SpiderView

Digital Holter Recorder

USER MANUAL

MicroPort

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1. INTRODUCTION

This icon is used to draw your attention to a particularly important point.

This icon alerts you to a hazard that may result in equipment damage or personal injury. Carefully read the instructions provided with this icon.

1.1. USE IN THE UNITED STATES

USA only	[CAUTION: Federal law restricts the sale of this device by or on the order of a physician.]

2. SPIDERVIEW PRESENTATION

2.1. INTENDED USE

SpiderView is a digital ECG Holter recorder intended for long-term ambulatory ECG recordings, multi-channel, and High-Resolution ECG recordings.

WARNING: The holter analyzing SyneScope software is needed to download and analyze the recordings.

2.2. SPECIFIC FEATURES OF SPIDERVIEW

SpiderView uses flash cards: MMC cards (Multi Media Cards), SD cards (Secured Data) or MicroSD cards.

SpiderView is not compatible with the ELATEC and SyneView analysis software systems.

SpiderView recordings longer than 24h and with more than 3 channels must be read with SyneScope.

SpiderView 24h recordings, 2/3 channels can be read with SyneScope, SyneTec, EasyScope, SyneView2 and SyneCom.

TYPE OF RECORDING

SpiderView offers three types of recording:

— Holter recording only.
— High-Resolution ECG recording only.
— High-Resolution ECG recording followed by a 24-hour standard Holter recording.

RECORDING QUALITY

SpiderView offers 24-hour Holter recordings in three different formats:

— Standard quality: standard bandwidth. Smaller file size (approx. 5MB per channel).
— High quality: wide bandwidth. Mid-range file size (approx. 10MB per channel).
— Uncompressed: wide bandwidth (file size: 17.3 MB per channel).

2.3. PACKAGING

SpiderView is supplied in a case containing:

— one SpiderView device
— one 1.5 V AA lithium battery
— one reusable bag and strap
— one disposable bag
— one Bluetooth dongle
— bag of 30 single-use electrodes
— Spiderview, HookUp Go and MyRhythm Pro user manuals on CD-Rom
— HookUp Go Software on CD-Rom
— RED compliance leaflet

3.   USER PROFILE

3.1.   TRAINING

Any person who has followed the training required by the local regulatory authority. Training completion and effectiveness are under his/her medical supervisor's responsibility.

NOTE: Any serious incident that has occurred in relation to the device must be reported to MicroPort CRM S.r.l. and your competent authority.

4. PRECAUTIONS FOR USE AND MAINTENANCE

4.1. TRANSPORTATION

SpiderView is packaged for delivery as outlined in the packaging chapter.

If you want to repack and carry or deliver the SpiderView after its first usage, we recommend putting all the parts back into their initial positions.

Please take care putting the flash card case into the appropriate place.

Flash cards can be sent by postal service. They are light and extremely strong. Nevertheless, it is recommended that they be bubble-wrapped and sent in a double envelope.

When storing the device and the accessories, the SpiderView case can be stored upright or lying down.

4.2. END OF SERVICE

When SpiderView reaches the end of its service life, it should be returned to MicroPort for appropriate recycling.

The batteries should be recycled as appropriate.

ECG cables and pouch can be thrown away, since they do not contain specific dangerous materials. SpiderView parts and accessories do not contain mercury or mercury compounds.

4.3. CONDITIONS FOR USE AND STORAGE OF THE DEVICE AND FLASH CARDS

The following table shows the conditions for use, storage and transportation for SpiderView:

Use	Temperature	Humidity	Pressure
Operation	0° to 45°C	10% to 95% non condensing	700 hPA to 1060 hPa
Storage and Transportation	-20° to 65°C	5%* to 93% non condensing	500 hPA to 1060 hPa

(*: Flash cards 8%)

If exposed to a severely wet or humid environment, a protective bag like RG008 is needed.

During transportation or storage for a prolonged period, remove the battery from the device.

WARNING: If a leak or a powdery deposit is visible on the battery, in the compartment or on the electrical contacts, remove the battery and dispose of it following local environmental legislation and/or the intended procedures. **If the leak is not significant (no oxidation on the electrical contacts of the battery), it is possible to clean it with a damp cloth, and then carefully dry the cleaned parts**. In the event of traces of significant oxidation, it is strongly recommended not to use the device (risk of recording failure) and return it to MicroPort After Sales. Repair is excluded from the warranty and a fee will be charged.

SpiderView is not protected from external defibrillation shocks, high-frequency currents or strong electromagnetic disturbances. The use of cellular or cordless telephones may cause signal interference.

Flash cards can be used up to 300,000 times. Flash cards resist electrostatic discharges up to ± 4kV on contact pads and ± 8kV on non-contact pad area (coupling plane discharge). Flash cards will withstand an impact not exceeding 1 000 G.

WARNING: SpiderView does not start if a MicroPort flash card is not inserted.

SpiderView is only guaranteed to work properly if flash cards supplied by MicroPort are used. Furthermore, flash cards designed for use in MicroPort recorders should not be used for other applications.

WARNING: SpiderView shall not be used in environments with flammable anesthetic mixtures containing oxygen or nitrous oxide.

4.4. ELECTROMAGNETIC COMPATIBILITY

The use of portable and mobile RF communication equipment (e.g. cellular phones) can affect the recorder (if used at less than 30cm from the recording device) since the recorded ECG signal may be disturbed due to electromagnetic interference.

Tables on electromagnetic emission and immunity of the recorder are found in the appendix of this manual.

WARNING: The device shall not be used in the presence of ionizing radiations (x-rays, gamma rays...) or MRI systems that could damage SpiderView and/or flash cards. Remove the device before starting an MRI procedure.

4.5. CARE OF THE DEVICE AND FLASH CARD

No special maintenance is required.

The external case and the patient cables can be cleaned with a slightly damp cloth or a wet soapy cloth. Detergents, alcohol or acetone must not be used. The patient's cable may be cleaned after each use with an adhesive remover wipe.

The pouch may be washed at 30 °C. The pouch has not been designed for daily washing.

Do not tumble dry.

Under no circumstances should the SpiderView, patient cables or flash cards be sterilized.

The patient should never take a shower or bath while wearing the device, since this will damage the device or make it completely unusable.

WARNING: Do not immerse the snap-on cable clips in a cleaning or disinfectant solution. This method considerably shortens the life of cables and causes an important oxidation between the clip and the wire of the cable. The quality of the ECG could be affected.

If the device fails to work properly, contact the MicroPort After-Sales Service or your distributor. Do not unscrew the case under any circumstances (see warranty section).

5. WARRANTY

SpiderView and flash cards are guaranteed for parts and work for two years from the date of delivery. After-sales service is available after the warranty has expired.

WARNING: The warranty is only valid under the condition that no attempts have been made to open or repair the device. The warranty will be void if the device or the cards have been used contrary to this user manual's recommendations.

Flash cards that are damaged, bent or have dust on components are not covered by warranty. Furthermore, only MicroPort CRM S.r.l. cards are guaranteed.

