

SmartView Connect™ App

USER MANUAL



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1. INTRODUCTION

The SmartView Connect™ App is part of the SmartView Remote Monitoring System. It transmits information stored in your MicroPort CRM implanted cardiac device to your doctor, automatically or manually.

2. INDICATION

The SmartView Connect App allows the remote monitoring of patients implanted with a MicroPort CRM Bluetooth® low energy-enabled pacemaker to treat symptomatic bradycardia. It is thus indicated in patients requiring atrial or ventricular pacing, or synchronous atrioventricular pacing, as detailed below.

According to guidelines, atrial or ventricular pacing is mainly indicated for the following conditions:

- Accepted patient conditions warranting chronic cardiac pacing include:
 - symptomatic paroxysmal or permanent second- or third-degree AV block;
 - symptomatic bilateral bundle branch block;
 - symptomatic paroxysmal or transient sinus node dysfunction with or without associated AV conduction disorders;
 - bradycardia-tachycardia syndrome to prevent symptomatic bradycardia or some forms of symptomatic tachyarrhythmias;
 - vasovagal syndromes or hypersensitive carotid sinus syndromes.

Synchronous atrioventricular pacing is indicated for patients who may benefit from maintenance of AV synchrony and for the treatment of conduction disorders that require restoration of both rates and which include:

- various degrees of AV block to maintain the atrial contribution to cardiac output;
- VVI intolerance (e.g. pacemaker syndrome) in the presence of persistent sinus rhythm;
- low cardiac output or congestive heart failure secondary to bradycardia.

Adaptive-rate pacing is indicated for patients exhibiting chronotropic incompetence and who may benefit from increased pacing rates concurrent with increases in physical activity.

Guidelines on cardiac pacing are provided by the European Society of Cardiology (2013 ESC Guidelines on cardiac pacing and cardiac resynchronization therapy. *Eur Heart J.* 2013;34:2281–2329), and the American College of Cardiology and the American Heart Association (2012 ACCF/AHA/HRS Focused Update of the 2008 Guidelines for Device-Based Therapy of Cardiac Rhythm Abnormalities. *J Am Coll Cardiol.* 2013; 61(3):e6-75).

3. USER PROFILE

The SmartView Remote Monitoring System, which contains the SmartView Connect™ App can be offered by physicians to patients that have been implanted with a MicroPort CRM Bluetooth® low energy-enabled pacemaker according to medical guidelines. No specific training is required by the patient to use the SmartView Connect App.

4. CONTRAINDICATIONS AND/OR LIMITATIONS

4.1. CONTRAINDICATIONS

No clinical contraindications to the use of the SmartView Connect™ App are known.

4.2. LIMITATIONS

No limitations to the use of the SmartView Connect App are known.

5. INTENDED CLINICAL BENEFIT(S)

The SmartView Connect App is non-implantable medical software (embedded on an off-the-shelf smartphone-like device) that is part of the SmartView Remote Monitoring System (RMS) intended for patient management.

The SmartView RMS includes SmartView Remote Monitoring Software, in addition to the SmartView Connect App. These pieces of software do the following:

- The SmartView Connect App¹ ensures the scheduled or patient-initiated wireless transmission of data from a BLE-enabled implanted cardiac device to a back-office data management system.
- Then, the SmartView Remote Monitoring Software retrieves these data from the back-office data management system and makes them available to the physician to enable patient management.

The intended clinical benefit of the SmartView RMS is patient management, as it allows physicians to monitor device/patient status. Benefit is ensured by the successful wireless transmission of data (scheduled and patient-initiated transmission) associated with the intended use of the SmartView Connect App. Therefore, the success of the wireless transmission of data (scheduled and patient-initiated transmission) is considered to reflect the intended clinical benefit of the SmartView Connect App.

The measurable, relevant clinical outcome parameters reflecting this clinical benefit (success of scheduled and patient-initiated wireless transmissions of data) are the percentage of patients that can be monitored, and the rates of successful scheduled and patient-initiated transmissions.

1. The SmartView Connect App, designed by MicroPort CRM, is fully automatic so does not require any specific patient interventions when working normally, in operational mode. A patient can, however, initiate a transfer of information manually, if necessary.

6. WARNINGS AND PRECAUTIONS

6.1. WARNINGS



The SmartView Remote Monitoring System is not intended as an emergency response system.

If at any time you feel that you need a fast response, CALL YOUR LOCAL EMERGENCY SERVICE IMMEDIATELY and inform your doctor, who might suggest you execute a manual data transmission.

The SmartView Remote Monitoring System is not intended to replace face-to-face follow-up with the doctor.

6.2. PRECAUTIONS FOR PROPER OPERATION

Interference – The function of the SmartView Connect App may be affected by other electrical appliances. Please avoid putting the SmartView Connect system near any electrical appliance that could emit interference.

7. PACKAGE CONTENTS

The package contains:

- The SmartView Connect system, composed of a monitor (containing the SmartView Connect™ App) and a docking station;
- a mains power adaptor;
- a USB power cable



THE MONITOR



THE DOCKING STATION

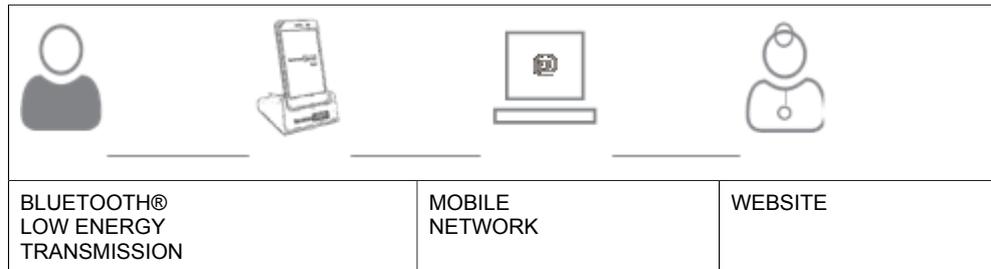


THE POWER ADAPTOR
AND CABLE

8. USING YOUR SMARTVIEW CONNECT SYSTEM

8.1. HOW DOES THE SMARTVIEW CONNECT SYSTEM WORK?

The SmartView Connect system, which includes the SmartView Connect™ App, is part of the SmartView Remote Monitoring System that enables your doctor to retrieve an implanted cardiac device report easily, and to use it in planning your care.



The SmartView Connect system transfers information from your implanted cardiac device to the clinic at regularly scheduled times, determined by your doctor: from the implanted device to the monitor, the data encrypted by the implant are transferred through Bluetooth® Low Energy, while the link between the monitor and the website (“Back Office”) is on a mobile (cellular) network.

The data are then available to your doctor and other medical professionals for review. The SmartView Connect system checks many functions of your implanted cardiac device, such as the battery life and status of the leads that connect your implanted cardiac device to your heart. Your doctor can also determine if your heart has been beating regularly.

