This page intentionally left blank
Introduction

BIOTRONIK is the pioneer in wireless remote monitoring technology, offering the first internet-based home monitoring system in 2003. BIOTRONIK Home Monitoring® allows clinics the capability to replace device interrogation during in-office follow-up visits\(^1\) and to provide early detection of arrhythmias.\(^2\) Today, BIOTRONIK Home Monitoring is available in over 55 countries, optimizing patient management in more than 3,800 clinics around the world.

The Home Monitoring system is comprised of a Home Monitoring-enabled BIOTRONIK pacemaker or defibrillator, CardioMessenger home transmitter, which wirelessly and automatically collects and transmits implant data, and the BIOTRONIK Home Monitoring Service Center, which allows clinics to review and assess patient transmissions and device data via a secure website. Each component of this system requires basic setup and has a variety of customizable features that clinics can take advantage of to optimize patient care and clinic workflow.

This Home Monitoring Reference Guide describes set up of Home Monitoring-capable implants and CardioMessenger transmitters, as well as Home Monitoring Service Center website use, patient information, and general troubleshooting.

---

## Contents

### Chapter 1: HMSC Setup and Administration

1. **Requesting User Group Creation**
2. **Website Address and Login**
3. **User and Patient Group Organization**
   - 1.3.1 User Types
     - 1.3.1.1
     - 1.3.1.2
   - 1.3.2 User Access for Patient Groups
4. **Patient Groups**
   - 1.4.1 Patient Group Alert Communication Settings
5. **Adding/Removing a Patient**
   - 1.5.1 New Patient First Time Registration
   - 1.5.2 Patient Transferring from Another Doctor
   - 1.5.3 Existing Patient Receiving a Generator Change
   - 1.5.4 Deactivating and Deleting a Patient
6. **Patient Information and Consent**
   - 1.6.1 Home Monitoring Summary for Patients
   - 1.6.2 Patient Notice, Consent, and Disclosure Authorization Form

### Chapter 2: HMSC Website Layout

1. **Monitoring**
   - 2.1.1 Patients for Review
   - 2.1.2 All Patients
     - 2.1.2.1 Patients & Monitoring States
     - 2.1.2.2 Search Feature
   - 2.1.3 New Patients

2. **Home Monitoring Summary for Patients**
3. **Patient Notice, Consent, and Disclosure Authorization Form**
## Chapter 6: Quick Reference Guides

6.1  BIOTRONIK Devices and Release Dates 63
6.2  Transmitted IEGMs and Hierarchy 63
6.3  Periodic IEGM Transmission and Programming 65
6.4  Patient Status Finding Descriptions 66
6.5  CardioMessenger Types and Compatible Devices 71
6.6  CardioMessenger SMART Icons 72
Chapter 1: HMSC Setup and Administration

This chapter reviews the creation, organization, and administration of a clinic’s Home Monitoring Service Center account, including how to add a new patient to a User Group. Home Monitoring is a service for monitoring and managing patient care and, as a result, patient information. It is important to consider your HIPAA/HITECH policies when setting up and interacting with this system. Prior to implementing use of Home Monitoring in your facility, a Business Associate Agreement should be in place with BIOTRONIK, Inc.

Before initiating setup of a Home Monitoring site or User Group for your clinic, you should first determine the following information:

- What will the User Group name be? (Typically the clinic or hospital name)
- Who will be the Administrator responsible for site management across all Patient Groups?
  Note: There can be a maximum of two Administrators per User Group. Administrators have unrestricted access to the User Group and are responsible for patient record and user management.
- How many Patient Groups will need to be set-up?
  Note: User Access is granted or restricted at the patient group level and notification settings for alerts are set at the patient group level.
- How many user accounts are needed and what Patient Groups should each have access to?
  Note: User Accounts must be unique and meet requirements defined in HIPAA/HITECH for traceability to an individual.

Clinics should contact their local BIOTRONIK representative to answer any questions they may have prior to setting up a new Home Monitoring User Group.

1.1 Requesting User Group Creation

To initiate a request for a new Home Monitoring User Group, complete the Home Monitoring Service Account Registration form available online at: https://www.biotronik.com/en-us/healthcare-professionals.

Submit completed registration forms to BIOTRONIK Home Monitoring®:

- email: homemonitoring@Biotronik.com (Subject: Registration Request_Requested User Group Name)
- Fax: 888-387-2681

Upon creation of the new Home Monitoring User Group, the clinic will be emailed (if contact details are provided) a notification that provides the confirmed User Group name and a confirmed Administrator User Account name. All information should be verified upon receipt of the notification.

A second notification email will be sent with a temporary password; users will be prompted to update their password on the initial log-in to the Home Monitoring Service Center. Passwords are left to the discretion of the user, but should be compliant with HIPAA/HITECH regulation (mix of characters, numbers, symbols, case and not easily tied to the user).

BIOTRONIK representatives are trained on the Home Monitoring system and can assist with troubleshooting and general set-up questions. BIOTRONIK representatives should not be granted access to patient information or set up to receive system notifications or alerts.
1.2 Website Address and Login

The BIOTRONIK Home Monitoring Service Center can be accessed at https://www.biotronik-homemonitoring.com. The user will be prompted to enter site-specific access information, as shown in Figure 1-2.

- The User Group is the assigned name of the clinical site.
- The User name is the assigned log-in for each individual user.
- Passwords are specific to the individual user. Five failed log-in attempts will block access for that user. The User Group Administrator has the capability to reset passwords. Contact BIOTRONIK Customer Solutions at 1-800-547-0394 to reset the Administrator’s password.
1.3 User and Patient Group Organization

Each clinic will have one User Group and up to 100 Patient Groups. The User Group Administrator will be able to view all Patient Groups and can assign access for the other users. In the example in Figure 1-3, User 1 has access to Patient Group 1 and 2 and, therefore, can view Patients 1-4. User 2 only has access to Patient Group 3 and can only view patients 5-7 and, therefore, will not be able to view Patients 1-4.

1.3.1 User Types

Each user group allows for two kinds of users: Administrators and Physicians:

1.3.1.1 Each User Group has two User Administrators (default) available. These users have full access to add and change other user settings.

1.3.1.2 Each User Group can also have up to 25 “Physician” roles (Default), which are simply regular users in a clinic and do not necessarily need to be actual physicians. Physician roles may have limited access as depicted in Box 1 in Figure 1-4. User rights may be altered by a User Administrator at any time. BIOTRONIK representatives cannot be made administers or users to access patient data.

If more Administrator or Physician roles are needed, please contact BIOTRONIK Customer Solutions at 1-800-547-0394.

1.3.2 User Access for Patient Groups

An Administrator assigns each user access rights to a specific patient group from among three choices:

- **Full Access:** The user is allowed to review patient information, edit patient profiles, and acknowledge notifications.
- **Read Only:** The user is only allowed to review patient information.
- **No Access:** The user is not allowed to review patient information. This setting may be useful in multi-site clinics where users of one site should not be able to see patient group information for another site.

To modify access for a specific user, select “User” under the Administration menu. This opens the list of
Chapter 1 HMSC Setup and Administration
BIOTRONIK Home Monitoring® Reference Guide

Users. Select the Edit button under the Access rights column for the user name you wish to change access rights for. Access rights to individual patient groups for this user may be set by selecting the access button under Full access, Read only or No access for each patient group in this window. Select the Apply button to confirm changes.

To view a list of users and individual access rights for Patient group access, select “Patient groups” from the Administration menu, then click on the name of the patient group you wish to modify. This will bring up the Patient group profile window. Select the ‘Edit’ button in the lower right corner to bring up the User access rights screen. **This menu is where BIOTRONIK Customer Service access can be granted to allow BIOTRONIK Advanced Product Support to provide the account assistance with the Home Monitoring web service.** (Box 2 in Figure 1-4). Select the ‘Read only’ access button for the BIOTRONIK Customer Service user to allow BIOTRONIK to assist you with information on HMSC for patients within this patient group.

![Figure 1-4 - Home Monitoring Service Center website user access settings](image)

1.4 Patient Groups

After a user group account is created for a clinic, the first patient group will default as “Patient group 1” unless edited by a user (See Figure 1-5 below). New Patient groups can be created by selecting the “New patient group” link under the Administration menu on the left side of the Home Monitoring Service Center website. Up to 100 patient groups (Default) can be assigned to a User Group. Patient groups can be renamed to describe the patients within them such as “ICD patients” or “Dr John Doe Patients.”Patients already registered for Home Monitoring can be added to a Patient group by selecting the “Add patients” button.

![Figure 1-5 – Home Monitoring Service Center website user access settings](image)
1.4.1 Patient Group Alert Communication Settings

Users can be notified of alerts transmitted to their Home Monitoring sites in two different ways: E-mail, or SMS. SMS entries must follow a sequence of +1 followed by the ten digit number, with or without spaces or dashes. Users with access to the patient group can also specify which alerts will pass through to each person. For instance, an SMS can be sent only when red alerts are received, or for both yellow and red alerts. These notification preferences are set either when creating a new Patient Group by selecting the “New patient group” link under the Administration menu on the left of the Home Monitoring Service Center website or by viewing all Patient Groups, selecting the name of the specific Patient group and then selecting the “Edit profile” button. Please see Figure 1-6.

![Figure 1-6 – Patient group communication settings](image)

1.5 Adding/Removing a Patient

1.5.1 New Patient First Time Registration

New patients are added to a user group by selecting New Patient from the Monitoring Menu. The following information is required for adding a new patient:

- **Patient ID:** This information will identify the patient on the patient list. The typical format is the patient’s last name, first name.
- **Patient group:** Select the group where the patient should be assigned. This can be changed later, if necessary. Patients may only be assigned to one Patient Group.
- **Implant Serial Number:** Enter the patient’s implant serial number.
- **Implant PID:** The Product Identification number (PID) is assigned based on the implant serial number. This can be found on the implant device packaging or in the interrogation report. Figure 1-7 shows where the PID # is placed. Please contact BIOTRONIK Customer Solutions for assistance at 1-800-547-0394 if the PID # is not available.
Chapter 1 HMSC Setup and Administration

BIOTRONIK Home Monitoring® Reference Guide

Figure 1-7 - The New Patient form is found by selecting the link on the left side of the site under the Administration section.