6. GENERAL DESCRIPTION

6.1. SPIDERVIEW COMPONENTS
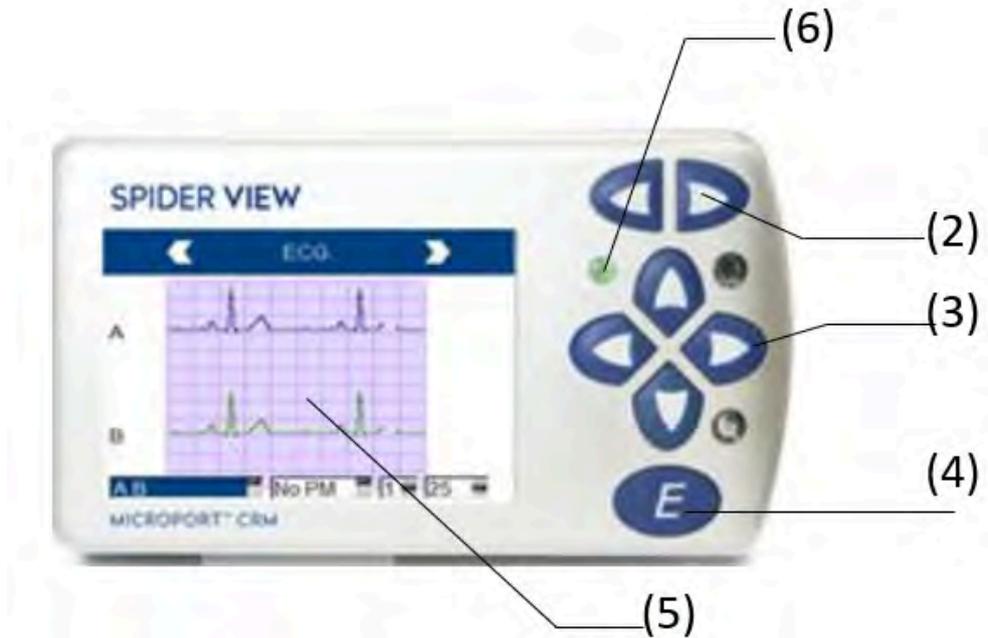
(2) Screen buttons	(3) Cursor buttons
(4) Event button	(5) LCD display
(6) Operating light (LED)	
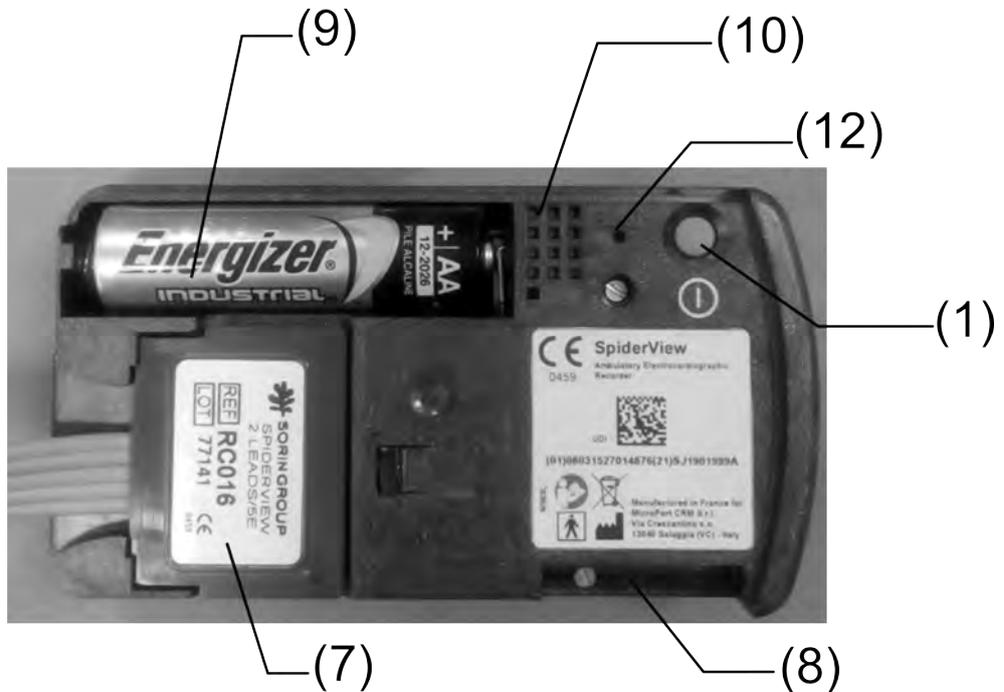
(1) On/off button	(7) Patient cable connector

(8) Flash card insertion slot	(9) Battery compartment
(10) Service connector (reserved for maintenance)	(12) Reset button

6.2.   DESCRIPTION OF SYMBOLS ON THE CASE AND PACKAGING

The following symbols are displayed on the SpiderView case and packaging:

	Device classified as BF (IEC 60601-1).
	Refer to the SpiderView user manual before handling the part of the device with this symbol.
	Consult instructions for use available on CD-ROM
	Consult the documentation and manual enclosed in the packaging.
	On/Off switch
	CE mark: SpiderView complies with EC directive 93/42/EEC.
SN	Serial number
	The equipment must be recycled according to European Directive 2012/19/EU
	Caution
	Manufacturer
	This symbol indicates the minimum and maximum storage humidity.
	This symbol indicates the minimum and maximum storage pressure.
	This symbol indicates the minimum and maximum storage temperature.
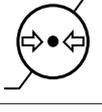
6.3. OPENING THE BATTERY COVER

In order to open the battery cover, users need a thin tool such as a pencil. This tool is to be inserted into the hole while sliding the cover with the thumb as shown below:
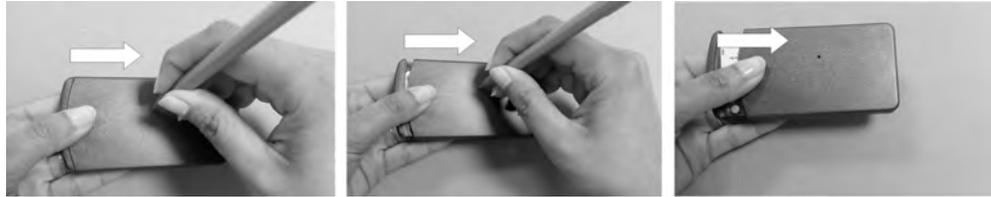
6.4. CABLE INSERTION AND EXTRACTION

The insertion (first A then B) and extraction (first C then D) of the patient cable should be done as indicated in the picture below.
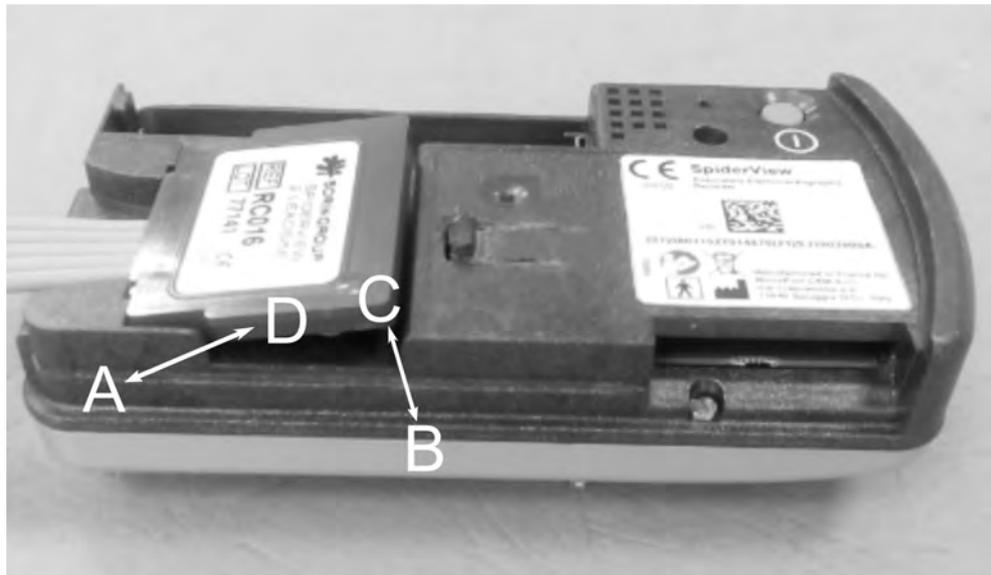
NOTE: When SpiderView is not in use, it can be stored without disconnecting the patient's cable from the plug.

7.   USE OF BATTERIES

Open the recorder. Insert the battery in the battery compartment (9), respecting the polarity as marked in the compartment.

7.1.   BATTERIES

SpiderView is powered by one AA 1.5 V battery (lithium or alkaline).

A new lithium battery will last between one and seven consecutive days of recording, depending on the brand of battery, the recording quality mode, and the number of channels.

A new alkaline battery will last between one and four consecutive days of recording, depending on the brand of battery, the recording quality mode, and the number of channels.

After using the device for one recording, it is recommended to keep the battery inside the device for the next usage. If the voltage is not sufficient for another 24h recording, a warning message will appear after switching on the device.

NOTE: If SpiderView is switched on when the battery is low, the duration of the recording will be one day only (24h), regardless of the programmed time.

7.2.   RECHARGEABLE BATTERIES

For 24-hour recordings SpiderView may also be powered by a re-chargeable battery with a minimum capacity of 1500 mA/h.

We recommend that you read carefully through the instructions that came with the batteries.

NOTE: Use a suitable charging device to recharge the batteries and follow the battery manufacturer's instructions.

7.3.   INTERNAL MEMORY BATTERY

SpiderView contains an internal battery that ensures the maintenance of the system's date and time and other parameters (contrast, recording quality mode) for about a week.