In addition to the regular transmissions scheduled by your doctor, the SmartView Connect system checks every night that your implanted cardiac device is functioning normally. Under certain conditions, your implanted cardiac device signals an alert that the SmartView Connect system transmits to your clinic. Your doctor can then detect any problems with the function of your implanted cardiac device and will contact you if necessary.

The SmartView Connect system is designed to use the mobile network (4G/3G/2G) to transmit your personal data to your doctor. The operator name and number are already recorded on the MicroPort CRM SIM card, which is specific to the SmartView Connect system. As such, the MicroPort CRM SIM card can only be used by the SmartView Connect system: inserting the MicroPort CRM SIM card into a mobile telephone does not allow you to make calls.

You're also strongly advised against replacing the MicroPort CRM SIM by another one, as it might not allow you to transmit pacemaker data to your doctor.

8.2. SET UP OF THE SMARTVIEW CONNECT SYSTEM

8.2.1. Installing the SmartView Connect system

1. Place the SmartView Connect system within 2 meters (6.5 feet) of the position where you normally sleep. The device shall not be in direct sunlight or near other heat sources where temperature could exceed 45 °C (113 °F).
2. Connect the larger end of the USB power cable to the power adaptor plug
3. Connect the power adaptor plug to a wall socket

4. Connect the small end of the USB power cable to the rear of the docking station



The cable socket

5. Slide the monitor into the docking station

Result: The power indicator light on the top-left corner should light up (red or green)



Note: the steps above (1 to 5) can be done in any order.

6. If the power indicator light does not light up:

6.1. Check that the SmartView Connect monitor has been correctly inserted into the docking station

6.2. Check that the power cable has been correctly inserted into the wall socket

6.3. Check that the USB power cable has been correctly inserted into the power adaptor

6.4. Check that the USB power cable has been correctly inserted into the docking station

Result: The power indicator light should light up (red or green)



Note: the points above (6.1 to 6.4) can be checked in whatever order.

7. If the indicator light is red, the SmartView Connect system has been properly connected but is not yet fully charged and is charging

7.1. Wait until the power indicator light turns green (it can take a maximum of six hours)

Result: The green power indicator light indicates that the SmartView Connect system is fully charged.

END RESULT: The SmartView Connect system is plugged in and fully charged.

8.2.2. Activating the SmartView Connect system

The SmartView Connect system needs to be activated before it is first used, in order to connect it to your implanted cardiac device so that the system is able to automatically recognize it later, whenever it is needed.

Requirement: The SmartView Connect system is charged.

1. Remove the SmartView Connect monitor from the docking station
2. Turn the SmartView Connect monitor on:

- 2.1. Press on the power button located on the upper right side of the monitor
- 2.2. Hold it until the screen lights up

Result: The screen lights up.



The power button to turn your monitor ON or OFF

3. Release the power button
4. An animated screen will be displayed until the SmartView Connect App is ready to be executed
5. Wait, for the display of the “MicroPort CRM” logotype to appear

Result:

- If the doctor has already partially initialized SmartView Connect the following is displayed: a page with the logotype “MicroPort CRM”, then, an instruction to go to your bedroom
- If the doctor has already completely initialized SmartView Connect the following is displayed: a page with the logotype “MicroPort CRM”, then, an indication of the date of last automatic transmission
- If the doctor has not yet initialized SmartView Connect the following is displayed: a page with the logotype “MicroPort CRM”, then a page with a choice of languages.



Figure 1: The home page

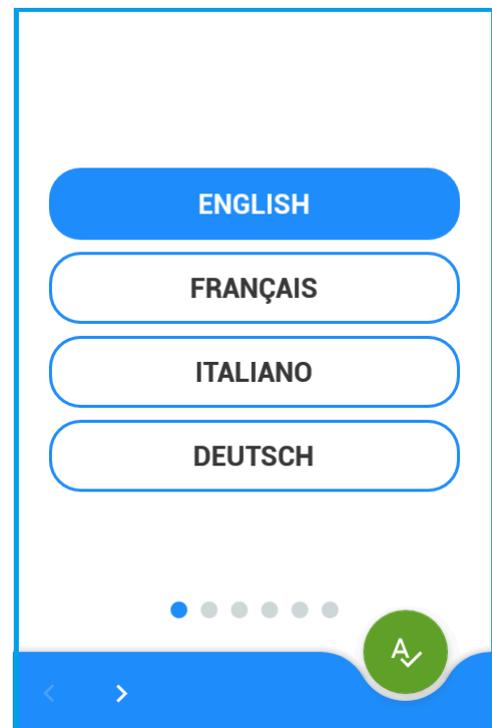


Figure 2: a choice of languages is displayed if the doctor has not yet initialized the SmartView Connect

Activating the SmartView Connect system when the doctor has already partially initialized it (continued)

Requirement: an instruction to go to your bedroom is displayed.

- Fit the monitor on the docking station.

END OF ACTIVATION: SmartView Connect is initialized and activated, and needs to perform the first transmission.



Important Reminder: Always keep your SmartView Connect system plugged into the mains to ensure that it transmits properly.

Activating the SmartView Connect system when the doctor has already completely initialized it (continued)

Requirement: information on Last Transmission Date is displayed.

- Fit the monitor on the docking station.

END OF ACTIVATION: SmartView Connect is initialized and activated, and the first transmission has been already performed.



Important Reminder: Always keep your SmartView Connect system plugged into the mains to ensure that it transmits properly.

Activating the SmartView Connect system when the doctor has not yet initialized it (continued)



Note: The advancement of the activation procedure from one screen to another is always based on intentional commands given by the user, through pushbuttons at the bottom of the different views. No automatic advancement mechanism is in place.

Requirement: A list of languages is displayed.

1. Select your language

1.1. If your preferred language is not displayed, scroll the page by swiping a finger on the screen, or using the arrows at the bottom

1.2. Validate the choice using the green button

Result: a page is displayed asking for the serial number of your implanted cardiac device.

2. Type on the displayed keyboard the characters of your serial number, one by one, from left to right, as they appear on the implanted cardiac device card that your doctor has given you.

The serial number is a sequence of eight digits and letters preceded on the left by the symbol

SN

- 2.1. Type a digit

Result: the digit is displayed in the first empty box on the left

- 2.2. In case you type the wrong digit:

