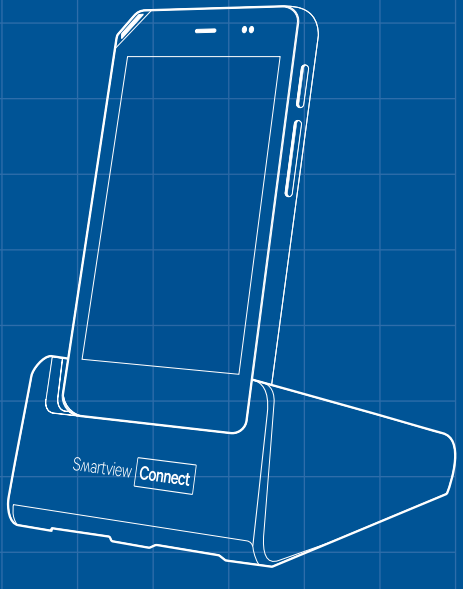
Smartview Connect

MONITORING DEVICE FOR SMARTVIEW
REMOTE MONITORING SYSTEM



Technical specifications

MicroPort™ CRM

Declaration of conformity

MicroPort™ declares that this device:

- ✓ contains the SmartView Connect App that is in conformity with the essential requirements of the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices.
- ✓ bears the CE marking accordingly.

REFER TO USER MANUAL FURNISHED WITH THE DEVICE FOR INTENDED USES AND RELEVANT WARNINGS, PRECAUTIONS, SIDE EFFECTS AND CONTRAINDICATIONS. REFER TO USER MANUAL AVAILABLE AT MICROPORTPATIENTS.COM FOR COMPLETE INSTRUCTIONS FOR USE.

NOT AVAILABLE FOR DISTRIBUTION OR SALE IN THE USA.

SmartView Connect™

PART NUMBER — **V10050C**

MANUFACTURED — **FRANCE**

PHYSICAL CHARACTERISTICS

DIMENSIONS (W X H X D) — **MONITOR: 65 X 118 X 15 mm**
DOCKING STATION: 84 X 46 X 115 mm

WEIGHT — **MONITOR: 150 g**
DOCKING STATION: 95 g

POWER SUPPLY

AC INPUT — **100-240 V ~ 50-60 Hz 0.2 A (TO WALL SOCKET)**

CABLE LENGTH — **1 m**

WIRED CONNECTIVITY — **USB C (USB OTG 2.0)**

ENVIRONMENT

TEMPERATURE — **OPERATING:**
FROM -5°C TO +60°C (23°F TO 140°F)
TRANSPORT AND STORAGE:
FROM -10°C TO +70°C (15°F TO 158°F)

HUMIDITY — **OPERATING:**
FROM 5% TO 93% RH NON-CONDENSING
STORAGE:
FROM 5% TO 90% RH NON-CONDENSING

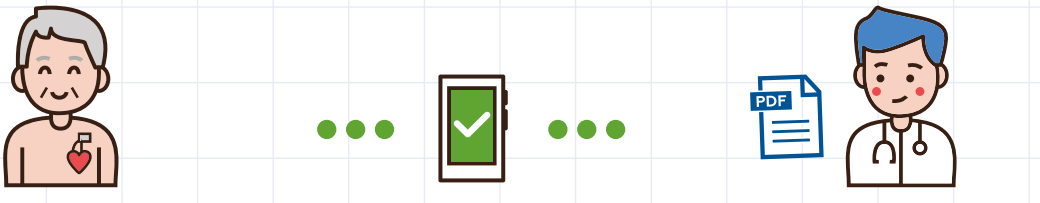
WIRELESS DATA COMMUNICATIONS

BLUETOOTH — **4.2 BLE**

WIFI — **802.11 A/B/G/N DUAL BAND (2.4 GHz AND 5 GHz)**

CELLULAR CONNECTIVITY

— **2G:** GSM850/900/DCS1800/PCS1900 MHz
3G: 850/900/1900/2100 MHz (B5/B8/B2/B1)
4G: FDD: 700/800/850/900/1800/2100/2600 MHz (B28B or B28A/B20/B8/B5/B3/B1/B7)
TDD: 2300/2600 MHz (B40/B38/B41)



1. THE PATIENT'S IMPLANTED DEVICE COMMUNICATES CLINICAL INFORMATION TO THE MONITOR PLACED IN THE PATIENT'S HOME
2. FROM HOME, THE CLINICAL INFORMATION IS SENT TO A WEB BASED APPLICATION THAT GENERATES REPORTS FOR HEALTH PROFESSIONALS
3. CAREGIVERS ACCESS REPORTS AND SYSTEM CONFIGURATION FROM THEIR COMPUTER

Remote Follow-ups

The SMARTVIEW™ system provides the ability to remotely interrogate the range of supported implanted cardiac devices. Follow-up transmissions are initiated automatically according to the schedule set by the clinic.

