SmartTouch

USER MANUAL

MicroPort™ CRM

TABLE OF CONTENTS

1. WARNINGS AND PRECAUTIONS

- The programmer is not a life-saving device. In case of emergency, use an external defibrillator.
- The programmer is Magnetic Resonance (MR) unsafe. Don't bring the programmer into MRI site Zone 3 or 4 as defined by the Guidance Document for Safe MR Practices published by the American College of Radiology [1].
- The equipment must be operated by qualified personnel only: physicians, nurses, technical members of hospital staff, company representatives. All of them being trained and having a comprehensive or partial knowledge of cardiac rhythm management, in keeping with their assigned task: surgery, follow-up, servicing, etc. For additional information please contact your company representative.
- To avoid damage or hazards, NEVER make any changes or modifications to the equipment. For maintenance services and support, please contact your company representative.
- To avoid the risk of electric shock, this equipment must only be connected to a mains supply socket with protective earth. If earth protection is unsure, the tablet programmer must be operated in battery mode.
- Make sure the means of disconnection/isolation from the mains supply are easily accessible to the user.
- The programmer should not be used adjacent to or stacked with other equipment and if adjacent or stacked use is necessary, check that the device is working normally in the configuration in which it will be used.
- The use of accessories or cables other than those specified, with the exception of those sold by the manufacturer as replacement parts, may result in increased emissions or decreased immunity of the programming system.
- Be sure to eliminate any static charge from your body before touching the device when you are in an environment with a risk of electrostatic discharge (carpeted floors, etc.). In order to do so, touch a water line, gas line, etc. or, if none is available, a large metal object (operating table, etc.).
- The operator shall not touch the patient and the metallic accessible connectors of the programmer simultaneously.
- In high environmental temperatures, the inductive programming head may become hot (up to 46 °C) and must not be directly applied to the patient's skin for longer than 10 minutes. For detailed information about the temperature constraints please refer to chapter 13.6.
- Do not use the programmer should there be any sign of visible damage.
- Shocks or rough handling could damage the device's housing. Mishandling may affect the programmer's operation. Even if the device appears to be operating well after the impact, damage that is not immediately detectable may arise.
- When designing and manufacturing the device, every precaution is taken to minimize the risks of infiltration. However, any liquid penetration shall alter its operation.
- Prolonged storage in a high-humidity location may alter the device's operation. For detailed information about the storage humidity constraints please refer to section 13.7.
- The programmer must be stored in a secure and locked room when not in use.

1. Kanal E, et al., American Journal of Roentgenology 188:1447-74, 2007

— The medical centre shall control access to the programmer and prevent its use by unauthorized personnel.

For warnings and precautions on the ‘Radio Frequency (RF) Link’ accessory, please refer to the associated user manual.

2. WARRANTY CONDITIONS

For detailed information about the compatibility of programming devices and implantable patient devices, please refer to the Device-Compatibility-Matrix that is available under the reference number UA193 at www.microportmanuals.com.

The manufacturer agrees to replace any defective material.

If a technical problem occurs, please contact your company representative or the company's service department.

WARNING: Never modify the configuration of the programmer. Do not install any software on the programmer.

The programmer contains no internal parts that can be repaired by the user. In the event of a problem, please return the programmer to your company representative in the condition in which it was received.

The manufacturer waives all responsibility if a malfunction occurs following manipulation by the user as described above.

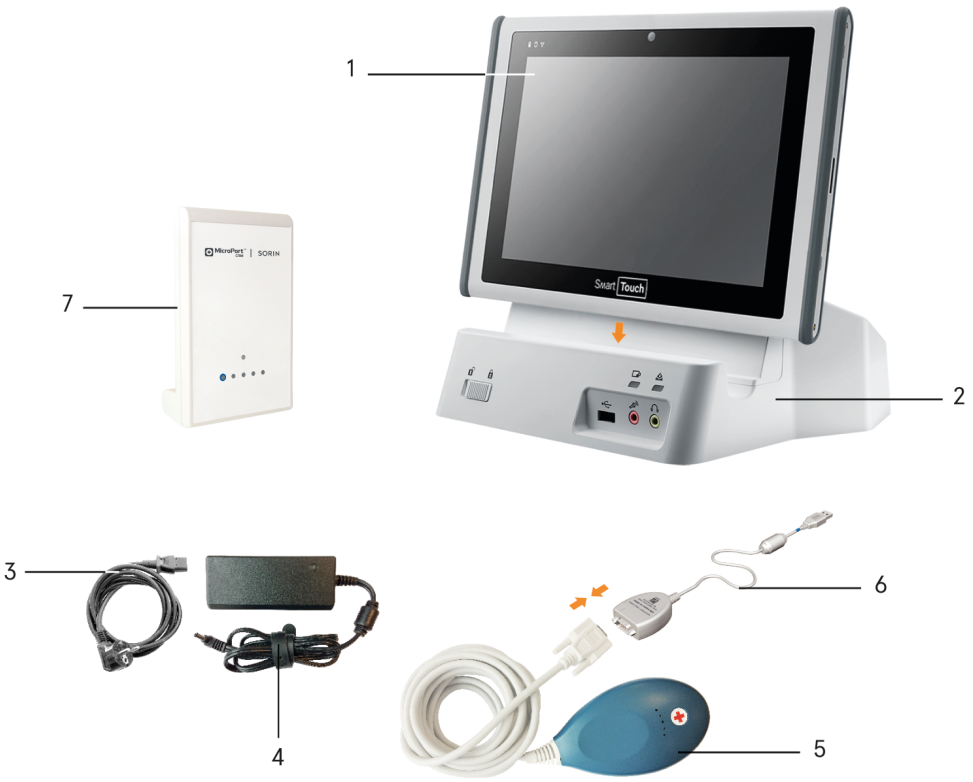
3. THE PROGRAMMER SYSTEM

3.1. GENERAL INFORMATION

The SmartTouch programmer is a microprocessor-based medical tablet used to program pacemakers and defibrillators. Additionally, it provides measurement, ECG display and report printing functions.