2.2.1. Select it by tapping it on the screen

2.2.2. Select and type a new digit

Result: the new digit is displayed in place of the old one

OR

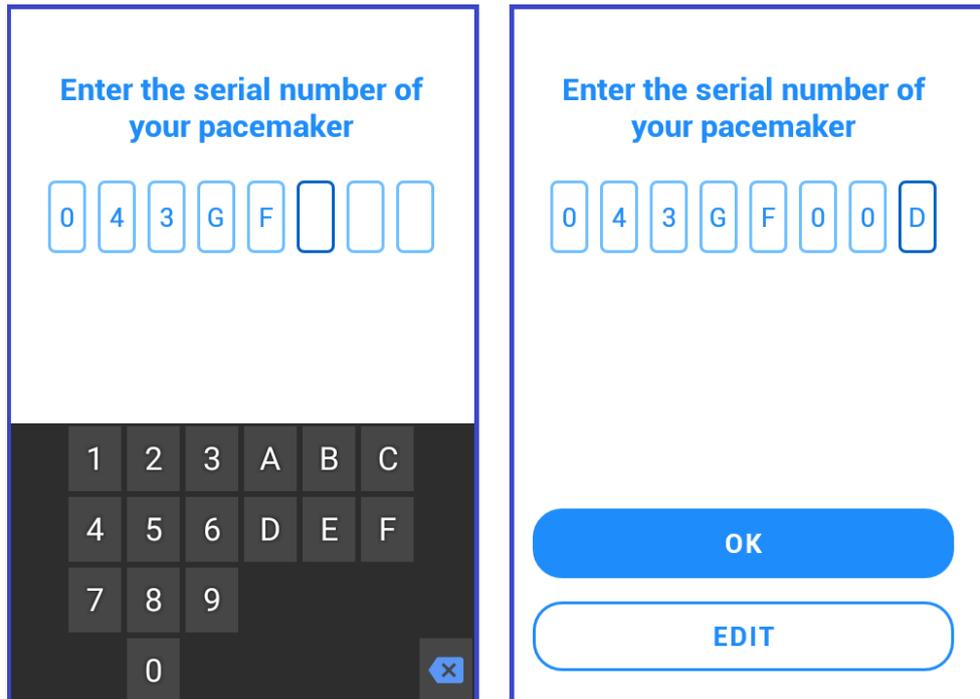
2.2.1. Press the “X” key

Result: the digit is erased

2.2.2. Select and type a new digit

Result: the new digit is displayed in place of the old one

Result: When the serial number is complete, the keyboard is replaced by the buttons “OK” and “Edit” (see figures below).



3. If the serial number is wrong:

3.1. Press the “Edit” button

Result: the serial number is erased.

3.2. Type the serial number again as explained in step 2

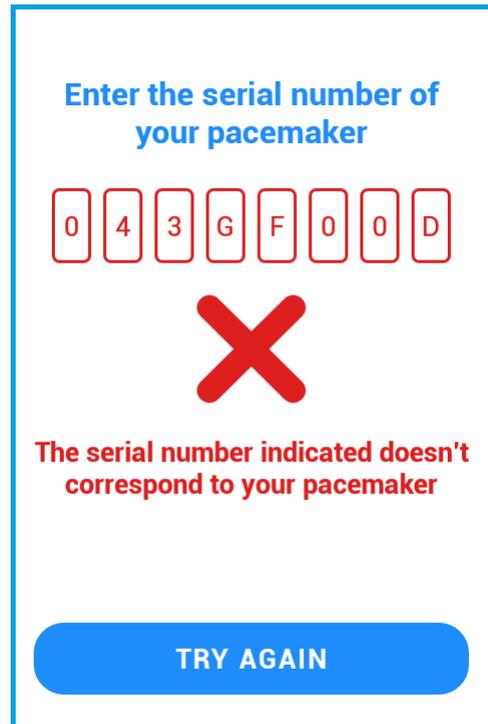
4. If the serial number is correct:

4.1. Press the “OK” button.

Result: the SmartView Connect verifies that the serial number is correct:

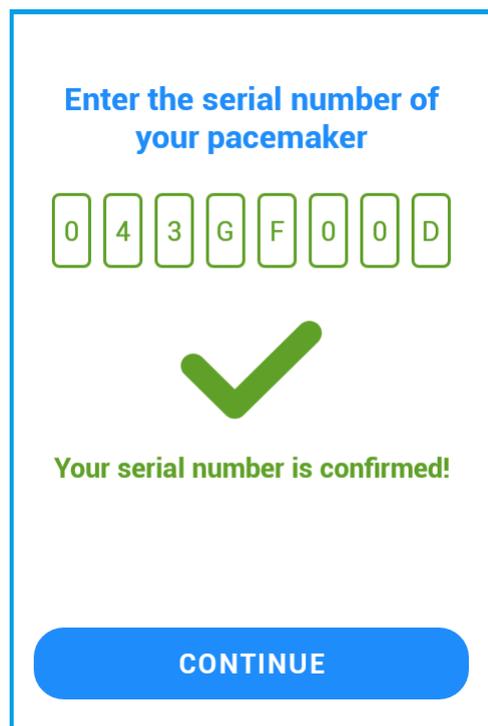
4.2. If the serial number is invalid, a page is displayed asking you to type in the serial number again (see figure below):

4.2.1. Press the “Try again” button



4.2.2. Type the serial number again as explained in step 2

4.3. If the serial number is valid, confirmation of a valid serial number is displayed (see right)



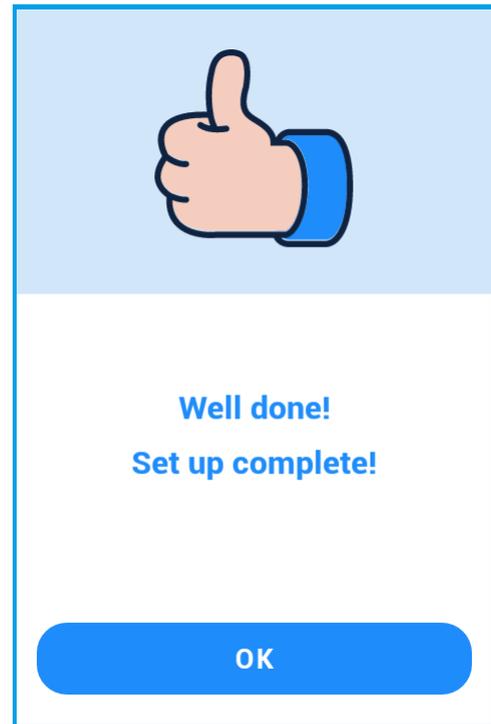
4.3.1. Press the “Continue” button

Result: instructions to go to your bedroom and to put the monitor beside your bed are displayed.

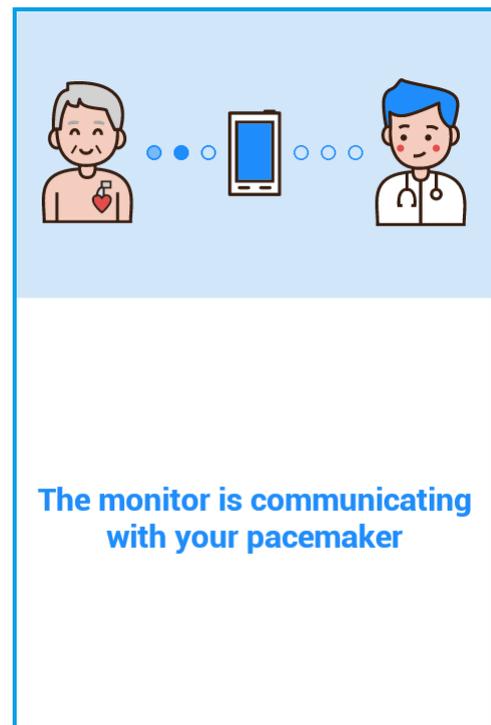
4.3.2. Put the monitor back on the docking station.