After the data above has been entered, click “Continue” and a new dialog box will appear that allows set-up and editing of Remote Scheduling, as seen in Figure 1-8. Both the device and the CardioMessenger need to be compatible with Remote Scheduling for this feature to be available.

The programming options for the Remote Scheduling include:

- **Next HM follow-up**: Date when the next Home Monitoring follow-up will occur.
- **Days between two HM follow-ups**: The desired period between follow-ups. This can be programmed from 20 days to 366 days.
- **HM follow-ups shall occur on**: Users can program the specific day for a Home Monitoring follow-up to occur. If a certain day is selected (e.g., Monday), the data will always be sent on the next Monday after the “Days between two HM follow-ups” time has passed.
- **Next HM follow-ups**: Displays the next five dates when Home Monitoring supported follow-up data will be sent by the device.
1.5.2 Patient Transferring from Another Doctor

To register a patient to your Home Monitoring site that was previously followed by another doctor, first contact the previous clinic to request they deactivate the patient from their site. Once the patient is deactivated, the new clinic may enroll the individual as a new patient. If the patient does not know where he or she was followed previously, please contact the Customer Solutions department for assistance at 1-800-547-0394.

1.5.3 Existing Patient Receiving a Generator Change

If a patient received a device upgrade, follow the steps below:

- Select the patient from the “All Patients” list, then “Patient profile”.
- Select “Register new device”, as shown in Figure 1-9 below.
- Fill in the updated patient device data. For more information regarding what is needed, refer to section 1.5.1.
- Once the device information is entered, select “Identify” and verify that the correct device model is displayed.
- Enter implantation date of the new device.
- Select “continue”, then “confirm” to verify the changes made.

The patient’s new implant should automatically pair with their existing CardioMessenger and transmit normally. See Figure 1-9.

![Figure 1-9](image)

Figure 1-9 – The “Register new device button” allows clinicians to change the serial number of the device the patient has implanted

1.5.4 Deactivating and Deleting a Patient

If a patient no longer needs to be followed by a clinic, needs to be released so another clinic can register the patient, or have their data completely removed from the patient group, select the “Deactivate Home Monitoring” button at the bottom of the Patient profile tab [See Figure 1-9]. After confirming the change, the patient will move to a “deactivated” status and appear on the patient group’s deactivated patient list. The patient’s data can be deleted completely by selecting the “Delete patient data” button at the bottom of the deactivated patient’s Patient profile tab. After deactivation or deletion, a patient can be registered by another clinic. A patient can be reactivated by selecting the “Activate Home Monitoring” button at the bottom of the Patient profile tab of a deactivated patient.
1.6 Patient Information and Consent

1.6.1 Home Monitoring Summary for Patients

Patients should be informed of the role that CardioMessenger and Home Monitoring play in their overall health care. While patients and clinicians can request from their local BIOTRONIK representative Home Monitoring patient education brochures which provide in-depth explanation for the patient to read, here are a few key points to review with each patient prior to being registered for Home Monitoring:

- The patient’s cardiac implant communicates with the CardioMessenger through an antenna inside the implant automatically. Once the CardioMessenger receives data from the device, it forwards this information to the patient’s physician via a secure website for clinic staff to review.
- For pacemaker, ICD, and implantable cardiac monitor patients, transmissions only occur at the scheduled transmission time and data cannot be reviewed “real time.” If an ICD patient has an arrhythmia and is near their CardioMessenger with successful transmission, a clinician can review this arrhythmia episode data sooner than the scheduled transmission time.
- If the physician needs to see the patient based on the transmitted data, he or she will notify the patient directly. The BIOTRONIK Customer Solutions department cannot review data with a patient over the phone or otherwise. BIOTRONIK representatives cannot be made users to view patient data.
- The lights or indicators on the CardioMessenger neither indicate the functioning of the patient’s implant nor indicate any cardiac events. Rather, these indicators show whether the CardioMessenger is appropriately connecting to the Home Monitoring service.
- The physician will decide if the patient needs to carry the CardioMessenger when traveling away from home. Instruct the patient to notify the physician of planned travel.
- Home Monitoring is not a substitute for appropriate medical attention in the event of an emergency. The system is subject to outages due to maintenance, updates, or cellular coverage.

1.6.2 Patient Notice, Consent, and Disclosure Authorization Form

Before a clinic registers a patient for Home Monitoring, the patient should complete and sign the Patient Notice, Consent, and Disclosure Authorization form. (See figure that follows.) A clinic staff member or BIOTRONIK representative must then scan and send the completed form to patient.tracking@biotronik.com with the implant serial number in the subject line.
BIOTRONIK Home Monitoring®
Patient Notice and Disclosure Authorization

You have been prescribed an implanted pacemaker, defibrillator, or cardiac monitor. In order for your physician to remotely monitor this implanted device, you will be given a CardioMessenger® transmitter that transmits information from your implanted device and send reports to your physician. For this service to function, your physician must register your device with the BIOTRONIK Home Monitoring® service. It is important for you to read and understand the following information.

Please read all materials included with your CardioMessenger®. They explain how BIOTRONIK Home Monitoring® works. It is important to follow all instructions and be sure to ask your physician if you have any questions.

BIOTRONIK Home Monitoring® is not a replacement for emergency care. PLEASE CALL 911 IN AN EMERGENCY. BIOTRONIK Home Monitoring® is included with your device and may be periodically unavailable, or otherwise modified or cancelled at any time. Replacements for a lost, stolen or damaged CardioMessenger® are available from BIOTRONIK for a nominal fee.

In accordance with the requirements of applicable privacy laws, such as the Health Insurance Portability and Accountability Act (HIPAA), BIOTRONIK, INC., BIOTRONIK SE & Co. KG, and their affiliates (collectively, “BIOTRONIK”) will collect, use, and disclose your Protected Health Information related to your implanted device to your physician and other care providers for treatment purposes as required by law. This “Protected Health Information or PHI” may include your name, address, physician information, implant serial number, information relating to your health condition and treatments, and data sent by the CardioMessenger® transmitter. BIOTRONIK may use hardware or software vendors to electronically transmit your PHI. BIOTRONIK may also use your transmitted data, along with the implant serial number, for quality assurance, performance and benchmarking purposes, however your name, address and other identifiable information will be removed.

BIOTRONIK is requesting your authorization to use your depersonalized data for purposes of scientific research, including the creation and maintenance of a research database or research repository. Please note that privacy laws may not govern those entities to whom your depersonalized data (which may contain the implant serial number) may be redisclosed.

Your treatment, payment, enrollment, or eligibility for benefits will not change based on whether or not you sign this authorization. You are free to refuse to sign this authorization. You also have the right to revoke this authorization in writing at any time (except to the extent that BIOTRONIK has acted in reliance upon it) by sending written notice to BIOTRONIK Legal Department, 6024 Jean Rd., Lake Oswego, OR 97035.

I authorize the use of data as described above and hereby agree to the terms of this Patient Notice and Disclosure Authorization by signing below.

Signature: ___________________________ Date: ___________________________
Name: ________________________________ Personal Representative (if applicable): ________________________________
Address: __________________________________ Name: ________________________________
_____________________________________________ Relationship: ________________________________
Email: ____________________________________
Chapter 2: HMSC Website Layout

This chapter describes the navigation toolbar on the left side of the Home Monitoring Service website and the available menu options under each section header. Patient data tab locations and descriptions are found in chapter 3.

The Home Monitoring website has three menus, as seen on the left side of the page: Monitoring, Administration, and Site tools. (These sections are boxed in red in Figure 2-1 below.) Each section is described in detail to allow for easier navigation of the Home Monitoring site.

![Figure 2-1 - Home Monitoring Service Center main screen. Monitoring, Administration and Site tools subheadings are outlined in red.](image)

### 2.1 Monitoring

The Monitoring section provides links to quickly navigate to patients that may have alerts or transmitted periodic IEGMs. Users can view the entire patient list, as well as add new patients.

#### 2.1.1 Patients for Review

This list shows patients that have outstanding alerts. When an alert is acknowledged, the patient will no longer be classified as a “Patient for Review”. The Workflow Assist feature located on the home page of the HMSC can prioritize patients based on findings in three different ways: Early detection, HM follow-up, and Administration.

- **Early Detection** – Displays patients having at least one new clinical finding, medical or device related.
- **HM follow-up** – Displays patients whose Home Monitoring supported follow-up has been received. The QuickView report can be used to view the periodic IEGM and other information to assess patient rhythm management status.
- **Administration** – Displays patients with a new administrative finding, such as first message received or missing messages. Administrative findings are only informative and non-urgent.
2.1.2 All Patients

This link lists all patients enrolled in the clinic, up to and including those enrolled on the last date of Home Monitoring transmission. By default only actively monitored patients are shown on the list.

2.1.2.1 Patients & Monitoring States

There are two possible monitoring states for patients in Home Monitoring. (See Number 2 outlined in red in Figure 2-2.)

- **Active:** The default state when a patient is added to a User group. The patient’s data is available for review when data is received from the HMSC.
- **Deactivated:** When a patient is deactivated, neither implant data nor alerts will be received by the HMSC. To view deactivated patients, select “All patients” then “Deactivated monitoring” from the filter at the bottom of the screen (Figure 2-2). There are two ways a patient is deactivated:
  - **Automatically Deactivated:** A patient is automatically deactivated if they have not transmitted to the HMSC for 90 consecutive days. Home Monitoring needs to be programmatically reset in the device for transmissions to occur again.
  - **Manually Deactivated:** Users with full access to patients are able to deactivate patients by going to the patient profile tab and selecting “Deactivate Home Monitoring”. By the same method, a user can reactivate the patient at any time.