The internal battery recharges automatically during the daily usage of the recorder.

WARNING:
When the recorder is not used, it is recommended that the 1.5 V battery power supply not be removed, in order to constantly guarantee the recharge of the internal memory battery. If the internal memory battery is completely charged, the system's parameters will be maintained without the 1.5 V battery power supply for approximately one week.

8.   POSITIONING THE ELECTRODES

![warning] **WARNING**: Connect the patient to the SpiderView only when the back of the SpiderView is in place.

Electrodes supplied with SpiderView have been designed to withstand long-term ambulatory recording while ensuring patient comfort. Nevertheless, other ECG electrodes may be used.

To ensure a good quality ECG recording, special care must be taken when preparing the patient's skin, positioning the electrodes and connecting the leads. Clean the patient's skin with soapy solution, cleanse it and dry the skin to reduce impedance and obtain a good electrode-skin contact.

Electrodes must be firmly attached to avoid air bubbles which could impede proper contact.

A loop should be made in each lead and the lead then attached with adhesive strips close to the electrode. Pressure on an electrode could produce artifacts.

The proposed electrode placements are an example. It is essential to ensure that the QRS complex amplitude is sufficient in at least one lead, to make automatic data analysis possible. The user can verify electrode placement using the ECG preview.
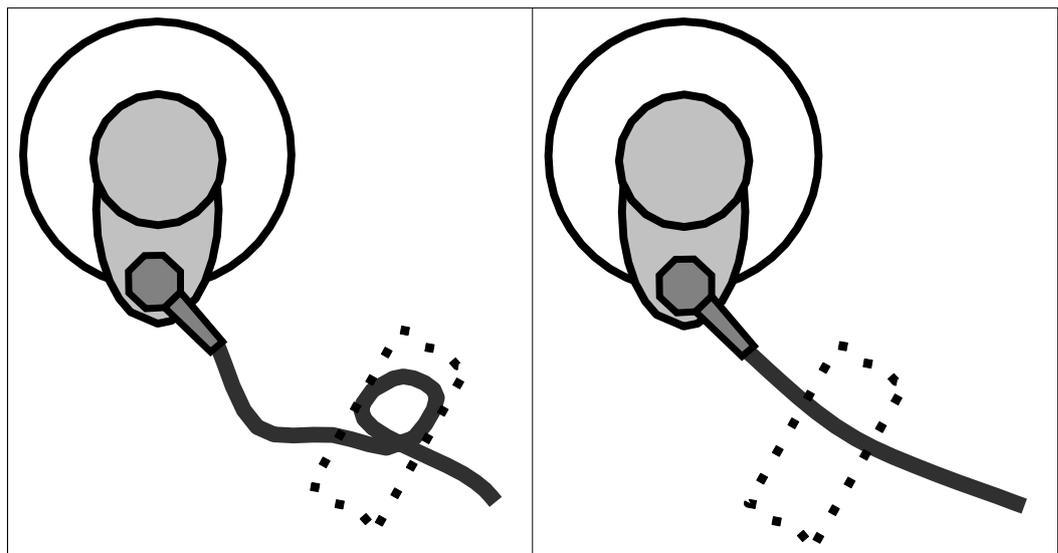
| Right | Wrong |

![warning] **WARNING:** Conductive parts of electrodes (including the neutral electrode), should not be put in contact with conductive parts or grounded parts.

8.1.   TWO-CHANNEL RECORDING (3 ELECTRODES)

8.1.1.   ELECTRODES

Channel:	+ pole	Common – pole
A	2: red (112 cm)	1: white (122 cm)
B	3: brown (112 cm)	1: white (122 cm)

Cable length: 122 cm

8.1.2. ELECTRODE PLACEMENT

This electrode configuration allows you to obtain the maximal number of independent ECG channels with the smallest possible number of electrodes.

Place the red electrode (+) over a rib at V5, the brown electrode (+) on the xiphoid muscle at the bottom of the sternum and the white electrode (common – pole) on the sternum over the manubrium.

Positioning of electrodes for this configuration is shown in the figure below.
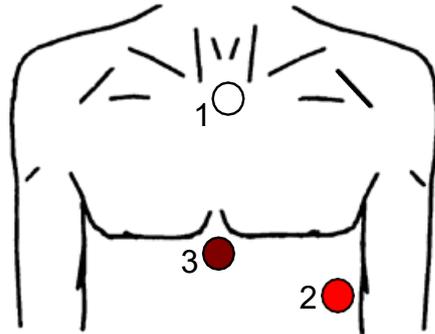
8.2.   TWO CHANNEL RECORDING (5 ELECTRODES)

8.2.1. ELECTRODES

Channel:	+ pole	Common – pole
A	1: white	2: red
B	3: black	4: brown
Ground	5: green	5: green

Cable length: 122 cm

8.2.2. ELECTRODE PLACEMENT

The CMV5 lead (+60° axis) detects identifiable P waves and high-amplitude QRS complexes. It is also acknowledged as being sensitive in detecting myocardial ischemia during exercise testing. Place the white (-) electrode on the sternum, over the manubrium and the red (+) electrode over a rib at V5.

The CMAVF2 lead (+90° axis) provides high-amplitude P waves. The black electrode is also placed on the manubrium as close as possible to the white electrode but not on top of it. The brown electrode is placed on the xiphoid muscle at the bottom of the sternum.

The ground electrode is placed on a rib on the right side of the chest.

Positioning of electrodes for CMV5, CMAVF2 is shown in the figure below:
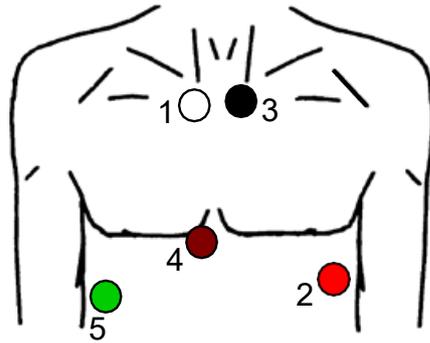
8.3.   THREE CHANNEL RECORDING (7 ELECTRODES)

8.3.1.   ELECTRODES

Channel:	+ pole	Common – pole
A	1: white	2: red
B	3: black	4: brown
C	5: blue	6: orange
Ground	7: green	7: green

Cable length: 152 cm

8.3.2.   ELECTRODE PLACEMENT

Generally, it is recommended that a completely different lead be used in addition to the two leads used for a two-channel recording. CBV2 is an anteroposterior lead close to the Z axis that allows thorough study of changes in the ST segment related to the left coronary artery, as well as the LAD artery and circumflex artery.

The blue electrode lies posteriorly and paravertebrally facing V2. The orange electrode is placed in V2.

The ground electrode is placed on a rib on the right side of the chest.
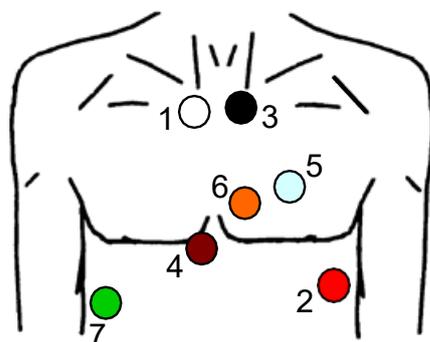
8.4. XYZ CHANNEL RECORDING (7 ELECTRODES)

8.4.1. ELECTRODES

This electrode configuration is suggested for:

— Derived 12 channel ambulatory recordings*.

— High Resolution 20min recordings for late potential analysis; for this application a shielded cable is recommended to reduce noise level.

White	X-	Fourth intercostal space in right midaxillary line
Red	X+	Fourth intercostal space in left midaxillary line
Black	Y-	Superior aspect of the manubrium
Brown	Y+	Lower ribs
Blue	Z-	Directly posterior to V2
Orange	Z+	Standard V2 position
Green	ref	Over 8th rib in right midclavicular line

Cable length: 152 cm

* Available with SyneScope Holter software.