Result: information that the configuration was successfully completed is displayed

4.3.3. Press the “OK” button



Result: a screen is displayed informing that the monitor is communicating with your pacemaker.



END OF ACTIVATION: the SmartView Connect system is initialized and activated: now that it has the serial number of the implanted cardiac device, it will try to communicate with the implanted cardiac device.



Important Reminder: Always keep your SmartView Connect system plugged into the mains to ensure that it transmits properly.

Checking the first transmission

Requirement: the SmartView Connect system is initialized and activated.

After first initialization and activation, the SmartView Connect system will check your implanted cardiac device for the first time and will perform the first data transmission to your doctor when you are nearby (in a steady position) (within 2 meters [6.5 feet] from the SmartView Connect system) for a sufficient time period (from 15 minutes to approximately 2 hours).

We suggest you allow the following procedure to occur automatically during the night while you are sleeping in your bed. If you are hospitalized, or need to stay in bed anyway, any moment can be adequate.

You will not notice the interaction of SmartView Connect system with the implanted device, and the SmartView Connect system won't alter the therapies or the functioning of the connected implanted device in any way.

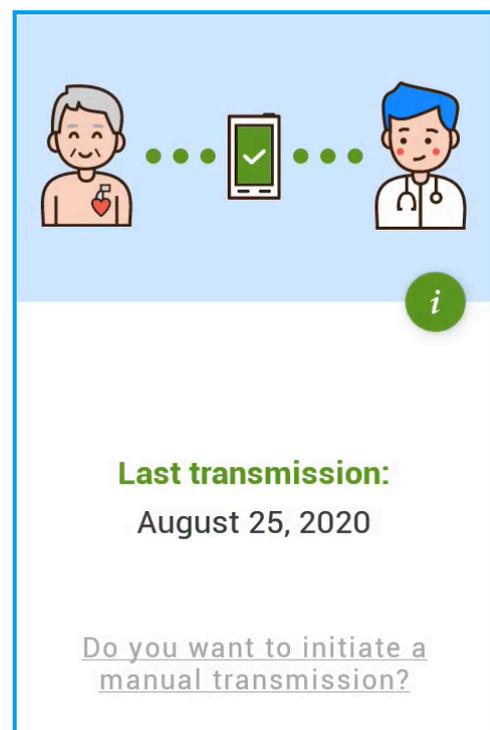
1. Stay close to the SmartView Connect system (within 2 meters [6.5 feet]) for a sufficient time period (a maximum of two hours is requested, staying a longer time has no adverse effect)
2. On waking up the next morning, or anyways not before 15 minutes, briefly press the power button

Result: the screen lights up

3. Check the status of the transmission

Result:

1. The message on the screen as shown right indicates that the transmission was successful.



Screenshot of a successful transmission

2. If the first transmission has not yet occurred:
 - If the screen message is reporting that the transmission is in progress, no action is requested. Let the process continue and check the status of the transmission later
 - If an error message is displayed, follow the on-screen instructions to retry.

END FIRST TRANSMISSION: all the data from your implanted cardiac device have been transmitted to your doctor for the first time.

8.3. DAILY LIFE WITH THE SMARTVIEW CONNECT SYSTEM

After the initial set up, the SmartView Connect system works automatically.

You do not have to do anything else with the SmartView Connect system, unless your doctor asks you to send a transmission manually (see section 8.3.2 Manual Transmissions).



Important Reminder: Always keep your SmartView Connect system plugged into the mains to ensure that it transmits properly.

8.3.1. Automatic Transmissions

At time intervals scheduled by your doctor, your SmartView Connect system communicates with your implanted cardiac device in order to retrieve recorded data and transmit them to your doctor. Additionally, once a day the SmartView Connect system quickly communicates with your implanted device to check whether any clinical or technical events, about which your doctor has requested notification, have been detected. If this is the case, the SmartView Connect system collects and transmits the recorded data.

In order for communication to occur, you need to stay within 2 meters (6.5 feet) of the SmartView Connect system for about two hours: this is why both the automatic transmissions and the daily checks are usually scheduled at nighttime, while you are sleeping beside your SmartView Connect system.

If you know that you will be at work at night or away from your SmartView Connect system for an extended period of time for any reason (for example, a vacation or family visit), contact your doctor to adjust the transmission schedule.

End automatic transmission messages

If the automatic transmission is successful, its date will be displayed when you turn on the display.

The screen will go black again after a few seconds.

If the SmartView Connect system detects an issue with the automatic transmission, an error message (see section 9 PROBLEMS AND SOLUTIONS) will be displayed on the screen and will remain visible for some minutes. The screen will then go black again, but the error message will be displayed again as soon as you activate the screen.

8.3.2. Manual Transmissions

Although the transmission of data through the SmartView Connect system is completely automatic, under some circumstances your doctor may ask you to initiate a transmission yourself.



Remember: do not initiate a transmission on your own initiative, except if your doctor has expressly advised to do so.

If you feel unwell, the right thing to do is to contact your doctor first, to describe your symptoms and receive the most appropriate advice.

Full implementation of this procedure usually lasts a few minutes, but in some cases it can take up to two hours.

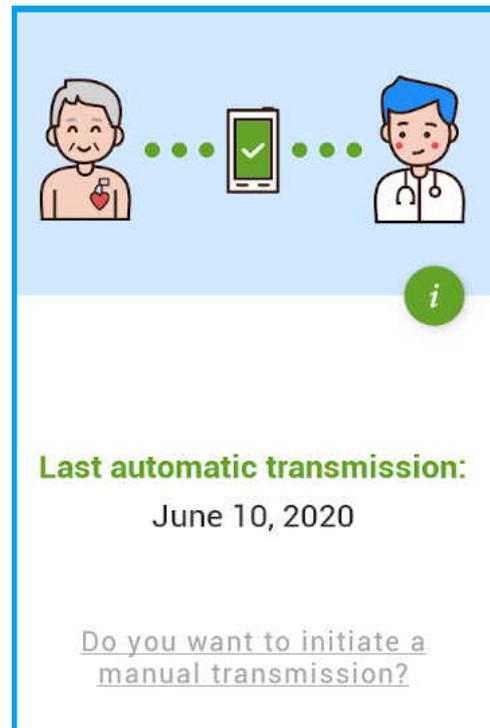
If the mobile signal is weak, your SmartView Connect system will suggest moving to another room.

