User's manual

SORIN | SMARTVIEW

KA961 – Wireless model

TABLE OF CONTENTS

LIST OF SYMBOLS

This symbol is used to encourage you to consult the documentation and manual enclosed in the packaging.

This symbol confers the approval of the US Federal Communications Commission.

This symbol indicates that the device meets UL requirements.

Remote Cardiac Monitor (Medical Equipment) WITH RESPECT TO ELECTRIC SHOCK, FIRE AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH IEC 60601-1, CAN/CSA 60601-1, ANSI/AAMI ES 60601-1.

Name and address of the manufacturer.

Sorin Reference of the SMARTVIEW monitor

Serial number

Temperature limits for storage and transportation

Humidity limits for storage and transportation

USB Type B Power supply connector at SMARTVIEW Monitor level

Ref. P601006

Use only power block ref. P601006 with your monitor

The monitor shall be powered only with direct current. The power block packaged with your monitor fulfils this requirement.

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 2002/96/CEE.

Keep the device dry – Keep it away from liquid and do not spill or drip water on it.

SYMBOLS USED IN THIS MANUAL

This icon is used to call 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.

ABOUT THIS MANUAL

Your doctor should be your first source of information regarding your health.

This manual addresses many of the questions you or your family may have about your SMARTVIEW monitor and its use.

If you have technical or usage questions that are not covered in this manual or you want more in-depth information, please contact the Sorin toll-free technical assistance.

1. INTRODUCTION

The SMARTVIEW monitor you received is part of the SMARTVIEW Remote Monitoring System. This system has been specially designed to transmit information stored in your Sorin implanted cardiac device to your doctor on a regular basis. Your Sorin cardiac device is equipped with a transmitter which sends clinical information and device parameters to your doctor through the SMARTVIEW monitor using Radio Frequency wireless technology. The data retrieved by your SMARTVIEW monitor is routed through the cellular network, converted to a format that can be reported to your doctor.

The SMARTVIEW Remote Monitoring System designed by Sorin is a fully automated system which does not need any specific interaction in operational mode. It can, however, also be used manually but only on your doctor's instruction.

2. INDICATION

The SMARTVIEW monitor is designed for use with the Sorin radio frequency implanted cardiac device only.

3. WARNINGS AND PRECAUTIONS

3.1. WARNINGS

If at any time you feel that you need a fast response, CALL YOUR LOCAL EMERGENCY SERVICE IMMEDIATELY.

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

3.2. SAFETY PRECAUTIONS

Alteration – Your SMARTVIEW monitor and supplied accessories shall not be modified, altered, or changed in any way without signed written permission from Sorin. Unauthorized modification may void the equipment authorization from the FCC and will void the Sorin warranty. Use only Sorin supplied accessories.

Keep Children Away – Do not let children touch the SMARTVIEW monitor.

Environmental factors – To reduce the risk of fire, electric shock and personal injury, do not expose this appliance to rain, moisture or extreme temperatures and avoid any installation or Patient Initiated Transfer operation during an electrical storm. If the SMARTVIEW monitor is damaged due to a shock or liquid exposure, do not plug it in again and call our toll-free technical assistance.

Keep dry the device – Keep it away from liquid and do not spill or drip water on it.

3.3. PRECAUTIONS FOR SAFE OPERATION

Location – Preferably the SMARTVIEW monitor should be placed in a stable position on the nightstand of the patient, as close as possible to the side of the bed the patient usually sleeps.

Power supply – The SMARTVIEW monitor should be connected exclusively to a Sorin power adaptor.

Power supply protection – Power adaptors should be routed so they are not likely to be walked on or pinched by items placed on or against them.

Power supply disconnection – The power socket must be near the SMARTVIEW monitor and easily accessible. You can only remove power from the SMARTVIEW monitor by disconnecting the power adaptor from the outlet. Always carefully disconnect all plugs by pulling on the plug and not on the cord.

Wireless communication – The SMARTVIEW monitor is designed for use with cellular network. It is intended to transmit your personal data using a cell phone operator. The operator and number to call are pre-configured, there is nothing to tune.

Check button – Do not press the Check button on the bottom of the monitor unless requested to do so by our toll-free technical assistance.

Interferences – The SMARTVIEW monitor can be influenced by other household appliances (such as alarm clock, mobile phone). If possible, you should avoid placing electrical appliances next to the SMARTVIEW monitor.