2.1.2.2 Search Feature

A user may search by specific device model by using the search bar at the top of the “All Patients” list. Typing the first few letters of the model name will populate a list of potential devices that fit the search. This can also be used to locate a patient based on Patient ID, implant serial number, or information typed in the patient profile comment section. (See Number 1 outlined in red in Figure 2-2.)

Figure 2-2 - All patients Screen: Item 1: The Search Bar will allow searching of devices, patients and other information: Item 2: Using the drop-down menus under the view category enables the user to view patients in all monitoring states. Various monitoring states are selectable.
2.1.3 New Patients

This page allows new patients to be added into the system. For additional information on how to add patients, refer to Section 1.5 Adding/Removing a Patient.

2.2 Administration

The Administration link provides access to information specific to each facility regarding users, adding new users, and maintaining patient groups. It also allows the user to view any transmitters associated with a patient and adjust how data is stored and synchronized for each patient. See Figure 2-3.

2.2.1 Users

The Users view is available for administrators only. It will display all users. Administrators can edit patient group access from this window. Click on the user name to display the user profile. If a user has entered a wrong password five times, “(blocked)” will appear next to that user’s name. If the user is ‘blocked’, contact the administrator or the Home Monitoring department.

2.2.2 New User

The New user tab is used to create a new user and to set a password for access. This view is available for administrators only. Refer to Chapter 1.3 for more information regarding new users. When creating new user, ensure a non-generic username is entered (e.g., BINC_Admin) as well as a unique password (i.e., do not select “cardiac” as a password).

2.2.3 Patient Groups

Selecting Patient Groups under the Administration Heading will display the patient groups that the user has access to, along with the number of patients in each group. Patients can be added to groups in this tab, and user access to groups can be edited. For administrators, all patient groups are displayed.
2.2.4 New Patient Groups

The New Patient Groups view is available for administrators only. It is used to create new patient groups. For each patient group, the administrator can define communications settings for notifications on alerts via fax, email and/or SMS. Settings for a new patient group can also be copied from other existing patient groups.

2.2.5 Transmitters

The transmitter view displays all the transmitter serial numbers that have ever transmitted to the User Group (Figure 2-4 below). The Patient ID, device serial number, and date of last message will also be displayed. Transmitter serial numbers cannot be deleted, even if a patient is no longer registered with the clinic. A clinic can request a patient call back or cancel a call back request on this page.

The function check status (indicated by the red rectangle) is used to determine whether the transmitter can connect with the HMSC. When a CardioMessenger is switched on, a Technical Message is sent by the transmitter, and a clinic will be able to check if this message was received.

![Transmitter View](image)

Figure 2-4 - Transmitter serial number, type and status can be checked on this page. The device serial numbers are 8-digits long and have been blanked out for the purpose of this guide.

2.2.6 Option Templates

This page stores all option templates. It can be used to view all available templates and delete templates that are no longer used. Patient option settings define what findings invoke an alert. Option settings can be saved in a template and used as the settings for multiple patients.

2.3 Site Tools

The Site tools menu found at the bottom of menu bar provides information for the current user, access to the Help site, and also a fillable form that can be used to contact the Home Monitoring department.
2.3.1 Home
The home page displays an overview of patient status, the message of the day, and any available batch print jobs.

2.3.2 What’s New
Selecting “What’s New” will show the most recent updates to the Home Monitoring Service Center and will communicate information regarding scheduled system outages for service.

2.3.3 User Profile
The User Profile displays the current user’s information, as shown in Figure 2-6. Users have access and may edit their profile and change their password. The Administrator has capability of editing patient group access.
2.3.4 Contact

Filling out a contact will send a message to the Home Monitoring department at BIOTRONIK. A BIOTRONIK Home Monitoring associate will respond to your query.

2.3.5 Imprint

This feature is not available in the US.

2.3.6 Help

Selecting the Help tab opens an additional window, which will allow you access to a searchable outline database with basic support for using the Home Monitoring website, shown in Figure 2-7.

![Figure 2-7 – The Help page provides a searchable repository of Home Monitoring topics to assist in troubleshooting](image)

2.3.7 Sign Out

Clicking “Sign Out” will log the user off of the website. A message will confirm that the user was signed out successfully.
Chapter 3: Patient Report Tab Descriptions

This chapter describes the transmitted data available for a patient. The diagnostics are grouped into tabs and will be described by tab moving from left to right. Some tabbed sections have subtabs with further detailed information.

3.1 Status Tab

3.1.1 Summary Tab

The Summary tab is divided into four main sections: Alerts and Automatic Remarks, Quick View, Status Comment, and Timeline.

3.1.1.1 Alerts and Automatic Remarks

The Alerts section displays any alerts from the patient. They will be classified one of three ways: or , meaning red alert, yellow alert, and administrative alert, respectively. Alert types are defined within the patient Options tab.

If any IEGMs were transmitted with the alert, the alert will include the symbol ; clicking this symbol will display the IEGM. Refer to Figure 3-1, circled in red.

The symbol present in the adjacent column, circled in green in Figure 3-1, can be clicked to postpone an alert. The alert may be postponed for one day, two days, three days, one week, two weeks, or three weeks. Once the postponement period has ended, a notification will be sent.

Figure 3-1 – The main patient report screen provides access to alerts and basic device information
Not all alerts may be postponed; therefore, this symbol may not be present next to all alerts. A postponement period may be cancelled at any time by clicking the symbol again.

The Acknowledge button on the right of the screen will clear an alert. Once clicked, an “Undo Acknowledge” will appear for a short time to provide the user with the option to reverse the action so that the alert still remains. Previously acknowledged alerts may remain displayed on this tab, depending on the type of alert. Once acknowledged, the alert will change from “New” to “Acknowledged Today”. Acknowledged findings will turn white, while others may persist as they require a device measurement to return to an “in-range” state before being cleared from the findings list. (This range is set on the Options tab in Chapter 3.6.) All alerts will be saved in the patient history list displayed in the History tab.

### 3.1.1.2 Remote Scheduling

For devices that support the Remote Scheduling feature (Edora, Inventra, Itrevia, Iperia, Ilivia and Intica models), the currently scheduled dates for Remote Home Monitoring follow-ups are listed in this tab. Selecting the Show details button will open the Remote Scheduling sub-tab under the Patient profile tab, where Remote follow-up dates may be programmed.

![Remote Scheduling](image)

*Figure 3-1-2 – The Remote Scheduling screen*
3.1.3 Quick View

Selecting the “Show Quick View” button (circled in blue in Figure 3-1) displays the Quick View page shown below in Figure 3-1-3, which is a summary of all the information gathered from the patient.

The Quick View data can be considered in three categories:

- The device data section includes device and battery status, the programmed parameters and the lead test measurements (outlined in orange in this picture).
- The arrhythmia statistics section for atrial and ventricular arrhythmias, as well as AT/mode switch information, atrial burden and pacing percentages and event sequences (outlined in green in this picture.)
- The lead trends section includes long term impedances, amplitudes, thresholds, heart rate, patient activity, atrial burden and P-P variability trends (outlined in purple in this picture).

3.1.4 Status Comment

This section allows the user to insert a note regarding the patient status. The note can be inserted by typing the desired comment and clicking “Add Comment” button (Figure 3-1 above).
3.1.1.5 Timeline

Selecting “Show Timeline” will display major findings by the device in chronological order. It contains information regarding the patient registration date, first message, and any important alerts. Periods of unacknowledged status alerts are highlighted in yellow/red. See Figure 3-2.

![Timeline Diagram]

Figure 3-2 – The Timeline

3.1.2 Device Tab

The Device tab, outlined in red in Figure 3-3, provides basic information about the device itself, including device model, longevity, and communication with the Home Monitoring service.

![Device Tab Diagram]

Figure 3-3 - The Device tab is a subtab of the Status tab

Battery

- **Status or Battery status:** Displays estimated longevity of the battery. In pacemakers, examples of status are “OK”, “ERI” (Elective Replacement Indicator) and “---” (Measurement is not available). In ICDs, examples of status are “BOL” (Beginning of Life), “MOL1” (Middle of Life 1), “MOL2” (Middle of Life 2), “ERI” (Elective Replacement Indicator), “EOS” (End of Service), and “---” (Measurement is not available).


- **Date of implantation:** Displays the date and time when the device was implanted.
- **Voltage [V]:** Displays battery voltage measurement.
- **Date of last battery voltage measurement:** Displays date of last battery voltage measurement.
- **Max charge time since last follow-up:** Maximum number of seconds that have been required to charge the capacitor in order to give a shock. Only charging events since the previous follow-up are taken into account.

### 3.1.2.1 Device Status

- **Device status:** Displays any status variations or special modes in the device. Examples of status in pacemakers are “OK”, “MRI mode”, and “Backup mode”. Examples of status in ICDs are “OK”, “Special device status” (abnormal condition detected), “VT/VF therapy inactive”, “Emergency brady pacing active”, “Backup mode active”, “EOS”, and “---” [Measurement is not available].
- **Last manual MRI mode activation:** Date when the MRI mode was most recently activated.
- **Last automatic MRI mode activation:** Date when MRI mode was most recently activated while the device was programmed into automatic MRI mode (Outlined in green in figure 3-3, for devices which have this feature.)
- **Available episode memory bins:** Indicates how many episodes can be stored before the device memory is full (For BioMonitor and BioMonitor 2 models). The device memory can be emptied via device interrogation with the programmer.
- **Available memory bins for pat. trig. recordings:** [BioMonitor 2-AF] Indicates how many patient triggered recordings can be stored before the device memory is full for this type of recording. Additional patient trigger recordings will overwrite according to the recording storage hierarchy for each type.
- **Device model:** Displays product name.
- **Date of implantation:** Displays the date that the device was implanted.

