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<i>Title: Smartview Monitor operational description</i>			

Abstract: High-level description of the structure and operation of the Smartview Monitor and associated Implantable Medical Device

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REVISION HISTORY

Rev.		Sect.	Change	Author	Release date
A	1		Initial release	Fabio Belletti	09-Mar-2009
	2		Functional description added	Fabio Belletti	25-Feb-2010
	3		IMD description add-on	Philippe Barou	01-Mar-2010
	4		SM software test scheme	Fabio Belletti	05-Mar-2010
	5		Transfer in FF929 format	Cecile de Jeso	18-Mar-2010
	6		New ICD image, approver	Fabio Belletti	19-Mar-2010
B			§ 1.3.3 Block Diagram removed (FCC req) Everywhere: Home Monitor (or SM) updated to Smartview Monitor (or SM) Everywhere: MICS updated to MedRadio	Georges Wanderstok	

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1. INTRODUCTION

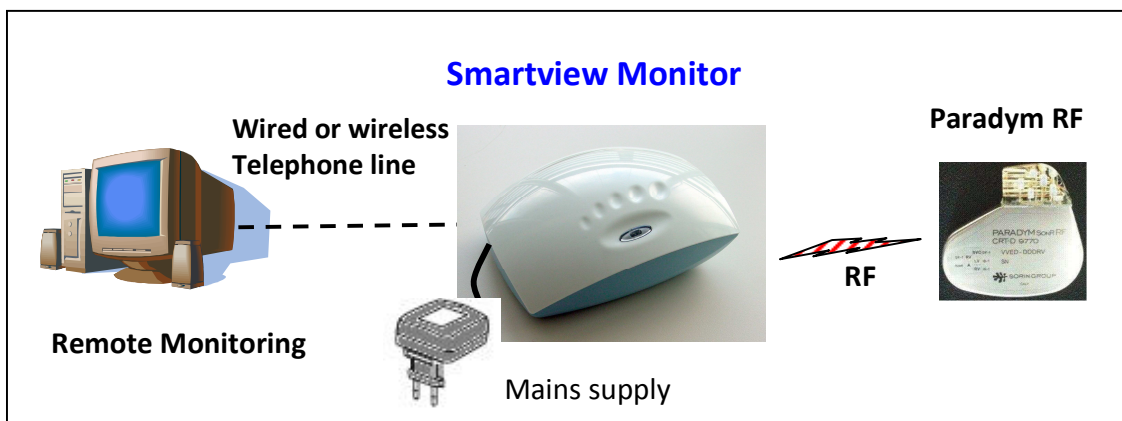
1.1. PURPOSE

The purpose of the present document is to provide a high-level description of the structure and operation of the following sub-systems of Sorin Remote Monitoring System: the Smartview Monitor and the Implantable Medical Device.

The Smartview Monitor (SM) is intended to collect patient’s clinical data from an Implantable Medical Device (IMD) and transfer them to data management system (Back Office server).

The IMD is implanted into the patient’s body. The Smartview Monitor is installed at patient home and is intended to collect data from the IMD remotely in absence of physician according to scheduled operation. It is not intended to act as emergency response system.

The connection between the Smartview Monitor and the implant is achieved through Radio-Frequency (RF) telemetry while the connection to the server is performed through the telephone line (fix or mobile net).



1.2. ACRONYMS

Acronyms	Definition
IMD	Implantable Medical Device
SM	Smartview Monitor
RF	Radio-Frequency
RMS	Remote Monitoring System
BO	Back Office

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Acronyms	Definition
ISM	Industrial Scientific Medical band
MedRadio	Medical Device Radiocommunication Service (previously MICS)
FU	Follow-up
OD	On demand
CCA	Clear Channel Assessment

1.3. SYSTEM DESCRIPTION

In the following sections, the Smartview Monitor and the Implantable Medical Device are described, highlighting their hardware functionalities and features.