4. FAMILIARISE YOURSELF WITH YOUR SMARTVIEW MONITOR

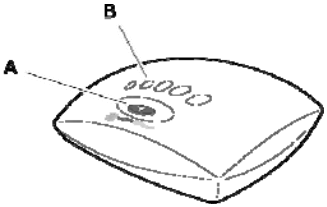
4.1. PACKAGE CONTENTS

Inside the box you will find:

		
1 SMARTVIEW monitor	1 Power adaptor	User's manual

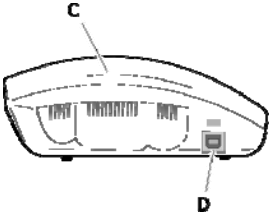
Do not use any other parts than the ones supplied with the SMARTVIEW monitor, as this may result in increased emissions or decreased immunity of the equipment.

4.2. DESCRIPTION



A/ Patient initiated transfer button

B/ Progress bar



C/ Status light

D/ Power supply inlet
(cable with the orange mark)

4.3. MEANING OF THE LIGHTS AND BUTTONS

Light or button	State	Colour	Meaning
Status light	OFF	No colour	The SMARTVIEW monitor is not plugged in properly. Please check the connections. If the status light remains off, please contact our toll-free technical assistance.
	ON	Constant amber	You have just connected the SMARTVIEW monitor to the wall socket. The SMARTVIEW monitor is setting up. Please wait. This process takes less than 5 minutes.
		Constant green	The SMARTVIEW monitor is operational.
Patient initiated transfer button	Flashing	Green	The SMARTVIEW monitor is gathering data. Stay as close as possible to the SMARTVIEW monitor and don't disconnect it.
		Red	The SMARTVIEW monitor could not gather the information stored in your implanted defibrillator. Move closer to the SMARTVIEW monitor and restart the process. If the button turns red again, please contact our toll-free technical assistance.
	ON	Green	You pushed the button to request a Patient Initiated Transfer transmission. The SMARTVIEW monitor is checking that the function is active before performing the transmission.
Progress lights	Progress	Green	The SMARTVIEW monitor is gathering information from your implanted defibrillator. Stay as close as possible to the SMARTVIEW monitor and don't disconnect it.

5. USING YOUR SMARTVIEW MONITOR

The Sorin SMARTVIEW monitor works automatically. Therefore, you will have no interaction with it except at installation and only on your doctor's request.

5.1. SETTING-UP YOUR SMARTVIEW MONITOR

In order to perform the installation of your SMARTVIEW monitor in a quick, easy and safe way, we recommend you to call our technical assistance (see toll-free phone numbers at the end of this manual). Our technicians will assist you. It is free and takes little time.

Step	Operation
1	Take all the items out of the box.
2	Place your SMARTVIEW monitor in a stable position, preferably on your nightstand, as close as possible to the side of the bed you usually sleep on.
3	Remove the power adaptor from the little white box and plug the end of the cable with the orange mark into the appropriate inlet in the SMARTVIEW monitor identified with the same orange mark.
4	Plug the power supply block into the mains. A green light turns ON immediately on this block.
5	You should observe the following: The status light turns stable amber for around 45 seconds and then turns green. Your SMARTVIEW monitor is now ready for the next step: Communication.
6	The Patient Initiated Transfer button is now flashing green. It will continue flashing as long as you do not press this button.

To operate properly, your SMARTVIEW monitor should always be connected to the mains power outlet.

5.2. COMPLETE THE INSTALLATION WITH COMMUNICATION SETUP

At this stage, your SMARTVIEW monitor will need to "talk" with your Sorin implanted device. You will not feel anything as it is fully independent of your clinical treatment.

Press the Patient Initiated Transfer button gently until you feel a click. You will see the Patient Initiated Transfer button will now be constant green for between 30 seconds and 1 minute. Wait until the green light turns completely OFF.

Your SMARTVIEW monitor is fully operational and your doctor has already been notified that the installation has run successfully. Your Sorin implanted device is now being monitored.

The communication setup is requested at first installation only. Disconnecting and reconnecting the SMARTVIEW monitor does not require setting up the communication again.

5.3. OPERATIONAL USAGE

In order to reduce any inconvenience, your SMARTVIEW monitor is set up to read your Sorin implanted device at night while you sleep.