### 3.1.2.2 Last Entry of a Shock List

This section displays information about the last charging event in ICDs. This information includes charge time, programmed shock energy, impedance at shock delivery, and indicates whether the shock was aborted or successful.

### 3.1.2.3 Home Monitoring

This tab displays information on the latest transmitted Home Monitoring message. Information includes message type [time triggered, event triggered, or programmer triggered], date the message was created, when the monitoring interval ended (if applicable), and date of last follow-up.

### 3.1.2.4 Transmitter

The transmitter tab provides information about the CardioMessenger, such as the serial number, last transmission, message type, and when the last follow-up was received.

### 3.1.3 Lead or Sensing Tab

The Lead tab displays information on pacing and sensing values of implanted leads, as seen in Figure 3-4. Clicking on next to a specific statistic displays the respective graph further down the page.
Sensing

The Sensing tab provides access to information on sensing, such as the daily mean ventricular sensing amplitude and percentage of noise per day.

3.1.3.1 RA Lead

- **Pacing impedance [ohm]**: In pacemakers, impedance is measured continuously and the value displayed is the last measurement of the day. In ICDs, impedance is measured four times a day and the value displayed is the daily mean value.
- **Pacing threshold [V]**: Displays the pacing threshold that has been measured with the Automatic Threshold Monitoring (ATM) of the device.
- **Pulse amplitude [V] or Pulse amplitude [AUTO] [V]**: If capture control is activated, the pulse amplitude is recalculated after each successful threshold test. If capture control is not activated, the programmed pulse amplitude is displayed.
- **Last Threshold Measured**: Displays date and time of last threshold measurement.
- **Capture Control Status**: Displays current programming of Capture Control. Possible statuses are OK, OFF, and DISABLED.
- **Sensing amplitude [daily mean] [mV]**: Displays the mean measured sensing amplitude value of the day. This is measured continuously in pacemakers and four times a day in ICDs.
- **Sensing amplitude [daily min.] [mV]**: Displays the lowest measured sensing amplitude value of the day.
- **Lead Check**: Displays the current status of the right atrial lead. Possible statuses are OK, OFF, BIPOLAR lead failure and UNIPOLAR lead failure.
- **Pacing Polarity**: Displays the right atrial pace polarity.
- **Sensing Polarity**: Displays the right atrial sensing polarity.
- **Last mean P-wave safety margin [%]**: Displays the average value over 18 hours.
- **Sensing**: Displays the programmed sensing settings for the lead. Possible settings are: STANDARD, INDIVIDUAL, and OFF.
3.1.3.2 RV Lead

This tab displays information regarding the right ventricular lead. Options available for single-chamber pacemakers are in this tab, as well, and may refer to the atrial or ventricular chamber depending on where the lead for the device has been placed.

For a detailed explanation regarding what data is available in this tab, refer to section 3.1.3.1 RA Lead, as the type of information given for each lead is similar.

3.1.3.3 LV Lead

This tab displays data regarding the left ventricular lead, if applicable. For a detailed explanation regarding what data is available in this tab, refer to section 3.1.3.1 RA Lead, as the information given for the leads are similar.

3.1.3.4 Shock Lead

The Shock Lead tab displays information on the shocking coils such as daily shock impedances and the shock impedance of the last delivered shock.

3.1.4 Bradycardia/CRT Tab

The Bradycardia/CRT tab displays information regarding the stimulated rhythm, AV sequences, LV-VV sequences, PVARP, and CRT, as seen in Figure 3-5. Clicking on \( \text{\textbullet} \) brings you to the respective graphs further down the page.

3.1.4.1 Paced Rhythm

Paced Rhythm displays the percentage of paced events over the previous 24 hours or average value since follow-up.

- **Atrial pacing (Ap):** Displays the percentage of paced atrial events per day.
- **Ven. pacing (Vp):** Displays the percentage of paced ventricular events in relation to all ventricular events per day.
- **Right ven. pacing (RVp):** Displays the percentage of paced right-ventricular impulses per day in relation to all right-ventricular events per day.
• Left ven. pacing (LVp): Displays the percentage of paced left ventricular impulses per day in relation to all left-ventricular events per day.
• Pacing: Displays the percentage of paced events per day. If RVp and LVp are not available, only this value will be displayed.
• VV sequences (Vx-Vx): Displays the percentage of consecutive ventricular events with no atrial sensed events.

3.1.4.2 AV Sequences (except during mode switch)
AV Sequences displays information regarding the patient’s intrinsic sinus activity over the previous 24 hours and averaged since last follow-up. All values will total 100%.

• Intrinsic rhythm [As-Vs]: Displays the percentage of intrinsic AV sequences.
• VAT stimulation [As-Vp]: Displays the percentage of ventricular paces that were triggered by an intrinsic atrial event.
• Conducted atrial pacing [Ap-Vs]: Displays the percentage of atrial paced events with intrinsic ventricular events.
• Dual-chamber pacing [Ap-Vp]: Displays the percentage of AV sequences paced in the atrium and the ventricle.
• V sequence [Vx-Vx]: Displays the percentage of two consecutive ventricular events without an atrial event.

3.1.4.3 LV-RV sequences
All values in the LV-RV sequences parameter group total to 100%. Statistics shown are reported over the last 24 hours or the mean value since the last follow-up that was reported to the Home Monitoring Service Center.

• BiVp or BiV stimulation: Displays the percentage of ventricular events where both ventricles were paced in relation to all LV-RV sequences.
• RVp without LVp: Displays the percentage of ventricular events in which the right ventricle was paced and the left ventricle was not paced.
• RVs triggered LVp: Displays the percentage of ventricular events in which a right-ventricle sensed event triggered a left-ventricle pace, if RVs triggering is activated.
• RVs without LVp: Displays the percentage of ventricular events in which a right-ventricle sensed event did not trigger a left-ventricle pace.
• PVC triggered LVp [%]: Displays the percentage in which a PVC is sensed in the right ventricle and the result is a triggered left-ventricle pace, if PVC triggering is activated.
• PVC without LVp [%]: Displays the percentage in which a PVC is sensed in the right ventricle and does not trigger a left-ventricle pace.

3.1.4.4 PVARP
This tab displays the current PVARP value if Auto PVARP is programmed on. It will display the PVARP length in ms over the previous 24 hours and as an average since last follow-up.

3.1.4.5 CRT
The CRT section displays the percentage of ventricular events that are considered resynchronization therapy. The CRT pacing percentage relates to all LV pacing, whereas BiV pacing relates to only LV pacing with RV pacing. CRT pacing percent is BiV pacing (RVp / LVp) plus trigger-pacing (RVs /LVp).
3.1.5 Atrial Arrhythmia Tab

The Atrial Arrhythmia tab, shown in Figure 3-6 displays information on atrial arrhythmias such as the atrial burden or high atrial rate episodes. Clicking on makes the respective graphs visible.

![Figure 3-6 - The Atr. arrhythmia tab is a subtab of the Status tab](image)

3.1.5.1 Atrial Burden or Atrial Episodes

The Atrial Arrhythmia tab displays information regarding atrial burden and episodes. All statistics are reported as the average over 24 hours and since last follow-up.

- **Atrial burden**: Displays the percentage of time during which the patient had atrial arrhythmias.
- **Atrial arrhythmia episodes per day**: Displays the number of atrial arrhythmia episodes per day.
- **New long atrial episode detected (ongoing)**: Indicates that a newly detected atrial episode was ongoing when the device transmitted.
- **Start of ongoing atrial episode**: Start time and date of the last atrial episode are shown if they were ongoing at the end of the monitoring interval.
- **Duration of longest atrial episode**: Displays the duration of the longest atrial episode during the last monitoring interval.
- **End of last atrial episode**: Displays date and time when the last atrial episode ended.
- **Atrial arrhythmia ongoing at end of monitoring interval**: YES is displayed if the atrial arrhythmia was ongoing at the end of the monitoring interval. The date and time of last measured atrial burden is also displayed.
- **Mean ven. heart rate during atr. burden**: Statistics show the mean value reported over the previous 24 hours or since the last follow-up.
- **Max. ven. heart rate during atr. burden**: Statistics show the maximum value reported over the previous 24 hours or since the last follow-up.
- **Number of mode switching per day**: Displays the number of mode switching episodes that started in a 24-hour period. Statistics shown are reported over the previous 24 hours or as the mean value since last follow-up.
- **Number of atrial episodes per day**: Displays the number of atrial episodes started in a 24-hour period. Statistics shown are reported over the previous 24 hours or the mean value since the last follow-up.
3.1.5.2  Mode Switching/Mode Switching Episodes

The Mode Switching tab displays information on mode switching episodes. All statistics are reported as the average over 24 hours and since last follow-up.

- **Number of mode switching episodes per day**: Displays the number of mode switches that started in the Home Monitoring interval.
- **Duration of mode switching**: Displays percent of the day that the patient was in a mode switch.
- **Mean ventricular rate during mode switching [bpm]**: Displays the mean ventricular heart rate during mode switching per day.
- **Max. ventricular rate at mode switching episode [bpm]**: Displays the maximum heart rate in the ventricle measured at the time when a mode switching episode occurs.
- **New long mode switching episode detected (ongoing)**: Indicates that a newly detected mode switching episode was ongoing when the device message was sent and exceeds the time limit that was programmed in the device.
- **Start of ongoing mode switching episode**: Start time and date of the last mode switching episode are shown if they were ongoing at the end of the monitoring interval.

3.1.5.3  High Atrial Rate Episodes

The High Atrial Rate tab displays information regarding high atrial rates such as episodes per day, duration of longest episode, as well as alerts for ongoing high atrial rate episodes. These values are reported over the previous 24 hours and as an average since the last follow-up. For single-chamber devices (SR-T), these statistics are available only when the device is programmed to AAI or AAIR mode.