8.4.2. ELECTRODE PLACEMENT

For an ambulatory orthogonal ECG recording close to the XYZ late potential configuration, the following hook-up is recommended. However, due to constraints of daily activities, some minor variations may be introduced, provided that polarity of electrodes and axis orientations are maintained.
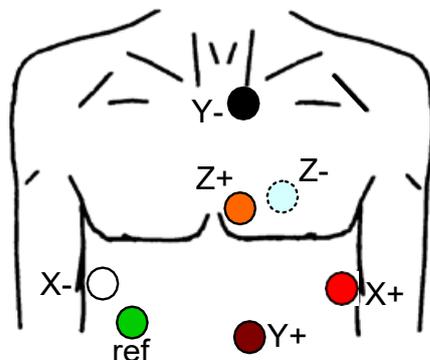
8.5. TWELVE-LEAD RECORDING* (10 ELECTRODES)

8.5.1. ELECTRODES

1	Yellow	LA	Left Anterior acromium
2	Red	RA	Right Anterior acromium
3	Green	LL	Left Interior iliac crest
10	Black	GND	Right Interior iliac crest
4	Purple	V1	V1 position

5	Purple	V2	V2 position
6	Purple	V3	V3 position
7	Purple	V4	V4 position
8	Purple	V5	V5 position
9	Purple	V6	V6 position

Cable length: 150 cm

* Available with SyneScope Holter Software.

8.5.2. ELECTRODE PLACEMENT
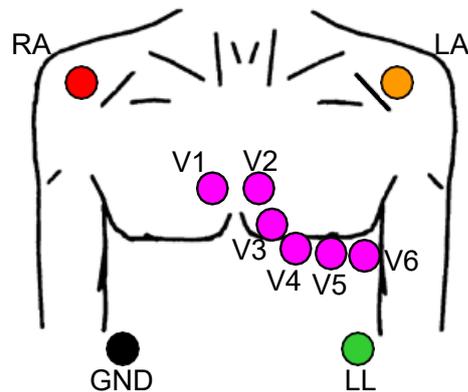
This configuration is intended to provide a standard 12 lead recording similar to that obtained from a resting ECG:

— Lead I, II, III (Einthoven leads)

— Leads avR, avL, avF (augmented limb leads)

— Leads V1 to V6 (precordial leads)

The central terminal of Wilson is automatically calculated by SpiderView.

Because of ambulatory conditions we recommend placing electrodes on the roots of the limbs (Mason-Likkar configuration), often used in exercise testing.

NOTE: Due to the positioning of peripheral leads on the upper extremity of the limbs, ambulatory recordings obtained in this configuration are more likely to contain movement artifacts than other bipolar configurations previously described in this manual.

9. USING THE PROGRAMMING BUTTONS

9.1. USER INTERFACE STRUCTURE

The user interface is structured as a sequence of several screens, which allow you to set the parameters of the device and of the recording. The programming keypad contains 7 buttons (the numbers refer to the "general description" section):

◀▷	These buttons (2) are used to move from one screen to another.
◇△▷▽	These buttons (3) are used to move the cursor inside one screen and to modify the parameters of the screen.
Ⓔ	This button (4) is used for final confirmation to start a recording. During the recording it is also used as an event button by the patient.

The ON/OFF button (1) is placed on the back of the device under the back cover.

i NOTE: The event button has a flat surface in order to avoid accidental activation of the button and causing false patient events in the report.
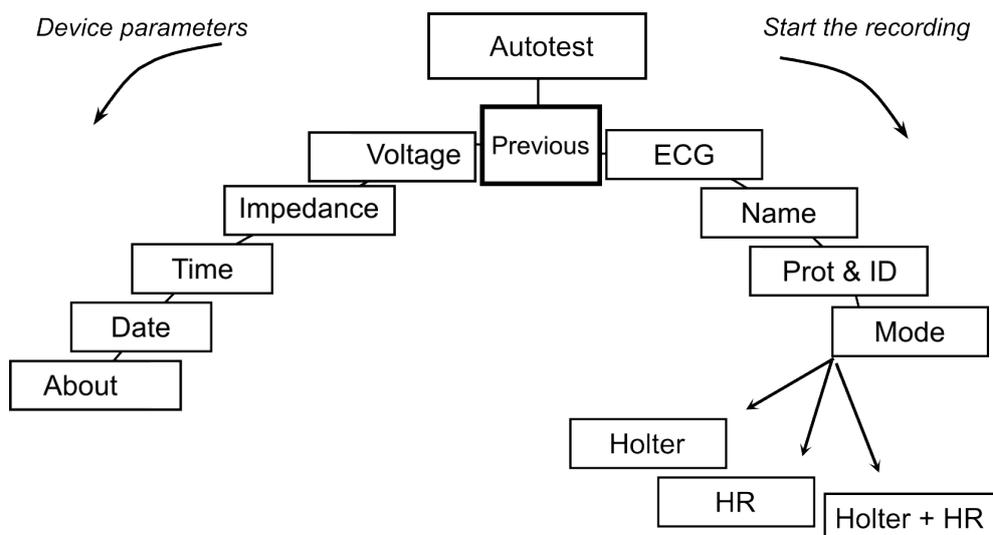
After switching on the recorder and inserting a flash card, the device displays the name of the last patient recorded on it. Moving to the left allows access to the device's parameters (date, time, voltage, contrast …). Moving to the right allows you to set the recording's parameters and to begin the recording. The following chapters will explain the details about the SpiderView screens.

9.2. STARTING THE DEVICE

9.2.1. SWITCHING ON

In order to insert the battery, please refer to section 6.2 "Opening the battery cover".

After inserting a battery and connecting the patient cable, press the On/Off button (1).

A beep indicates the start-up of the recorder. The LCD screen lights up and the device performs a number of automatic tests to check that all of its components are functioning properly and carries out various initialization procedures.

If the display remains blocked on an AUTOTEST number, this indicates that a problem has been detected. Contact MicroPort After-Sales Service.

If all tests are normal, the message INSERT CARD is displayed.

If no operations are performed within 5 minutes, SpiderView beeps and then automatically switches off.

9.2.2. INSERTING THE SD CARD

1. Insert the card into the slot (8), as shown in the illustration, with the front of the card facing up. The card has a beveled edge in one corner, which should be at the top right-hand side when inserting the card.

2. Push the card completely in, in order to ensure a good connection. If the card is not correctly inserted, the cover of the case cannot be closed.

WARNING: SpiderView has been designed to fully support flash cards with NAND technology. Older MMC cards with NOR technology do not guarantee optimal performance of the device.

WARNING: SpiderView is only guaranteed to work properly if flash cards supplied by MicroPort are used. If you do not use a MicroPort card, the following message will appear: "**Warning: Unknown card provider**". Furthermore, a flash card designed for use in MicroPort recorders should not be used for other applications; if this does happen, the SpiderView may no longer be able to read the card.

If the flash card is not blank, the name of the last patient recorded is displayed on the screen. This allows you to check the card that you are going to use to perform a new recording. The recording on the flash card will be automatically erased by starting a new recording.

Move to the next screen using the right screen button (2) to visualize the patient's ECG.

10. STARTING THE HOLTER RECORDING

10.1. PROGRAMMING USING THE BUTTONS

10.1.1. ECG screen

This screen allows you to:

— Visually check the quality of the ECG leads

— Program the type of pacemaker to record
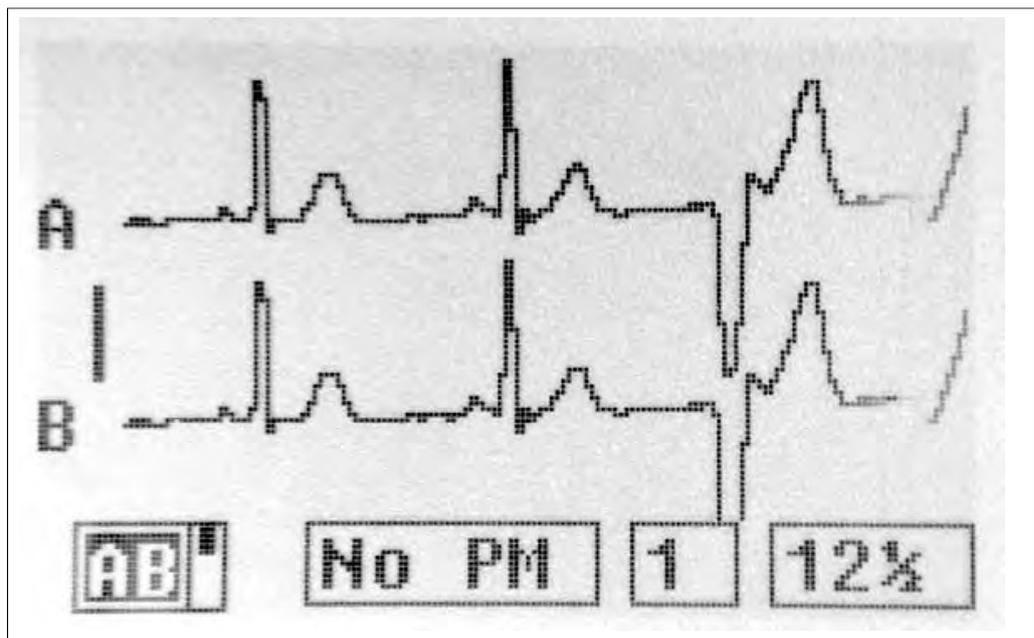
ECG's amplitude and scrolling speed can be changed for a better visualization on the screen. This will not be taken into account during the recording.