This manual does not explain how to use the programming software; please refer to the corresponding user manual or programming guide at www.microportmanuals.com

3.2. SYSTEM OVERVIEW [2]



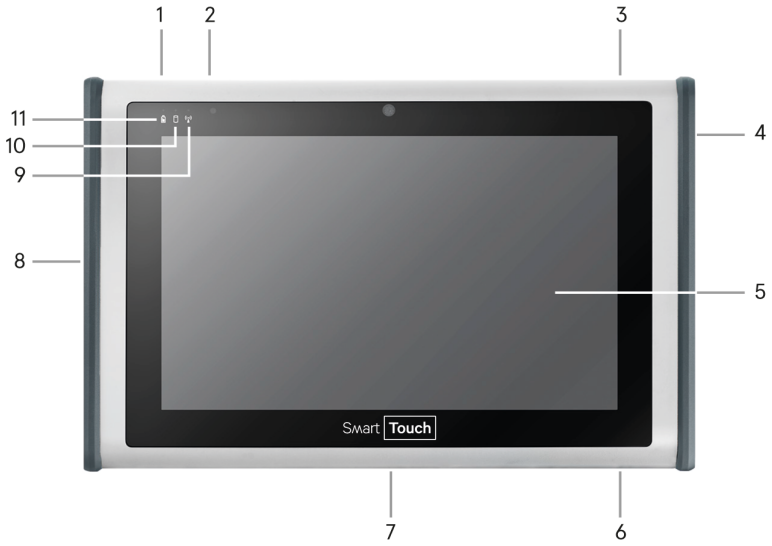
1) SmartTouch tablet	5) Inductive programming head (CPR3H)
2) SmartTouch docking station	6) Dongle (USB adapter for CPR3H)
3) Power cable	7) Radio Frequency Link (Orchestra Plus Link)
4) Power adapter	

2. Images and diagrams are non-contractual and are for illustrative purposes only.

4. THE PROGRAMMER TABLET

4.1. COMPONENTS

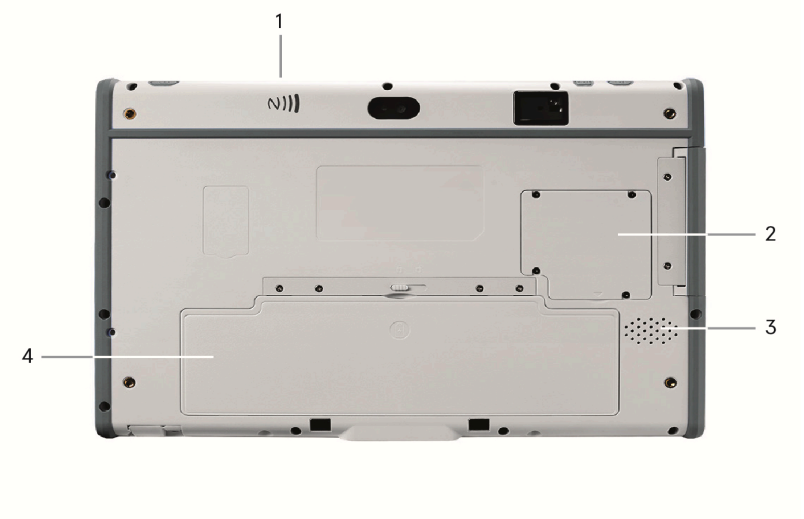
Front view



1) P1: for maintenance purpose only	7) Docking connector
2) P2: for maintenance purpose only	8) I/O ports
3) Power on/off button	9) Connectivity LED indicator -Blue: Bluetooth module is on
4) Expansion module connection (not in use)	10) HDD LED indicator -Flashing green: Hard Disk Drive is working
5) Touch screen	11) Battery status LED indicator -Green: Battery is fully charged (>95%) -Amber: Battery is charging -Amber: Battery life is lower than 10%
6) Power adapter port	

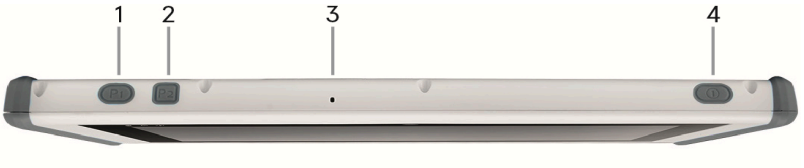
NOTE: There is no camera installed in the programmer tablet.