3.1.5.4  Atrial Episodes or Atrial Monitoring Episodes

The Atrial Episodes tab displays appropriate counters for detected atrial episodes such as the amount of atrial monitoring episodes, atrial therapy episodes, and ongoing atrial episodes detected.

3.1.5.5  ATP (stable AT)

The ATP (antitachycardia pacing) tab displays appropriate counters for ATP delivered in the AT zone. This shows the number of ATPs that were started and how many were successful.

3.1.5.6  HF burst (unstable AT)

The HF burst tab displays appropriate counters for HF burst delivered in the AT zone. This shows the number of HF bursts that were started and how many were successful.

3.1.5.7  Atrial Rhythm

Atrial Rhythm displays information on atrial arrhythmias detected, such as the total events of atrial tachycardia, atrial flutter, and atrial fibrillations per day.

3.1.5.8  High Ventricular Rate Episodes

This section displays information on heart rate during high ventricular rate [HVR] episodes. The max HVR will be displayed as well as the duration of the episode. If “---” is displayed, then the device did not transmit an IEGM.
3.1.5.9 SVT

The SVT (supraventricular tachycardia) tab displays counters on SVT episodes detected by ventricular-only detection and episodes detected by SMART.

3.1.5.10 SMART Episode Details

Details on SMART detected episodes can be found here. SMART detection classifies SVT episodes based on AV synchrony in one of four ways: atrial fibrillation, atrial flutter, sinus tachycardia, and 1:1 SVT. Each counter will increment when an event is detected.

3.1.5.11 Last Episode

The last episode section will display information on the most recent episode detected such as the episode number, type of episode, as well as the date and time that the episode was detected.

3.1.6 Ventricular Arrhythmia Tab

The Ventricular Arrhythmia tab, as shown in Figure 3-7, displays information on ventricular arrhythmias. Clicking on brings you to the respective graphs.

![Figure 3-7- The Ven. arrhythmia tab is a subtab of the Status tab](image)

3.1.6.1 High Ventricular Rate Episodes

This section displays information regarding high ventricular rate (HVR) episodes.

- **High ven. Rate episodes per day**: Displays the average of ventricular episodes per day.
- **Duration of longest HVR episode per day**: Displays the duration of the longest HVR episode per day.
- **Start of ongoing HVR episode**: Displays the start time and date of the HVR episode that was ongoing at the time of transmission.
- **Max ventricular heart rate**: Highest heart rate of HVR episode displayed. If “---” is displayed, the IEGM of the episode was not transmitted.
- **Duration of HVR episode**: Displays duration of HVR episode. If “---” is displayed, the IEGM of the episode was not transmitted.
3.1.6.2 PVC
The PVC section shows information on premature ventricular contractions (PVCs). All statistics are reported as the average over 24 hours and since the last follow-up.

- **Mean PVC/h**: Displays the average number of PVCs per hour.
- **Max PVCs/h**: Displays the maximum number of PVCs per hour.
- **No. of ven. Runs per day**: Displays the number of ventricular runs with 4 to 8 PVCs per day.
- **No. of ven. episodes per day**: Displays the number of ventricular episodes with more than 8 PVCs per day.

3.1.6.3 Ventricular Detection
Displays the number of tachycardia episodes detected since the last follow-up and since the device was implanted. The respective counter will increment by one for each of the following detected episodes: VT1 monitoring, VT1 therapy, VT1 episode, VT2 episode, VF, episode during temporary program, and SVT.

3.1.6.4 Ventricular ATP
This section displays ATP therapy statistics since the last follow-up, as well as since implantation. The counters will increment when ATP in the VT zone was started and if ATP was successful. This will also display ATP One shot in the VF zone, specifically, when ATP was started and whether it was successful.

3.1.6.5 Ventricular Shock
The Ventricular Shock section displays details on started, aborted, ineffective, and successful shocks since last the follow-up.

- **Shocks started**: Number of times the implant began charging to deliver therapy.
- **Shocks aborted**: Number of times the implant canceled a shock that began charging.
- **Shocks successful**: Number of times a delivered shock terminated an episode.
- **Ineffective max energy shock**: Number of maximum energy shocks that were delivered and did not terminate the tachycardia episode.

3.1.6.6 Last Episode
The last episode section displays information on the most recent episode detected, such as the episode number, type of episode (VT, VF, SVT, etc.), as well as date and time when the episode was detected.

3.1.7 Physiological Parameters Tab
The Physiological Parameters tab, shown in Figure 3-8, displays information on ventricular arrhythmias. Clicking on [ ] brings you to the respective graphs.
3.1.7.1 Heart Rate

This tab displays information on the mean heart rate over the previous 24 hours and since the last follow-up. This section shows mean atrial and ventricular heart rate, mean resting heart rate, as well as heart rate variability.

NOTE: The Time scale of charts and graphs can be changed by selecting the drop-down triangle (shown in Figure 3-8 as currently set to “1 month”) and a new value selected. Options are 1 month, 3 months, 6 months and 1 year. Selecting 1 month allows the most precise values to be visualized on graphs.

3.1.7.2 Heart Rate Variability

The Heart Rate Variability displays the standard deviation averages of the P-P variability of intrinsic beats.

3.1.7.3 Activity

This tab displays the percentage of time per day the patient is above the activity sensor threshold.

3.1.7.4 Thoracic Impedance (TI)

Thoracic impedance is measured between the RV tip of the lead and implant housing. The value is displayed only if the device’s thoracic impedance measurement has been switched on via the programmer. A TI trend analysis does not replace assessments that are part of standard of care for the clinical practice. The clinical value of this feature has not been established for the management of patients. The displayed value is the daily mean of 24 measurements per day.

NOTE: Pocket and/or lead revisions may affect the TI trend data. Therefore, TI trend data should be interpreted cautiously within 6-10 weeks of a revision.

3.1.7.5 Number of Recordings

The Number of Recordings section displays the number of patient-triggered recordings per day.
3.1.8 HF Monitor Tab

The HF Monitor tab, shown in Figure 3-9 displays heart failure diagnostics which are particularly useful in tracking and managing the progression of heart failure. The table displays the device status and the pacing mode programmed for the device. The last section contains HF related parameters and graphically displays them over the previous 180 days. Diagrams with alerts are marked with yellow or red frames depending on which alert was transmitted. Clicking on [ ] will display the respective graphs.

![Figure 3-9 - The HF monitor tab is a subtab of the Status tab](image)

3.1.8.1 Device Status

The table displays the device and battery status.

- **Device Status:** Displays any status variations or special modes activated. This section will display one of the following: “OK”, “Special device status” (abnormal condition detected), “VT/VF therapy inactive”, “Emergency brady pacing active”, “Backup mode active”, “EOS”, or “---” (measurement is not available).

- **Battery Status:** Displays the estimated longevity of the battery. Pacemakers will display “OK”, “ERI”, or “---”, while ICDs will display “BOL” (Beginning of Life), “MOL1”, “MOL2” (Middle of Life 1 and 2), “ERI”, or “EOS”. “ERI” stands for “Early Replacement Interval” where devices can be and typically changed out. “EOL” stands for “End of Life” where the implant’s battery is depleted and BIOTRONIK can no longer guarantee the performance of the implant.

- **Pacing Mode:** Displays the current pacing mode the device is programmed.

3.1.8.2 Arrhythmias

This table displays numbers and kinds of episodes since last follow up.

- **Atrial arrhythmia episodes per day:** Displays the mean number of atrial arrhythmia episodes per day since the date listed beside the title.

- **High ventricular rate episodes per day:** Displays the mean number of high ventricular rate episodes per day since the date listed beside the title.
• **High rate episodes per day**: Displays the mean number of high rate episodes per day since the date listed beside the title.

• **Episodes or Therapy episodes**: Displays the total number of Atr, VT1 episodes, VT2 episodes, and VF episodes since the date provided above.

• **ATP started/successful**: Displays the total number of ATP therapies that were started and the total number of ATP therapies that were successful since the date provided above.

• **Shocks started/aborted/successful**: Displays the total number of shocks that were started, the total number that were aborted, and the total number that were successful since the date provided above.

### 3.1.8.3 Long-Term Trends

Long-Term Trends displays diagrams relating to heart failure parameters over the previous 180 days. The latest value of the respective parameter is displayed in numbers on the right side of the diagram. Diagrams with alerts are marked with yellow or red frames depending on what alert was transmitted.

• **RV pacing**: Displays percentage of paced ventricular events in relation to all ventricular events per day.

• **Pacing [%]**: Displays percentage of paced events in relation to all events per day.

• **BiV pacing [%]**: Displays the percentage of pacing where both ventricles are paced in relation to all LV-RV sequences.

• **CRT pacing [%]**: CRT pacing represents BiV pacing plus right ventricular sense trigger pacing.

• **Mean heart rate**: Displays the mean atrial heart rate, mean ventricular heart rate, and mean resting heart rate over an extended period of time.

• **Heart Rate Variability [ms]**: Displays the mean value of the standard deviation of the five-minute averages of the cycle lengths of intrinsic beats over an extended period of time.

• **Patient activity [% of day]**: Displays the percentage of time per day the patient is above the set activity sensor threshold over an extended period of time. The threshold is set using the programmer.

• **Atrial burden [% of day]**: Displays the percentage of time per day that the patient had atrial arrhythmias over an extended period of time.

• **Ventricular heart rate during atrial burden [bpm]**: Displays the maximum ventricular heart rate during atrial burden per day and the mean ventricular heart rate during atrial burden per day over an extended period of time.

• **Mean PVC/h**: Displays the average amount of PVC occurring per hour over an extended period of time.

• **Thoracic Impedance [ohm]**: Displays the mean value of 24 measurements per day over an extended period of time.

