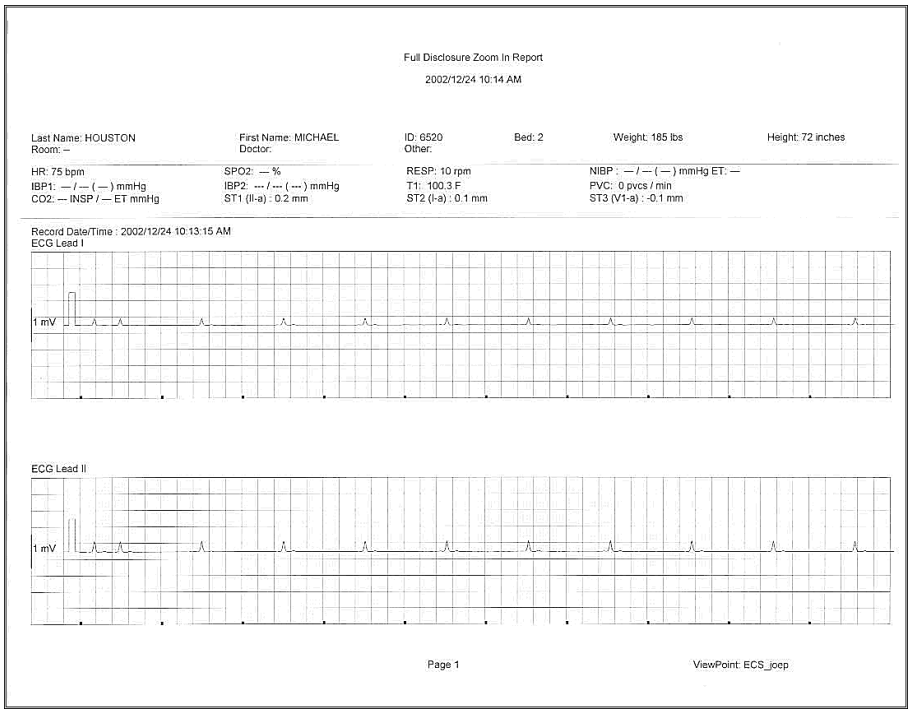


FIGURE 10-9 Full Disclosure Zoom-In Report

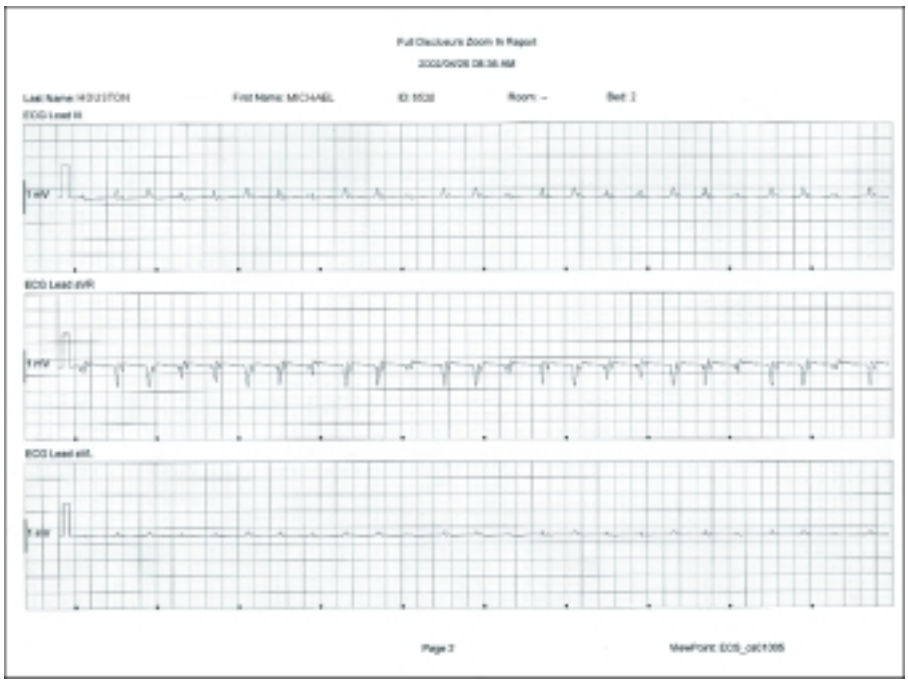


FIGURE 10-10

10.2.2.12 Specifications of the Full Disclosure Zoom-In Report

This section discusses the layout of the Full Disclosure Zoom-In Report and the data that is included in the report.

Paper Orientation

The Full Disclosure Zoom-In Report uses the Landscape paper orientation.

Header Information

The Full Disclosure Zoom-In Report uses the standard report header with the "Full Disclosure Zoom-In Report" header string.

Report Body

The Full Disclosure Zoom-In Report includes sections for Digital and Waveform data.

Digital Data Section

The Digital Data section of the Full Disclosure Zoom-In Report displays data for each parameter that is measured by the ViewPoint Central Station. The report shows unit labels for each piece of data in the report.

If multiple units of measurement can be used to measure the data in the report, the report will show the unit of measure for which the patient is configured. For information regarding the types of measurement available for each variable, See "System Alarm Limits and Ranges for Parameters" on page 10-24.

The following information is shown in the Digital Data section of the Full Disclosure Zoom-In Report:

- HR
- SpO2
- RESP
- NIBP
- IBP1
- IBP2
- T1
- PVC
- CO2
- ST1and ECG lead for ST1

  The Digital Data section of the Full Disclosure Zoom-In Report will include a lead label in parentheses for the lead from which the displayed data is acquired. The labels that are available for ST1 lead include: I, II, III, avL, avR, avF, and V1.

- ST2 and ECG lead for ST2

  The Digital Data section of the Full Disclosure Zoom-In Report will include a lead label in parentheses for the lead from which the displayed data is acquired. The labels that are available for ST2 lead include: I, II, III, avL, avR, avF, and V1.

- ST3 and ECG lead for ST3

  The Digital Data section of the Full Disclosure Zoom-In Report will include a lead label in parentheses for the lead from which the displayed data is acquired. The labels that are available for ST3 lead include: I, II, III, avL, avR, avF, and V1.

  All ST lead labels in the Full Disclosure Zoom-In Report include a tag that indicates if the ST measure is seen by the bedside monitor as a delta value (-d) or an absolute values (-a).

The Full Disclosure Zoom-In Report will show dashes for all missing or invalid data and square brackets around alarming parameters.

Digital data is only shown on the first page of the Full Disclosure Zoom-In Report.

Waveform Data Section

The Waveform Data section of the Full Disclosure Zoom-In Report displays a 10-second strip for all of the available waveforms. A label is shown above each waveform strip to identify the source of the waveform data. Waveforms in the Full Disclosure Zoom-In Report are shown in the wave gain for which the system is configured.

The first page of the Full Disclosure Zoom-In Report contains 2 waveform strips. The middle pages of the Full Disclosure Zoom-In Report contains 3 waveform strips. The last page of the Full Disclosure Zoom-In Report will show either 1, 2, or 3 waveforms strips depending on the amount of waveforms available.

ECG Waveforms

All of the ECG waveforms in the Full Disclosure Zoom-In Report have a calibration pulse and a scale bar indicator.

The Full Disclosure Zoom-In Report will show an empty waveform strip for ECG waveform leads that are not connected.

Non-ECG Waveforms

All of the non-ECG waveforms in the Full Disclosure Zoom-In Report have a scale range indicator.

The Full Disclosure Zoom-In Report will not include non-ECG waveform leads that are not connected in the report.

Footer Information

The Full Disclosure Zoom-In Report uses the standard report footer.

The ST Report Format

Figure 10-11 shows the layout of the ST Report.

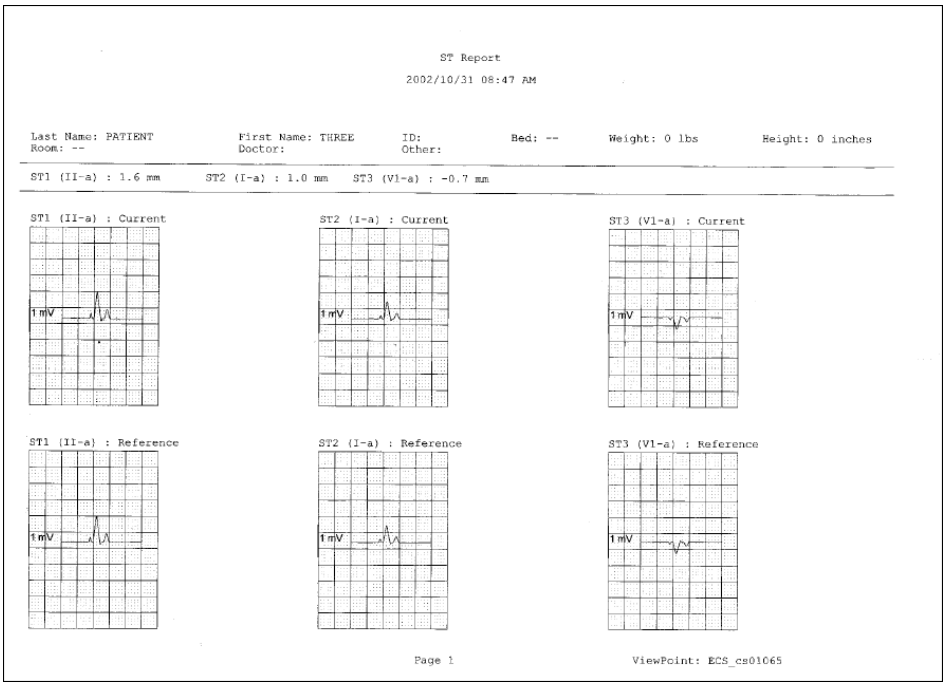


FIGURE 10-11 ST Report

10.2.2.13 Specifications of the ST Report

This section discusses the layout of the ST Report and the data that is included in the report.

Paper Orientation

The ST Report uses the Landscape paper orientation.

Header Information

The ST Report uses the standard report header with the "ST Report" header string.

Report Body

The ST Report is a single page report that includes sections for Digital and Waveform data.

Digital Data Section

The Digital Data section of the ST Report displays data for each parameter that is measured by the ViewPoint Central Station. The report shows unit labels for each piece of data in the report.

The following information is shown in the Digital Data section of the ST Report:

- ST1 and ECG lead for ST1

  The Digital Data section of the ST Report will include a lead label in parentheses for the lead from which the displayed data is acquired. The labels that are available for ST1 lead include: I, II, III, avL, avR, avF, and V1.

- ST2 and ECG lead for ST2

  The Digital Data section of the Full Disclosure Zoom-In Report will include a lead label in parentheses for the lead from which the displayed data is acquired. The labels that are available for ST2 lead include: I, II, III, avL, avR, avF, and V1.

- ST3 and ECG lead for ST3

  The Digital Data section of the Full Disclosure Zoom-In Report will include a lead label in parentheses for the lead from which the displayed data is acquired. The labels that are available for ST3 lead include: I, II, III, avL, avR, avF, and V1.

  All ST lead labels in the ST Report include a tag that indicates if the ST measure is seen by the bedside monitor as a delta value (-d) or an absolute values (-a).

The ST Report will show dashes for all missing or invalid data and square brackets around alarming parameters.

Waveform Data Section

The Waveform Data section of the ST Report displays 3 current templates and 3 reference templates. Each template in the report is labeled as either current or reference with a lead label.