For an accurate analysis of the ECG on the Holter analyzing software, the amplitude of the QRS complexes on the first two channels should be at least 1 mV. This corresponds to the amplitude of the calibration bar on the left side of the display.

10.1.2. Pacemaker recordings

If the patient undergoing a Holter recording has a pacemaker, it is mandatory to declare the presence and type of pacemaker to ensure the ECG analysis software classifies the paced beats correctly.

This must be done on the ECG screen: move the cursor to the field "No PM" and modify it

using the buttons and .

The device records single chamber or dual chamber pacemakers with two different sensitivities: Unipolar (less sensitive) or Bipolar (more sensitive).

i | NOTE: If the type of pacemaker is unknown, it is suggested to select bipolar mode.

A high sensitivity mode is available. It can be used to detect very low amplitude PM spikes. Because of the high sensibility, it is likely that noise and muscular or movement artifacts are detected as stimulation spikes. A shielded cable is suggested in order to reduce false pacing spike detections.

10.1.3. Insert patient name

The next screen allows you to enter the patient's name onto the flash card. This is necessary so that the Holter recording will be unequivocally associated with this patient's name when downloaded.
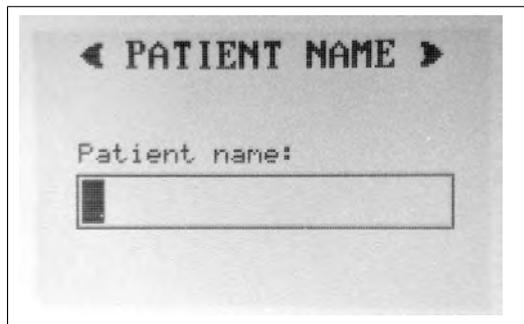
10.1.4. Select recording protocol, insert patient ID and activate the accelerometer sensor

In this screen the ECG analysis protocol can be selected with or without activating the accelerometer sensor:

Adult	Normal analysis protocol
Infant	From 0 to1 year (or weight <10Kg)
Long QT	Patients with long QT or wide T waves
Adult, Infant, Long QT Acc	Adult, Infant or Long QT protocol with accelerometer activated

The protocol can be modified on the Holter software after the card has been downloaded, but if the accelerometer sensor has not been activated at the start those data cannot be displayed. You may also insert a patient ID number that will be downloaded together with patient's name.
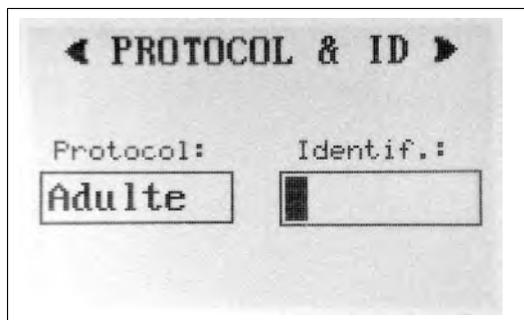
10.1.5. Select the recording mode

SpiderView can work in different recording modes using different resolutions:

— Holter recording

— High Resolution recording (HR)

— Holter recording + HR recording

The Holter mode is always available if any flash card and cable is inserted into the device.

The High Resolution mode is only available if a 3-channel cable is inserted (XYZ shielded, XYZ non shielded or standard 3 channels). The duration of the HR recording depends on the size of the card.

The two can be performed sequentially: the recorder starts in HR mode and switches to Holter mode after the programmed HR duration time.
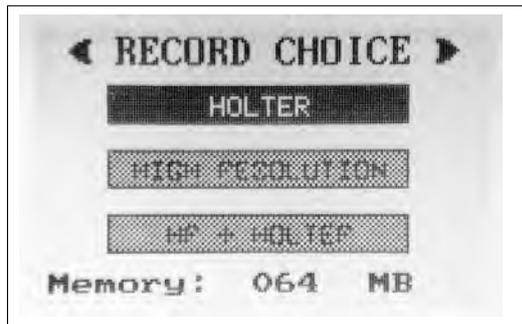
Select one of the available modes using the arrow buttons and move to the next screen.

10.1.6. Holter mode

The Holter screen displays the setting of the most important parameters. According to the flash card and the cable used, here you can select the recording quality and the recording duration*.
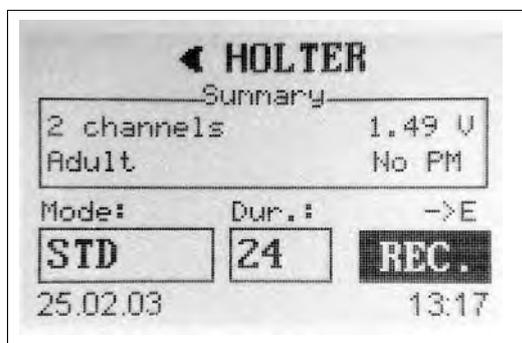
* Duration longer than 24h available with SyneScope Holter software

Please refer to the table in this manual to check which combinations of modes and duration you can select according to the size of your card. For patients weighing less than 10kg (22lbs), Enhanced (ENH) or Uncompressed (NoComp) mode is recommended. By moving the cursor to "REC" and pressing the "E" button you will start the Holter recording. A card initialization phase will precede the recording.

WARNING: Please check that the display of the recorder is switched off and that the LED (6) is blinking before putting the recorder back into the pouch. This guarantees that the initialization phase has finished and that the device has started to record correctly.

10.1.7. High resolution mode

If this mode has been selected in the mode choice screen, the device will now display the high resolution ECG. The high scrolling speed (25mm/s) and amplitude (2 cm/mV) grant a high quality visualization of the ECG and allow you to check if the recording is affected by undesired muscle noise or electromagnetic interference (transformers, neon lights, mobile phones and other devices can affect the ECG with baseline noise).

In this screen the 3 ECG channels can be displayed individually. Use the arrow keys to select the channel.

Use the right arrow to move to the next screen.

Select the duration* of the high resolution recording on this screen. The maximum duration of the recording depends on the capacity of the flash card inserted.
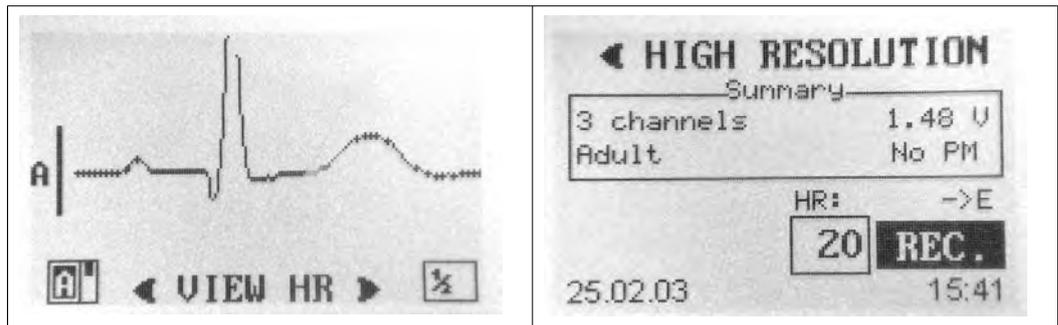
Move to "REC" and press the "E" button to start the high resolution recording.

* Duration longer than 24h available with SyneScope Holter software.

10.1.8. HR + Holter mode

If this mode has been selected in the mode choice screen, the recorder is going to perform a short high resolution recording (20 minutes by default) followed by a 24h Holter recording (or longer).