Launch a manual transmission

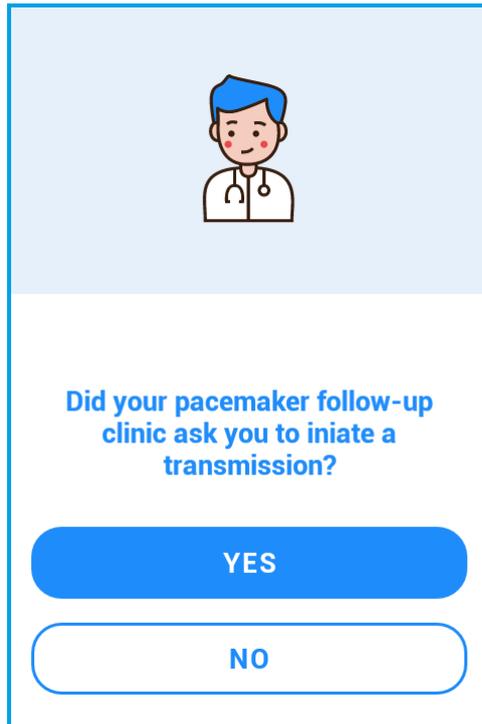
When your doctor asks you to perform a manual transmission,

1. Stay within 2 meters (6.5 feet) of your SmartView Connect system during the procedure
2. Briefly press the power button

Result: an image like the one on the right will be displayed.

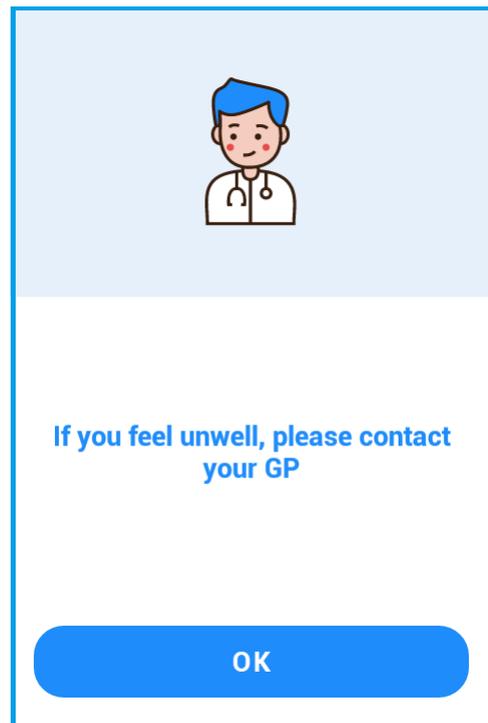


3. Select the underlined sentence: "Do you want to initiate a manual transmission?"



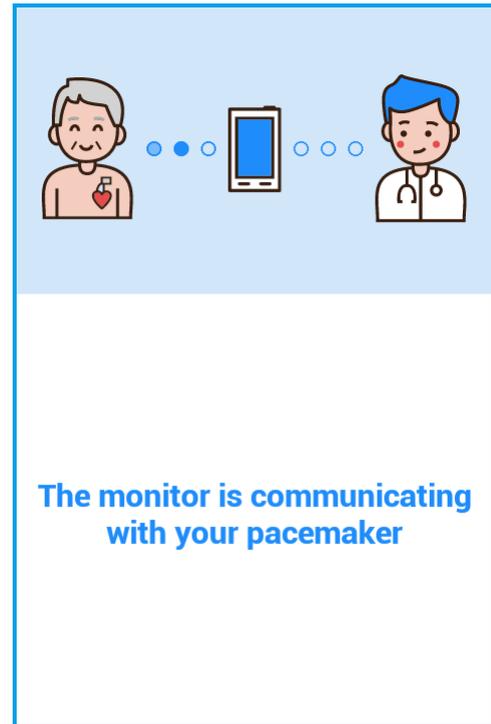
4. Press "Yes" to confirm that you are acting under your doctor's instructions

Result: if the system is not aware of the permission from your doctor to perform the manual transmission, you are notified by the message shown right.



- 4.1. Tap on "OK"
 - 4.2. Contact your doctor to update the system settings
- Result:** the system settings are updated.
- 4.3. Restart the procedure from step 1

Result: the image on the right is displayed



The SmartView Connect system establishes a link with your implanted cardiac device to retrieve the stored data.

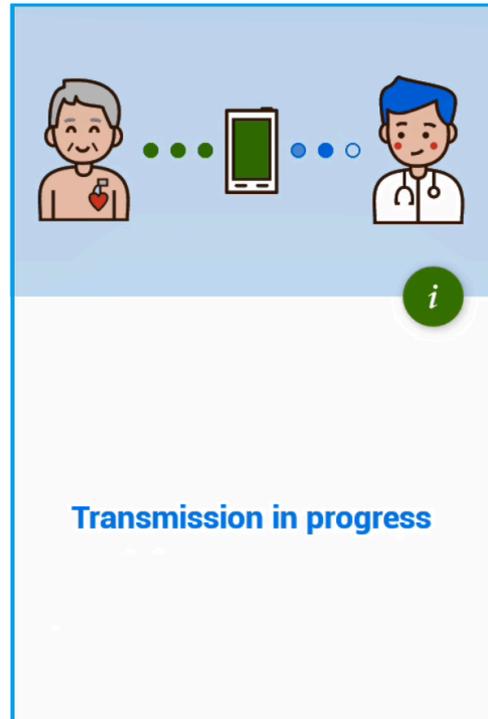
If no link to your implanted cardiac device is established, a message will ask you to come closer:

5. Move closer to the SmartView Connect system

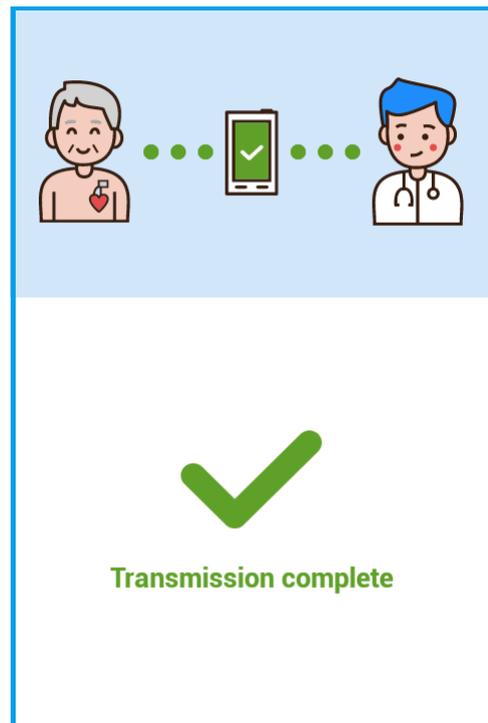
Result: communication between the SmartView Connect system and your implanted cardiac device is restored.

When the collection of data from your implanted cardiac device is complete, the SmartView Connect system transmits the data to your doctor.

The displayed picture changes to the one shown right.



As soon as the transmission is complete, the successful outcome will be displayed for a few seconds as shown right.



Lastly, the screen will turn off as usual.

8.3.3. Recharging the battery

If the indicator light in the top-left is red and blinking: the SmartView Connect system will soon turn off.

If the indicator light in the top-left is off and the monitor does not switch on after pressing the power button: the battery of the SmartView Connect system is completely discharged.

In these two cases:

1. check that the monitor has been properly inserted into the docking station (if not, insert it properly),
2. check that the plug of the power adaptor is properly inserted into the wall socket and on the back of the docking station (if not, insert it properly).