- The Waveform Data section of the ST Report will include a lead label in parentheses for the lead from which the displayed data is acquired. The labels that are available for ST1 lead include: I, II, III, avL, avR, avF, and V1.
- The Waveform Data section of the ST Report will include a lead label in parentheses for the lead from which the displayed data is acquired. The labels that are available for ST2 lead include: I, II, III, avL, avR, avF, and V1.
- The Waveform Data section of the ST Report will include a lead label in parentheses for the lead from which the displayed data is acquired. The labels that are available for ST3 lead include: I, II, III, avL, avR, avF, and V1.
- All ST lead labels in the ST Report include a tag that indicates if the ST measure is seen by the bedside monitor as a delta value (-d) or an absolute values (-a).

Waveforms in the ST Report print in the wave gain for which the system is configured.

The *Passport 2®* provides the following information:

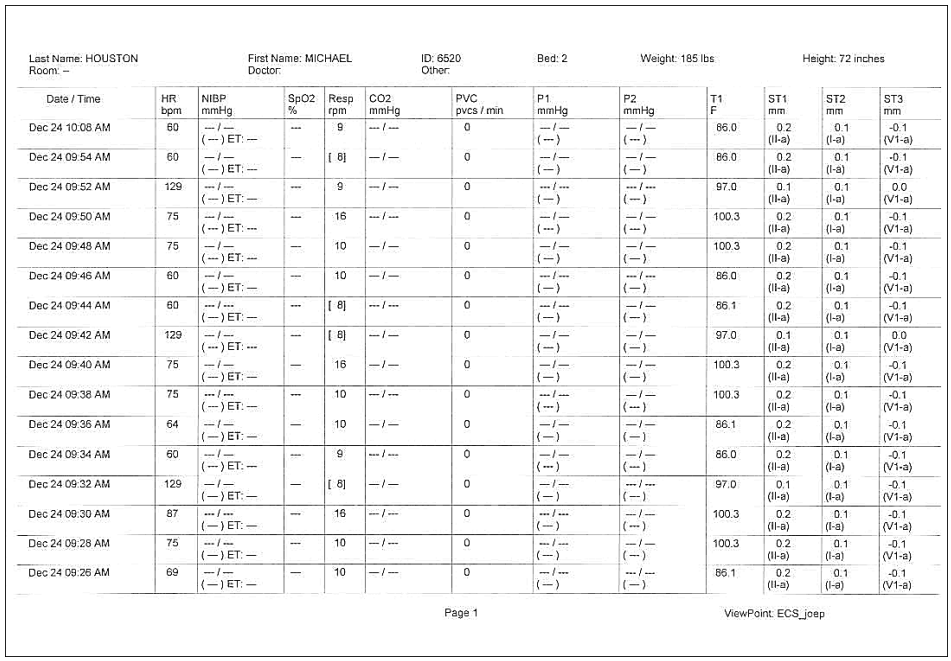
- ST information
- The lead numbers that are shown in the window
- The order in which the leads are presented.

Footer Information

The ST Report uses the standard report footer.

10.2.2.14 The Trends List Report Format

Figure 10-12 shows the layout of the Trends List Report.



Last Name: HOUSTON First Name: MICHAEL ID: 6520 Bed: 2 Weight: 185 lbs Height: 72 inches
Room: -- Doctor: Other:

Date / Time	HR bpm	NIBP mmHg	SpO2 %	Resp rpm	CO2 mmHg	PVC pvcs / min	P1 mmHg	P2 mmHg	T1 F	ST1 mm	ST2 mm	ST3 mm
Dec 24 10:08 AM	60	— / — (---) ET: ---	---	9	--- / ---	0	— / — (---)	— / — (---)	86.0	0.2 (II-a)	0.1 (I-a)	-0.1 (V1-a)
Dec 24 09:54 AM	60	— / — (---) ET: ---	---	[8]	— / —	0	— / — (---)	— / — (---)	86.0	0.2 (II-a)	0.1 (I-a)	-0.1 (V1-a)
Dec 24 09:52 AM	129	--- / --- (---) ET: ---	---	9	— / —	0	--- / --- (---)	--- / --- (---)	97.0	0.1 (II-a)	0.1 (I-a)	0.0 (V1-a)
Dec 24 09:50 AM	75	— / — (---) ET: ---	---	16	--- / ---	0	— / — (---)	— / — (---)	100.3	0.2 (II-a)	0.1 (I-a)	-0.1 (V1-a)
Dec 24 09:48 AM	75	— / — (---) ET: ---	---	10	— / —	0	— / — (---)	— / — (---)	100.3	0.2 (II-a)	0.1 (I-a)	-0.1 (V1-a)
Dec 24 09:46 AM	60	— / — (---) ET: ---	---	10	— / —	0	--- / --- (---)	--- / --- (---)	86.0	0.2 (II-a)	0.1 (I-a)	-0.1 (V1-a)
Dec 24 09:44 AM	60	--- / --- (---) ET: ---	---	[8]	--- / ---	0	--- / --- (---)	— / — (---)	86.1	0.2 (II-a)	0.1 (I-a)	-0.1 (V1-a)
Dec 24 09:42 AM	129	— / — (---) ET: ---	---	[8]	— / —	0	— / — (---)	— / — (---)	97.0	0.1 (II-a)	0.1 (I-a)	0.0 (V1-a)
Dec 24 09:40 AM	75	— / — (---) ET: ---	---	16	— / —	0	— / — (---)	— / — (---)	100.3	0.2 (II-a)	0.1 (I-a)	-0.1 (V1-a)
Dec 24 09:38 AM	75	--- / --- (---) ET: ---	---	10	--- / ---	0	--- / --- (---)	— / — (---)	100.3	0.2 (II-a)	0.1 (I-a)	-0.1 (V1-a)
Dec 24 09:36 AM	64	— / — (---) ET: ---	---	10	— / —	0	— / — (---)	— / — (---)	86.1	0.2 (II-a)	0.1 (I-a)	-0.1 (V1-a)
Dec 24 09:34 AM	60	— / — (---) ET: ---	---	9	--- / ---	0	— / — (---)	— / — (---)	86.0	0.2 (II-a)	0.1 (I-a)	-0.1 (V1-a)
Dec 24 09:32 AM	129	— / — (---) ET: ---	---	[8]	— / —	0	— / — (---)	--- / --- (---)	97.0	0.1 (II-a)	0.1 (I-a)	-0.1 (V1-a)
Dec 24 09:30 AM	87	--- / --- (---) ET: ---	---	16	--- / ---	0	--- / --- (---)	— / — (---)	100.3	0.2 (II-a)	0.1 (I-a)	-0.1 (V1-a)
Dec 24 09:28 AM	75	--- / --- (---) ET: ---	---	10	— / —	0	--- / --- (---)	— / — (---)	100.3	0.2 (II-a)	0.1 (I-a)	-0.1 (V1-a)
Dec 24 09:26 AM	69	— / — (---) ET: ---	---	10	— / —	0	--- / --- (---)	--- / --- (---)	86.1	0.2 (II-a)	0.1 (I-a)	-0.1 (V1-a)

Page 1 ViewPoint: ECS_joep

FIGURE 10-12 Trends List Report

10.2.2.15 Specifications of the Trends List Report

This section discusses the layout of the Trends List Report and the data that is included in the report.

Paper Orientation

The Trends List Report uses the Landscape paper orientation.

Header Information

The Trends List Report uses the standard report header with the "Trends List Report" header string.

Report Body

The Trends List Report displays 16 trends per page. The most current data is shown at the beginning of the report.

If multiple units of measurement can be used to measure the data in the report, the report will show the unit of measure for which the patient is configured. For information regarding the types of measurement available for each variable, See "System Alarm Limits and Ranges for Parameters" on page 10-24.

The following information is shown in the Digital Data section of the Trends List Report:

- A Date/Time column which shows data in the system date/time format.
- A HR column
- A NIBP column
- A SpO2 column
- A RESP column
- A CO_2 column
- A PVC column
- A P1 column
- A P2 column
- A T1 column
- A ST1 column and ECG lead for ST1

  The ST1 column in the Trends List Report will include a lead label in parentheses for the lead from which the displayed data is acquired. The labels that are available for ST1 lead include: I, II, III, avL, avR, avF, and V1.

- A ST2 column and ECG lead for ST2

  The ST2 column in the Trends List Report will include a lead label in parentheses for the lead from which the displayed data is acquired. The labels that are available for ST2 lead include: I, II, III, avL, avR, avF, and V1.

- A ST3 column and ECG lead for ST3

  The ST3 column in the Trends List Report will include a lead label in parentheses for the lead from which the displayed data is acquired. The labels that are available for ST3 lead include: I, II, III, avL, avR, avF, and V1.

- All ST lead labels in the Trends List Report include a tag that indicates if the ST measure is seen by the bedside monitor as a delta value (-d) or an absolute values (-a).

The Trends List Report will show dashes for all missing or invalid data and square brackets around alarming parameters.

Footer Information

The Trends List Report uses the standard report footer.

10.3 System Alarm Limits and Ranges for Parameters

*Patient Alarm Limits use System Alarm Limits as the default for new patients

CHOICES	PARAMETER	FACTORY DEFAULT	SELECTOR TYPE	COMMENTS
HR	**Adult:** OFF, 60 – 250 **Ped:** OFF, 100 – 300 **Neonate:** OFF, 100 – 350 **H**	OFF	Continuous slider 5 increment per press	Units beats/min, increment 5. Alarm limit is off at maximum position.
	Adult: OFF, 30 – 120 **Ped:** OFF, 30 – 150 **Neonate:** OFF, 30 – 200 **L**	OFF	Continuous slider 5 decrement per press	Units beats/min, increment 5. Alarm limit is off at minimum position.
NIBP Sys	**Adult:** OFF, 70 – 240 **Ped:** OFF, 40 – 180 **Neonate:** OFF, 40 – 180 H	**Adult:** OFF **Ped.:** OFF **Neonate:** OFF	Continuous slider increment by 5 per press	NIBP Systolic high limit in mm Hg. Alarm limit is off at maximum position.
	Adult: OFF, 50 – 150 **Ped:** OFF, 15 – 130 **Neonate:** OFF, 15 – 130 **L**	**Adult:** OFF **Ped.:** OFF **Neonate:** OFF	Continuous slider decrement by 5 per press	NIBP Systolic low limit in mm Hg. Alarm limit is off at minimum position.
NIBP Mean	**Adult:** OFF, 60 – 200 **Ped:** OFF, 50 – 180 **Neonate:** OFF, 40 – 160 **H**	**Adult: OFF Ped.: OFF Neonate: OFF**	Continuous slider increment by 5 per press	NIBP Mean arterial pressure high limit in mm Hg. Alarm limit is off at maximum position.
	Adult: OFF, 40 – 140 **Ped:** OFF, 10 – 100 **Neonate:** OFF, 10 – 70 **L**	**Adult:** OFF **Ped.:** OFF **Neonate:** OFF	Continuous slider decrement by 5 per press	NIBP Mean arterial pressure low limit in mm Hg. Alarm limit is off at minimum position.