1. **The SMARTVIEW™ system offers a variety of scheduling options that can be tailored to meet the needs of patients and clinicians:**
   - Manually schedule single or recurrent follow-up appointments
   - Set recurring automatic schedule templates for the clinic to apply for all patients
   - Enter and view both in-clinic and remote follow-up dates in the same system to avoid having the dates scheduled too closely
   - Enter patient unavailability dates to record periods when the patient will not be monitored
   - Specify an interrogation time adapted to the patient's lifestyle
2. **To facilitate clinician review of remote follow-ups, the SMARTVIEW™ website displays:**
   - An overview table of all new transmissions
   - A fast access link to the patient report and patient profile information
   - A message that indicates transmissions in progress on the scheduled date

Alerts

The implanted devices automatically detect implant and clinical events according to clinician defined parameters allowing alerts to be sent to the medical team.

1. **The SmartView Connect™ scans on a daily basis:**
   - System alerts (e.g. device reset, battery over-consumption…)
   - Battery elective replacement indicator
   - Leads alerts
   - Clinical events (AF burden…)
2. **The SMARTVIEW™ system offers a large variety of notification options:**
   - Receive notifications of alerts via the web, e-mail, fax or SMS
   - Set notifications for critical alerts and / or significant events
   - Ability to receive daily alerts in a single notification at 7:00 am
   - Option to notify another healthcare professional (physician, nurse, assistant, etc.) whenan alert has not been reviewed in a timely manner
3. **The SMARTVIEW™ system facilitates alert management:**
   - Scheduled follow-ups or Patient Initiated Transmissions that generate alerts will appear as “alerts” and trigger notification
   - To prevent redundant information, alert notifications are limited to 2 occurrences per alert type
   - A reminder is sent for highly critical alerts

✓ **Escalating unopened alerts to ensure timely management of alerts, the SMARTVIEW™ remote monitoring solution escalates unopened alerts to a second caregiver.**

Patient Initiated Transmission (PIT)

Physicians can suggest patients who experience symptoms initiate a manual transmission for remote consultation. Device interrogation and data transmission will then be performed, and clinicians will be able to access the information when transmission is completed.

1. **The PIT capability is physician-enabled and can be configured for each patient to:**
   - Allow a one-time transmission - can be reinitialized as necessary
   - Always allow the patient to initiate transmissions
   - Prevent the patient from initiating transmissions
   - Define a global setting that applies to all new patients in the clinic by default
2. **Fast and responsive transmission:**
   - Patients can initiate transmissions immediately after a clinician authorizes access
3. **The SMARTVIEW™ system allows for a number of notification options to facilitate management of PITs within the clinic workflow:**
   - Receive PITs via the web, e-mail, fax or SMS
   - Enable escalations of unopened PITs

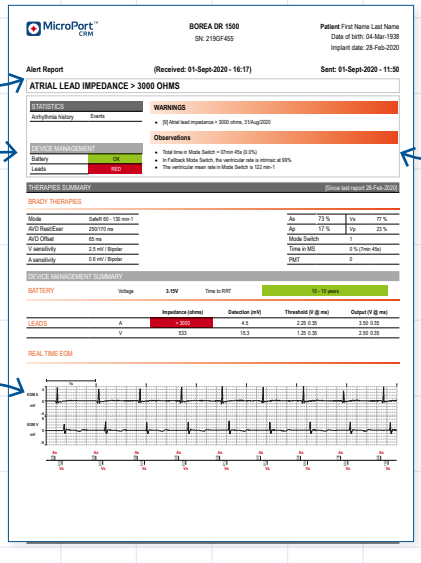
✓ **Flexible PITs: Patient Initiated Transmissions are physician-enabled allowing for control and flexibility**

Transmission Report

The SMARTVIEW™ system displays transmission reports which provide a summary of the main technical and diagnostic data required to evaluate the functional status of the implanted cardiac device and the patient's health condition.