Result: The power indicator light stays red but stops blinking: the monitor is recharging.

If the monitor turned off due to a discharged battery:

3. Press the power button for 5 seconds.

Result: the monitor switches on.

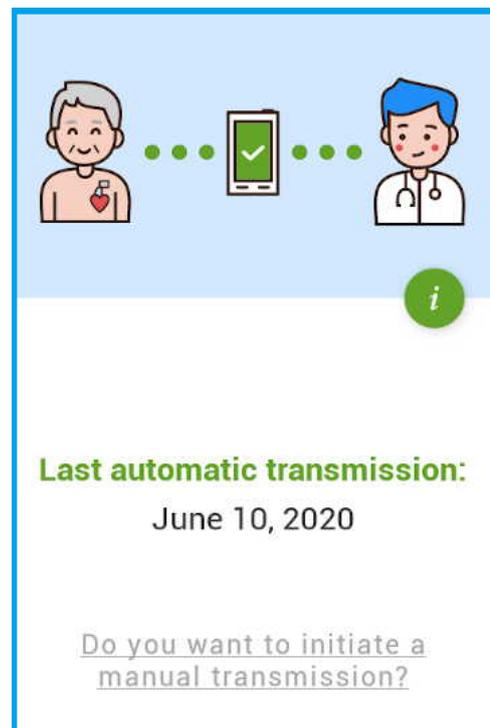
After a maximum of three hours, the power indicator light turns green; the SmartView Connect system is recharged.

END RESULT: the SmartView Connect system is plugged in, recharged and switched on.

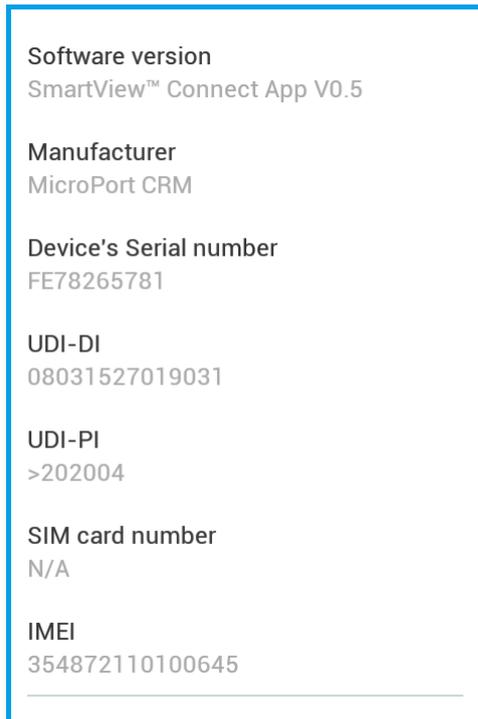
8.3.4. Change language

In order to change the language of your SmartView Connect, proceed as follows:

1. Activate the screen by briefly pressing the power button: the **Last automatic transmission** screen should be displayed (if not, see PROBLEMS AND SOLUTIONS in chapter 9).

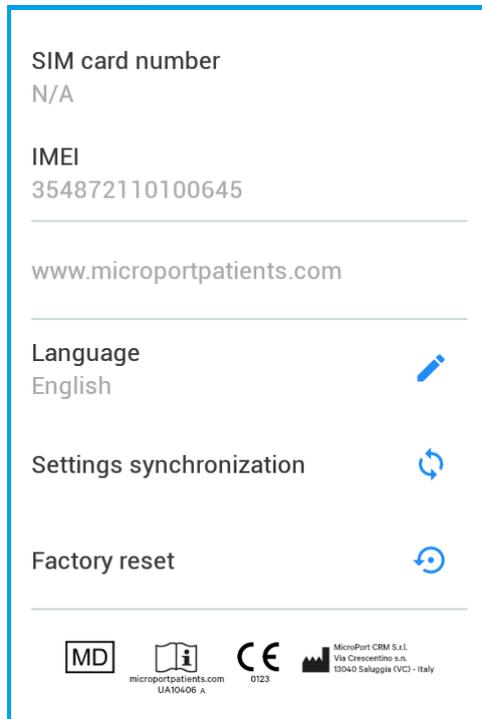


2. Tap on the green “i” icon: this will present a page containing information about your SmartView Connect.

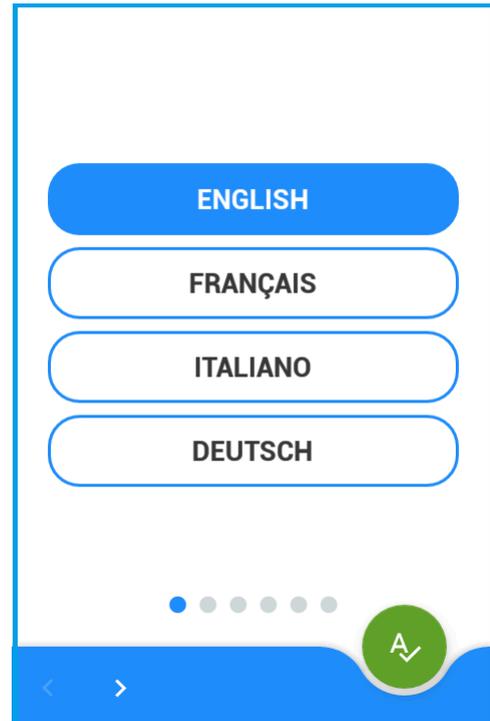


3. Slide a finger from the bottom to the top of the screen: this moves up the page showing additional information. Locate “Language” and tap on the little pencil icon beside it, to show the language selection screen.

Result: The language selection screen is displayed.



4. Select your language, then confirm by tapping the round green button at the bottom of the screen.

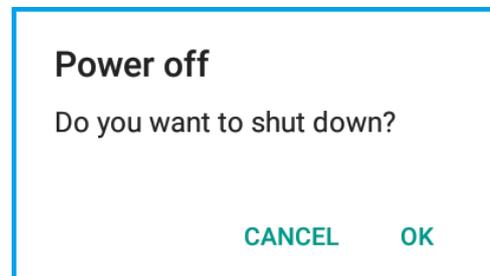


To dismiss the information page, slide your finger on the screen from top to bottom.

8.3.5. Turn off the monitor

In order to turn off your SmartView Connect, proceed as follows:

1. Keep the power button pressed until the message displayed on the opposite will appear



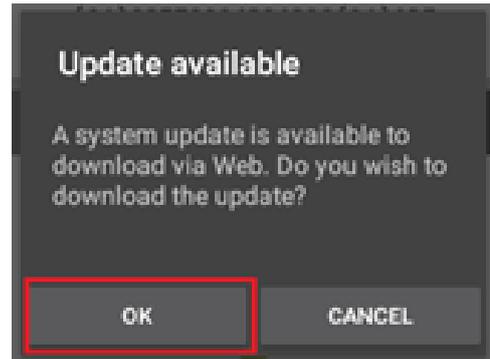
2. Keep your finger on OK and wait until the display becomes black.