### 3.2 Device Settings Tab

The Device settings tab, shown in Figure 3-10, displays current programmed settings in the patient’s device. The Overview tab shows bradycardia mode, the tachycardia zones and therapies, and the lead settings. The Lead tab details all the programmed values for each lead, including the blanking and refractory periods. The Bradycardia/CRT tab details all the basic bradycardia parameters including basic rate programming, night rate, upper rate, AV delay, CRT pacing, post shock pacing, and sensor information. The Atrial Arrhythmia tab includes information regarding mode switching, PMT, and atrial monitoring/therapy zones. The Ventricular Arrhythmia tab details all the ventricular detection zones, all discriminators programmed, and programmed therapies. The Home Monitoring tab provides information on transmission time and other Home Monitoring features. Note that programmed device settings changes will update under Device settings with the normal Trend Message transmission. However, should Lead Check cause a change in lead polarity or the device go
into a backup mode, the device settings will not reflect the device settings changes caused by these features. Only a status alert would indicate the device is in one of these conditions.

![Device settings tab](image1)

**Figure 3-10** - The Device settings tab provides access to currently programmed device, diagnostic, and Home Monitoring settings.

The Device settings/MRI tab, if available, will show the current MRI settings if enabled for a device with MRI programmed to ON or AUTO MRI mode.

![Device settings/MRI tab](image2)

**Figure 3-11** - The Device settings/MRI tab

### 3.3 Recordings Tab

The Recordings tab, shown in Figure 3-12, provides IEGMs that are transmitted to the Home Monitoring Service Center. Types of IEGMs may include Periodic IEGMs, atrial and ventricular arrhythmias, and non-arrhythmia technical triggers, depending on implant model. Date and time of the most recent follow up are also listed. From the episode list, you may select an episode and display the IEGM, along with the episode details. The displayed episode parameters depend on the device model of the patient. The time stamp is taken from the internal device clock. The device clock can be synchronized with the programmer.

In the View section below the episode list, you may set a filter for episode types to reduce the number of displayed episodes. Please note that this section is not available for all devices.
3.3.1 Recordings numbering on the programmer compared to the HMSC website

Biotronik ICDs will show periodic IEGMs on the programmer under the Recordings Tab as well as on the HMSC website. Biotronik pacemakers and BioMonitor/BioMonitor2 will only store periodic recordings (IEGMs/sECGs) on the HMSC website, and will not list them under the Recordings tab on the programmer.

IEGMs for BIOTRONIK ICDs have a recording number which will be the same on both the programmer and the HMSC website. Thus gaps in recording numbers may be seen if recordings were deleted on the programmer before transmission to the HMSC website. Pacemakers may have a differing number scheme for recordings shown on the programmer than on the HMSC website. The HMSC website will show sequential numbering for pacemaker and BioMonitor/BioMonitor2 recordings.

3.4 History Tab

The History tab, depicted by the red box marked 1 in Figure 3-13, provides a record of all alerts and events that have occurred including those that have been acknowledged. Further, all status and diagnostic information for a particular day can be viewed.
3.4.1 Timeline Tab

The Timeline tab depicted by the green box marked 2 in Figure 3-13, is subdivided into the following sections:

- **Patient profile comment**: Displays the current content of the Comment field on the Patient profile tab.
- **Finding options comment**: Displays the current content of the Finding options comment field on the Options tab.
- **Timeline**: The timeline bar displays the patient history for the last three months. Displayed are:
  - Medical and administrative events
  - Findings (abbreviated)
  - Patient status

Note: If there isn’t enough room to display all events and findings beneath each other, two or more events or findings are pooled under the expression Events.

- Patient history list: The patient history list contains all Findings, all User actions (e.g., acknowledgement of a finding, activation/deactivation of the patient) and all Status comments throughout the patients’ transmission history. Clicking on “Status” for a specific date will take the user to the Overview page for that day.
- **Viewing past data**: The Timeline tab allows a user to view the Home Monitoring status and device settings for a date in the past. Notice the Status bar at the top of the Home Monitoring page (depicted as the blue box marked 3 in Figure 3-13) shows “Status on” the current date. To view the Status, Device settings, Recordings, Patient Profile and Options tabs for a previous date, scroll to the bottom of the History/Timeline tab and select the date you wish to view under the Status by date section (as shown in Figure 3-14 with the blue arrow marked 4.) Change this date to the date you wish to view and click the “Status” button.

![Figure 3-14 Viewing Past Dates](image)

- The Status bar at the top of the page will now read “Status on” your chosen date. As in the example shown in Figure 3-15 March 4, 2018 was selected. The Status bar in Figure 3-15 now shows March 4, 2018 as the date. Tabs will be viewable with 24 hour data, recordings listed, and device settings as shown by Home Monitoring for that date. To return to the current date, change the Status date back to the current date. Alternatively, if you leave this patient the date will also return to the current date.
3.4.2 Archive Tab

The History / Archive tab, shown in Figure 3-16 provides patient history for download in PDF format. For each year, you can download quarterly archives or a yearly archive.

3.5 Patient Profile
3.5.1 Patient Profile Tab

The patient profile tab, as shown in Figure 3-18, provides access to basic patient and Home Monitoring settings. Users may enter personal patient information into the patient’s profile when registering a new patient, as seen in Figure 3-18. This allows patient contact information to be easily accessible. Some additional uses for this section may include the following:

- Alternate contacts, with phone numbers
- Doctors who follow the patient, and the patient contact information

To use this feature, the user must select “Patient has agreed that BIOTRONIK may store his/her personal data.” Next, select the “Enter Personal Data” button. Note that this consent and entry of personal information can only occur when the patient is first added to a Patient group.

Existing patient data can be modified by selecting the “Edit profile” button at the bottom of the Patient Data tab.

![Patient profile tab screenshot](image)

**Figure 3-18 - Patient contact information can be entered into a patient’s profile and easily accessed by the user.**

3.5.2 Remote Scheduling Tab

3.5.2.1 Device Capabilities

Ilesto and newer ICDs, as well as the Edora pacemaker, support Remote Scheduling of follow-ups from the Home Monitoring Service Center (HMSC). With this feature, patients transmit remote follow-ups on scheduled dates and can decrease the frequency of in-office follow-ups.
The first Home Monitoring follow-up must be scheduled for a date at least 12 days after the patient has been registered. If the scheduling is edited at a later time, and if the device has already sent seven messages via the same transmitter, the first remote follow up has to be at least five days after patient registration. When programming the days between HM follow-ups, the minimum number of days is 20, and the maximum is 366.

3.5.2.2 Configuration

This section details the current Remote Scheduling parameters setup for the patient. In order to understand how Remote Scheduling is initially programmed, please refer to Chapter 1.5 – Adding/Removing patients. By selecting the “Edit” button, shown in Figure 3-19, the user may make changes to the Remote Scheduling in the same manner as the initial registration of the patient.

![Figure 3-19 – The patient profile tab allows remote scheduling of Home Monitoring follow-ups.](image)

3.5.2.3 Intermediate Home Monitoring Follow-Up

The clinic can request an unscheduled Home Monitoring follow-up by selecting the “Request” button at the bottom of the Remote Scheduling screen (Figure 3-19). Home Monitoring follow-up data will be available within five days. The request for unscheduled Home Monitoring follow-up data has no impact on the generation and/or transmission of the scheduled transmissions. Unscheduled Home Monitoring follow-up data can be requested even if Remote scheduling is deactivated.

Only one unscheduled transmission of Home Monitoring follow-up data can be requested at a time per patient. Once the Home Monitoring follow-up data is received (regardless of whether this is scheduled or unscheduled), data may be requested again. If no Home Monitoring follow-up data is received within a period of five days, it is possible to request data again. If multiple requests are made, it is possible to get more than one follow-up.

If the transmitter has not successfully transmitted to the HMSC, it is not possible to request an unscheduled follow-up.
3.5.3 Lead Information Tab

For patients who received an implant after January 1, 2009, the Lead information tab, shown in Figure 3-20, is available. The displayed lead information is automatically imported from the Medical Device Registration Form (MDRF) database, regardless of manufacturer. Because the information is pulled from the MDRF database directly to HMSC, the implant does not need to transmit to HMSC to populate the data. Listed on the Lead information tab are the model name, manufacturer, serial number of the leads, and implant date. Lead specifications also include lead polarity, channel where bradycardia therapy (pacing and sensing) would be delivered, where tachycardia therapy would be delivered, and lead location.

![Lead Information Tab](image)

Figure 3-20 - Users will be able to access lead information through this page.

3.6 Options Tab

BIOTRONIK Home Monitoring gathers patient data for analysis and monitors data for anomalies. If any anomalies are found within the data gathered, the clinician is immediately notified. This allows for the patient to receive the highest level of care, while maximizing the physician’s time.

![Options Tab](image)

Figure 3-21 – The Options tab lists the triggerable alerts and what status and notification are provided for each.

Under the Options tab, shown in Figure 3-21, the notification options available for each patient can be edited to suit the clinician’s requirements and the patient’s specific needs. Templates can also be created so that the same set of options may be applied to different patients without having to program options individually. The alert options for a patient can be edited by selecting the “Edit” button. Note that notification options cannot be edited if there is an unacknowledged finding or postponement of the finding.
3.6.1 Patient Options

Each device has a variety of options that can be programmed to alert the physician.

3.6.2 Notification Option Template Settings

A setting may be picked from the drop down in the Option Templates section and the check mark button must be selected to apply the settings. There are three basic forms of option settings.

- **Default:** Patients added to a user group will automatically have their options set to a default template according to their implant.
- **Individual:** A patient’s options may be manually adjusted specific to each patient.
- **Minimum:** Options will be adjusted to a template where all settings are OFF except those deemed necessary for patient safety (i.e., ERI) when applied. (See Figure 3-22.)