1. **The SmartView Connect™ transmission report shows the most important clinical insights first, followed by statistics and the complete details**
   - Quick assessment of the device
   - Lead Status
   - Warnings and Indications
   - Programmed parameters
   - High Definition EGMs
2. **The SmartView Connect™ transmission report provides an automatically recorded 7-second EGM strip during the data transmission from the implanted device to the monitor**
   - Real Time EGM at the time of transmission
3. **The SMARTVIEW™ system provides a separate EGM report of sustained episodes recorded by the implantable device since the last transmission, to analyze the corresponding EGM and Tachogram**

MOST IMPORTANT CLINICAL INSIGHTS FIRST,
FOLLOWED BY STATISTICS AND COMPLETE DETAILS



Interoperability

The SMARTVIEW™ system allows an external data consumer to be connected to the SMARTVIEW™ website to automatically exporting the implanted device data in a standard IEEE format, so that data can be processed by an external data management and processing software solution. This connection is performed with a data export API web service.

1. **The data export API is activated / deactivated at clinic level** by MicroPort™ CRM
2. **The information transmitted by the data export API is encrypted to ensure the privacy and security of the transmission.** In order to enable a connector, the clinic account manager obtains an authentification certificate from the SMARTVIEW™ website and provides it to the external party who will then have to define a password. Further communications between the external provider and the web service are secured by the need to provide the password and by using TLS 1.2 with authentication, using the certificate
3. **Once the connection to the external data management system is set up,** the export of data does not require the intervention of the clinic or MicroPort™ CRM customer support
4. **The data export API uses** the supported formats of the SMARTVIEW™ system to communicate
   - PDF reports
   - Paceart™ files
   - IEEE 11073 files

System Support

The SMARTVIEW™ remote monitoring system provides support to physicians and patients to facilitate and optimize utilization. MicroPort™ CRM provides technical support to centers and patients equipped with the SMARTVIEW™ solution to help to keep the system operational:

- Monitors communication between the implanted device and the online system. Caregivers can choose to be notified after 14 days in case of communication failure
- Provides online help for SMARTVIEW™ website users
- Ensures data security and archives transmissions for a duration defined by law (called data retention)
- Performs regular maintenance of the overall infrastructure

User Rights & Data Management

Physicians can access standardized patient reports from their computer by connecting to the SMARTVIEW™ website. Various tools are available to help users manage transmissions easily within the clinic workflow.

1. **The SMARTVIEW™ website enables clinicians to find a patient by using the predefined search criteria.**
2. **To improve clinic effectiveness, tools are available to:**
   - Set status to “Complete” for transmissions that have been reviewed
   - Set status to “Pending” to indicate a follow-up action is required
   - Add comments for pending transmissions
   - View historical transmissions
   - Transfer a patient to another clinic
   - Export transmissions in PDF, Paceart™ format and IEEE 11073 format (I3E not available for Inductive Brady implants).
3. **To provide access to multiple users while protecting patient privacy, four different user rights are available:**
   - Clinic administrator - can perform all activities
   - Physician with write privileges - can perform all activities related to transmissions. Each patient created in the database can be referred to a physician
   - Assistant - can perform all activities related to transmissions
   - Referral with read only privileges - can view transmissions of assigned patients

Cybersecurity

The SMARTVIEW™ Remote Monitoring System and Help Desk solution is governed by a review of applicable regulatory data security and privacy requirements (including GDPR and HIPAA) as well as from a complete Cybersecurity risk analysis.

1. **Technical measures guarantee that all Information and Personal Data remain confidential, accurate, available and traced**
   - Multi-tiered security system that ensures the safeguard and surveillance of processing and data
   - Access controls (usernames and passwords) are required for each user
   - User accountability tracking (audit trails to track access to the system)
   - Data to be transmitted is encrypted only once, in the implant
   - Encryption is preserved over transmission from implant to SmartView Connect™ via BLE and further to the website (“Back Office”) over mobile (cellular) network
   - Security safeguards protect critical data from external interference or tampering
2. **Patient data from outside USA* are stored in a cloud data center located in France (accredited personal healthcare data hosting service provider)**
   - The full Technical and Organizational Measures undertaken by MicroPort™ CRM are detailed in a dedicated document (TOM) available on request

** Patient data for US patients are stored in a data center located in the United States*

Technical Features

SUPPORTED DEVICES

SmartView Connect™ App is compatible with MicroPort™ CRM Alizea™, Borea™, Celea™ pacemakers (all versions)