1.3.1. SM OPERATING MODES

The Monitor unit shall have two configurations to fit two different cases of use:

- 1) Home Monitoring. When it is installed at patient home in the context of RMS, with two different Back Office (BO) connection options
 - a. PSTN modem when it is connected to BO through the fix telephone line
 - b. GPRS modem when it is connected to BO through the mobile cellular telephone net.
- 2) Programmer RF Head. When it is installed in hospital and connected to the Orchestra Plus programmer through USB port for adding the RF telemetry feature to the Programmer itself. This mode is currently out of scope

The Smartview Monitor communicates with the implanted device on two wireless RF bands:

- ISM band (2.45- GHz) for communication initialization (implant wake-up)
- MedRadio (402-405 MHz) band for data transfer

1.3.2. IMD OPERATING MODES

The IMD communicates with the Smartview Monitor on two wireless RF bands:

- ISM band (2.45 GHz) for communication initialization (implant wake-up)
- MedRadio (402-405 MHz) band for data transfer

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1.3.3. IMD HARDWARE

RF bi-band communication is done using the same ultra low consumption transceiver module connected through a stripe line and a hermetic bipolar feed-thru to a unique RF antenna loop embedded to the external connector of the device. The transceiver is driven by the CPU of the device upon dedicated interrupt request raised by the RF module.

2. SMARTVIEW MONITOR FUNCTIONAL DESCRIPTION

In the following sections the Smartview Monitor is described, highlighting its Features and Operation.

Note: IMD is also described through this section as a slave of the SM.

2.1. SMARTVIEW MONITOR OPERATION

The summary of mission / operation of the Smartview Monitor is the following:

- SM is a device to be installed in Patient Home.
 - Connection to telephone line (RTC version)
 - Connection to power line (wall plug adapter)
- SM shall be activated after connecting it to power supply. Executes:
 - bootstrap;
 - self-diagnostic;
 - implant pairing (at first boot)
- SM is paired through an automatic procedure to the Implant present at first boot
- SM shall collect patient's clinical data from Implanted device and transfer them to data management system (Back Office server).
- The Implant data collection shall be performed according to 3 use cases:
 - Scheduled Patient Remote Follow-up
 - On Alert event/status evidenced by the Implant diagnostic features
 - On-Demand by Patient (if enabled)
- SM shall give indication to user about its correct operation and the function in progress:
 - SM health is ok (HW and code)
 - Patient should stay close to SM
 - Communication to IMD or BO is in progress

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- Error in IMD or BO communication