The device will now display the high resolution ECG. The high scrolling speed (25mm/s) and amplitude (2 cm/mV) grant a high quality visualization of the ECG and allow you to check if the recording is affected by undesired muscle noise or electromagnetic interference (transformers, neon lights, mobile phones and other devices can affect the ECG with baseline noise).

In this screen the 3 ECG channels can be displayed individually. Use the arrow keys to select the channel.

Use the right arrow to move to the next screen.

A screen summarizing all recording parameters is displayed. Here you can select the duration of the high resolution recording as well as the duration and the quality mode of the Holter recording. Please refer to the table in this manual to check which combinations of modes and duration you can select according to the size of your card.
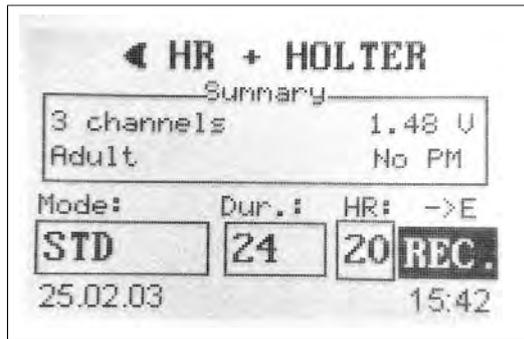
Move to "REC" and press the "E" button to start the high resolution recording. During the high resolution recording the LED will blink fast. At the end of the high resolution mode the device will beep and switch to Holter mode. The LED will blink slowly.

10.1.9. Switching off the device

At the end of the ECG recording, the device can be switched off in two different ways:

— Automatic switch off

If the programmed recording time (1 to 7 days) has expired, the recorder will automatically switch off. Therefore the cover can be opened and the flash card is ready to be downloaded to MicroPort analysis software.

— Manual switch off

To switch off the device while it is still recording, open the back cover (the recorder will start beeping) and keep the on/off button (1) pressed for a few seconds until the device stops beeping. The LED (6) will now stop blinking and the flash card can be removed for download.

WARNING: Removing the flash card or the battery while the device is recording, or stopping the device with any other method than those described in this paragraph may damage the data on the card and may render the card unreadable during the download.

10.1.10. Duration capability tables

The following tables show the duration capability of the recorder (in days) depending on the flash card in use, on the number of recorded channels and on the recording quality mode.

This table is calculated on the size of the card and the amount of data recorded; it does not consider the type of battery in use. The battery capacity must be high enough to support the programmed duration and mode.

WARNING: Only flash cards provided by MicroPort are fully compatible with SpiderView. Other flash cards can cause recording problems.

WARNING: It is strongly recommended not to use Windows formatting tools to erase the flash card.

64 MB FLASH CARD duration in days (d)

Nbr of channels	2	3 ABC or XYZ	9*	12*
STD	4 d	4 d (3 + HR)	2 d	1 d
Enh	2 d	1 d + HR	1 d	–

No Comp	1 d	1 d + HR	–	–
High resolution only	–	345 min	–	–

128 MB FLASH CARD duration in days (d)

Nbr of channels	2	3 ABC or XYZ	9*	12*
STD	4 d	4 d + HR	4 d	2 d
Enh	4 d	4 d (2 + HR)	2 d	1 d
No Comp	3 d	2 d + HR	1 d	–
High resolution only	–	690 min	–	–

256 MB FLASH CARD duration in days (d)

Nbr of channels	2	3 ABC or XYZ	9*	12*
STD	4 d	4 d + HR	4 d	2 d
Enh	4 d	4 d + HR	2 d	1 d
No Comp	6 d	3 d + HR	1 d	1 d
High resolution only	–	1400 min (23h20min)	–	520 min (8h40min)

512 MB FLASH CARD duration in days (d)

Nbr of channels	2	3 (ABC or XYZ)	9*	12*
STD	4 d	4 d + HR	4 d	4 d
Enh	4 d	4 d + HR	4 d	2 d
No Comp	7 d	3 d + HR	2 d	1 d
High resolution only	–	2800 min (46h40min)	–	1050 min (17h30min)

1 GB FLASH CARD duration in days (d)

Nbr of channels	2	3 (ABC or XYZ)	9*	12*
STD	4 d	4 d + HR	4 d	4 d
Enh	4 d	4 d + HR	4 d	2 d
No Comp	7 d	3 d + HR	2 d	1 d
High resolution only	–	4095 min (68h15min)	–	2100 min (35h)

HR: 20 minutes of recording in "high resolution" mode

* Devices available with SyneScope Holter software.

11. DEVICE PARAMETERS

11.1. VOLTAGE SCREEN

This screen allows the user to check the voltage of the external battery (AA 1.5 V) in order to evaluate if there is sufficient power to perform a 1 to 7-day recording.

The voltage of the internal battery (VL 3V) is also displayed so that the user can estimate the autonomy of the configuration of the device (date, time, contrast, recording mode).
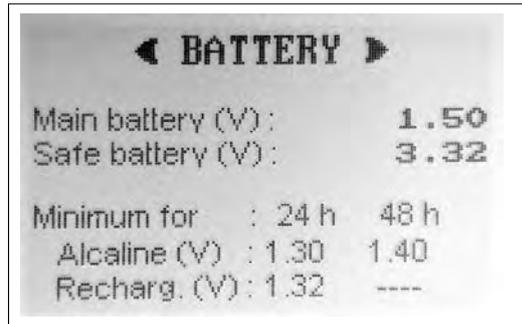
11.2. IMPEDANCE SCREEN

Here the user can check the quality of the connection between the electrodes and the patient's skin.

The screen shows four or six vertical bars, according to the cable in use. Each bar is an indicator of the contact quality of an electrode.

If the height of one bar does not reach the dotted line placed at the middle of the scale, the impedance is not enough to guarantee a good quality signal for the whole duration of the recording. In this case it is suggested to check the quality of the electrode (potentially dried out) and to better prepare the skin's surface.
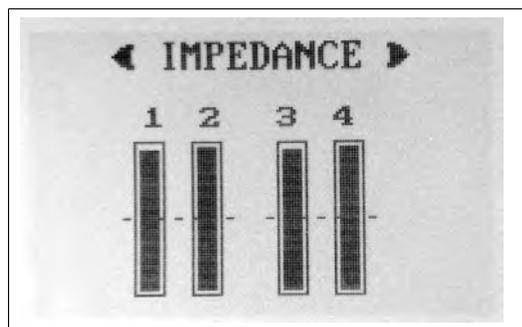
Press the "E" button to know the correspondence between the impedance bar and the positioning of the electrode on the patient. An image will show how to position the electrodes on the patient's thorax.
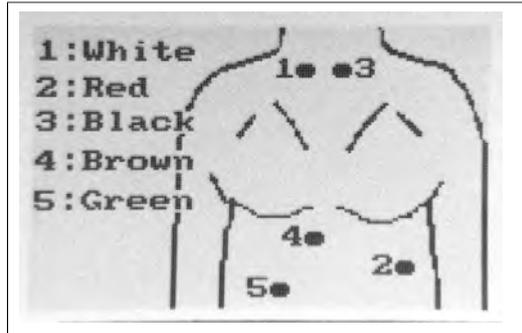
This image can be seen from every screen on the device (except the final Summary screen) by pressing the "E" button.

11.3. TIME AND DATE SCREEN

The device's time and date can be modified in the Time screen and Date screen. Use the
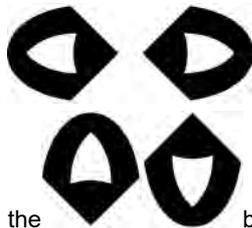
buttons to select hours/minutes/seconds or day/month/year and use

the buttons to modify the value.

European and US date and time systems are available.

NOTE: Time and Date are stored on the device and kept updated by the internal rechargeable battery for about a week.

After switching on the recorder, if the SpiderView fails to retrieve the language, time or date from its memory, it will automatically display the setting screen for these parameters (language, date then time) so that you can re-enter this data.

11.4. ABOUT SCREEN

This screen displays the serial number of the device, the version of the firmware and
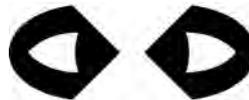
the copyright. Use the buttons to modify the level of contrast of the display.