SOFTWARE REQUIREMENTS

BROWSER
— Internet Explorer 8, 9, 10 and 11 ; Firefox 60.0 ; Chrome 67.0

SOFTWARE
— JavaScript
— Any PDF reader (or equivalent PDF reader)

USER INTERFACE

NEW TRANSMISSION
— View all new transmissions
— View new alert transmissions first
— View upcoming scheduled follow-ups for the clinic
— Manage transmissions with new, pending, or complete status
— Add comments to transmissions

ALL PATIENTS
— View full list of patients
— Search and filter using the following criteria: Date of the next scheduled follow-up ; Name of the physicians in charge of the device follow-up ; Patient date of birth / implant date ; Device type
— Access historical transmissions for a patient
— Enroll patients
— Transfer a patient to another clinic

CLINIC
— Add users
— Set a recurring schedule for remote follow-ups that applies to all new patients
— Set default parameters for Patient Initiated Transmissions that apply to all new patients at the clinic
— Set notification options for critical alerts, significant events, Patient Initiated Transmissions, and patient absence while monitoring
— Set clinic profile
— Set data sharing to allow the export of patient data from SMARTVIEW™ system to other electronic patient data management solutions

REPORTS
— SMARTVIEW™ monitor activity report
— SMARTVIEW™ transmission report
— SMARTVIEW™ user activity report
— SMARTVIEW™ replacement report

CLINICAL DATA REPORTS

PATIENT REPORT
— PDF format
— Executive summary
— Strip of “real time” EGM, gathered at the time of data download
— Therapies: Brady therapy statistics ; Arrhythmia history ; Therapy trends – 6-month curves
— Device management: Battery status ; Lead status ; P&R wave amplitude distribution
— Programmed alerts

EGM REPORT DEVICE
— PDF format
— Arrhythmia episodes with synchronized EGM and markers
— Tachogram: atrial and ventricular intervals displayed with time

FOLLOW-UP SCHEDULE

MANUAL SCHEDULING
— Define the next follow-up dates
— Add/update a follow-up: manually select the date
— Designate the type of follow-up: in-clinic or remote

RECURRING SCHEDULING
Choose the clinic or custom setting:
— Clinic setting: applies settings defined at the clinic level
— Custom setting
Select the recurrence frequency: day, week, month
Select the week: 1st, 2nd, 3rd, 4th
Select the day: Monday to Friday

UNAVAILABLE DATES
— Indicate dates the patient will be away from their SmartView Connect™

INTERROGATION TIME
— Select a time for data download; indicate when a data download should occur during the day, as opposed to overnight interrogation

LATENCY TO PROGRAM FOLLOW-UP DATES
— Follow-up settings defined by the clinician are transmitted to the SmartView Connect™ with a latency of around 7 days

ALERTS

Refer to the implantable device technical specifications for the list of alerts applicable to a specific implantable device.
The list of alerts is specific to each implantable device and programmable thanks to the Smart Touch™ and the Orchestra™ Plus programmers. SmartView Connect™ will communicate up to two occurrences of the same alert between two device interrogations with a programmer.

RED ALERTS - CRITICAL EVENTS
— System alerts
Battery Depletion – RRT
Device Reset
System Integrity
— Lead alerts
Abnormal A Lead Impedance
Atrial Autothreshold
Atrial Lead Polarity Switch
Abnormal V Lead Impedance
Ventricular Autothreshold
Ventricular Lead Polarity Switch
— Other alerts
Asynchronous Mode

YELLOW ALERTS – SIGNIFICANT EVENTS
— Clinical alerts
AF Burden Low
AF Burden Mid
AF Burden High
Fast V Rate During AT/AF
Sleep Apnea (Alizea™ only)
— Other alerts
MRI Notifications

DATA EXPORT

Exportable formats
— Patient reports in PDF format
— Source file format (IDF format compatible with Smart Touch™ and Orchestra™ Plus programmers)
— XML format (IEEE 11073 report)
— Paceart™ format (which is compatible with Paceart™ *)

** Paceart™ is a trademark of Medtronic, Inc.*

Manufactured for MicroPort CRM.

MICROPORT CRM S.R.L.
VIA CRESCENTINO S.N. 13040 SALUGGIA (VC)
ITALY

CE MARK PENDING
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SPECIFICATIONS STILL SUBJECT TO CHANGE

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