Rear view



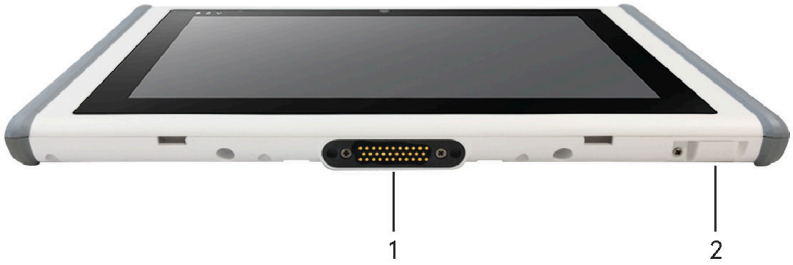
1) NFC (not in use)	3) Speaker
2) SSD cover	4) Battery

Top view



1) P1: For maintenance purpose only	3) Built-in microphone (not in use)
2) P2: For maintenance purpose only	4) Power on/off button

Bottom view



1) Docking connector

2) Power adapter port

Left view

1) I/O ports cover	3) USB 3.0 (blue marking)	5) Audio jack (not in use)
2) Micro HDMI	4) USB 2.0	

Power adapter and cable

NOTE: The power adapter connects the programmer tablet or the docking station with the external power supply.

4.2. CHARGING THE TABLET

Only use the power adapter provided by the manufacturer for charging the programmer tablet.

Fully charge the battery of the programmer tablet before using it in battery mode for the first time.

Ensure that the programmer tablet is ALWAYS sufficiently charged when using it in battery mode. Therefore, keep the tablet connected to a power supply in case of non-mobile usage or when not in use. If the tablet is not charged sufficiently, you may not be able to complete the procedure without re-connecting the tablet to an external power supply.

Connect the power cable with the power adapter. To charge the programmer tablet connect the free end of the power adapter to the tablet or to the rear of the docking station and the free end of the power cable to the power socket. The battery status LED in the upper left corner of the tablet screen will light up.

The battery LED in the upper left corner of the tablet screen will give an indication about the tablet's battery status:

- Green: Battery is fully charged (>95%).
- Amber: Battery is charging (tablet connected to a power supply)
- Amber: Battery life is lower than 10% (tablet not connected to a power supply)

Leave the tablet to charge for a minimum of 2 hours.

If the battery performance decreases due to aging, programmer maintenance will be required. Please contact your company representative.

4.3. SETTING UP THE SYSTEM

Before using the programmer follow the steps below:

Step 1: Installing the tablet battery

1. Align and insert the battery at the rear of the programmer tablet.
2. Secure the battery by moving the mechanical lock to the “locked” position.

Step 2: Charging the programmer tablet

Please refer to the preceding chapter 4.2.

Step 3: Installing the programmer tablet

To ensure proper operation of the programmer tablet, place it on a secure and stable surface or in the docking station. When using the tablet with the docking station, make sure the tablet is correctly inserted and locked into the docking station. For more information about the docking station please see chapter 5. Inappropriate installation of the equipment may prevent it from functioning correctly!

Step 4: Connecting the inductive programming head (CPR3H)

1. Securely connect the serial connector of the inductive programming head with the dongle (for detailed information about the CPR3H inductive programming head and dongle please see chapter 7).
2. Tighten the fixation screws between the inductive programming head and the dongle.
3. Open the I/O ports cover at the left side of the programmer tablet and connect the dongle to the USB 3.0 port (blue marking). See figure below.

To ensure a stable telemetry operation the inductive programming head must be connected to the USB 3.0 port (blue marking).

To maintain a stable telemetry connection the dongle must always be tightly attached to the inductive programming head and the USB 3.0 port of the programmer tablet.

To interrogate radiofrequency-enabled implanted devices connect the Radio Frequency (RF) Link to the USB 2.0 port on the left side of the programmer tablet.

4.4. STARTING THE PROGRAMMER

1. Be sure to follow the steps described in chapter 4.2. and 4.3. before using the programmer.
2. Start the programmer with a short press on the power on/off button in the top right corner of the tablet.
3. The welcome window will be displayed on the screen.

The software boots automatically when the programmer starts up.

4.5. USING THE TOUCH SCREEN

The programmer tablet is equipped with capacitive touch screen technology. Simply tap the screen with your fingers or a stylus for capacitive touch screens in order to select tabs, files and text fields, or to run applications. The tablet screen will automatically switch to a black screen saver after a few minutes not in use (a Bluetooth LED in the upper left corner of the tablet is still lit up). Wake up the tablet programmer by tapping on the screen.

4.6. SWITCHING OFF THE TABLET

1. Press the power on/off button in the top right corner of the tablet and hold it down for 1 second (Bluetooth LED in the upper left corner of the tablet goes off).
2. There is a guard around the power on/off button to avoid a software interruption due to a handling error.
3. It is not possible to switch the programmer to standby mode during an interrogation session.
4. The tablet will automatically switch to standby mode when remaining unused in the ‘Manager’ software. In order to restart the tablet, press briefly on the power on/off button.

For information about the programmer software, please see chapter 5.

5. THE PROGRAMMER SOFTWARE

5.1. GENERAL INFORMATION

The programmer software consists of the ‘Manager’ software and of application software ‘Modules’ which are specific for each implantable cardiac device.

After starting the programmer, the home screen of the ‘Manager’ software will be displayed:

This screen allows you to perform the following actions:

— View, enter, import and export data to/from the programmer’s ‘Manager’ software. Choose the relevant tabs in the menu bar at the top of the screen.

— Program the implanted patient device in nominal mode using the ‘Red Cross’ button in the top right corner of the screen.

— Interrogate the implantable patient device by pressing the ‘Interrogate’ button. This action will open the associated Application Software ‘Module’ for the interrogated patient implant.