12. SPECIAL FUNCTIONING MODES AND ERROR MESSAGES

If an error has been generated that can be easily corrected by the user or if it is an error of use, the screen displays a message followed by a recommendation.

i The following messages may appear:

Initialization impossible, use another card	Displayed when an error appears during the flash card initialization phase. Use another flash card, this one is defective.
Write protected card - Check the WP switch	If this message appears while you are using an flash card, you have to put the write protection switch on "write" position.
Unreadable card - Use another card	Displayed when the flash card format is not one used by SpiderView.

If an error of any type occurs during the functioning of the device, an error code is generated by the device and stored on the internal memory. The user can visualize the "Critical error" screen containing the last error that occurred and the time and date of the occurrence by switching the device on (1) and keeping the left cursor button (3) pressed until the end of the auto-test phase. The "Critical error" screen will then be shown until the left arrow button (3) is released.


```
CRITICAL ERROR

SOFT ERROR      : 000D
SYSTEM ERROR  : 5A45
NMI                  : 417B


04.03.03                    14:34
```
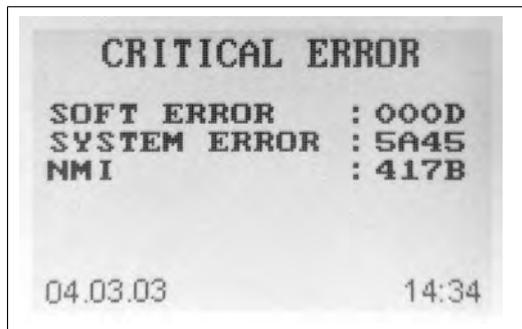
i **NOTE:** Carefully note all information displayed on the screen in order to communicate it to the MicroPort after-sales service or to your distributor if necessary.

To reset the error code memory to zero, switch the device on and keep the right cursor button (3) pressed until the end of the auto-test phase. A message will confirm the reset.

12.1. LIST OF ERROR MESSAGES

0100	Generic media error	0200	Generic HDTK error
0101	Media insertion error	0201	Invalid file descriptor
0102	Media initialization error	0202	File not found or path to file not found
0103	Reading error during init. of recording	0203	No file descriptors available (too many files open)
0104	Writing error during init. of recording	0204	Exclusive access requested but file already exists

0105	Opening error during init. of recording	0205	Attempt to open a read only file or a special (directory)
0106	Closing error during init. of recording	0206	Seek to negative file pointer attempted
0107	Media access error during recording	0207	Write failed. Presumably because of no space
0108	Opening error during recording	0208	Open failed due to sharing
0109	Closing error during recording	0209	No Valid Disk Present
010A	Reading error during recording		
010B	Writing error during recording		
010C	No identif file found	0300	
010D	Error while creating file errlog	0301	Unknown type of compress.
010E	Error while writing file errlog	0302	Overrun on follow-up comp buffer
010F	Error while creating file identif	0303	Overrun on comp buffer
0110	Error while writing file identif		
0111	Error while reading file identif		
0112	Error while creating of ECG file	0400	
0113	Error while writing of ECG file	0401	Overrun on average buffer
0114	Error while creating file errlog	0402	Overrun on acquisition buffer 1
0115	Error while writing file errlog	0403	Overrun on acquisition buffer 2
0116	Error while creating file media		
0117	Error while writing file media		
0118	Error while creating file follow-up	0500	
0119	Error while opening file follow-up	0501	Unknown cable type
011A	Error while writing file follow-up	0502	Cable not connected
011B	Error while flushing on media		
011C	De-synchronization sample counters		
011D	Error while creating HFreq file	0600	Generic supervision error
011E	Error while writing HFreq file	0601	Recording type unknown
011F	Extend file error	0602	Compression type unknown
0120	Truncate file error	0603	PM type unknown
0121	Error while creating file spike	0604	Averaging type unknown
0122	Error while writing file spike		
0123	Error while buffer-writing on file		
0124	Overrun on write-FIFO	0700	
0125	Error while creating daily files	0701	Overrun on spike buffer
0126	Error while opening daily files		
0127	Overrun on follow-up buffer		
0128	Overrun on marker buffer		
0129	Overrun on ECG CRC buffer		

13. TECHNICAL SPECIFICATIONS

13.1. TYPE

SpiderView digital Holter ECG and high resolution ECG recorder.

USA only	This device is a AECG device type 1.

13.2. NUMBER OF LEADS

Depending on the cable used, the device records the following leads:

— 2 or 3 bipolar leads

— 12 leads* (6 peripheral leads + 6 precordial leads)

— 3 leads XYZ to calculate 12 leads according to Dower matrix*

* Available with SyneScope Holter software.

13.3. ELECTRICAL CHARACTERISTICS

Standard quality frequency response:	0.05 - 25 Hz
High-quality and uncompressed mode frequency response	0.05 - 80 Hz
Common-mode rejection:	94 dB
Input dynamic range:	± 16 mV
Power supply:	One 1.5 V AA long-life lithium battery (for seven 24-hour recordings) or one NIMH type rechargeable batteries with a minimum capacity of 1500 mAh.

13.4. MECHANICAL CHARACTERISTICS

Weight	85g (3oz) without battery (25g (0.9oz) for standard 1.5V AA)
Dimensions	97 x 54 x 23 mm (3.8'' x 2.1'' x 0.9'')

For information on operating temperature, storage temperature, atmospheric pressure range, humidity, read conditions for use and storage on paragraph 4.3.

13.5. ACQUISITION CHARACTERISTICS

Storage on flash cards

Acquisition frequency	1000 Hz
Resolution	10 µV (16 bits)
Pacemaker spike detection	✓
High-resolution ECG	1000 Hz, 2.5 µV

The recorded signal, sampled at 1000 Hz, is averaged every 5 ms and is compressed for storage. In standard recording mode (STD), the ECG signal is filtered with a low pass 50 Hz filter to have a good signal/noise ratio and to optimize the size of recorded files (5MB/channel/24h). In enhanced recording mode (ENH), there is no 50 Hz filter and the signal has an excellent quality as long as there is not much noise (10MB/channel/24h).

In uncompressed mode (NoComp) there is no compression, which means that files can be very large (17.3 MB/channel/24h). A downloaded 3 channel 24h recording takes around 54 Mb on your computer's hard drive.

13.6.   RADIO EQUIPMENT EMISSION

Radio Equipment	Transmitter Bands / Maximal Power	Receiver Frequency Bands
SpiderView Bluetooth® Low Energy	[2400 ; 2483.5] MHz ; ≤ 10 mW (0 dB)	[2400 ; 2483.5] MHz

14. ACCESSORIES

The following products, items and accessories listed in the table below are available for SpiderView:

Code	Description	Available on AA Catalogue
LA456T	SpiderView Pack	✓
LA456T SP	SpiderView	N/A
LK600C, LK601C, LK602C	SyneScope Software v3.30c	✓
RC013	ECG Cable SpiderView 3 electrodes / 2 Channels	✓
RC014	ECG Cable SpiderView 7 electrodes / 3 Channels XYZ shielded	✓
RC015	ECG Cable SpiderView 10 electrodes / 12 channels	✓
RC016	ECG Cable SpiderView 5 electrodes / 2 channels	✓
RC017	ECG Cable SpiderView 7 electrodes / 3 channels ABC	✓
RC019	ECG Cable SpiderView 7 electrodes / 3 channels ABC & XYZ and ABC	✓
RF004	Adhesive remover wipes	✓
RG008	Disposable bag	✓
RG006	Reusable Pouch and shoulder strap (without window)	✓
RG016	Shoulder strap replacement	✓
THLA001B	Pack of 30 hypoallergenic ECG electrodes	✓
RE150	Pack of 4 AA Alkaline batteries	✓
RE154	Pack of 4 AA Lithium batteries	✓
LA459	1 GB MEMORY CARD	✓
LA464	256 MB SD card for SpiderView and SpiderFlash recorders	✓

15. APPENDIX

15.1. GUIDANCE AND MANUFACTURER'S DECLARATION: ELECTROMAGNETIC EMISSIONS

All information below is based on the normative requirements to which the manufacturers of electro-medical devices are subject, in the sense of IEC60601-1-2.

The medical device complies with applicable electromagnetic compatibility standards, however, the user will ensure that any electromagnetic interference does not create an additional hazard, such as radio frequency transmitters or other electronic devices.

In this chapter you will find information necessary to ensure the installation and commissioning of your medical device under the best conditions in terms of electromagnetic compatibility.

The different cords of the medical device must be separated from each other.

Certain types of mobile telecommunication devices such as mobile phones are likely to interfere with the medical device. The separation distances recommended in this chapter must therefore be strictly observed.