If the status light is OFF, check all connections. If the problem persists, call our toll-free technical assistance.

5.4. PATIENT INITIATED TRANSFER OPERATION

Your doctor may ask you to press the Patient Initiated Transfer button. Follow his instructions closely, but do not use this button unless your doctor requests it.

6. TRAVELLING

If you are planning to travel, you should inform your doctor of your dates of absence. Some of the scheduled events may need to be temporarily changed.

To know whether your SMARTVIEW monitor will operate in the country where you travel, please call our toll-free technical assistance who will give you relevant instructions.

7. MOVING HOME

If you move home, you will have to re-install your SMARTVIEW monitor in your new home by following the installation procedure. Please call our toll-free technical assistance.

8. SMARTVIEW MONITOR BASIC CARE

Your SMARTVIEW monitor has been designed to successfully pass the safety and regulatory standards. To ensure that it works, always protect your SMARTVIEW monitor 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 monitor. Do not use any kind of detergents even dry ones.

9. MAINTENANCE AND RECYCLING

Your SMARTVIEW monitor remains property of Sorin.

It requires no maintenance.

If you don't have anymore use of the SMARTVIEW Monitor, please call Sorin helpdesk toll-free number and we will organize its collection. Sorin will be in charge of recycling it in compliance with European Directive 2002/96/CEE.

10. FAQ

Why do I need to be monitored?

You have been advised to install Sorin's monitor in your home 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 shall I do if I do not feel well?

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

Is there a risk due to Radio Frequency?

No, because the SMARTVIEW monitor has successfully passed the security tests regarding normative level of radiation.

Does the communication cost me anything?

The communication won't cost you anything.
Our SMARTVIEW monitor does not use your personal phone lines to transfer information to your doctor. It uses an embedded phone solution, which costs are covered by Sorin.

11. TECHNICAL SPECIFICATIONS

If you suspect any kind of default, please call our toll-free technical assistance. Our technicians will help you and run investigations if needed.

Part number	KA961
Dimensions	Height: 59 mm Width: 156 mm Depth: 122 mm
Weight	250 g
Power supply	AC input : 100-240 V~ 50-60 Hz 250 mA (to wall socket)
Operating conditions	from 0°C to +40°C (32 °F to 104 °F) from 5% to 93% RH non condensing
Transport and storage conditions	from -15°C to +70°C (5 °F to 158 °F) from 5% to 95% RH non condensing
Transmitter frequency	2400-2483 MHz (ISM) 402-405 MHz (MedRadio)
Characteristics of the transmitters	ISM: uses frequency hoping, ERP = 100 mW max, OOK modulation. MedRadio: uses Listen Before Talk algorithm, ERP = 25 µW max, FSK modulation.
Receiver frequency	402-405 MHz (MedRadio)
Modem	Quad-band GSM/GPRS, 850/900/1800/1900 module. GPRS multi-slot class 10/8, GPRS mobile station class B. Compliant to GSM phase 2/2+: • Class 4 (2 W @ 850/900 MHz), • Class 1 (1 W @ 1800/1900 MHz). CE & FCC approvals.

The SMARTVIEW monitor may be interfered with by other equipment, even if that other equipment complies with CISPR emission requirements.

12. DATA PROTECTION

Any clinical data is fully secured with restricted access. You have the right to access this information at any time and ask for any change by request only. Please contact your doctor or our toll-free technical assistance.

13. DECLARATION OF CONFORMITY

Sorin declares that this device conforms to the following Product Specifications:

Safety - IEC 60601-1:2005 (Ed. 3) - Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.

EMC - IEC 60601-1-2:2007 (Ed. 3) - Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and Tests.

EN 50371:2002 - Generic standard to demonstrate the compliance of low power electronic and electrical apparatus with the basic restrictions related to human exposure to electromagnetic fields (10 MHz - 300 GHz).

EN 50385:2002 - Product standard to demonstrate the compliance of radio base stations and fixed terminal stations for wireless telecommunication systems with the basic restrictions or the reference levels related.

EN 301 489-1 v1.8.1 - Electromagnetic compatibility and Radio spectrum Matters (ERM); Electromagnetic Compatibility (EMC) standard for radio equipment and services. Part 1: Common technical requirements.