See an example of an application software ‘Module’ screen for an implantable device below:

The application software ‘Module’ allows interrogation, programming and testing of the implantable patient device.

5.2. INITIAL INSTALLATION OF THE PROGRAMMER SOFTWARE

Before using the programmer for the first time, the programmer software needs to be installed on the tablet. In order to do so, please perform the steps described below. It is recommended to keep the tablet connected to a power supply during the software installation.

1. Switch on the tablet by pressing the “Power” button as described in chapter 4.4.
2. You will be asked to select “your region” from a drop-down list. Select the geographical region where the programmer will be operated and press the “Next” button.
3. A pop-up window will request a confirmation of the chosen geographical region in order to ensure that the correct region was selected. Please check that the selected region is correct and confirm by pressing “Yes”. In case an incorrect region was selected, press “No” and return to the previous screen to correct the region entered.

WARNING: In case an incorrect geographical region is installed, the programmer has to be returned to the manufacturer. Please contact your company representative for further instructions.

4. After selecting and confirming the correct geographical region, you will be asked to enter the time zone, local date and time. After doing so, press “Next” and confirm the entry in the displayed pop-up window.
5. Insert the USB key that has been provided by the manufacturer in the USB port at the left side of the tablet. Press “Next”.
6. Select the language which is to be used during the software installation and that will be set as default language afterwards. Confirm by pressing “OK”.
7. Proceed with the software installation by following the instructions displayed on the screen. A message will indicate the successful installation of the software.

8. Remove the USB key and press “OK” in order to confirm that the installation was successful.
9. The programmer tablet will shut down automatically and will be ready for use when restarted.

5.3. STORING THE PATIENT DATA

Patient data is stored on the programmer tablet hard drive.

We recommend regular back-up of the patient data stored on the programmer tablet hard drive.

In case the programmer has to be retrieved from the field all patient data must be deleted from the programmer hard drive. Patient data can be saved on an external storage medium prior to deletion.

1. Connect a USB flash drive to the USB port at the left side of the programmer tablet or to the USB port of the docking station, in case the tablet is placed in the docking during usage.
2. Select the files required and press the “Export” button to transfer the files to the chosen external storage medium (see *Figure - Export files screen* below).

- In order to protect the patient data from unauthorized use, the patient data files will be automatically anonymized when exported to an external storage medium.
- During this automated file anonymization the patient’s name will be deleted in the exported file.
- **CAUTION**: In addition to deleting the patient’s name, the patient’s birthdate will be anonymized by changing the original day of birth to the “15th” of the same month. However, the original month and year of patient’s birth shall be maintained.

5.4. UPGRADING THE PROGRAMMER SOFTWARE

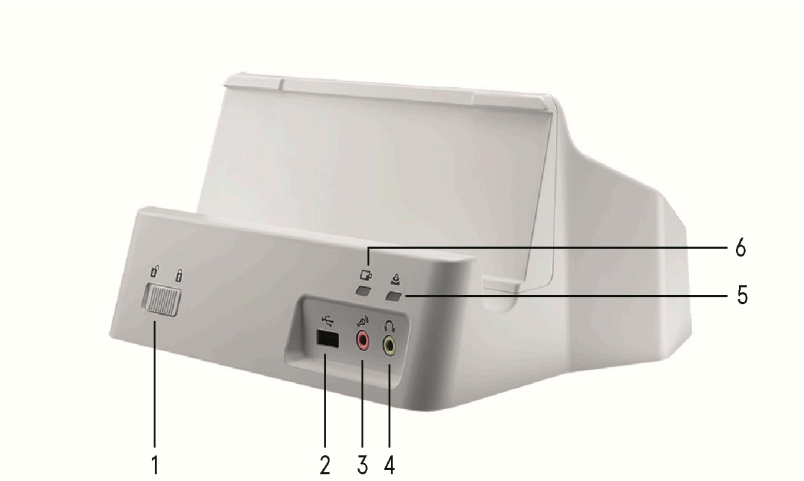
Before starting a software upgrade on the programmer, plug the tablet to the power supply to prevent the tablet shutting down during the software upgrading process.

6. THE DOCKING STATION

The docking station is used to place the programmer tablet in a fixed, vertical position during implantation, follow-ups, charging or storage, when programmer tablet mobility is not required.

6.1. COMPONENTS

Front View



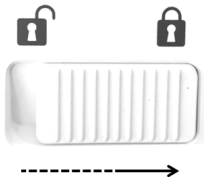
1) Lock mechanism	4) Earphone jack (not in use)
2) USB 2.0 port	5) Detection LED
3) Microphone jack (not in use)	6) Battery status LED indicator

Rear View

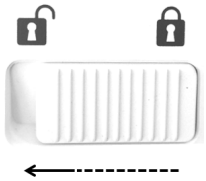
7) Power adapter port	10) VGA port
8) LAN port (not in use)	11) COM port
9) USB 2.0 port	12) Battery charging bay

6.2. GENERAL INFORMATION

When placing the programmer tablet in the docking station, ensure that the docking station is positioned on an even, stable surface. The lock mechanism of the docking station will automatically lock in the tablet when placed in the correct position.



The docking station can be used to charge the tablet. To do so, connect the docking station with an electrical outlet using the power adapter as described in chapter 4.2. The tablet is charging when the battery status LED indicator at the front of the docking station lights up. Before removing the tablet from the docking station, move the mechanical lock of the docking station to its 'unlocked' position.