The medical device must not be used near or on another device. If this cannot be avoided, it must be checked for proper operation under the conditions of use before use.

The use of accessories other than those specified or sold by MicroPort CRM as replacement parts, may result in an increase in the emission or a decrease in the immunity of the medical device and may cause an inappropriate operation.

15.2. GUIDANCE AND MANUFACTURER'S DECLARATION: CABLE LENGTH

Cables and accessories	Maximum length	Test type	In compliance with
Cables/Cords	< 3m	RF emission	CISPR 11, Class B
		Harmonic current emission	IEC61000-3-2
		Voltage fluctuation and flickers	IEC61000-3-3
		Electrostatic discharge immunity	IEC61000-4-2
		Radiated immunity – Electromagnetic fields	IEC61000-4-3
		Electrical fast transient/ burst immunity	IEC61000-4-4
		Surge immunity	IEC61000-4-5
		Immunity to conducted disturbances, induced by radio-frequency fields	IEC61000-4-6
		Radiated immunity - Magnetic fields	IEC61000-4-8
		Voltage dips, short interruptions and voltage variation immunity	IEC 61000-4-11

15.3. GUIDANCE AND MANUFACTURER'S DECLARATION: ELECTROMAGNETIC EMISSIONS

Emissions test	Compliance	Electromagnetic environment - guidance
Electromagnetic radiation disturbance (radiated EMISSIONS) CISPR 11	Group 1	The SpiderView 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.
Disturbing voltage at supply terminals conducted emissions CISPR 11	Class B	The SpiderView is suitable for use in a professional health care establishment.
Harmonic current EMISSIONS IEC 61000-3-2	Non applicable	
Voltage variations, voltage fluctuations and flicker IEC 61000-3-3	Non applicable	

15.4. GUIDANCE AND MANUFACTURER'S DECLARATION: ELECTROMAGNETIC IMMUNITY

SpiderView is intended for use in the electromagnetic environment specified below. The customer or the user of the SpiderView should ensure 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	±8 kV contact ±15 kV air	± 8 kV contact ± 15 kV air	Home health care environment and professional health care establishment.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines	Non applicable	Home health care environment and professional health care establishment.
	± 1 kV for input/output lines		
Surge IEC 61000-4-5	± 1 kV between phases	Non applicable	Home health care environment and professional health care establishment.
	± 2 kV between line(s) to earth		
Magnetic field at industrial rated frequency (IEC61000-4-8)	30 A/m	Non applicable	Home health care environment and professional health care establishment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Voltage dips (IEC 61000-4-11)	0% U_T For 0.5 cycle A 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% U_T for 1 cycle and 70% U_T for 25 cycles, 50Hz 30 cycles, 60 Hz, Monophase: 0°	Non applicable	Mains power quality should be that of a Home health care environment or professional health care establishment. If operation of the system requires continued use during power cuts, it is recommended that the medical device be powered by a separate power source (UPS, etc.).
Voltage Interruptions (IEC 61000-4-11)	0 % U_T; For 250 cycles, 50 Hz For 300 cycles, 60 Hz	Non applicable	Mains power quality should be that of a Home health care environment or professional health care establishment If operation of the system requires continued use during power cuts, it is recommended that the medical device be powered by a separate power source (UPS, etc.).

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

WARNING: Portable RF communication devices (including peripherals such as antenna cables and external antennae) should not be used closer than 30 cm (12 inches) to any part of the SpiderView, including the specified cables. Otherwise, the performance of this device may be impaired.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electromagnetic fields Radiated RF (IEC 61000-4-3)	10 V/m 80 MHz – 2,7 GHz 80 % MA at 1 kHz	10 V/m 80 MHz – 2,7 GHz 80 % MA at 1 kHz	Home health care environment and professional health care establishment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Proximity fields emitted by RF wireless communication devices IEC61000-4-3 (provisional method)	9 V/m 710 MHz, 745 MHz, 780 MHZ, 5240 MHz, 5550 MHz, 5785 MHz 27 V/m 385 MHz 28 V/m 450 MHz, 810 MHz, 870 MHz, 930 MHz, 1720 MHz, 1845 MHz, 1970 MHz, 2450MHz	9 V/m 710 MHz, 745 MHz, 780 MHZ, 5240 MHz, 5550 MHz, 5785 MHz 27 V/m 385 MHz 28 V/m 450 MHz, 810 MHz, 870 MHz, 930 MHz, 1720 MHz, 1845 MHz, 1970 MHz, 2450MHz	Home health care environment and professional health care establishment.
Conducted disturbances, induced by RF fields (IEC610004-6)	3 V 150 kHz to 80 MHz 80% MA at 1 KHz 6 V in ISM band between 0.15 MHZ and 80 MHZ, Radio Amateur band includes 80% MA at 1 KHz	3 V 150 kHz to 80 MHz 80% MA at 1 KHz 6 V in ISM bande between 0.15 MHZ and 80 MHZ, Radio Amateur band includes 80% MA at 1 KHz	Home health care environment and professional health care establishment.

Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range.

Interference may occur in the vicinity of equipment marked with the following symbol:

NOTE: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

15.5. SPIDERVIEW AND MOBILES (RECOMMENDATIONS)

The SpiderView is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled.

Portable RF communication devices (including peripherals such as antenna cables and external antennae) should not be used closer than 30 cm (12 inches) to any part of SpiderView, including the specified cables. Otherwise, the performance of this device may be impaired.

15.6. CANADA

This device contains licence-exempt transmitter(s)/receiver(s) that comply with Innovation, Science and Economic Development Canada's licence-exempt RSS(s).

Operation is subject to the following two conditions:

1. this device may not cause interference, and
2. this device must accept any interference, including interference that may cause undesired operation of the device.

Under ISED regulations, this radio transmitter may only operate using an antenna of a type and maximum (or lesser) gain approved for the transmitter by ISED. To reduce potential radio interference to other users, the antenna type and its gain should be so chosen that the equivalent isotropically radiated power (e.i.r.p.) is not more than that necessary for successful communication.

This equipment complies with ISED radiation exposure limits set forth for an uncontrolled environment and meets RSS-102 of the ISED radio frequency (RF) Exposure rules.

This equipment has very low levels of RF energy that is deemed to comply without testing of specific absorption rate (SAR).

Cet appareil contient des émetteurs / récepteurs exemptés de licence conformes aux RSS (RSS) d'Innovation, Sciences et Développement économique Canada.

L'exploitation est autorisée aux deux conditions suivantes :

1. *il ne doit pas produire de brouillage, et*
2. *l'utilisateur du dispositif doit être prêt a accepter tout brouillage radioélectrique reçu, même si ce brouillage est susceptible de compromettre le fonctionnement du dispositif.*

Conformément à la réglementation d'ISDE, le présent émetteur radio peut fonctionner avec une antenne d'un type et d'un gain maximal (ou inférieur) approuvé pour l'émetteur par ISDE.

Dans le but de réduire les risques de brouillage radioélectrique à l'intention d'autres utilisateurs, il faut choisir le type d'antenne et son gain de sorte que la puissance isotrope rayonnée équivalente (p.i.r.e.) ne dépasse pas l'intensité nécessaire à l'établissement d'une communication satisfaisante.

Cet équipement est conforme aux limites d'exposition aux rayonnements énoncées pour un environnement non contrôlé et respecte les règles d'exposition aux fréquences radioélectriques (RF) CNR-102 de l'ISDE. Cet équipement émet une énergie RF très faible qui est considérée comme conforme sans évaluation du débit d'absorption spécifique (DAS).

15.7. UNITED STATES

This device complies with part 15 of the FCC rules. Operation is subject to the following two conditions:

1. this device may not cause harmful interference, and

2. this device must accept any interference received, including interference that may cause undesired operation of the device.

This 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 try to correct the interference by one of the following measures:

— Reorient or relocate the receiving antenna.

— Increase the separation between the equipment and 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 radio/TV technician for help.

CAUTION: This equipment may not be modified, altered, or changed in any way without signed written permission from MicroPort CRM. Unauthorized modification may void the equipment authorization from the FCC and will void the MicroPort CRM warranty. This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment and meets the FCC radio frequency (RF) Exposure Guidelines. This equipment has very low levels of RF energy that is deemed to comply without testing of specific absorption rate (SAR).

◆ MicroPort