CHOICES	PARAMETER	FACTORY DEFAULT	SELECTOR TYPE	COMMENTS
NIBP Dia	**Adult:** OFF, 40 – 130 **Ped:** OFF, 50 – 100 **Neonate:** OFF, 50 – 100 **H**	**Adult:** OFF **Ped.:** OFF **Neonate:** OFF	Continuous slider increment by 5 per press	NIBP Diastolic high limit in mm Hg. Alarm limit is off at maximum position.
	Adult: OFF, 30 – 120 **Ped:** OFF, 10 – 50 **Neonate:** OFF, 10 – 50 **L**	**Adult:** OFF **Ped.:** OFF **Neonate:** OFF	Continuous slider decrement by 5 per press	NIBP Diastolic low limit in mm Hg. Alarm limit is off at minimum position.
IBPx Sys	**Adult:** OFF, 5 – 300 **Ped:** OFF, 5 – 240 **Neonate:** OFF, 5 – 180 **H**	**Adult:** OFF **Ped.:** OFF **Neonate:** OFF	Continuous slider increment by 5 per press	IBP Systolic high limit in mm Hg. X is substituted with 1 or 2. Alarm limit is off at maximum position.
	Adult: OFF, 0 – 150 **Ped:** OFF, 0 – 130 **Neonate:** OFF, 0 – 130 **L**	**Adult:** OFF **Ped.:** OFF **Neonate:** OFF	Continuous slider decrement by 5 per press	IBP Systolic low limit in mm Hg. X is substituted with 1 or 2. Alarm limit is off at maximum position.
IBPx Mean	**Adult:** OFF, 5 – 150 **Ped:** OFF, 5 – 100 **Neonate:** OFF, 5 – 100 **H**	**Adult:** OFF **Ped.:** OFF **Neonate:** OFF	Continuous slider increment by 5 per press	IBP Mean high limit in mm Hg. X is substituted with 1 or 2. Alarm limit is off at maximum position.
	Adult: OFF, 2 – 100 **Ped:** OFF, 2 – 50 **Neonate:** OFF, 2 – 50 **L**	**Adult:** OFF **Ped.:** OFF **Neonate:** OFF	Continuous slider decrement by 2 per press	IBP Mean low limit in mm Hg. X is substituted with 1 or 2. Alarm limit is off at maximum position.
IBPx Dia	**Adult:** OFF, 0 – 140 **Ped:** OFF, 0 – 100 **Neonate:** OFF, 0 – 70 **H**	**Adult:** OFF **Ped.:** OFF **Neonate:** OFF	Continuous slider increment by 5 per press	IBP Diastolic high limit in mm Hg. X is substituted with 1 or 2. Alarm limit is off at maximum position.
	Adult: OFF, 0 – 120 **Ped:** OFF, 0 – 100 **Neonate:** OFF, 0 – 50 **L**	**Adult:** OFF **Ped.:** OFF **Neonate:** OFF	Continuous slider decrement by 5 per press	IBP Diastolic low limit in mm Hg. X is substituted with 1 or 2. Alarm limit is off at maximum position.

CHOICES	PARAMETER	FACTORY DEFAULT	SELECTOR TYPE	COMMENTS
SpO_2	**Adult:** OFF, 80 – 100 **Ped:** OFF, 80 – 100 **Neonate:** OFF, 80 – 100 **H**	**Adult:** OFF **Ped.:** OFF **Neonate:** OFF	Continuous slider increment by 1 per press	Units -%
	Adult: 50 – 99 **Ped:** 50 –99 **Neonate:** 50 – 99 **L**	**Adult:** 85 **Ped.:** 85 **Neonate:** 85	Continuous slider decrement by 1 per press	Units -%
T1	**°F** OFF, 95 – 110 **°C** OFF, 35 – 43 **H**	**°F** OFF **°C** OFF	Continuous slider increment by 1 per press	Temperature. Units – °F or °C.
	°F OFF, 80 – 100 **°C** OFF, 26 – 38 **L**	**°F** OFF **°C** OFF	Continuous slider decrement by 1 per press	Temperature. Units – °F or °C.
ST Single	OFF, +.5 – 10 **H**	OFF	Continuous slider increment by. 5 per press	Units mm **Note:** The ViewPoint Central Station will display an 'ST Single alarm' every time that its alarm limit boundaries have been violated for a period of thirty consecutive seconds. **Note:** The ViewPoint Central Station will generate a separate ST Single alarm for each lead of ST that independently violates the alarm.
	OFF, -.5 – (-)10 **L**	OFF	Continuous slider increment by.5 per press	Units mm

CHOICES	PARAMETER	FACTORY DEFAULT	SELECTOR TYPE	COMMENTS
ST Dual	OFF, .5 – 10 **H**	OFF	Continuous slider increment by.5 per press	Units mm **Note:** The ViewPoint Central Station will display an 'ST Dual alarm' every time that its alarm limit boundaries have been violated for a period of thirty consecutive seconds. **Note:** The ViewPoint Central Station will generate a separate ST Dual alarm for each pair of ST leads that violate the alarm.
	OFF, -.5 – (-)10 **L**	OFF	Continuous slider increment by .5 per press	Units mm
PVC	OFF, 1-30	OFF	Continuous slider increment by 1 per press	Units PVC's per min
Resp	**Adult:** OFF, 10 – 100 **Ped.:** OFF, 15 – 150 **Neonate:** OFF, 30 – 200 **H**	**Adult:** OFF **Ped.:** OFF **Neonate:** OFF	Continuous slider increment by 1 per press	Respiration. Units – RPM (respirations per minute)
	Adult: OFF, 5 – 30 **Ped.:** OFF, 5 – 40 **Neonate:** OFF, 5 – 50 **L**	**Adult:** OFF **Ped.:** OFF **Neonate:** 5	Continuous slider decrement by 1 per press	Respiration. Units – RPM (respirations per minute)
ET CO_2	OFF, 2.0 – 10.0%; OFF, 2 –10 kpa OFF, 20-80 mmHg **H**	5% 5 kpa 40 mmHg	Continuous slider increment by .5%, .5kpa, 5mmHg per press	Units%, kpa, mmhg
	OFF, 1.0 – 6.0%; OFF, 1 – 6 kpa OFF, 5-50 mmHg **L**	OFF OFF OFF	Continuous slider increment by .5% per press	Units %, kpa, mmhg

CHOICES	PARAMETER	FACTORY DEFAULT	SELECTOR TYPE	COMMENTS
CO_2	OFF, 1 – 4% OFF, 1 – 4 kpa OFF, 5-30 mmHg	1%; 1.0 kpa 10 mmHg	Continuous slider increment by .5%, .5kpa, 5mmHg per press	Units %, kpa, mmhg
	Adult: 10 – 60 **Ped:** 10-20 Neonate: 10-20	**Adult:** 30 **Ped:** 15 **Neonate:** 15	Continuous slider increment by 1 sec per press	Units seconds
	OFF, 4 – 8	4	Continuous slider increment by 1 per press	Units Ventricular beats

10.4 Unit Priorities System Defaults

PARAMETER NUMBER	PARAMETER LABEL
1	HR
2	ST Alarm (single)
3	ST Alarm (dual)
4	NIBP
5	SpO_2
6	RESP
7	CO_2
8	PVC
9	P1
10	P2
11	T1
12	Arrhythmia Run (alarm only)
14	Apnea Delay (alarm only)
14	ST1 (parameter only)
15	ST2 (parameter only)
16	ST3 (parameter only)

CAUTION: The Passport 2 should be disconnected from the patient when changing the CO_2 units of measurement.

10.5 System Installation Table

FILE FOLDER TAB	FIRST LEVEL	SECOND LEVEL	THIRD LEVEL
Volume	Touch -click with a slide bar ranging from off to maximum		
	Physiological Alarm - with a slide bar going from min. to max.		
	System Alarm - with a slide bar going from min to max.		
	Physiological Alarm Volume time range presets. (allows volume to be set to different volume levels at three different times daily)	0:00 to 23:59	slide bar going from min to max.
System Alarms	System Alarm Options	Latched Alarm (If latched alarms are enabled here, all alarms will be latched and the option to turn this function on or off for an individual patient will not be available.)	ON – this indicates that the user must acknowledge the alarm before it will reset. OFF – the alarm will automatically reset when the alarm condition stops.
		Show HR Limits in Tile	ON OFF
		Mute Duration (sec.)	10, 15, 30, 45, 60, 120
		Technical Event Sounds	ON OFF
		Password Protection	ON OFF

FILE FOLDER TAB	FIRST LEVEL	SECOND LEVEL	THIRD LEVEL
System Alarms (cont.)		Bedside Alarms Tracking	ON-Alarms at the ViewPoint Central Station track bedside OFF-Alarms at the ViewPoint Central Station independent of bedside
	System Alarm Responses (the user can set these response for each parameter being monitored and for the arrhythmia alarms)	Severity Level Asystole, V-Tach and V-FIB are always severity level one alarms	1 2 3
		Print On Alarm	ON OFF
		Freeze on Alarm	ON OFF
		Alarm Delay	0 seconds
	System Alarm Limits	See "System Alarm Limits and Ranges for Parameters" on page 10-24.	
	Restore Previous Settings	Momentary contact	
	Restore Factory Settings	Momentary contact	
Passwords	Alarm	Change	Keyboard, Done button
	System	Change	Keyboard, Done button
Equipment Setup Assign equipment to tile location Find all Equip.	Scrolling List Add/Edit, Delete	Alphanumeric keyboard (enter serial # of equipment), Clear button	Tile location #
Date/Time	Date	Yyyy-mm-dd dd-mm-yyyy mm-dd-yyyy	
	Time	AM/PM hh:mm h:mm:ss 24hh:mm 24hh:mm:ss	
	Date/Time Set	Date	-Year -Month -Day (with scroll arrow up & down)
		Time	-Hour -Min -Sec (with scroll arrow up & down)
Recalibrate Touch Screen	Momentary contact		
More	Momentary contact		
Previous	Momentary contact		

FILE FOLDER TAB	FIRST LEVEL	SECOND LEVEL	THIRD LEVEL
Unit Priorities	Priority/Parameter	See "Unit Priorities System Defaults" on page 10-29.	
	Restore previous settings		
	Restore factory default		
Unit Choices	Demographic Line - Position 1	Last Name, First Name, Rm, Bed, ID, OFF	
	Demographic Line - Position 2	Last Name, First Name, Rm, Bed, ID, OFF	
	Demographic Line - Position 3	Last Name, First Name, Rm, Bed, ID, OFF	
	Demographic Line - Position 4	Last Name, First Name, Rm, Bed, ID, OFF	
	Demographic Line - Position 5	Last Name, First Name, Rm, Bed, ID, OFF	
	Enable in View Mode	Yes No	
	Done	Momentary Contact	
Parameter Color	ECG color - (In all cases, the colors must be contrasting - the user can never set the colors for blue on blue)	Green Light Green Purple Light Purple Red Light Red Orange Yellow Blue Light Blue White Turquoise	
	SpO2 color	Green Light Green Purple Light Purple Red Light Red Orange Yellow Blue Light Blue White Turquoise	

FILE FOLDER TAB	FIRST LEVEL	SECOND LEVEL	THIRD LEVEL
Parameter Color	NIBP color	Green Light Green Purple Light Purple Red Light Red Orange Yellow Blue Light Blue White Turquoise	
	P1	Green Light Green Purple Light Purple Red Light Red Orange Yellow Blue Light Blue White Turquoise	
	P2	Green Light Green Purple Light Purple Red Light Red Orange Yellow Blue Light Blue White Turquoise	
	PVC color	Green Light Green Purple Light Purple Red Light Red Orange Yellow Blue Light Blue White Turquoise	