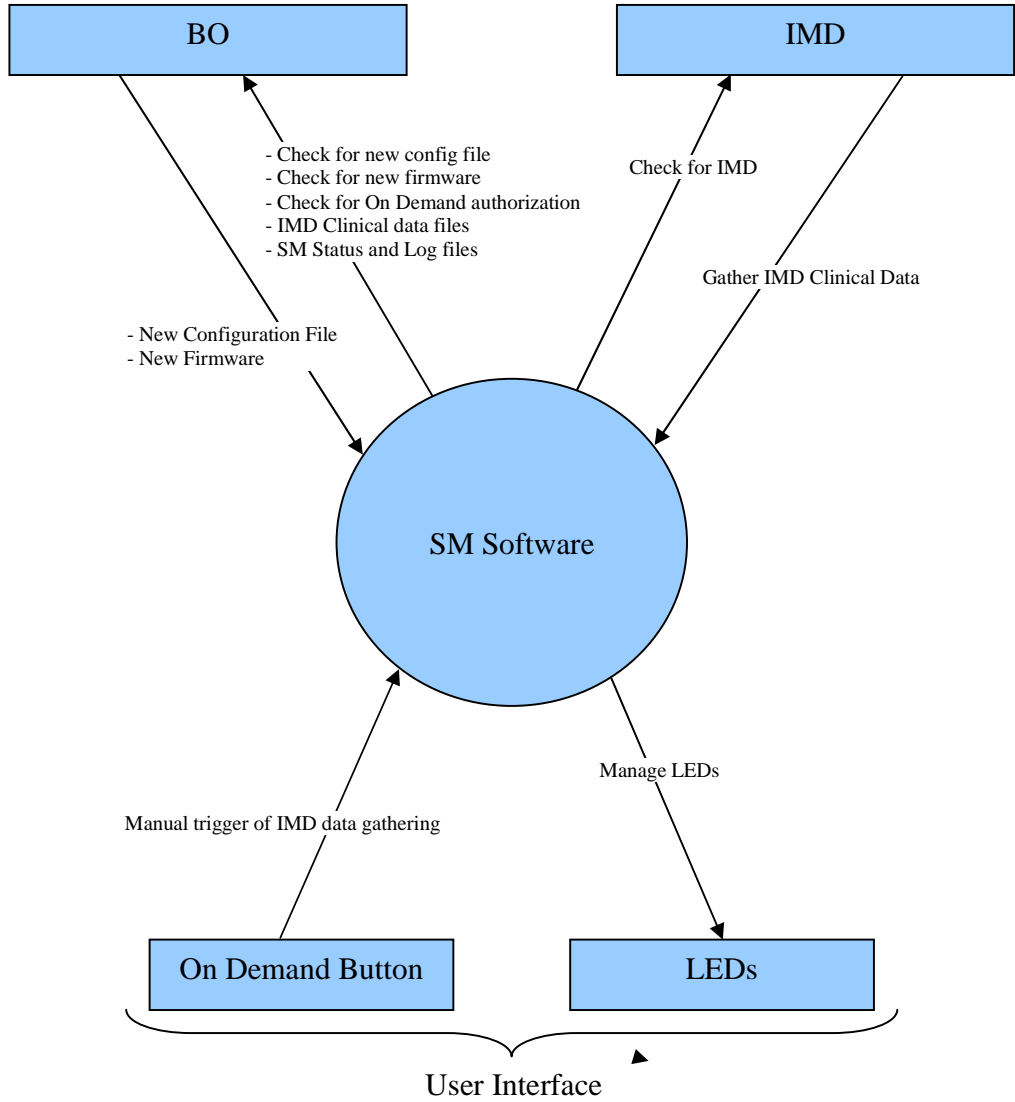
2.2. SMARTVIEW MONITOR MAIN FEATURES

2.2.1. FUNCTIONAL DESCRIPTION OF THE SMARTVIEW MONITOR SOFTWARE

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2.2.2. USER INTERFACE

- Status LED
 - Amber during boot and self-test
 - Green if self-test passed
 - Off on failure
- On-Demand Button
 - Button for patient request to execute a FU (collect FU IMD Clinical Data)
- On-Demand LED
 - Green during communication with IMD or BO in progress (flashing on Pairing request)
 - Red when communication with IMD or BO fails (flashing on pairing error)
- Progress LEDs
 - During OD IMD Data gathering, progress LEDs will turn on, one after the other in a rotating manner, and all on once done

2.2.3. NORMAL OPERATION

- SM shall collect Clinical Data from the IMD at the scheduled FU date in the *SM Configuration File*.
- If the scheduled date is passed SM shall collect the FU at next available time slot.
- SM shall periodically check and gather Alerts IMD Clinical Data if the IMD has Alerts. If no Alerts are present, SM shall close communications instantly to minimize RF activity.
 - Period defined in the *SM Configuration File*.
- SM shall periodically check into the BO.
 - Period defined in the *SM Configuration File*.
- If the scheduled date is passed (SM was left off for too long), SM will connect instantly to BO for a check in.
- SM shall instantly initiate a BO communication to upload FU, OD, Alert and Log/Stat/Trace data after the following events:
 - successful data gathering of any of the 3 triggers (FU, OD or Alert) or of their eventual retry pattern
 - retry pattern of a given trigger has expired completely

2.2.4. ON-DEMAND FOLLOW-UP

In short, an On-Demand (OD) Sequence is:

- Verification of OD Authorization

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- Gathering of IMD Clinical data
- Scheduling an instant BO Communication