EN 301 489-27 v1.1.1 - Specific conditions for Ultra Low Power Active Medical Implants (ULP-AMI) and related peripheral devices (ULP-AMI-P)

EN 301 489-17 v2.1.1 - Specific conditions for Broadband Data Transmission Systems.

EN 301 489-7 v1.3.1 - Specific conditions for mobile and portable radio and ancillary equipment of digital cellular radio telecommunications systems (GSM and DCS).

EN 300 328 - Electromagnetic compatibility and Radio spectrum Matters (ERM); Wideband transmission systems; Data transmission equipment operating in the 2,4 GHz ISM band and using wide band modulation techniques; Harmonized EN covering essential requirements under article 3.2 of the R&TTE Directive.

EN 301 511 v9.0.2 - Global System for Mobile communications (GSM); Harmonized EN for mobile stations in the GSM 900 and GSM 1 800 bands covering essential requirements under article 3.2 of the R&TTE directive (1999/5/EC).

ETSI EN 301 839-1 v1.3.1 - Electromagnetic compatibility and Radio spectrum Matters (ERM); Short Range Devices (SRD); Ultra Low Power Active Medical Implants (ULP-AMI) and Peripherals (ULP-AMI-P) operating in the frequency range 402 MHz to 405 MHz; Part 1: Technical characteristics and test methods.

ETSI EN 301 839-2 v1.3.1 - Electromagnetic compatibility and Radio spectrum Matters (ERM); Short Range Devices (SRD); Ultra Low Power Active Medical Implants (ULP-AMI) and Peripherals (ULP-AMI-P) operating in the frequency range 402 MHz to 405 MHz; Part 2: Harmonized EN covering essential requirements of article 3.2 of the R&TTE Directive.

47 CFR Part 2 - Code of Federal Regulations - Frequency allocations and radio treaty matters; General rules and regulations.

47 CFR Part 15 - Code of Federal Regulations - Telecommunication - Radiofrequency devices: Part 15.247 - Operation within the bands 902-928 MHz, 2400-2483.5 MHz, and 5725-5850 MHz.

47 CFR Part 22 - Code of Federal Regulations - Telecommunication - Public mobile services.

47 CFR Part 24 - Code of Federal Regulations - Telecommunication - Personal communications services.

Part 95 - Personal Radio Services - Part 95.628 MedRadio transmitters.

The FCC Product ID is YSGKA961, contains FCC ID UDV-0606020080701.

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 Sorin. Unauthorized

modification may void the equipment authorization from the FCC and will void the Sorin warranty.

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.

This device may not interfere with stations operating in the 400.150 - 406.000 MHz band in the Meteorological Aids, Meteorological Satellite, and Earth Exploration Satellite Services and must accept any interference received, including interference that may cause undesired operation.

14. GUIDANCE AND MANUFACTURER'S DECLARATION

14.1. ELECTROMAGNETIC EMISSIONS

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

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The SMARTVIEW monitor uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The SMARTVIEW monitor is suitable for use in all establishments, including domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

14.2. ELECTROMAGNETIC IMMUNITY

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

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical home environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Mains power quality should be that of a typical home environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % UT (>95 % dip in UT) for 0,5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 5 s	<5 % UT (>95 % dip in UT) for 0,5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 5 s	Mains power quality should be that of a typical home environment. If the user of the SMARTVIEW monitor requires continued operation during power mains interruptions, it is recommended that the SMARTVIEW monitor be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical bedroom in a typical home environment.
NOTE: UT is the a.c. mains voltage prior to application of the test level.			

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

Portable and mobile RF communications equipment should be used no closer to the SMARTVIEW monitor, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.

Recommended separation distance:

Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V	$d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = 1.2\sqrt{P}$ 80 to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz

where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in metres (m).

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

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

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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

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

14.3. RECOMMENDED SEPARATION DISTANCES BETWEEN PORTABLE AND MOBILE RF COMMUNICATIONS EQUIPMENT AND THE SMARTVIEW MONITOR

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

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

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

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

15. TECHNICAL ASSISTANCE

For any assistance or question you may have about your SMARTVIEW monitor, please call our toll-free Sorin technical assistance.

Our technical assistance desk is open from Monday to Friday from 8:00 AM to 6:00 PM local time, except public holidays.

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SORIN GROUP
AT THE HEART OF MEDICAL TECHNOLOGY

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