![Figure 3-22 - Minimum Option Settings Template](image)

Notification options may be grayed out, as in Figure 3-23, or unavailable for the following reasons:

- The option is not available for the implant type.
- In the interest of patient safety, certain notifications such as ERI cannot be programmed off.
- If a current event finding has not been acknowledged or resolved, the user may be locked out from changing the notification option related to that finding.
- If a previous alert had been postponed for a later date, the user will not be able to change the notification option related to the postponed finding.

![Figure 3-23 - Grayed Out Notification Options](image)
3.6.3 Creating Alert Option Templates

Users can create and save specific option settings as a template. A template may be applied to any patient with the same device. These template settings must be applied manually by a user for each patient profile.

To create a new template, change option settings as desired for a patient and select the “Apply” button. After applying and confirming the settings, select the “Save” button, as shown in Figure 3-24. This will prompt you to give the template a name or use an existing template name, as shown in Figure 3-25. Using an existing template’s name will not automatically apply the changes to any other patient’s profile. This template can now be used for other patients by following the steps in section 3.6.4 below.

![Figure 3-24](image)

Figure 3-24 – The “Save” button will appear at the bottom of the Options tab after making and confirming notification settings. This button can be selected to create a new template using the currently selected options.

![Figure 3-25](image)

Figure 3-25 - Creating Option Templates

3.6.4 Applying Alert Option Templates

Users can apply an existing Option Template by performing the following actions:

- Access the patient profile.
- Select the Options tab.
- At the bottom of the page, access the drop-down menu that will show all created templates. (See Figure 3-25.)
- Choose the appropriate template and select the check mark.
- Apply and confirm changes made.
3.7 Saving or Printing Data

3.7.1 Creating Home Monitoring Cardio Reports

A patient’s Home Monitoring Cardio Report is made available for printing by performing the following:

- Select the “Save/Print [PDF]” button found on the top right or bottom right of any patient screen currently viewed.
- Select the information to be contained in the Cardio Report, as seen in Figure 3-26.
- Select the Create PDF button.
  - To print the file, select open, then review and print.
  - To save the file, select save, then select the file location.

Please note: If an IEGM is to be included in the report, the user must first select the IEGM(s) from the Recordings tab and then create the PDF from that screen.

![Figure 3-26](image-url) - Selectable information to be included in Cardio Reports
3.7.2 Batch Printing

Batch printing allows a user to print multiple Cardio Reports at once. There are two methods to create a print job:

*Cardio Report from multiple patients. From the “All Patients” view:

- Select the Save/Print (PDF) button. The user will then be prompted to select the patient names and content to be included in the report (Figure 3-27).
- Once the Create PDF button is selected, a system message will confirm that the batch print job is being created (Figure 3-28).
- On the home page, a system message will indicate the status of the current job (Figure 3-29).
- Once completed, a link to the report will be provided on the home page of the clinic’s web page in the “Batch printing” box for printing or saving (Figure 3-30). The report will be available for one week.

*Multiple episodes for a single patient:

- Select three or more episodes to print from the Recordings Tab.
- Select Save/Print (PDF) button
- A system message will confirm that the print job is being created (Figure 3-27).
- On the home page, a system message will indicate the status of the current print job (Figure 3-28).
- Once completed, a link to the report will be provided on the home page of the clinic’s web page in the “Batch printing” box for printing or saving (Figure 3-29). The report will be available for one week.
Chapter 3 Patient Report Tab Descriptions
BIOTRONIK Home Monitoring® Reference Guide

Figure 3-28 - Batch Print Job Confirmation

Figure 3-29 - Status of Current Print Job

Figure 3-30 - Web Link to Batch Printing Report
To import multiple files into Adobe and print as a single PDF document, follow the steps outlined below:

- An individual patient report will appear as a PDF document. A report for multiple patients will appear as a ZIP file. PDF files can be attached to Paceart or an EHR system.
- Select and open the Batch print zip file. Copy and paste all files into a new folder.
- Open Adobe Acrobat Standard 9 or higher.
- Select “Combine Files into PDF” from the menu, as shown in Figure 3-31. You may also select the Create icon followed by “Combine Files into a Single PDF” in the upper right of the screen, as shown in Figure 3-32.
- Drag and drop files from the new folder which was created from the Batch print zip folder in step 1 into the Combine Files window shown in Figure 3-33. You can select multiple files by holding down the Shift key on the keyboard and then clicking multiple files with the left mouse button.
- Select “Combine Files”, as shown in Figure 3-34 to create a single PDF of multiple Home Monitoring follow-ups which can be easily printed.

![Figure 3-31 - Combine Files into PDF option](image1)

![Figure 3-32 - Combine Files into Single PDF option](image2)
Chapter 3 Patient Report Tab Descriptions
BIOTRONIK Home Monitoring® Reference Guide

Figure 3-33 - File Drag and Drop Option

Figure 3-34 - Combine Files Option
Chapter 4: Programming the Implant and Transmitted Information

This chapter will review how to program Home Monitoring ON in an implant, as well as the transmission schedule for events and recording hierarchies for information that devices can transmit to the Home Monitoring Service Center for clinicians to review including diagnostics, significant events, and recordings. Finally, this chapter provides instructions for verifying that a patient’s implant successfully communicates with their CardioMessenger and how to restart Home Monitoring in the implant.

4.1 Turning on Home Monitoring in the Implant

Home Monitoring needs to be enabled on the implant device to transmit to the Home Monitoring website. BioMonitor 2, BioMonitor, and all devices with a ‘-T’ suffix in the model name have Home Monitoring capability. This can be turned on by interrogating a device, going to the Home Monitoring tab on the Parameters screen, and selecting ON and then the Program button (Figure 4-1).

Figure 4-1 - Where to enable Home Monitoring on the programmer

The tables on the next page describe the basic Home Monitoring programming setting options programmable for each family of device that can be configured on the Home Monitoring tab of the programmer 4.1.1 Programmable Home Monitoring Parameters for Pacemakers.
<table>
<thead>
<tr>
<th>Parameter</th>
<th>Parameter (Increment)</th>
<th>Standard</th>
</tr>
</thead>
<tbody>
<tr>
<td>Home Monitoring</td>
<td>On; Off</td>
<td>Off</td>
</tr>
<tr>
<td>ERI response</td>
<td>Daily ERI notification for 14 days after initial ERI notification</td>
<td>Off</td>
</tr>
<tr>
<td>Time of transmission</td>
<td>Auto; 00:00-23:00 (30 minute intervals)³</td>
<td>Auto</td>
</tr>
<tr>
<td>Periodic IEGM or Cycle duration</td>
<td>Off; Date; 30; 60; 90; 120; 180 days</td>
<td>30 days</td>
</tr>
<tr>
<td></td>
<td>Selection - 5 programmable Transmission Dates¹²</td>
<td></td>
</tr>
<tr>
<td>High atrial rate</td>
<td>Off; Mode Switching; AT</td>
<td>AT</td>
</tr>
<tr>
<td>High ventricular rate</td>
<td>On; Off</td>
<td>On</td>
</tr>
<tr>
<td>High rate³</td>
<td>On; Off</td>
<td>On</td>
</tr>
<tr>
<td>Patient trigger</td>
<td>On; Off</td>
<td>On</td>
</tr>
<tr>
<td>Thoracic Impedance (TI)⁴</td>
<td>On; Off</td>
<td>Off</td>
</tr>
</tbody>
</table>

¹ Only available for Edora, Eluna and Etrinsa models
² Edora Home Monitoring is programmed via the Remote scheduling feature of the HMSG website
³ This option is shown on the Entovis SR-T, the Evia SR-T, and the Estella SR-T models
⁴ Feature unavailable on Evia and Entovis SR-T and DR-T models
⁵ Evia HF-T model Time of transmission is in 1 hour increments

Table 4-2 – Edora, Eluna, Etrinsa, Entovis, Estella, and Evia Home Monitoring Programmability
<table>
<thead>
<tr>
<th>Parameter</th>
<th>Parameter (increment)</th>
<th>Standard</th>
</tr>
</thead>
<tbody>
<tr>
<td>Home Monitoring</td>
<td>On; Off</td>
<td>On</td>
</tr>
<tr>
<td>ERI response</td>
<td>Daily ERI notification for 14 days after initial ERI notification</td>
<td>On</td>
</tr>
<tr>
<td>Time of transmission</td>
<td>hh:mm [10 minute interval[s]]</td>
<td>0:00</td>
</tr>
<tr>
<td>Patient message</td>
<td>On; Off</td>
<td>Off</td>
</tr>
<tr>
<td>Event message</td>
<td>On; Off</td>
<td>On</td>
</tr>
</tbody>
</table>

Table 4-3- Philos II and Cylos DR-T Home Monitoring Programmability

4.1.2 ICD Programmable Parameters for Home Monitoring.

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Parameter (increment)</th>
<th>Standard</th>
</tr>
</thead>
<tbody>
<tr>
<td>Home Monitoring</td>
<td>On; Off</td>
<td>Off</td>
</tr>
<tr>
<td>ERI response</td>
<td>Daily ERI notification for 14 days after initial ERI notification</td>
<td>On</td>
</tr>
<tr>
<td>Time of transmission</td>
<td>Std; 00:00 - 23:00 [1 hour intervals]</td>
<td>Std</td>
</tr>
<tr>
<td>Periodic IEGM or Cycle duration(^1) \via Remote Scheduling</td>
<td>Off; Date; 30; 60; 90; 120; 180 days Selection - 5 programmable Transmission Dates</td>
<td>30 / Off</td>
</tr>
<tr>
<td>IEGM for therapy episodes</td>
<td>Off; Mode Switching; AT</td>
<td>AT</td>
</tr>
<tr>
<td>IEGM for monitoring episodes</td>
<td>On; Off</td>
<td>On</td>
</tr>
<tr>
<td>Ongoing atrial episode</td>
<td>Off; 6; 12; 18 hours</td>
<td>12 hours</td>
</tr>
<tr>
<td>Thoracic impedance (TI)</td>
<td>On; Off</td>
<td>Off</td>
</tr>
</tbody>
</table>