8.3.6. Upgrade of SmartView Connect

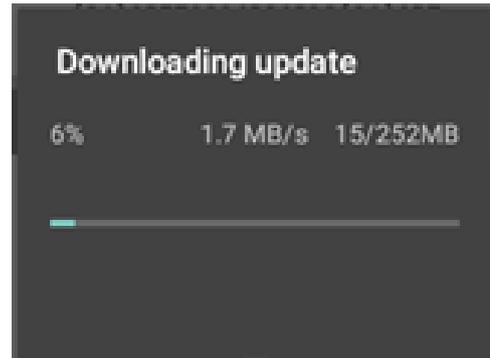
Whenever a new version of the software of your SmartView Connect becomes available, it will usually be installed on your monitor without any need for intervention from you.

In some very rare cases, however, a major upgrade will request your acknowledgement through the procedure detailed in the following.

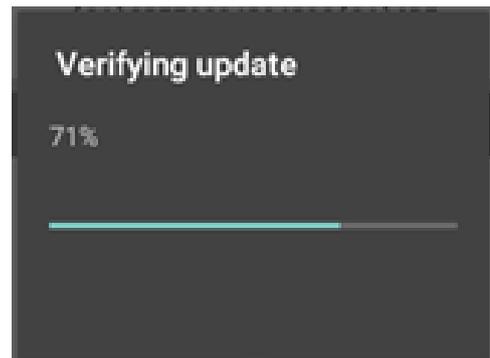
1. If the message on the right is displayed, tap "OK" to approve the download of the new software version.



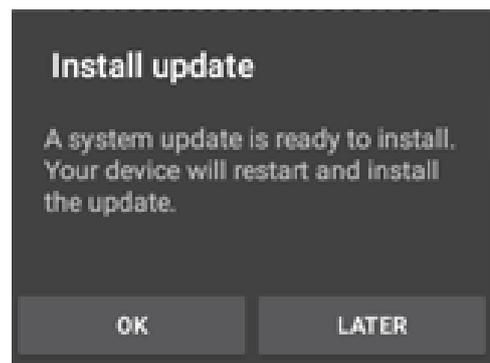
2. During the download of the software, you will be informed of the operation's progress.



3. At the end of the download, the integrity of the update will be verified: a similar progress indication will be displayed.



4. Once the software is verified, it's ready to be installed. You will be prompted through the opposite message. Tap "OK" to launch the update of your SmartView Connect.



Result: At the end of this operation, the monitor will restart by itself. The system is updated.

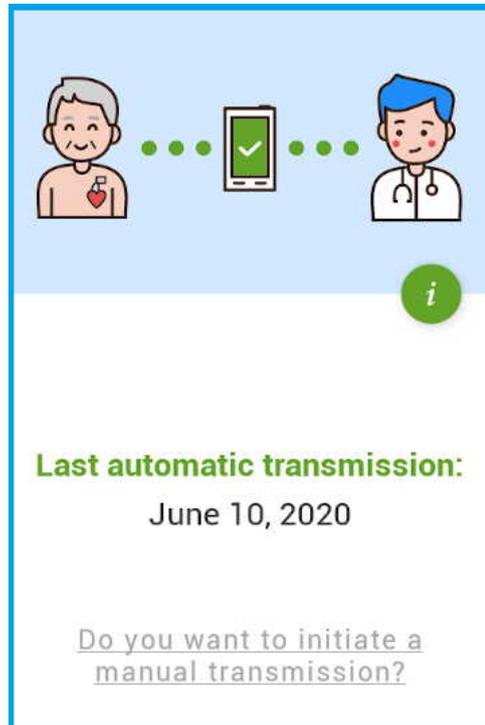


Note: Even in case of a major update, your implanted device and the SmartView Connect will still be paired, so you won't have to re-perform any configuration step.

9. PROBLEMS AND SOLUTIONS

The SmartView Connect system is designed to directly suggest the appropriate actions to perform when it detects difficulty in transferring data from your implanted cardiac device to your doctor.

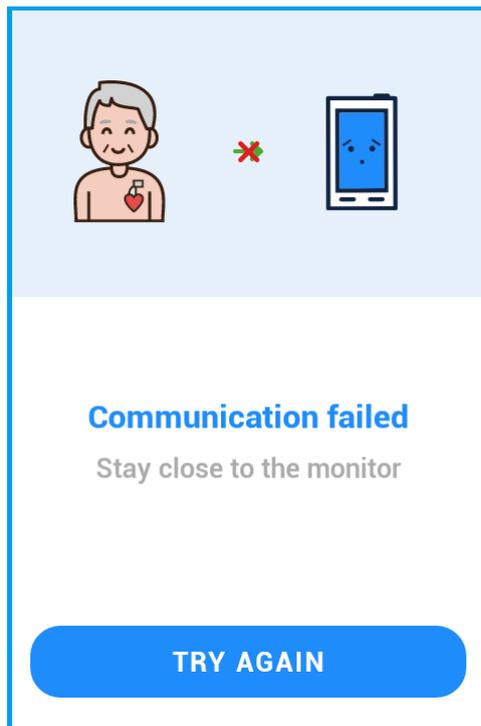
As long as the SmartView Connect system is working properly, a screen like the one on the right shall be displayed (after pressing the power button briefly)



Whenever the screen switches on by itself, this is to present information about something you should do to improve the quality of data transmission.

9.1. DIFFICULTY INTERACTING WITH YOUR IMPLANTED CARDIAC DEVICE

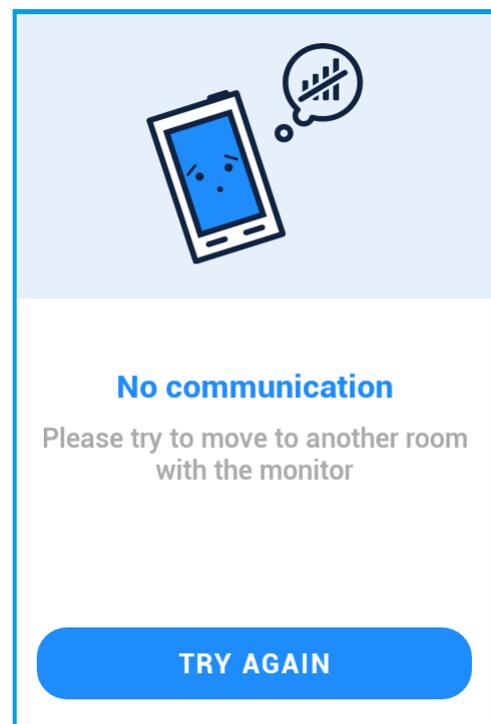
The SmartView Connect system may have difficulties in communicating with your implanted cardiac device, particularly if the distance between them is more than 2 meters. The SmartView Connect system will attempt to communicate with the implanted cardiac device several times. Then after several unsuccessful attempts, it will notify you to place the equipment closer to your sleeping position as shown on the next page.