10.6 Alarm Messages

ALARM MESSAGE TYPE	DISPLAY LOCATION	MESSAGE TEXT	COMMENTS
Lethal Arrhythmia: Asystole message	Patient Demographic line	Asystole	Toggles on line with patient demographics
Lethal Arrhythmia: Ventricular Tachycardia message	Patient Demographic line	V-Tach	Toggles on line with patient demographics
Lethal Arrhythmia: Ventricular Fibrillation message	Patient Demographic line	V-Fib	Toggles on line with patient demographics
Non-Critical Arrhythmia: Bigeminy message	Patient Demographic line	VBigeminy	Toggles on line with patient demographics
Non-Critical Arrhythmia: Couplet message	Patient Demographic line	Couplet	Toggles on line with patient demographics
Non-Critical Arrhythmia: Irregular Heart Rate message	Patient Demographic line	Irregular HR	Toggles on line with patient demographics
Non-Critical Arrhythmia: Paused/Missed Beat message	Patient Demographic line	Missed Beat	Toggles on line with patient demographics
Non-Critical Arrhythmia: PVC Run message	Patient Demographic line	Run	Toggles on line with patient demographics
Non-Critical Arrhythmia: Trigeminy message	Patient Demographic line	Trigeminy	Toggles on line with patient demographics
Non-Critical Arrhythmia: Triplet message	Patient Demographic line	Triplet	Toggles on line with patient demographics
Parameter Threshold violation PVC's/minute	Patient Demographic line	High PVC	Toggles on line with patient demographics
Respiration Apnea message	Patient Demographic line	Apnea	Toggles on line with patient demographics
High Heart Rate Alarm message	Patient Demographic line	High Heart Rate Alarm	Toggles on line with patient demographics
High Respiration Rate Alarm Message	Patient Demographic line	High Respiration Rate Alarm	Toggles on line with patient demographics
High Temperature 1 Alarm Message	Patient Demographic line	High Temperature 1 Alarm	Toggles on line with patient demographics
High SpO_2 Alarm Message	Patient Demographic line	High SpO_2 Alarm	Toggles on line with patient demographics
High IBP1 Systolic Alarm Message	Patient Demographic line	High IBP1 Systolic Alarm	Toggles on line with patient demographics
High IBP1 Diastolic Alarm Message	Patient Demographic line	High IBP1 Diastolic Alarm	Toggles on line with patient demographics
High IBP1 Mean Alarm Message	Patient Demographic line	High IBP1 Mean Alarm	Toggles on line with patient demographics
High IBP2 Systolic Alarm Message	Patient Demographic line	High IBP2 Systolic Alarm	Toggles on line with patient demographics
High IBP2 Diastolic Alarm Message	Patient Demographic line	High IBP2 Diastolic Alarm	Toggles on line with patient demographics
High IBP2 Mean Alarm Message	Patient Demographic line	High IBP2 Mean Alarm	Toggles on line with patient demographics

ALARM MESSAGE TYPE	DISPLAY LOCATION	MESSAGE TEXT	COMMENTS
High NIBP Systolic Alarm Message	Patient Demographic line	High NIBP Systolic Alarm	Toggles on line with patient demographics
High NIBP Diastolic Alarm Message	Patient Demographic line	High NIBP Diastolic Alarm	Toggles on line with patient demographics
High NIBP Mean Alarm Message	Patient Demographic line	High NIBP Mean Alarm	Toggles on line with patient demographics
High CO_2 Inspired Alarm Message	Patient Demographic line	High CO_2 Inspired Alarm	Toggles on line with patient demographics
High CO_2 ET Alarm Message	Patient Demographic line	High CO_2 ET Alarm	Toggles on line with patient demographics
Low Heart Rate Alarm Message	Patient Demographic line	Low Heart Rate Alarm	Toggles on line with patient demographics
Low Respiration Rate Alarm Message	Patient Demographic line	Low Respiration Rate Alarm	Toggles on line with patient demographics
Low Temperature 1 Alarm Message	Patient Demographic line	Low Temperature 1 Alarm	Toggles on line with patient demographics
Low SpO_2 Alarm Message	Patient Demographic line	Low SpO_2 Alarm	Toggles on line with patient demographics
Low IBP1 Systolic Alarm Message	Patient Demographic line	Low IBP1 Systolic Alarm	Toggles on line with patient demographics
Low IBP1 Diastolic Alarm Message	Patient Demographic line	Low IBP1 Diastolic Alarm	Toggles on line with patient demographics
Low IBP1 Mean Alarm Message	Patient Demographic line	Low IBP1 Mean Alarm	Toggles on line with patient demographics
Low IBP2 Systolic Alarm Message	Patient Demographic line	Low IBP2 Systolic Alarm	Toggles on line with patient demographics
Low IBP2 Diastolic Alarm Message	Patient Demographic line	Low IBP2 Diastolic Alarm	Toggles on line with patient demographics
Low IBP2 Mean Alarm Message	Patient Demographic line	Low IBP2 Mean Alarm	Toggles on line with patient demographics
Low NIBP Systolic Alarm Message	Patient Demographic line	Low NIBP Systolic Alarm	Toggles on line with patient demographics
Low NIBP Diastolic Alarm Message	Patient Demographic line	Low NIBP Diastolic Alarm	Toggles on line with patient demographics
Low NIBP Mean Alarm Message	Patient Demographic line	Low NIBP Mean Alarm	Toggles on line with patient demographics
Low CO_2 ET Alarm Message	Patient Demographic line	Low CO_2 ET Alarm	Toggles on line with patient demographics
Bedside Heart Rate Alarm Message	Patient Demographic line	Bedside Heart Rate Alarm	Toggles on line with patient demographics
Bedside Respiration Rate Alarm Message	Patient Demographic line	Bedside Respiration Rate Alarm	Toggles on line with patient demographics
Bedside Temperature 1 Alarm Message	Patient Demographic line	Bedside Temperature 1 Alarm	Toggles on line with patient demographics
Bedside SpO_2 Alarm Message	Patient Demographic line	Bedside SpO_2 Alarm	Toggles on line with patient demographics
Bedside IBP1 Systolic Alarm Message	Patient Demographic line	Bedside IBP1 Systolic Alarm	Toggles on line with patient demographics

ALARM MESSAGE TYPE	DISPLAY LOCATION	MESSAGE TEXT	COMMENTS
Bedside IBP1 Diastolic Alarm Message	Patient Demographic line	Bedside IBP1 Diastolic Alarm	Toggles on line with patient demographics
Bedside IBP1 Mean Alarm Message	Patient Demographic line	Bedside IBP1 Mean Alarm	Toggles on line with patient demographics
Bedside IBP2 Systolic Alarm Message	Patient Demographic line	Bedside IBP2 Systolic Alarm	Toggles on line with patient demographics
Bedside IBP2 Diastolic Alarm Message	Patient Demographic line	Bedside IBP2 Diastolic Alarm	Toggles on line with patient demographics
Bedside IBP2 Mean Alarm Message	Patient Demographic line	Bedside IBP2 Mean Alarm	Toggles on line with patient demographics
Bedside NIBP Systolic Alarm Message	Patient Demographic line	Bedside NIBP Alarm	Toggles on line with patient demographics
Bedside NIBP Diastolic Alarm Message	Patient Demographic line	Bedside NIBP Diastolic Alarm	Toggles on line with patient demographics
Bedside NIBP Mean Alarm Message	Patient Demographic line	Bedside NIBP Mean Alarm	Toggles on line with patient demographics
Bedside CO_2 Inspired Alarm Message	Patient Demographic line	Bedside CO_2 Inspired Alarm	Toggles on line with patient demographics
Bedside CO_2 ET Alarm Message	Patient Demographic line	Bedside CO_2 ET Alarm	Toggles on line with patient demographics
Bedside PVC Alarm Message	Patient Demographic line	Bedside PVC Alarm	Toggles on line with patient demographics
IBP1 Not Calibration/ Zeroed Message	Patient Demographic line	IBP1 Not Calibration/ Zeroed	Toggles on line with patient demographics
IBP2 Not Calibration/ Zeroed Message	Patient Demographic line	IBP2 Not Calibration/ Zeroed	Toggles on line with patient demographics
ST Single Alarm Message	Patient Demographic line	ST Single Alarm	Toggles on line with patient demographics
ST Dual Alarm Message	Patient Demographic line	ST Dual Alarm	Toggles on line with patient demographics
Bedside ST Alarm Message	Patient Demographic line	Bedside ST Alarm	Toggles on line with patient demographics

10.7 ViewPoint Central Station Messages

MESSAGE TYPE	DISPLAY LOCATION[1]	MESSAGE TEXT[2]
Printer not selected or unavailable	Status Message Line	No Printer Selected or Available*
Bedside Alarm	Patient Tile	Alarm at Bedside
Lead Off	Patient Tile	XX Lead Off (XX is the lead identifier)
RL Lead Off	Patient Tile	Cycle through all Lead Off Messages
No signal	Patient Tile	Communication Lost
Printer paper jam	Status Message Line	Printer in offline state * **
Printer out of paper	Status Message Line	Printer Out of Paper * **
Printer door open	Status Message Line	Printer in offline state * **
Toner Low	Status Message Line	Printer Toner Level is Low * **
Sensor not plugged in	Patient Tile	SpO_2 No Sensor
Sensor failed	Patient Tile	SpO_2 Sensor Failed
Board failed	Patient Tile	SpO_2 Board Fault
Sensor Off	Patient Tile	SpO_2 Sensor Off
Interference	Patient Tile	SpO_2 Interference
Pulse search	Patient Tile	SpO_2 Pulse Search
No Pulse	Patient Tile	SpO_2 No Pulse
Check Sensor	Patient Tile	SpO_2 Check Sensor
System Check	Patient Tile	SpO_2 System Check
Motion	Patient Tile	SpO_2 Motion
Weak Pulse	Patient Tile	SpO_2 Weak Pulse
Low Perfusion	Patient Tile	SpO_2 Low Perfusion
Too Much Light	Patient Tile	SpO_2 Too Much Light
Unrecognized Sensor	Patient Tile	SpO_2 Unrecognized Sensor
Unrecognized Cable	Patient Tile	SpO_2 Unrecognized Cable
Communication Error	Patient Tile	SpO_2 Communication Error
Motion and No Pulse (Motion Alarm)	Patient Tile	SpO_2 Motion Alarm
Bad 5V Power Supply	Patient Tile	SpO_2 Failure
Bad Positive 15V Power Supply	Patient Tile	SpO_2 Failure
Bad Negative 15V Power Supply	Patient Tile	SpO_2 Failure
Alarms Suspended	Patient Tile	Alarms Suspended *
Alarms Muted for Parameter	Patient Tile	Alarms muted for XX:XX *
Printer Out of Paper	Patient Tile	Printer Out of Paper
Printer Offline and Report requested	Status Message Line	Printer in offline state * **
IBP, CO_2, NIBP Messages	Patient Tile	Not Calibrated/Zeroed XX (XX is the parameter type)
NIBP Error	Patient Tile	NIBP Cuff Overpressure
NIBP Error	Patient Tile	NIBP Unable to Measure [3]
NIBP Retry	Patient Tile	NIBP Retry

MESSAGE TYPE	DISPLAY LOCATION[1]	MESSAGE TEXT[2]
NIBP Pump Higher	Patient Tile	NIBP Pump Higher
Printer Door Open	Patient Tile	Printer Door is Open
Communications between the *Passport 2*® and ViewPoint are lost	Patient Tile	Communications Lost
Patient placed in standby when location is selected	Patient Tile	Standby XX (XX is the standby location) *
Patient placed in standby when location is not selected	Patient Tile	Standby *
Time or Date change	Patient Tile	Clock Adjusted *
Patient in standby	Event List	Standby *
Patient taken out of standby	Event List	UnStandby *
Admitted patient	Event List	Admit *
Discharged patient	Event List	Discharge *
Title to tile transfer	Event List	Central Transfer *
Transferred patients	Event List	Transfer *
CVA condition	Patient Tile	Respiration CVA Present
Low Battery	Patient Tile	Battery Low
Nurse Call (Telepack)	Event List Patient Tile	Nurse Call
Attendant Present (Telepack)	Event List Patient Tile	Attendant Present

NOTE: 1 System and Technical events (except those marked*) have audible sound. See "Technical Events/System Events" on page 5-19.

NOTE: 2 After the message text the sensor name will appear for that message type.

NOTE: 3 The "unable to measure" message will persist until a valid measurement is obtained.

NOTE: * Message text that is marked with a single asterisk (*) does not have an audible sound.

NOTE: ** Message text that is marked with a double asterisk (**) is not displayed when print sharing is used. For additional information see the ViewPoint Central Monitoring System, Printer Configuration Manual (0070-00-0561).