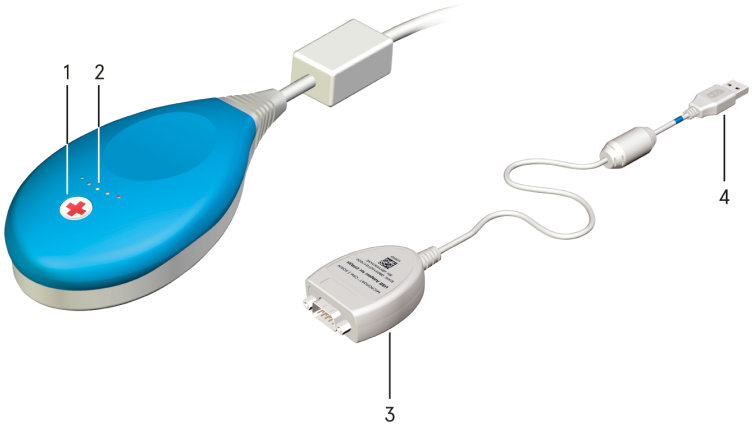


7. THE INDUCTIVE PROGRAMMING HEAD

The programming head provides inductive communication between the programmer tablet and the implanted cardiac device.

The programmer tablet must only be used with a ‘CPR3H’ inductive programming head.

7.1. COMPONENTS



Inductive programming head	Dongle (USB adapter for CPR3H)
1) Nominal mode button	3) Serial connector
2) Locator LEDs	4) USB connector

The blue marking indicates that the USB connector of the dongle needs to be connected to the USB 3.0 port of the tablet

7.2. GENERAL INFORMATION

The CPR3H inductive programming head must only be connected to the USB 3.0 port of the programmer tablet via the dongle.

1. Connect the dongle with the inductive programming head before connecting the dongle to the programmer tablet. For more information on how to connect the inductive programming head with the dongle please refer to chapter 4.3.
2. The head is automatically turned on when the programmer tablet is switched on.
3. An automatic test is run when the head is turned on in order to verify that it is operating properly.
4. During the test the yellow and green LEDs located on top of the programming head switch on.
5. The programming head is functional when the yellow LED is on.

The inductive programming head is used to:

— activate the telemetry,
— identify the implanted device model,
— conduct telemetry in order to communicate with the implanted device when telemetry is performed in inductive mode.

The inductive programming head can be used in auto-interrogation mode. After pressing the interrogate button on the programmer screen, the physician has up to 5 minutes to place the inductive programming head over the implanted device for the telemetry to start automatically.

When using the Radio Frequency (RF) Link, the programmer beeps when RF communication has been activated and the inductive programming head can be removed from the patient. For more information about the usage of the RF Link, please refer to the associated user manual.

WARNING:
There is no magnet in the head. However, it may temporarily disturb the rate response function during interrogation.

7.3. USING THE INDUCTIVE PROGRAMMING HEAD

You can use the inductive programming head to directly trigger the nominal mode without interrogating the implant. However, the programmer must be switched on.

The inductive programming head must be positioned above the pacemaker or defibrillator during programming or interrogation procedures. The array composed of green LEDs is a locator. The number of highlighted green LEDs relates to the superposition of the head over the implant.

The LEDs do not indicate the degree of telemetry contact.

For optimal telemetry, you are advised to keep the inductive programming head away from electromagnetic interference, which can be generated by any electronic equipment including medical.

The upper part of the inductive programming head can produce localised heat from the LEDs. Under normal conditions of use, the heat produced is at a level that will affect neither the patient nor the functioning of the inductive programming head.

Nominal mode

The  button allows the pacemakers and defibrillators to be programmed in nominal mode.

In order to do so, press the  button once, when the head is turned on.

Compatibility

The CPR3H inductive programming head is compatible with software version SmartView 3.00 or higher.

During the use of the inductive programming head, reciprocal interferences with other electrical instruments may happen, causing a deterioration of performance (slow-down of the communication, interruption of the communication) or the inability to perform the requested action.

8. THE RADIO FREQUENCY (RF) LINK

Wireless Radio Frequency (RF) communication between the programmer tablet and compatible Radio Frequency implantable devices is provided by the Radio Frequency (RF) Link (Orchestra Plus Link).

8.1. COMPONENTS

1. Functioning status LED

— Orange: Device is running software initialization and self-tests
— Green: Device is ready for use

2. RF Link indicator LED (RF signal strength 5 LEDs)

— All 5 LEDs lit up: Indicates optimal RF communication quality
— 1 LED flashing: Device is trying to restore the RF communication
— All 5 LEDS flashing sequentially: Device software is being updated

3. USB cable

8.2. GENERAL INFORMATION

Associated with the programmer, the RF Link has been specially designed to program and interrogate compatible RF implantable medical devices.

Compatible RF implantable cardiac devices are equipped with a transceiver which receives clinical commands and sends clinical information and device parameters through the RF Link wireless technology. Please note that an audio signal is emitted once RF communication has been established between the RF Link and the implantable medical device.

For more information about implant RF wireless programming compatibility, please refer to the implant user manual.

For more information about the use, maintenance and recycling of the Radio Frequency (RF) Link, please refer to the associated user manual.

The use of the Radio Frequency (RF) Link as described in the associated manual applies to all compatible programmers. Please refer to the Device-Compatibility-Matrix that is available under the reference number UA193 at www.microportmanuals.com. For details regarding the connection of the RF Link to the Smart Touch programmer, please refer to the following

section (8.3).