- SM shall check the *SM Configuration File* for a positive On Demand Authorization. If negative, the Smartview Monitor shall connect to BO to check for Authorization status.
- Possible configuration are:
 - Always
 - One Time
 - Never
- Given On Demand Authorization and trigger, SM shall instantly connect to the IMD to gather IMD Data.
- This Data consists of:
 - Full memory dump
 - Configured EGM duration

2.2.5. ALERTS

- The SM shall connect to the IMD on a periodic basis to check for Alerts.
- If Alerts are present, the SM shall gather the relative Alerts IMD Clinical data, and send them to the BO.
- SM shall store log files in a non volatile memory.
- SM shall have failsafe mechanisms for storing and retrieving data from a non volatile memory.
- SM shall keep all stored data in separate non volatile memory blocks, in order to stop improper overwriting of data.
- In case of SM is unable to store the data in non volatile memory then it shall be able to log a failure status and cause of failure.
- SM shall store a minimum of 4 *IMD Clinical Data Files* in a non volatile memory immediately after collecting it from the IMD.

2.2.6. SM-BO COMMUNICATION

- SM shall connect/authenticate and communicate with the BO over internet using a dial up modem or a cellular data connection depending on hardware configuration.
- SM shall log-into the internet service provider server using the user name and password specified in the *SM Configuration File*.
- This interface shall include an acknowledgement mechanism when exchanging data

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- SM shall transfer all stored IMD Clinical data files to the BO.
- SM shall have error detection mechanism to detect any error in communication with the BO.

2.2.7. SM-IMD COMMUNICATION

- SM shall communicate with IMD using the Sorin RF Protocol.
- Communications shall always be initiated by the SM.
- SM shall scan all available channels in MedRadio band before initiating the communication with the IMD.
- Relevant Clear Channel Assessment (CCA) data shall be collected, and recorded for analysis.
- The CCA algorithm shall be used to open the most suited communication channel with the IMD.
- The SM-IMD communication protocol shall include an acknowledgement mechanism when exchanging data
- SM shall have error detection mechanism to detect any error in communication with the IMD.

2.2.8. SELF TEST

- SM shall perform daily following tests of the system during self diagnostics:
 - Memory Test
 - Button test (verify that the Button is not permanently pressed)
 - RF Transceiver communication test (for example: check that the CC2550 and the Zarlink are operational)
 - Modem / Cellular communication test (and tonality check)
 - Phone line tonality shall be tested before opening any communication. (Same for GPRS).
In case of failure of this test, SM shall turn off the SM Status LED.
 - RTC test
 - Non volatile Data memory test
- As part of the self test, SM shall test correct connection of Phone line cable, or correct functioning of the Cellular modem.
- SM Logs, traces and IMD Data shall be stored in non volatile memory and be protected against power outages.
- SM boot code shall be able to verify the application code using checksum mechanism before executing it.

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2.2.9. UPGRADES

- SM shall download new firmwares from the location specified in the *SM Configuration File*, when it is available.
- SM shall always report the running firmware.
- The firmware switching mechanism shall revert to the old firmware in case of detected firmware errors

3. SMARTVIEW MONITOR TEST

This section describes the rationale for the implementation of the Smartview Monitor operation to be used during the Qualification test.

For EMC / environmental test a dedicated functional loop has been implemented in order to reproduce the basic operation of the SM in the same way the normal Application Program does but with an accelerated and simplified sequence. The rationale for this is:

- The normal SM operation is based on task scheduler programmed by Back Office (RMS)
- The SM is mainly in idle state for the main part of the day waiting for OD FU requests and to execute scheduled Alerts check or Follow-up IMD data collection
- The BO server / application are not available during the SM Qualification test and it is anyway more convenient to not be BO dependent.