10.8 Alarm Responses for Parameters

Patient Alarm Responses use System Responses as the default for new patients.

Factory settings underlined and used until System Alarms Responses are initiated.

PARAMETER	LEVEL	PRINT ON ALARM	FREEZE ON ALARM	ALARM DELAY	SAVE TO EVENT
HR	1,2	ON, OFF	ON, OFF	0	ON, OFF
Asystole	1	ON, OFF	ON, OFF	0	ON, OFF
V Fibrillation	1	ON, OFF	ON, OFF	0	ON, OFF
V Tachycardia	1	ON, OFF	ON, OFF	0	ON, OFF
Couplet	2, 3	ON, OFF	ON, OFF	0	ON, OFF
Triplet	2, 3	ON, OFF	ON, OFF	0	ON, OFF
Run	2, 3	ON, OFF	ON, OFF	0	ON, OFF
Bigeminy	2, 3	ON, OFF	ON, OFF	0	ON, OFF
Trigeminy	2, 3	ON, OFF	ON, OFF	0	ON, OFF
Irregular Heart Rate	2, 3	ON, OFF	ON, OFF	0	ON, OFF
Missed Beats	2, 3	ON, OFF	ON, OFF	0	ON, OFF
PVC	2, 3	ON, OFF	ON, OFF	0	ON, OFF
NIBP	2, 3	ON, OFF	ON, OFF	0	ON, OFF
P1	2, 3	ON, OFF	ON, OFF	0	ON, OFF
P2	2, 3	ON, OFF	ON, OFF	0	ON, OFF
SpO_2	2, 3	ON, OFF	ON, OFF	0	ON, OFF
T1	2, 3	ON, OFF	ON, OFF	0	ON, OFF
Resp.	2, 3	ON, OFF	ON, OFF	0	ON, OFF
CO2, Insp. CO2	2, 3	ON, OFF	ON, OFF	0	ON, OFF
ST Single	2, 3	ON, OFF	ON, OFF	0	ON, OFF
ST Dual	2, 3	ON, OFF	ON, OFF	0	ON, OFF
Apnea	2, 3	ON, OFF	ON, OFF	0	ON, OFF

10.9 Pacer Filtration and Enhancement

FILTRATION*	ENHANCE*	EFFECT ON ECG SIGNAL DISPLAYED ON VIEWPOINT CENTRAL STATION
OFF	OFF	The ECG signal is displayed without any modification for pacers.
OFF	ON	Enhanced pacer is displayed without filtering pacer signal from ECG.
ON**	OFF	The ECG signal is displayed with pacers filtered out. No enhanced pacer is added to the ECG signal.
ON**	ON	Pacer is filtered out of the ECG signal and an enhanced pacer is displayed in its place.

* *These effects are used for display only. There is no effect on full disclosure.*

* * *Any selection other than OFF will allow filtration to operate as long as pace status is set for a waveform sample.*

10.10 Patient Setup Menu Table

MENU	FILE FOLDERS	FIRST LEVEL CHOICES	SECOND LEVEL	DEFAULTS
Patient Set-up:	Parameter Display	ECG Lead	I, II, III, AVR, AVL, AVF, V	Lead II
		Waveform 2	I, II, III, AVR, AVL, AVF, V IBP – 1 IBP – 2 Pleth Resp. CO_2 OFF	OFF
		Parameter 1	HR	HR
		Parameter 2	Resp T1 SpO_2 IBP 1 IBP 2 NIBP CO_2 PVC OFF ST1 ST2 ST3	default will be unit priority
		Parameter 3	Same as above	default will be unit priority
		Parameter 4	Same as above	default will be unit priority
		Parameter 5	Same as above	Default will be unit priority
		Pacer	ON/OFF	ON

MENU	FILE FOLDERS	FIRST LEVEL CHOICES	SECOND LEVEL	DEFAULTS
Patient Set-up:	Wave Gain	ECG mm/mV	2.5, 5.0, 10.0, 20.0, 30.0	10.0
		Pacer filter	0ms, 10ms, 20ms, 30ms, 40ms, 50ms, 60ms, 70ms, 80ms	40ms
		P1 mm Hg/cm	-10 to 10 0 to 20 0 to 40 60 to 140 0 to 80 0 to 160 0 to 320	0 to 320
		P2 mm Hg/cm	Same as P1	0 to 320
		Resp. Gain	1, 2, 3, 4,5	1
		CO_2 Gain	5, 7.5, 10.0	10%
		Reset Wave Gain	Button (momentary contact)	
	Standby	Retrieve Patient Location	List of patient locations; Standby, Cath lab, X-Ray, Therapy, Bath, OR, ER, In Transit	Standby

NOTE: **Any change in the Patient Setup menu is immediately seen as a change in the patient tile.**

10.11 Patient Demographics and Admission

SUB-MENU BUTTON	FIRST LEVEL	TOGGLE CHOICES
Admit/Edit (Changes to "Edit" button automatically once patient is admitted)	Last name	• Alphanumeric keyboard • 15 characters maximum (data entry) • 15 characters maximum displayed (Admit/Edit screen) • 15 characters maximum (Normal display) • (Default = Blank)
	First name	• Alphanumeric keyboard • 15 characters maximum (data entry) • 15 characters maximum displayed (Admit/Edit screen) • 15 characters maximum (Normal display) • (Default = no data)
	ID #	• Alphanumeric keypad • 15 characters maximum • (Default = no data)
	Bed	• Alphanumeric keypad • 7 characters maximum • (Default -)
	Age	• Numeric keypad • 3 characters maximum • (years 0-150) • (Default = no data)
	Height	• Numeric keypad • 3 characters maximum • (20-305 cm / 8-120 in (default) • (Default value = no data)
	Weight	• Numeric keypad • 4 characters maximum • (1-1100 lbs (default) / 1-500 kgs) (Default value = no data)

SUB-MENU BUTTON	FIRST LEVEL	TOGGLE CHOICES
Admit/Edit (Changes to "Edit" button automatically once patient is admitted)	Room	• Alphanumeric keypad • 7 characters maximum • (Default -)
	Doctor	• Alphanumeric keypad • 15 characters maximum • (Default = no data)
	Patient Size	• This is received from the connected device and cannot be edited
	Other - free form text. type in age, date of birth, allergies, diagnosis....	• Alphanumeric keypad • 15 characters maximum • (Default = no data)
	Pacer Enhancement	• ON (Default) • OFF
	Retrieve from Bedside	• Patient alarm settings
	Retrieve Discharged Patient	• List of last 5 patients discharged. Retrieves selected patient and patient settings (Alarm Settings, Wave Gain, Parameter Display, etc.)
	Send to Bedside	• Demographic information

11.0 *ViewPoint Telepack 2.4*

The ViewPoint Telepack 2.4 (hereafter referred to as, Telepack) is a battery powered ambulatory device that acquires ECG information from a patient and transmits it to the ViewPoint Server for analysis. The ViewPoint Server is capable of performing data analysis functions such as Heart Rate determination. This information is then sent to the ViewPoint Central Station.

Figure 11-1 shows a sample illustration of the Telepack device.

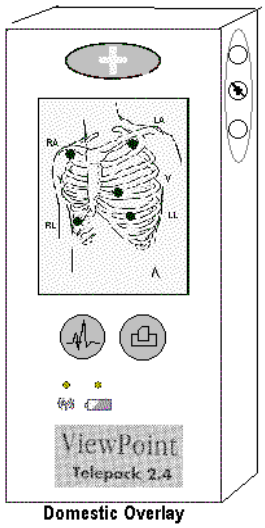


FIGURE 11-1 ViewPoint Telepack 2.4

WARNING: The ViewPoint Telepack 2.4 is a telemetry system and hence prone to intermittent signal dropout. Therefore, use the telepack monitoring only on the patients whose conditions tolerate intermittent monitoring interruptions.

The Telepack is controlled through the use of various buttons which are located on the front and side of the device. The status of the unit is shown via LED indicator lights. The Telepack will not turn off unless the batteries are removed from the unit or the batteries need to be replaced. The following are the key features of the Telepack:

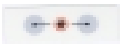
- Bi-directional data transmission (between ambulatory patient and ViewPoint Central Station) using wireless communication technology in the ISM band
- Functions such as Nurse call, Attendant present, Remote print and Lead/Battery/Link tests are performed easily via buttons
- LED indicator lights are used to indicate link status, battery status and ECG lead connection status
- 5 Lead ECG support

CAUTION: Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the ViewPoint Telepack 2.4 equipment.

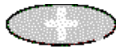
11.1 Telepack Buttons and Indicators

The Telepack device has buttons and LED indicators that control the usage of the device.

The Telepack uses buttons to manipulate its functionality. The following buttons are found on the Telepack device:

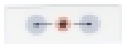
- one **NURSE CALL**  button
- two **ATTENDANT PRESENT**  buttons
- one **TEST**  button
- one **PRINT**  button

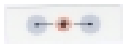
11.1.1 Nurse Call Button

The Telepack's Nurse Call  button is used to request the presence of a nurse.

- Pressing the **Nurse Call**  button on the Telepack displays a message on the ViewPoint Central Station to indicate that the Nurse Call button has been pressed.

11.1.2 Attendant Present Buttons

The Telepack's Attendant Present  buttons are used to indicate the presence of a clinician at the patient's bedside.

- Pressing the **Attendant Present**  buttons simultaneously displays a message on the ViewPoint Central Station indicating that the Attendant Present buttons have been pressed.

11.1.3 Test Button

The Telepack has a Test  button for testing the functionality of the ECG Lead connection, Link Status, and Battery Status LED indicator lights.

For information on interpreting the status of the ECG Lead, Link Status and Battery Status LED indicator lights, see the following sections: "Interpreting ECG LED Indicator Lights" on page 11-5, "Interpreting Link Status LED Indicator Lights" on page 11-5 and "Interpreting Battery Status LED Indicator Lights" on page 11-6.

11.1.4 Print Button

The Telepack has a Print  button for the remote printing of an All Strips report at the ViewPoint Central Station.

- Pressing the **Print**  button on the Telepack results in the printing of an 'All Strips' report if a printer is attached to the ViewPoint Central Station.

11.1.5 Telepack Indicator Lights

The Telepack uses LED indicator lights for testing the functionality of the Telepack device. The indicator lights on the Telepack device include the following:

- 5 ECG lead indicator lights
- 1 Link Status indicator light
- 1 Battery Status indicator light

11.1.5.1 ECG Lead Diagram LED Indicator Lights

The Telepack ECG Lead Diagram's LED indicator lights show the status of the lead connections with the patient.

The Figure 11-2 illustrates the front of the device with the ECG LED Lead indicator lights.