During the use of the RF Link, reciprocal interferences with other electrical instruments may happen, causing a deterioration of performance (slow-down of the communication, interruption of the communication) or the inability to perform the requested action.

8.3. CONNECTING THE RF LINK TO THE PROGRAMMER

The RF Link can be directly connected to the programmer tablet, or plugged in the USB port of the docking station when the programmer tablet is placed in the docking station during usage.

When the RF Link is connected to the USB port of the docking station, removing the programmer tablet from the docking station will disconnect the tablet from the Radio Frequency Link. Consequently, the RF communication between the programmer tablet and the implanted patient device will be disabled.

9. THE ECG

9.1. GENERAL INFORMATION

In order to display an ECG in the programmer's application software 'Module', the programmer can be connected with a compatible wireless ECG device via Bluetooth.

The tablet-based programmer has been tested for compatibility with selected wireless ECG devices. For detailed information about the wireless ECG devices that are compatible with the programmer, please contact your company representative.

9.2. PAIRING THE WIRELESS ECG DEVICE WITH THE PROGRAMMER

1. Turn on the ECG.
2. In the 'Manager' software screen of the programmer tablet, under the tab 'Settings', select 'Bluetooth'. All Bluetooth devices captured by the programmer are displayed.
3. From the listed devices, select the ECG device which is to be paired, and press the 'Pair' button.
4. Enter the Passcode for the ECG device in the text field of the pop-up window. The ECG Passcode can be found in the ECG manufacturer's user manual. Press the 'Confirmation' button to start the pairing process with the programmer software.

The programmer can only be paired with one ECG device at a time. In case multiple ECG devices are used with the same programmer, unpairing the ECG used in a preceding session before pairing a different ECG device will be necessary. In this case, press the 'Unpair' button next to the device which won't be used in the current session before pressing the 'Pair' button next to the ECG device that will be used in the current session.

When using the same ECG device during successive sessions, repeating the steps described above is not necessary. In this case, the programmer software will automatically pair with the ECG via Bluetooth.

9.3. STARTING THE ECG DISPLAY

Before interrogating the implanted device, ALWAYS verify that the serial number of the wireless ECG attached to the patient corresponds with the serial number of the ECG displayed in the 'Manager' software screen of the programmer. The programmer may have captured the signal of a different wireless ECG device used in close proximity and paired with it.

The Bluetooth communication link is very low power and therefore unlikely to interfere with cardiac pacemakers. To preempt any interference, it is recommended to locate the ECG distant from the immediate vicinity of the heart.

1. Interrogate the patient's implanted device. The ECG will automatically be displayed in the application software 'Module' screen after interrogation.
2. The display will end when switching off the ECG, when the battery runs out, or when the display is stopped by the software.

10. THE PRINTER

10.1. GENERAL INFORMATION

In order to print report files or in-session data, the programmer tablet can be paired with supported ‘plug and play’ printers via Bluetooth or USB.

The programmer has been tested for compatibility with selected printers. For detailed information about the printers that are supported by the programmer software, please contact your company representative.

10.2. PAIRING A PRINTER WITH THE PROGRAMMER

1. In order to pair the programmer with a printer via Bluetooth, first, turn on the printer which is to be paired with the programmer tablet.
2. In the ‘Manager’ software screen of the programmer tablet, under the tab ‘Settings’, select ‘Bluetooth’. All Bluetooth devices captured by the programmer are displayed.
3. From the listed devices, select the printer which is to be paired, and press the ‘Pair’ button.
4. Enter the Passcode for the printer in the text field of the pop-up window. The printer Passcode can be found in the printer manufacturer’s user manual. Press "Confirm" to start the pairing process with the programmer software.

The programmer allows you to pair multiple printers. Printers that have been paired with the programmer will be displayed for selection in a drop-down list when printing.

11. MAINTENANCE

11.1. CLEANING

The programmer and its accessories should never be immersed in any liquid or cleaned with sterilization products. Avoid spilling liquid on any part of the programmer system.

In order to clean the following items:

— SmartTouch Tablet
— SmartTouch docking station
— CPR3H and Dongle

1. Visually inspect them for contaminants and remove loose material with a dry or water-moistened cloth.
2. Then clean them with a tissue pad or a wipe moistened with one of the following agents:

— Ethyl alcohol
— Isopropyl alcohol

The above-mentioned agents have been tested by the manufacturer, and validated to neither cause physical damage nor degradation to any part of the programmer.

For information on how to clean the RF Link, please refer to the associated user manual.

For information on how to clean the surface ECG, please refer to the associated user manual.

For information on how to clean the printer, please refer to the associated user manual.

11.2. DISINFECTION AND STERILISATION

All parts of the programmer system are delivered non sterile, and cannot be disinfected or sterilized. The inductive programming head must be covered with a sterile sleeve when using in sterile environments.

11.3. SYSTEM END-OF-LIFE

At their end of life, the programmer, its accessories and/or battery shall be sent back to the manufacturer for recycling.

11.4. SPARE PARTS

Description	Reference
SmartTouch tablet	V167
SmartTouch docking station	V174
Inductive programming head (CPR3H)	GB78
Dongle (USB adapter for CPR3H)	G999
Radio Frequency Link (Orchestra Plus Link)	KA351
Smart ECG	K379

Description	Reference
ECG cable	RC016 / V208-RC042US
Power adapter	TAC0188
Power cable	TAC0190
External thermal printer (WOOSIM)	V175
Thermal paper (for WOOSIM)	TAC0191
SmartTouch tablet battery	TAC0192

To order, please contact your company representative.