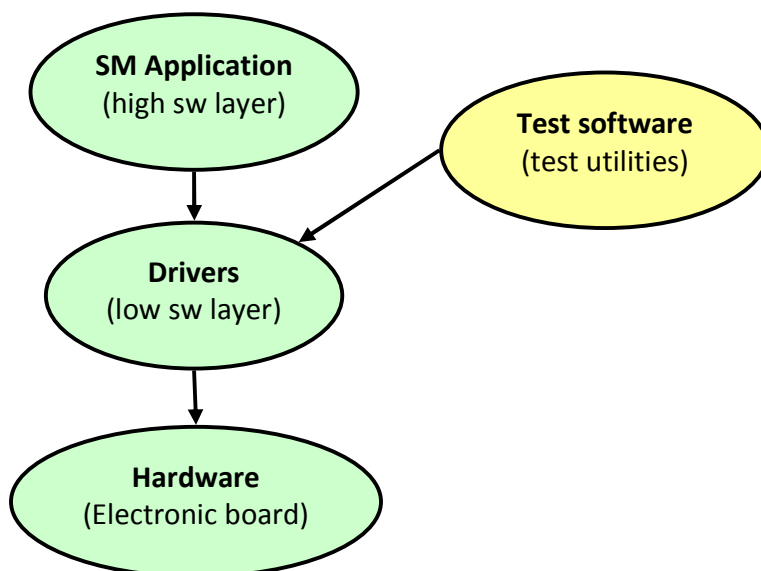
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3.1. SMARTVIEW MONITOR TEST UTILITIES

Smartview Monitor test utilities vs. Program application layers:



The Smartview Monitor standard compliance Qualification test is managed through dedicated software utilities including Basic Operation simulation and specific utilities to put the SM in specific operational condition.

3.2. SMARTVIEW MONITOR BASIC OPERATION

Keeping into account what is described here above, the test functional loop involves:

- SM installation (as for Patient Home).
 - Connection to telephone line (RTC version)
 - Connection to power line (wall plug adapter)
- SM activation after connecting it to power supply. Executes:
 - bootstrap;
 - self-diagnostic;
- SM opens a communication with Implantable device:
 - Check Alert execution
- SM communicate the result to data management system (Back Office server).

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- SM shall give indication to user about its correct operation and the function in progress:
 - SM health (HW and code) is ok on (Status LED)
 - Operation is in progress (OD LED)
 - Error in IMD or BO communication

The SM tasks not included in the functional loop do not add operating conditions which are significant versus the test itself.

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3.3. FAILURES AND RECOVERY

3.3.1. ADMITTED FAILURES

The following failures caused by external events (interferences, stress defined by the applicable standards) are admitted during the SM operation:

- Detected IMD communication either errors or interruptions
- Detected BO communication errors
- System reset (excluding ICD)

3.3.2. NOT ADMITTED FAILURES

The following failures, caused by external events (interferences, stress defined by the applicable standards) are not admitted during the SM operation:

- Unrecoverable electronic or mechanical components failure
- Unrecoverable software crashes
- Code or configuration corruption
- ICD reset

3.3.3. FAULTS RECOVERY

Strategy for recovering the admitted faults:

- IMD communication errors: retry and then communication to BO or user
- Detected BO communication errors: retry
- System reset: reboot and self diagnostic to check board and SW corruption

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4. IMD TEST

This section describes the rationale for the implementation of the IMD operation to be used during the Qualification test. Even-though IMD could be tested in the same way the SM will be, for planning matter IMD shall be tested before SM and dedicated tools availability.

For EMC / environmental test it has been implemented a dedicated RF Tool consisting-in connecting a RF head (SM + option) to a laptop via USB and running a special software tool. This tool consist-in providing every second a link called “ping” including identification header data control according to the private protocol. In this way and even though the application doesn’t require a continuous radio link (see below), we significantly increase the likelihood to trap any potential link stop during the immunity test time by raising a dedicated pop-up and confirm the RF communication can be restarted (only possible if no ICD reset occurred; reset being not admitted referring to section 3.3.2).

Therefore, this feature reproduces the basic operations the IMD is designed to respond but with a continuous and simplified sequence. The rationale for this is:

- The IMD operation is based on daily SM requests
- The IMD is mainly in RF idle state for the main part of the day waiting for SM request and potential data sending when appropriate (Alert ready or Follow-up forced request).
- The BO server / application is not available during the IMD Qualification test and it is anyway more convenient to not be BO dependent.

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