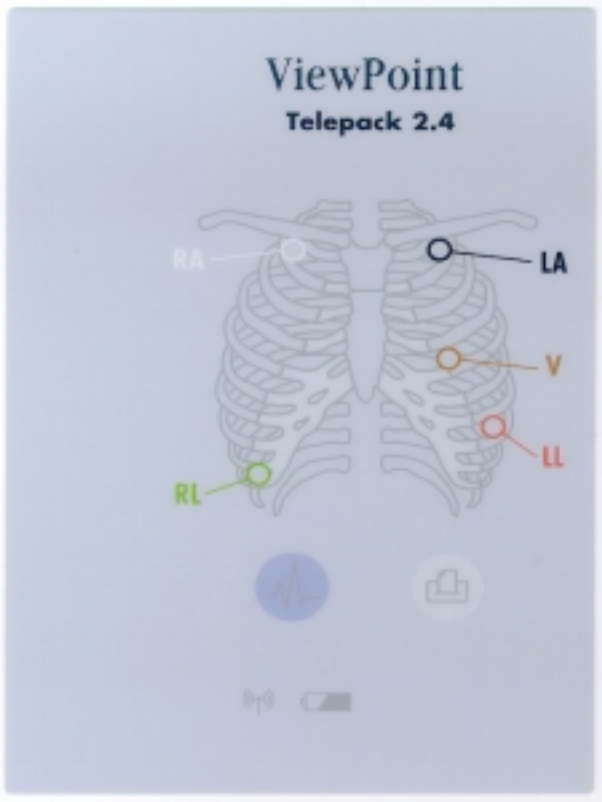


FIGURE 11-2 Front View of Telepack

- The Telepack's ECG LED Lead indicator lights (Figure 11-2), includes a green LED indicator light that corresponds to the white RA (right arm) lead connection.
- The Telepack's ECG LED Lead indicator lights (Figure 11-2), includes a green LED indicator light that corresponds to the black LA (left arm) lead connection.
- The Telepack's ECG LED Lead indicator lights (Figure 11-2), includes a green LED indicator light that corresponds to the brown V (chest) lead connection.

- The Telepack's ECG LED Lead indicator lights (Figure 11-2), includes a green LED indicator light that corresponds to the green RL (right leg) lead connection.
- The Telepack's ECG LED Lead indicator lights (Figure 11-2), includes a green LED indicator light that corresponds to the red LL (left leg) lead connection.

The ECG Lead LED indicator lights will remain OFF except during the initial power up phase and during a lead test sequence.

11.1.5.1.1 Interpreting ECG LED Indicator Lights

Pressing the **Test** button will test the Telepack's ECG lead connections.

The Telepack's ECG Lead LED indicator lights show the results of the ECG Lead connections test. The results can be interpreted as follows:

- The Telepack's ECG Lead LED indicator lights will remain on for approximately 10 seconds during a test sequence.
- A steadily lit ECG LED indicator light indicates that the Telepack has good lead connectivity.
- An unlit ECG LED indicator light indicates that the Telepack has poor or no lead connectivity.

11.1.5.2 Link Status LED Indicator Light

The Telepack Link Status LED indicator light is used to test the Telepack's connection status to the ViewPoint Central Monitoring Network.

- The Link Status LED indicator light will remain off except during the initial power up phase or during a TEST sequence.

Figure 11-3 shows the Link Status Indicator Light.

FIGURE 11-3 Link Status Indicator Light

11.1.5.2.1 Interpreting Link Status LED Indicator Lights

Pressing the **Test** button will test the Telepack's link status with the wireless network.

The Telepack's Link Status LED indicator light show the results of the link status test. The results can be interpreted as follows:

- The Telepack's Link Status LED indicator light will remain on for approximately 10 seconds during a test sequence.
- A flashing Link Status LED indicator light indicates that the Telepack's radio signal is in range with the wireless network, but not connected to the ViewPoint Central Station.
- A steadily lit Link Status LED indicator light indicates that the Telepack is successfully connected to a ViewPoint server.
- An unlit Link Status LED indicator light indicates that the Telepack's radio signal is out of range with the wireless network. Simultaneously, the message "Communication Lost" is displayed on the patient tile in the ViewPoint Central Station. Refer to the section "Usability Range" on page 11-11 for more information.

11.1.5.3 Battery Status LED Indicator Light

The Telepack 2.4 Battery Status LED indicator light is used to test the status of the Telepack's batteries.

- The Battery Status LED indicator light will remain OFF except during the initial power up phase or during a TEST sequence.

Figure 11-4 shows the Battery Status Indicator Light.

FIGURE 11-4 Battery Status Indicator Light

11.1.5.3.1 Interpreting Battery Status LED Indicator Lights

Pressing the Telepack's **Test** button will test the Telepack's battery status.

The Telepack's Battery Status LED indicator light shows the results of the battery status test. The results can be interpreted as follows:

- The Telepack's Battery Status LED indicator light will remain on for approximately 10 seconds during a test sequence.
- A steadily lit Battery Status LED indicator light indicates that the batteries in the Telepack are good.
- A flashing Battery Status LED indicator light indicates that the batteries in the Telepack are weakening and should be replaced soon.
- An unlit Battery Status LED indicator light indicates that the batteries in the Telepack should be replaced immediately.

NOTE: **The used alkaline batteries may be subject to local regulations regarding disposal. At the end of the battery life, do not dispose the batteries in fire but dispose of the batteries in accordance with any local regulations.**

11.2 Detailed Operating Instructions

This section of the Operating Instructions provides information on how to set up and program the Telepack device with the ViewPoint Central Station and also on how to secure the Telepack device to the patient and maintain the device.

This information is provided in two sections.

- The section ("Initial Setup of Telepack or First Time Set up of Telepack" on page 11-7) consists of instructions which is to be performed only once to set up the Telepack device. This is performed by Datascope authorized personnel.
- The section ("Using the Telepack device" on page 11-10) consists of instructions for the normal usage of the Telepack device.

The ViewPoint Central Station system should be installed and running before you begin to set up the Telepack device.

11.2.1 Initial Setup of Telepack or First Time Set up of Telepack

The following are the items that will be needed to initially set up and program the Telepack:

- Telepack 2.4 device
- 2 AA size Alkaline batteries
- Telepack Service Mode Cable

11.2.1.1 Powering on the Telepack device

The following instructions should be followed to power up the Telepack device. After the device is powered up, the Telepack device should be programmed and assigned before the Telepack device can be secured to the patient.

- Connect the Telepack service mode cable from the ViewPoint Central Station (it should be connected to the serial port on the right rear of the ViewPoint Central Station) into the serial port provided on the bottom of the Telepack device.

Inserting/Removing batteries

- Insert the 2 AA size alkaline batteries in the Telepack battery compartment. The positive end of each battery should be facing towards you. Use the label on the back of the Telepack as a guide. Secure the end cap by twisting it in the clockwise direction firmly. Improper insertion of batteries into the battery compartment may cause damage to the Telepack unit. This is the method by which the Telepack device powers up.

The Figure 11-5 illustrates the back of the device and the indication for the battery orientation.

WARNING: Visually inspect the battery compartment for any foreign object. A conductive object could cause the battery and battery compartment to overheat, resulting in burns to the patient and to the attendant removing the battery when the conductive object makes contact with the battery contacts.

WARNING: The Telepack may fail to operate if a foreign object blocks the battery contact resulting in the failure to transmit data.

CAUTION: The ViewPoint Telepack 2.4 unit may not function if the batteries installed in the device are corroded.

WARNING: Do not recharge the batteries, put in backwards, mix with used or other battery types. This may cause the batteries to explode or leak and cause personal injury.

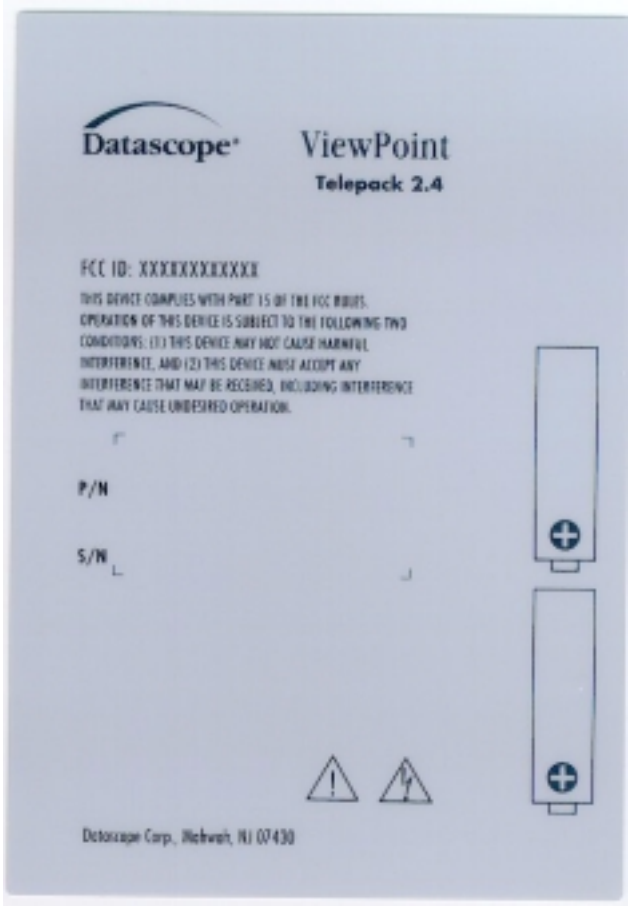


FIGURE 11-5 Back View of the Telepack

Wait for the Telepack device to power up.

The batteries should be removed from the battery compartment and then the Telepack device should be stored. This is the method by which the Telepack device powers off. See "Storing the Telepack" on page 11-11. for more information on how to store the device.

11.2.1.2 Telepack Power Up Sequence

The Telepack goes through a power up sequence each time the batteries are put in the device. The power up sequence includes an ECG Lead Connection Status test, a Link Status test, and a Battery Status test. A successful power up sequence is established when the LED Indicator lights turn on and then off.

For additional information on the status tests performed by the Telepack during the power up sequence see the section for the "Test Button" on page 11-3.

After the Telepack device powers up, you should program and then assign the Telepack to the patient using the ViewPoint Central Station, Equipment Setup tab. These operations are described in the following two sections.

NOTE: Programming and assigning of the ViewPoint Telepack 2.4 is required to be done only once for each device. This process is to be performed by authorized service personnel only.

11.2.1.3 Programming the Telepack

CAUTION: The ViewPoint Telepack 2.4 device should not be attached to the patient when the device is being programmed into the system.

After the Telepack device powers up, you should program the Telepack device in the 'Telepack' tab of the ViewPoint Central Station.

See the section "File Folder Tab: Telepack" on page 3-14 in Chapter 3 for details on the Telepack Tab and the fields in the ViewPoint Central Station.

The process to program the Telepack device is described below:

- Press the 'Read' button on the right in the Telepack Tab screen in the ViewPoint Central Station. The information from the Telepack device is read and displayed in the appropriate fields.
- Modify the information in the fields if required. Telepack IP, Wireless Server IP, Subnet Mask and Network Name are the fields that can be modified.
- Press the 'Program' button on the right in the Telepack Tab screen in the ViewPoint Central Station. The information is now programmed into the Telepack device.

If the Telepack device is not connected properly or if the ViewPoint Central Station is unable to detect the device, the error message 'Error Could not receive data' is displayed on the ViewPoint Central Station.

11.2.1.4 Assigning the Telepack device

The Telepack device should be assigned to the ViewPoint Central Station using the 'Equipment Setup' tab. See the section "Assigning new equipment" on page 3-10 on how to assign the Telepack device to the ViewPoint Central Station.

The Label ID is user defined and the Device ID is found in the back of the Telepack device.

After assigning the equipment to the ViewPoint Central Station, the Telepack device is ready to be secured to the patient.

11.2.2 Using the Telepack device

The normal usage of the Telepack involves powering up the device by inserting the 2 AA alkaline batteries (See "Inserting/Removing batteries" on page 11-7.) and then securing the device to the patient after the normal power up sequence of the device (See "Telepack Power Up Sequence" on page 11-8.).

The following sections provides instructions on how to secure the Telepack device to the patient, store the device and maintain the device for normal usage.

11.2.3 Securing the Telepack device

The Telepack device first needs to be connected to the ECG lead set. The arrow in the ECG lead set plug should be in line with the white dot on the top of the Telepack device when plugging and snapping the ECG lead cable into the port provided on the top of the Telepack.

<<Picture to be inserted showing the plugging area>>

CAUTION: Ensure that the ECG lead cable is plugged into the port firmly, the end cap of the battery is firmly secured and the serial port is also secured with the dummy plug to prevent fluids from entering into the ViewPoint Telepack 2.4 device.