12. GUIDANCE AND MANUFACTURER'S DECLARATION

NOTE: For the guidance and manufacturer's declaration of the Radio Frequency (RF) Link accessory, please refer to the associated user manual.

12.1. RADIO EQUIPMENT EMISSION

Radio Equipment	Transmitter Frequency Bands/ Maximal Power	Receiver Frequency Bands
Orchestra Plus Link	[2400; 2483] MHz; 10 mW (+10 dBm)	[402 – 405] MHz
	[402 – 405] MHz; 25 µW (-16 dBm)	
SmartTouch Tablet Bluetooth Low Energy and Bluetooth	[2400; 2483.5] MHz; ≤10 mW (+10 dBm)	[2400 – 2483.5] MHz
Inductive Telemetry CPR3H	**Slow mode:** frequency ~30kHz modulation pulsed, 12.4 dBµA/m at 3m **Fast mode:** frequency ~70 kHz modulation pulsed, 17.4 dBµA/m at 3m	8kHz, 16kHz

Note: Values provided are in accordance with Directive 2014/53/EU.

12.2. RECOMMENDED SEPARATION DISTANCES ACCORDING TO THE MAXIMUM OUTPUT POWER OF THE COMMUNICATIONS EQUIPMENT

The tablet programmer 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 antennas) should not be closer to 30 cm (12 inches) from any part of the programmer. Otherwise, the performance of these devices may be impaired.

12.3. 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

Cables and accessories	Maximum length	Test type	In compliance with
		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

12.4. ELECTROMAGNETIC EMISSIONS

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

Emissions test	Compliance	Electromagnetic environment - guidance
Electromagnetic radiation disturbance (radiated EMISSIONS) CISPR 11	Group 1	The programmer uses RF energy only for its own function. Its RF emissions are very low and are not likely to cause any interference to nearby electronic equipment.
Disturbing voltage at supply terminals conducted emissions CISPR 11	Class B	The programmer is suitable for use in a professional health care establishment.
Harmonic current EMISSIONS IEC 61000-3-2	Class A	
Voltage variations, voltage fluctuations and flicker IEC 61000-3-3	Complies	

12.5. MAGNETIC AND ELECTROMAGNETIC IMMUNITY

The programmer is intended for use in the electromagnetic environment specified below. The customer or the user of the programmer 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	Professional health care establishment.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines	± 2 kV for power supply lines	Professional health care establishment.
	± 1 kV for input/output lines	± 1 kV for input/output lines	
Surge IEC 61000-4-5	± 1 kV between phases	± 1 kV between phases	Professional health care establishment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
	± 2 kV between line(s) to earth	± 2 kV between line(s) to earth	
Magnetic field at industrial rated frequency (IEC61000-4-8)	30 A/m	30 A/m	Professional health care establishment.
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°	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°	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	0 % *U*T; For 250 cycles, 50 Hz For 300 cycles, 60 Hz	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: UT is the a.c. mains voltage prior to application of the test level.

12.6. ELECTROMAGNETIC IMMUNITY, PORTABLE RADIO FREQUENCY EQUIPMENT

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

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
WARNING: Portable RF communication devices (including peripherals such as antenna cables and external antennas) should not be used closer to 30 cm (12 inches) to any part of the Smart touch programmer, including the specified cables. Otherwise, the performance of this device may be impaired.			

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Radiated RF IEC 61000-4-3 Proximity fields emitted by RF wireless communication devices IEC 61000-4-3 (provisional method)	3 V/m 80 MHz to 2.7 GHz 80% MA at 1 KHz 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, 2450 MHz	3 V/m 80 MHz to 2.7 GHz 80% MA at 1 KHz 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, 2450 MHz	Professional health care establishment.
Conducted disturbances, IEC 61000-4-6	3 V 150 kHz to 80 MHz 6V in ISM Band between 0.15 MHz - 80 MHz 80% MA to 1 KHz	3 V 150 kHz to 80 MHz 6V in ISM Band between 0.15 MHz - 80 MHz 80% MA to 1 KHz	Professional health care establishment.

12.7. RAW MATERIALS

The following materials (CPR3H Head) may remain in contact with body tissues.

Item	Material	Description
Lower half shell screw cover	Novablend PC–ABS T 65 FR	POLYCARBONATE ABS (ABS-PC) Grey
Upper half shell	PC/ABS CYCOLOY C2100HF	POLYCARBONATE ABS (ABS-PC) Blue
Outer sole	Sconablend TPE 60 x 119	SEBS 60 SHORES
Light guide	Polycarbonate PC transparent Panlite L-1225L	POLYCARBONATE PC
Button	KE–951U	SILICONE
Firm label	Lexan 8B–35–112	POLYCARBONATE (PC)
Serial number label	Polyester B–423	POLYESTER
Main cable	LG-0475F	PVC

13. TECHNICAL DATA

NOTE:
For the technical specifications and declaration of conformity of the Radio Frequency (RF) Link accessory, please refer to the associated user manual.

13.1. CONFORMITY OF THE PROGRAMMER

Conformity with Directives	90/385/EEC, 2014/53/EU
Patient safety	IEC 60601-1, Class I, BF Type
EMC	IEC 60601-1-2 EN 301 489-1 EN 301 489-17 EN 301 489-27 EN 301 489-31
ERM	EN 300 328 EN 302-195 FCC CFR 47 RSS-GEN

13.2. US FEDERAL COMMUNICATIONS COMMISSIONS (FCC) AND INDUSTRY CANADA

13.2.1. Inductive programming head

FCC

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

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).