9.2. MOBILE NETWORK NOT AVAILABLE

If a signal from your mobile network is not available, you should try moving to another room to transmit the data.

You do not need to bring the docking station with you: it can stay beside your bed while you just take the monitor (remember to place the monitor back on the docking station afterwards!).



9.3. MEDICAL FILE NOT AVAILABLE

Your SmartView Connect system can only transmit data if a "Configuration file" has been created at your hospital at enrollment.

If this hasn't been done yet, the system will suggest you contact your doctor in order to create your file.



Configuration error with your medical file

Please contact your pacemaker follow-up clinic

TRY AGAIN

9.4. NEED FOR TECHNICAL ASSISTANCE

Your SmartView Connect system may detect an issue that prevents proper functioning, which cannot be solved by you directly. If this is the case, it will suggest that you contact your doctor to notify him/her that it is not possible to transmit reports, in order to receive the necessary support. The SmartView Connect system will then need the intervention of technical support to restore its functionality.



Configuration failed

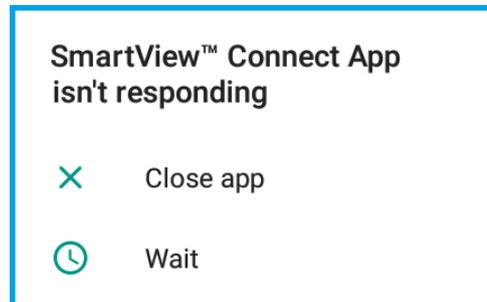
Please contact your pacemaker follow-up clinic

9.5. SOFTWARE APPLICATION NOT RESPONDING

9.5.1. Message displayed

In extremely unlikely cases, the message opposite may be displayed.

Should this happen, just tap on Close app: the software will automatically restart.



9.5.2. No message displayed

In case the software application doesn't respond to your commands, and yet no message like the (one above) is displayed, it's necessary to restart the monitor.

To do this, proceed as follows:

- Turn off the device as explained in § 8.3.5.
- Once the screen is black, turn the device on again by holding the Power button pressed until the screen lights up.

9.6. THE INDICATOR LIGHT IN THE TOP-LEFT IS BLINKING RED

See section 8.3.3 "Recharging the battery".

9.7. THE INDICATOR LIGHT IN THE TOP-LEFT IS OFF

See section 8.3.3 "Recharging the battery".

10. TRAVELLING / MOVING HOME

When you need to travel, check with your doctor if he/she deems it necessary for you to bring along your SmartView Connect system.

Simply rescheduling the next remote follow-up may be enough; in any case, it's always important that you inform your doctor when you will be absent.

10.1. TRAVELLING WITH THE SMARTVIEW CONNECT

If your doctor requests that you carry your SmartView Connect system with you, you will need to proceed as follows:

1. Turn off your SmartView Connect system (see paragraph 8.3.5 "Turn off the monitor")

Note: The SmartView Connect is equipped with a Li-Ion battery. If you travel by plane, it may be forbidden to put it in your checked baggage, so you should bring it in your hand luggage.

2. Once at destination, reposition the SmartView Connect system beside your bed, following the indications in paragraph 8.2.1 "Installing the SmartView Connect system".
3. Restart your SmartView Connect system by keeping your finger on the power button until the screen illuminates

10.2. TRAVELLING ABROAD



Before travelling abroad, you should inform your doctor. Your doctor will then confirm with you how the SmartView Connect system functions abroad.

10.3. MOVING HOME

If you change your place of residence permanently, inform your doctor as soon as possible, so that your patient file on the Remote Monitoring System be updated accordingly.

11. SMARTVIEW CONNECT SYSTEM BASIC CARE

To maintain your SmartView Connect system in proper working order, prevent it from being splashed with any kind of liquid. If you need to clean it, please use only a soft dry cloth. Any other cleaning method could damage your SmartView Connect system. Do not use any kind of detergents, even dry ones.

12. MAINTENANCE AND RECYCLING

The SmartView Connect system requires no periodic maintenance.

As with all electronic devices, recycling your SmartView Connect system is obligatory; please follow local regulations for the proper disposal of this product if it no longer functions or you no longer use or need it.

Please follow your local regulations for the disposal of electrical waste.

13. FAQ

Why do I need to be monitored?

You have been advised to use MicroPort's SmartView Connect system so that your doctor can closely follow your heart disease and identify potential needs for adjustments to your treatment. Should you have any questions or need further information, please contact your doctor.

What should I do if I don't feel well?

When experiencing symptoms, you should call your doctor or your local emergency service. Our technology does not replace them under any circumstances.

Does the communication cost me anything?

The communication will be free of charge.

The SmartView Connect system does not use your personal phone lines to transfer information to your doctor. It uses an embedded communication system, and costs are covered by MicroPort CRM.

14. DATA PROTECTION

MicroPort CRM undertakes to take all necessary security measures to protect the clinical data and in particular, to strictly restrict access to it. For any information regarding the processing of your personal data, please refer to the information and patient consent that you have signed with your physician who is the data controller.

15. INTENDED PURPOSE AND ESSENTIAL PERFORMANCE

The SmartView Connect App is non-implantable medical software, embedded on an off-the-shelf smartphone-like device, that is part of the SmartView Remote Monitoring System (RMS).

The SmartView Connect App is intended for the wireless transmission of data from MicroPort CRM Bluetooth® low-energy (BLE)-enabled implanted pacemakers to a back-office data management system. It uses a BLE connection and cellular network communication in order to:

- collect data from the BLE-enabled implanted pacemaker so that patients' heart rhythm data and diagnostic information can be retrieved,
- automatically and wirelessly transfer these data, on a periodic or events basis², to MicroPort CRM's back-office data management system so that the SmartView RMS is able to make the information available to the physician, thereby ensuring patient management through the monitoring of patient status.

The essential performance of the SmartView Connect™ App is to ensure data integrity when it transfers data from a compatible MicroPort CRM implanted cardiac device to the central data management system.

Any serious incident in relation to the device should be reported to MicroPort CRM and the local Competent Authority.

The Summary of Safety and Clinical Performance (SSCP) will be available on <https://ec.europa.eu/tools/EUDAMED> after the launch of European Database on Medical Devices/ Eudamed.

2. The SmartView Connect App, designed by MicroPort CRM, is fully automatic so does not require any specific patient interventions when working normally, in operational mode (periodic basis – scheduled transmission). A patient can, however, initiate a transfer of information manually (events basis – patients initiated transmission or PIT), if necessary (please note the application is not intended as an emergency response system).

16. EXPLANATION OF SYMBOLS

General symbols	Explanation of symbols	General symbols	Explanation of symbols
	Consult instructions for use		Unique Device Identifier
	This symbol indicates that the SmartView Connect™ App is in full conformity with European MDR 2017/745		Caution
	Manufacturer		This icon is used to call your attention to a particularly important point.
	Medical Device		This icon alerts you to a hazard that may result in equipment damage or personal injury. Carefully read the instructions provided with this icon.
	Catalogue number.		
	Batch code		
	Product serial number.		



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