CAUTION: When disconnecting ECG leads from the patient, do not pull on the leadsets. This will decrease the life of the leadsets. Grasp the connectors and pull gently.

The Telepack device can be secured to the patient after the ECG leads are connected to the device with the front of the device facing outside. The Telepack device should be secured in a telemetry pouch, or in the pocket of a patient gown.

NOTE: For optimal performance, the front of the Telepack device (the side with the button and indicator lights) should be facing outside and the ECG lead cable should be connected to the device from the top. This is the orientation in which the Telepack device should be secured to the patient.

The following warnings and cautions should be adhered to when securing the Telepack to the patient.

WARNING: Ensure that the ECG lead wires are secured in such a way to prevent the lead wires from encircling the patient's neck and causing possible strangulation.

WARNING: Patients with fragile skin, dermal allergies, or a history of skin reactions to adhesive tapes may show a dermatitis reaction to the adhesive in addition to possible side effects from the electrical current.

CAUTION: Ensure that the lead wires are not inadvertently caught in the bed rails. If this happens, the insulation may get cut or the leadset may break.

11.2.3.1 Usability Range

The range for the Telepack device to communicate and transfer data is within 100 feet of a network access point. This distance is subject to site survey and the building materials. The device is for indoor use only.

NOTE: The Technical Events Sounds option must be turned on in the ViewPoint Central Station System Alarms/System Alarm Options Tab for the alarm to be audible from the ViewPoint Central Station when the ViewPoint Telepack 2.4 device is out of range. The message "Communication Lost" is also displayed on the patient tile in the ViewPoint Central Station. Refer to section "Technical Events Sounds" on page 3-4.

11.3 User Maintenance

The following sections provide information about storing, and maintaining the Telepack device.

11.3.1 Storing the Telepack

When not in use, carefully store the Telepack by wrapping the leadset loosely around the casing of the Telepack device. The Telepack may be stored with the leadset attached and hanging freely. Do not wrap the leadset tightly around the casing of the Telepack as it may damage the wires.

The batteries should be removed from the Telepack when storing the device. This is the method by which the Telepack is powered off. This will also preserve battery life and prevent damage to the Telepack because of battery leakage.

NOTE: The ViewPoint Telepack 2.4 should be cleaned and disinfected before and after each patient's use. Refer to "Cleaning and Disinfecting the Telepack" on page 11-12 for information.

NOTE: The ViewPoint Telepack 2.4 equipment 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 equipment 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 equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to correct the interference by one or more of the following measures: Reorient or relocate the receiving antenna. Increase the separation distance between the equipment and the receiver. Connect the equipment into an outlet on a circuit different from that to which the receiver is connected. Consult the dealer or an experienced technician for help.

11.3.2 Cleaning and Disinfecting the Telepack

The information in this section is for cleaning and disinfecting the Telepack and its accessories. The three components that need to be cleaned and disinfected are:

- Telepack device
- Battery Compartment
- ECG Lead Sets

11.3.2.1 Cleaning the Telepack Device

The cleaning solutions used to clean the Telepack should be compatible with the cleaning solutions used to clean the ECG lead sets when the Telepack device is cleaned with the lead set attached. If the cleaning solution is not compatible ensure that the ECG leads do not come in contact with the cleaning solution of the Telepack.

Ensure that you remove the ECG lead wire set from the device to clean around the ECG connector.

When cleaning the Telepack, remove the batteries and reattach the end cap of the battery compartment firmly.

The cleaning solutions that can be used are:

- Soap and Water
- Glutaraldehyde 2% (Example: Cidex)
- Dilute Chlorine Bleach (Sodium hypochlorite), 10% solution, freshly made in past 24 hours
- Isopropyl Alcohol 70%
- Ethyl Alcohol

Follow the guidelines below to clean the Telepack:

- Use a cloth moistened with the cleaning solution and gently wipe the outside of the Telepack.

NOTE: Do not immerse the Telepack unit in the cleaning solution during the cleaning process.

- The cleaning solution should be wiped away with a cloth moistened with distilled water.
- A lint free cloth should be used to dry the Telepack unit thoroughly.

11.3.2.2 Cleaning the Battery Compartment

Inspect the battery compartment for fluids after each use by removing the batteries from the Telepack.

Follow the guidelines below to clean the battery compartment:

- Remove the batteries from the battery compartment.
- Use a gauze pad or long handle swab moistened with soap, water or alcohol to clean the battery compartment.

NOTE: Only soap, water or alcohol moistened in a damp cloth should be used to clean inside the battery compartment. Other cleaning solutions may damage the battery compartment.

- The cleaning solution should be wiped away with a cloth moistened with distilled water.
- A lint free cloth should be used to dry the inside of the battery compartment. Air dry the battery compartment prior to re-inserting the batteries.

NOTE: Remove any cleaning solution residue by wiping the cleaned surfaces with distilled water. Ensure that the battery contact leads and the battery compartment is dry prior to inserting the batteries again for use.

11.3.2.3 Cleaning the ECG Lead Sets

To clean the ECG leadsets use any one of the cleaning solutions listed below:

- Soap and Water
- Glutaraldehyde 2% (Example: Cidex)
- Dilute Chlorine Bleach (Sodium hypochlorite), 10% solution, freshly made in past 24 hours
- Ethyl Alcohol 30% (Example: Green soap tincture)

Follow the guidelines below to clean the ECG Lead sets:

- Use the cleaning solution to wipe and rinse the lead set.
- The cleaning solution should be wiped away with a cloth moistened with distilled water.
- A lint free cloth should be used to dry the lead set thoroughly.

CAUTION: The ViewPoint Telepack 2.4 unit should not be used with damaged cables, connectors or accessories.

NOTE: Do not immerse the leadsets in the cleaning solution during the cleaning process.

11.3.2.4 Sterilization of the Lead sets (Cannot claim yet????)

Use EtO to sterilize the leadsets. The sterilization should be done by following the hospital-approved procedure for EtO sterilization, such as those recommended by AAMI. The leadsets will remain effective up to 10 exposures to EtO sterilization cycles.

NOTE: Damage to the lead sets will result if steam or gamma radiation is used for the sterilization process.

CAUTION: Sterilize the leadsets only when indicated by specific patient or hospital requirements because repeated exposure to EtO sterilization will reduce the life span of the leadset.

11.3.2.5 Disinfecting the Telepack

Only hospital-approved disinfecting procedures like those recommended by AAMI or AORN should be used to disinfect the Telepack unit.

Follow the guidelines below to disinfect the Telepack unit:

- Use a 2% gluteraldehyde solution such as Cidex or a fresh 10% solution of chlorine bleach and water to wipe the Telepack or leadset.
- The cleaning solution should be wiped away with a cloth moistened with distilled water.
- A lint free cloth should be used to dry the Telepack unit or leadset thoroughly.

11.3.3 Disposal of the Telepack device

The following are the guidelines that need to be followed when disposing the Telepack for any reason.

- The Telepack should be disposed of in a very careful and attentive manner adhering to the State laws and Federal regulations regarding disposal of electronic and computer accessories. For example, the State of Minnesota prohibits disposing of electronic and computer accessories in the trash. Follow the laws of your State.
- If your state laws recommend recycling, you can dispose of the device by following the recycling program offered by State run agencies.

11.3.4 Disposing of Batteries

The following note should be adhered to when disposing the batteries.

NOTE: The used alkaline batteries may be subject to local regulations regarding disposal. At the end of the battery life, do not dispose the batteries in fire but dispose of the batteries in accordance with any local regulations.

11.4 Approved Accessories

DESCRIPTION	PART NUMBERS
Electrodes	0681-00-0091-01
	0681-00-0091-02
ECG Lead Set	0012-00-1448-02
Batteries	0146-00-0077-01

WARNING: Use of ACCESSORIES, transducers and cables other than those specified in "Approved Accessories" on page 11-14 may result in increased EMISSIONS or decreased IMMUNITY of the ViewPoint Telepack 2.4 device.

11.5 Safety Designations

Safety designations as per IEC 601-1 Standard:

Degree of protection against electric shock:	ECG Type CF defibrillation protected.
Supply Connection:	0.60 - 0.30 A 3 VDC Internal Battery
Mode of Operation:	Continuous
Protection Against Hazards of Explosion	Not Protected (Ordinary)
Protection Against Ingress of Liquids	IPX1 (Drip-proof)
Degree of Electrical Connection between Equipment and Patient	Equipment designed for non-electrical connection to the patient
Degree of Mobility:	Transportable, Intra-Hospital

11.6 System Performance Specifications

11.6.1 ViewPoint Telepack 2.4 Device Specifications

11.6.1.1 Pacer Detection

- The Telepack provides pacer detection.

11.6.1.2 ECG Performance Specifications

The ECG performance specifications required for the Telepack are in accordance with the requirements of the IEC60601-2-27:1994.

11.6.1.2.1 Acquired Leads

- Five Lead: Three vectors (I, II, V(n) are acquired)

11.6.1.2.2 Connector Types

- ISM: Six-pin. Submersion-proof per section 11.7.3, quick release connector

11.6.1.2.3 Cable Detection

- Automatically detected using Datascope auto-detecting cables

11.6.1.2.4 Radio Transceiver

- The Telepack 2.4 utilizes the 'Symbol' LA-302T-100 radio (FCC ID H9PLA3021-100)

11.6.2 EMI Requirements

11.6.2.1 Defibrillator Overload

- The Telepack can recover from a 5000V, 360 Joule discharge with a recovery time of 5 seconds as per IEC 60601-2-27:1994, 51.101.1.

11.6.2.2 Battery Runtime

- 8 hrs minimum using (2) AA Alkaline Cells with ECG at a HR of 60 bpm common to the ViewPoint Central Station.

11.6.2.3 Battery Shelf Life

- The battery shelf life is indicated on the battery casing.

11.6.3 ViewPoint Server Device Specifications

The Telepack is used in conjunction with a ViewPoint Server. Therefore, the specifications of the ViewPoint Server relative to the Telepack are described below.

11.6.3.1 Performance with Telepack

- The system shall support a maximum of 8 devices.

11.6.3.2 Displayable Leads

- 5 Lead - I, II, III, aVR, aVL, aVF, V(n)

11.6.3.3 Notch Filter

- Shall be set to 60 Hz

11.6.3.4 Pacer Rejection

- Pacer signals from ±2mV to ±700mV (RTI) amplitude and 0.1ms to 2ms in duration, and a maximum of 100µs rise time shall be rejected.

11.6.3.5 ECG

- Frequency response shall be 0.05Hz to 40.00Hz.

11.6.3.6 ECG Derived Heart Rate Meter

11.6.3.6.1 Range

- Shall be 30 to 300 BPM for Adult

11.6.3.6.2 Resolution

- Shall be 1 BPM

11.6.3.6.3 Accuracy

- Must be ± 3 BPM or ± 3% at 30 to 250 BPM, whichever is greater.
- Must be ± 5% 251 to 350 BPM.

11.6.3.6.4 EC11 and EC13

- Meets ANSI/AMI EC11:1991, ANSI/AAMI EC13:2002 where applicable.