IC: This equipment complies with IC radiation exposure limits set forth for an uncontrolled environment and meets RSS-102 of the IC 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 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'IC.

Cet équipement émet une énergie RF très faible qui est considérée comme conforme sans évaluation du débit d'absorption spécifique (DAS).

13.2.2. Programmer Tablet

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

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 distance 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.

13.3. ESSENTIAL PERFORMANCES

The operating mode defined for the SmartTouch Programmer for immunity tests according to the 60601-1-2 standard are:

— Mode 1: with an Inductive programmer device CPR3H communicating with an Implant. Bluetooth module of the tablet device transmitting in continuous test mode,
— Mode 2: with the Orchestra plus link communicating with an implant. Bluetooth module of the tablet device transmitting in continuous test mode.

The essential performance criteria in Mode 1:

— EGM displayed on tablet screen,
— CPR3H four LEDs ON,
— No disturbance on Bluetooth.

The essential performance criteria in Mode 2:

— EGM displayed on tablet screen,
— Orchestra Plus Link four LEDs ON,
— No disturbance on Bluetooth.

13.4. POWER SUPPLY

Voltage/Intensity	AC Adapter In 100 to 240 V / ~1.5A AC Adapter Out 19V / ~3.4A max
Frequency	50 - 60 Hz

13.5. DIMENSIONS PROGRAMMER TABLET

Height	196 mm
Width	292 mm
Depth	20 mm
Weight	1.1 kg

13.6. DIMENSIONS DOCKING STATION

Height	185 mm
Width	260.8 mm
Depth	103.8 mm
Weight	1 kg

13.7. DIMENSIONS INDUCTIVE PROGRAMMING HEAD

Height	160 mm
Width	80 mm
Depth	38 mm
Weight	0.471 kg

13.8. USE CONSTRAINTS

Temperature	From +10 °C to +35 °C (non-condensing)
Humidity	From 10% to 90 % HR (non-condensing)

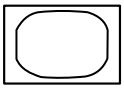
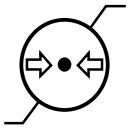
13.9. STORAGE CONSTRAINTS

Temperature	From -20 °C to +60 °C (non-condensing)
Humidity	From 10% to 90% HR (non-condensing)
Atmospheric pressure	From 500 hPa to 1060 hPa

13.10. SYSTEM SPECIFICATIONS OF THE PROGRAMMER

Processor	Intel® Celeron® Processor N2930 Quad Core 1.83GHz
Storage	1 x mSATA SSD, support up to 128GB
Memory	DDR3L 1066MHz SODIMM (up to 8GB)
Communication	Bluetooth

14. EXPLANATION OF SYMBOLS

General symbols	Explanation of symbols
	Manufacturer
	Product reference number.
	Product serial number.
	Connector for a USB device.
	Connector for an external screen.
	Connector for an Ethernet LAN connection.
	This symbol indicates the minimum and maximum storage temperature.
	This symbol indicates the minimum and maximum storage humidity.
	The product should be kept dry.
	This symbol indicates the minimum and maximum storage pressure.
	The equipment contains conductive parts and emits non ionizing radiation (according to standard IEC 60601-1).
	This symbol concerns the inductive programming head. It indicates that this is BF Type applied part, according to standard IEC 60601-1 for electrical medical equipment.

General symbols	Explanation of symbols
	Medical equipment with respect to electric shock, fire, and mechanical hazards, only in: — AAMI/ES 60601-1(2006) / A2 (2010) and — CSA 22.2 NO 60601-1 CAN/CSA:2008.
	Appropriate cables should be used to avoid adverse effects due to the possible discharge of a cardiac defibrillator.
	Magnetic Resonance (MR) unsafe.
	This electronic product is subject to disposal and recycling regulations that vary by country and region. Many countries prohibit the disposal of waste electronic equipment in standard waste receptacles. For more details, please refer to the European Directive 2012/19/EU (WEEE).
	This symbol confers the approval of the US Federal Communications Commission.
	The device is compliant with Japan's radio standards.
	The device is in full conformity with European Directive 90/385/EEC.
	Consult the documentation and instructions for use.
	Consult instructions for use available on the company website www.microportmanuals.com.

General symbols	Explanation of symbols
	This icon is used to call your attention to a particularly important point.

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

15. GLOSSARY

AC	Alternated current
ANSI	American National Standard Institute
AAMI	Association for the Advancement of Medical Instrumentation
BF Type	Applied part with high protection against electrical shock
CISPR	International Electrotechnical Commission (Comité International Spécial des Perturbations Radioélectriques)
COM	Communication port
CPR3H	Inductive Programming Head
ECG	Electrocardiogram
EEC	European Economic Community
EMC	European Standard

FCC	Federal Communications Commission
HDD	Hard Disk Drive
HDMI	High-Definition Multimedia Interface
IEC	International Electrotechnical Commission
I/O	Input/Output
LAN	Local Area Network
LED	Light Emitting Diode
MR	Magnetic Resonance
NFC	Near Field Communication
RF	Radiofrequency
SAM	Security access module (SmartCard integrated circuit)
SSD	Solid State Drive
USB	Universal Serial Bus
VGA	Video Graphics Array

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