11.6.3.7 EC11-1991, EC13-2002, ST Segment Analysis Performance Requirements

- Data computed on the ViewPoint Server shall be displayed on the ViewPoint Central Station.
- I, II, V leads shall be used
- Low pass filtering must be set at 0.05Hz

11.6.3.7.1 Enabling

- Shall be enabled in ADULT mode

11.6.3.7.2 ST Deviation Range

- Shall be –9.9 mm to + 9.9mm (-990µV to + 990µV RTI)

11.6.3.7.3 Resolution

- Shall be 0.1 mm (10 µV)

11.6.3.7.4 Default ST

- Shall be 80 ms after J point for heart rates <120 BPM

11.6.3.7.5 Measurement Point

- Shall be 60 ms after the J point for heart rates >120 BPM

11.6.3.7.5.1 User Selectable ST Measurement Points

- Default ISO Point - Shall be located between the P and Q waves. Shall also be user adjustable from J-30ms to J-300 ms in increments of 12ms
- Default J Point - Shall be the end of the QRS complex. Shall also be user adjustable from J-30ms to J+100ms in increments of 12ms

11.6.3.7.5.2 Numerical ST Measurement Display

- Shall be transmitted to the Central Station every two seconds
- Data shall be updated every 10 valid templates

11.6.3.7.5.3 Invalid ST

- ST data shall be invalidated when the measured ST value exceeds range, and/or paced rhythm persists for more than 45 seconds.

11.6.3.8 Arrhythmia Analysis

- Arrhythmia analysis shall identify ventricular arrhythmia only.
- Asystole, Missed Beat, Irregular Heart Rate, Couplets, Triplets, Runs, Bigeminy, Trigeminy, Ventricular Tachycardia, Ventricular Fibrillation, PVCs per minute in increments of 2ms

11.7 Environmental Characteristics

11.7.1 Maximum Size

- Height: 6.4" (162.56 mm)
- Width: 3.7" (93.98 mm)
- Depth: 1.5" (38.1 mm)

11.7.2 Maximum Weight

- 11.0 oz. without batteries (311.84 g)

11.7.3 Water Resistant

- The ViewPoint Telepack is drip-proof {IPX1} as defined in EN 60601-1:1990, section 44.6, when the ECG cable connector is properly installed and the serial port is covered.
- The ViewPoint Telepack has passed the tests required in EN 60601-1:1990, section 44.6, which reference 529, clause 6, table III, degree of protection against water level 1 (IPX1), and test condition 14.2.1.

11.7.4 External Connector Incompatibility

- Per IEC 60601-1-2:2001

11.7.5 Rigidity and Strength of Enclosure

- Per IEC 60601-1-2:2001 and UL 2601-1:1997

11.7.6 Surface Temperature

- Per IEC 60601-1-2:2001

11.7.7 Operating Temperature

- +5°C to +40°C (+41°F to +104°F)

11.7.8 Operating & Storage Humidity

- Storage: 10% to 90% maximum, non-condensing
- Operating: 15% to 90% maximum, non-condensing

11.7.9 Storage Temperature

- -20°C to +60°C (-4°F to +140°F)

11.7.10 Storage Altitude

- 1,060 hPa to 700 hPa

  -1250 feet to 9,889 feet ASL

  -380 m to 3,014 m

  795 mm Hg to 525 mm Hg

11.7.11 Operating Altitude

- 1060 hPa to 700 hPa

  -1250 feet to 9889 feet ASL

  -380 m to 3014 m

  795 mm Hg to 525 mm Hg

11.7.12 Shipping

- Meet ISTA Test procedure 1A

11.7.13 Shock and Vibration

- Shock Test per IEC 60068-2-27:1987
- Peak Acceleration: 15g
- Duration: 11 msec
- Pulse shape: Half sine
- Sinusoidal Vibration Test per IEC 60068-2-6:1995
- Frequency range: 10 to 500 Hz
- Acceleration amplitude: 1g
- Type and duration of endurance:10 sweep cycles in each axis
- Random Vibration Test per IEC 60068-2-34:1993
- Frequency range: 20 to 500 Hz
- Acceleration Spectral Density: 0.02 G^2/Hz
- Degree of reproductibility: low
- Duration of conditioning: 9 minutes per axis

11.7.14 Drop

UL2601-1:1997 for handheld devices.

11.7.15 Electromagnetic Compatibility

The Telepack meets the requirements of IEC 60601-1-2:2001.

NOTE: **The ViewPoint Telepack 2.4 needs special precautions regarding Electro Magnetic Compatibility (EMC) and needs to be installed and put into service according to the EMC information provided in section "Electromagnetic Compatibility" on page 11-20.**

NOTE: **Portable and mobile RF communications equipment can affect the Telepack. See Table 11-1 on page 11-21, Table 11-2 on page 11-21, Table 11-3 on page 11-23 and Table 11-4 on page 11-24.**

TABLE 11-1

GUIDANCE AND DATASCOPE CORP. DECLARATION - ELECTROMAGNETIC EMISSIONS

The Telepack is intended for use in the electromagnetic environment specified below. The customer or the user of the Telepack should assure that it is used in such an environment.

EMISSIONS TEST	COMPLIANCE	ELECTROMAGNETIC ENVIRONMENT - GUIDANCE
RF emissions CISPR 11	Group 1	The Telepack uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The Telepack is suitable for use in all establishments including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ Flicker emissions IEC 61000-3-3	Not applicable	

TABLE 11-2

GUIDANCE AND DATASCOPE CORP. DECLARATION - ELECTROMAGNETIC IMMUNITY

The Telepack is intended for use in the electromagnetic environment specified below. The customer or the user of the Telepack should assure that it is used in such an environment.

IMMUNITY TEST	IEC 60601 TEST LEVEL	COMPLIANCE LEVEL	ELECTROMAGNETIC ENVIRONMENT - GUIDANCE
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±8 kV contact ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/ output lines	Not applicable *	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	Not applicable *	Mains power quality should be that of a typical commercial or hospital environment.

TABLE 11-2

GUIDANCE AND DATASCOPE CORP. DECLARATION - ELECTROMAGNETIC IMMUNITY

The Telepack is intended for use in the electromagnetic environment specified below. The customer or the user of the Telepack should assure that it is used in such an environment.

IMMUNITY TEST	IEC 60601 TEST LEVEL	COMPLIANCE LEVEL	ELECTROMAGNETIC ENVIRONMENT - GUIDANCE
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % UT (>95 % dip in U_T) for 5 sec	Not applicable *	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Telepack requires continued operation during power mains interruptions, it is recommended that the Telepack be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

U_T *is the a.c. mains voltage prior to application of the test level.*

* *Telepack operates only from the internal battery*

TABLE 11-3

GUIDANCE AND DATASCOPE CORP. DECLARATION - ELECTROMAGNETIC IMMUNITY

The Telepack is intended for use in the electromagnetic environment specified below. The customer or the user of the Telepack should assure that it is used in such an environment.

IMMUNITY TEST	IEC 60601 TEST LEVEL	COMPLIANCE LEVEL	ELECTROMAGNETIC ENVIRONMENT - GUIDANCE
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	Not applicable	Portable and mobile RF communications equipment should be used no closer to any part of the Telepack, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** d = 1.2 x $\sqrt{P}$ d = 1.2 x $\sqrt{P}$ 80 MHz to 800 MHz d = 2.3 x $\sqrt{P}$ 80 MHz to 800 MHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).[b] Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a] should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	

TABLE 11-3

GUIDANCE AND DATASCOPE CORP. DECLARATION - ELECTROMAGNETIC IMMUNITY

The Telepack is intended for use in the electromagnetic environment specified below. The customer or the user of the Telepack should assure that it is used in such an environment.

IMMUNITY TEST	IEC 60601 TEST LEVEL	COMPLIANCE LEVEL	ELECTROMAGNETIC ENVIRONMENT - GUIDANCE
NOTE:	**At 80 MHz and 800 MHz, the higher frequency range applies.**		
NOTE:	**The EMC guidelines in Table 11-3 on page 11-23 may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.**		

a field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Telepack is used exceeds the applicable RF compliance level above, the Telepack should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Telepack.

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

TABLE 11-4

RECOMMENDED SEPARATION DISTANCES BETWEEN PORTABLE AND MOBILE RF COMMUNICATIONS EQUIPMENT AND THE TELEPACK

The Telepack is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Telepack can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Telepack as recommended below, according to the maximum output power of the communications equipment.

RATED MAXIMUM OUTPUT POWER OF TRANSMITTER W (WATTS)	SEPARATION DISTANCE ACCORDING TO FREQUENCY OF TRANSMITTER M (METERS)		
	150 KHZ TO 80 MHZ	80 MHZ TO 800 MHZ	800 MHZ TO 2.5 GHZ
	$D = 1.2 \times \sqrt{P}$	$D = 1.2 \times \sqrt{P}$	$D = 2.3 \times \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE:	**At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.**
NOTE:	**The separation distances guidelines in Table 11-4 on page 11-24 may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.**

11.7.16 FDA 11/93 Guidelines

The Telepack meets the following "FDA 11/93" Guidelines:

11.7.16.1 Magnetic Emissions

- MIL-STD-461/2D
- RE101 30 Hz to 100 kHz @ 7cm

11.7.16.2 Quasi-Static Field Susceptibility

- 500-2000 V/m sweep @ 0.5 Hz sine

Datascope.

Declaration of Conformity
European Community Council Directive 93/42/EEC

CE 0044

Datascope Corp. declares that the products listed below comply with the requirements of the Medical Device Directive 93/42/EEC. The Technical File required by this Directive is maintained at the manufacturer's address below.

Equipment type: Central Station - Class IIb device ***Models:*** View Point™

Quality System: ISO9001 / EN46001 ***Notified Body:*** RWTÜV Essen

ViewPoint™ Central Monitoring System *conforms to the following standards:*

Safety:	IEC 60950:1992 + A1:1993 + A2:1993 + A3:1995 + A4:1997 + A11:1997	
	IEC 601-1-1:1992 + A1:1995;	IEC 601-1-4:1996;
	UL 1950 3rd Edition (1995);	CSA C22.2 No. 950-95;
	QSR 21CFR 820	
EMC:	EN 55022:1998 (Class A);	EN 55024:1998;
	EN 61000-3-2:1995;	EN 61000-3-3:1995
	per the provisions of the **Electromagnetic Compatibility Directive** *89/336/EEC* of 3 May 1989 as Amended by *92/31/EEC* of 28 April and *93/68/EEC, Article 5* of 22 July 1993.	
Performance	EN 475:1995;	EN 1441:1997

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month/date/year

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1.1 Components of the ViewPoint™ Central Station System

The ViewPoint Central Station system is a Medical Electrical System that is comprised of both medical and non-medical devices (data processing equipment components) as shown in the following table. The Declaration of Conformity states that this Medical Electrical System complies with MDD and as such is declared as CE 0044. The system and its components are marked in accordance with MDD, Annex IX classification criteria: the devices are marked as CE 0044, while the components are marked as CE.

DESCRIPTION	MDD CLASSIFICATION AND RULE	COMMENT
Passport 2® Patient Monitor	Class IIb, Rule 10, dash 3, "unless..." phrase	CE 0044 mark on the unit and on individual package.
ViewPoint Central Station Tower	Class 1, Rule 12	CE mark on the unit and individual package.
20" Touchscreen Display	Class 1, Rule 12	ITE equipment. CE marked by the vendor for compliance with LVD and EMC Directives.
21" Touchscreen Display	Class 1, Rule 12	ITE equipment. CE marked by the vendor for compliance with LVD and EMC Directives.
18" Flat Panel Touchscreen Display	Class 1, Rule 12	CE marked by the vendor for compliance with MDD and EMC Directives.
Hub	Class 1, Rule 12	ITE equipment. CE marked by the vendor for compliance with LVD and EMC Directives.
UPS	Class 1, Rule 12	ITE equipment. CE marked by the vendor for compliance with LVD and EMC Directives.
Switch	Class 1, Rule 12	ITE equipment. CE marked by the vendor for compliance with LVD and EMC Directives.
Printer	Class 1, Rule 12	ITE equipment. CE marked by the vendor for compliance with LVD and EMC Directives.
ViewPoint Telepack 2.4	Class IIb, Rule 10, dash 3, "unless…" phrase	CE 0044 mark on the unit and on individual package.

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