\(^1\)Remote scheduling from the HMSC website is available for all ICDs after the Lumax 740 series

Table 4-4 ICD Programmable Home Monitoring Parameters
# Lumax 340 and Lumax 540: VR-T/DR-T/HF-T

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Parameter (increment)</th>
<th>Standard</th>
</tr>
</thead>
<tbody>
<tr>
<td>Home Monitoring</td>
<td>On; Off</td>
<td>Off</td>
</tr>
<tr>
<td>ERI response</td>
<td>Daily ERI notification for 14 days after initial ERI notification</td>
<td>On</td>
</tr>
<tr>
<td>Time of transmission</td>
<td>Time (hh:mm)</td>
<td>1:00</td>
</tr>
<tr>
<td>IEGM for therapy episodes</td>
<td>On; Off</td>
<td>Off</td>
</tr>
<tr>
<td>IEGM for monitoring episodes</td>
<td>On; Off</td>
<td>Off</td>
</tr>
<tr>
<td>Periodic IEGM</td>
<td>Off; 1; 2; 3; 4; 6 months</td>
<td>Off</td>
</tr>
<tr>
<td>Ongoing atrial episode</td>
<td>Off; 0.5; 6; 12; 18 hours</td>
<td>12 hours</td>
</tr>
<tr>
<td>Thoracic impedance¹ (TI)</td>
<td>On; Off</td>
<td>On²</td>
</tr>
</tbody>
</table>

¹Not available for Lumax 340 series
²Must be programmed ON

---

## Table 4-5 - Lumax 3 and 5 series Home Monitoring Programmability

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Parameter (increment)</th>
<th>Standard</th>
</tr>
</thead>
<tbody>
<tr>
<td>Home Monitoring</td>
<td>On; Off</td>
<td>Off</td>
</tr>
<tr>
<td>ERI response</td>
<td>Daily ERI notification for 14 days after initial ERI notification</td>
<td>On</td>
</tr>
<tr>
<td>Time of transmission</td>
<td>Std; 00:00 - 23:00 (1 hour intervals)</td>
<td>Std</td>
</tr>
<tr>
<td>Periodic subcutaneous ECG</td>
<td>Off; 1; 2; 30; 60; 90; 120; 180 days</td>
<td>30 days</td>
</tr>
<tr>
<td>Episode triggered sECGs</td>
<td>AF, HVR, Bradycardia, Asystole, Patient Triggered, Sudden Rate Drop¹</td>
<td>On</td>
</tr>
</tbody>
</table>

¹BioMonitor 2 only

---

## Table 4-6 - BioMonitor / BioMonitor2 Home Monitoring Programmability

# 4.2 Transmission Schedule

BIOTRONIK devices will transmit daily to the Home Monitoring Service Center at the programmed time. The daily transmission consists of a Trend Message containing diagnostic data, Periodic IEGMs if available, and Event Messages (upon meeting trigger criteria). Event messages include alerts and recordings. ICDs may also transmit episode data for a detected arrhythmia as they occur presuming the patient is near their CardioMessenger. This section describes when these transmissions to the Home Monitoring Service Center occur for a particular device.
4.3 Daily Trend Messages

Daily Trend Messages include device statistics and physiologic data such as pacing percentages, lead impedances, and pacing thresholds. When the Time of transmission parameter is programmed to Auto or Std. (default) under the Home Monitoring settings, transmission will occur between 12:00 A.M. and 3:00 A.M. The time of transmission can be reprogrammed to occur at a specific time of day in 30-minute or 1-hour increments. If a communication attempt fails, up to three additional attempts to transmit are made at 60-minute intervals. In addition to populating diagnostics with pacing and device data, data-specific alerts can also be configured under the Options tab.

4.4 Periodic IEGMs

BIOTRONIK devices will transmit a Periodic IEGM, which contains up to a 30-second recording that clinicians can use to evaluate device behavior and patient response:

- In pacemakers, the Periodic IEGM is comprised of three 10-second sections where settings on the implant are temporarily adjusted and show the patient response to normal device settings, encouraged sensing to evaluate underlying cardiac function, and encouraged pacing to evaluate capture.
- In ICDs, the Periodic IEGM is the entire 30-second recording using the patient’s permanently programmed settings.

The Periodic IEGM, together with the Daily Trend Message, comprises a Remote Follow-up. This section discusses the programmability of Periodic IEGMs for Home Monitoring Follow-up. More details about Remote-scheduling can be found in section 3.5.2 Remote Scheduling.

Evia and Entovis pacemakers¹:

- Periodic IEGMs can be programmed to transmit at 30, 60, 90, 120, or 180 day intervals, or programmed OFF.
- Changes to Periodic IEGM transmissions must be programmed on the device itself and cannot be programmed through the Home Monitoring Service Center.

Etrinsa and Eluna pacemakers¹:

- Periodic IEGMs can be programmed to transmit at 30, 60, 90, 120, or 180 day intervals, or programmed OFF

OR

- Periodic IEGMs can transmit on specific programmable dates using the “Date Selection” parameter.
- Changes to Periodic IEGM transmissions must be programmed on the device itself and cannot be sent through the Home Monitoring Service Center.
- After all 5 dates have been utilized, new dates need to be programmed on the implant via the programmer.

Edora pacemakers:

- The Periodic IEGM Cycle duration parameter can be programmed to OFF, Date Selection, 30, 60, 90, 120, or 180 days.
- Changes to Periodic IEGM transmissions must be programmed on the Home Monitoring Service Center in the “Patient profile” tab and “Remote Scheduling” sub-tab.

¹ Periodic IEGMs are not stored in device Recordings and can only be viewed on the Home Monitoring Service Center
Lumax ICDs:

- The Periodic IEGM Cycle duration parameter can be programmed to OFF, Date Selection, 30, 60, 90, 120, or 180 days.

Lumax 7 and newer devices:

- Periodic IEGMs can transmit on specific programmable dates using the “Date Selection” parameter.
- Changes to Periodic IEGM transmissions must be programmed on the device itself and cannot be programmed through the Home Monitoring Service Center.
- After all 5 dates have been utilized, new dates need to be programmed on the implant via the programmer.

Ilivia, Intica, Ilesto, Itrevia, Inventra, and Iperia ICDs:

- The Periodic IEGM Cycle duration parameter can be programmed to OFF, Date Selection, 30, 60, 90, 120, or 180 days.
- Changes to Periodic IEGM transmissions must be programmed on the Home Monitoring Service Center in the “Patient profile” tab and “Remote Scheduling” sub-tab.

BioMonitor and BioMonitor2:

- The periodic subcutaneous ECG (sECG) can be programmed OFF, or to transmit at 1, 2 (7 for BioMonitor 2), 30, 60, 90, 120, or 180 day intervals.
- The BioMonitor 2 also allows the user to program up to five specific transmission dates for Periodic IEGMs using the “Date Selection” parameter.
- After all 5 dates have been utilized, new dates need to be programmed on the implant via the programmer.
- Changes to Periodic IEGM transmissions must be programmed on the device itself and cannot be programmed through the Home Monitoring Service Center.
4.5 Event Messages

Critical cardiac events on the device generate an Event Message, which is flagged on the Home Monitoring Service Center. In the case of pacemaker and BioMonitor models, these messages are sent at the next scheduled Home Monitoring transmission time along with the daily Trend Message. In the case of ICDs, depending on the Event Message type, the implant will immediately attempt to transmit to a CardioMessenger and to the Home Monitoring Service Center. This section describes Event Message types and when they are transmitted. Note that other status alerts available on the Home Monitoring Service Center can be configured and are based on nightly Trend Message data.

Evia, Entovis, Etrinsa, Eluna and Edora Pacemakers: The following occurrences initiate a Home Monitoring Event Message and are transmitted to the Home Monitoring Service Center with the daily Trend Message:

- Right/Left Ventricular Lead Check < 100 +/- 50 ohm and > 2500 +/- 500 ohm
- ACC/RVCC/LVCC Disabled
- ERI detected
- Atrial Capture Control Disabled
- High Ventricular rate
- Atrial tachyarrhythmia persisting beyond a programmable time limit or Mode Switch episode persisting beyond a programmable time limit

Note that Edora, Eluna and Etrinsa pacemakers can provide Home Monitoring IEGMs for event-based events such as high ventricular rate and atrial tachycardia events. These IEGMs are in addition to periodic IEGMs. These additional triggers must be programmed on under the device’s Home Monitoring settings with a programmer. Only one IEGM will be sent per day and is sent at the scheduled Home Monitoring transmission time. The hierarchy for transmission is fixed and is as follows (where 1 is highest priority):

1. Scheduled remote follow-up IEGM
2. Most recent bipolar lead failure IEGM
3. Most recent unipolar lead failure IEGM
4. Most recent high atrial rate (HAR) or high ventricular rate (HVR) IEGM.

Note: To help conserve battery and maintain longevity, the number of triggered messages the device transmits to HMSC is limited to 5 IEGMs between follow-up visits for each individual trigger.

BioMonitor 2 / BioMonitor: The following messages are transmitted to the Home Monitoring Service Center with the daily Trend Message:

- Patient Triggered Event Recordings
- ERI detected
- Backup mode active
- Available device memory alert
- Episode details received
- Subcutaneous ECG received
- Episode details received

Lumax, Iforia, Ilesto, Itrevia, Inventra, Iperia, Intica and Ilivia ICDs: The following occurrences initiate an immediate Event Message transmission. If the patient is not near a CardioMessenger when an event occurs, attempts are made to send the Event Message on these schedules:
• **Lumax, Iforia, Ilesto:** Continuous attempts are made to send the Event Message at 72-minute intervals until communication is successful or is sent at the next regular Trend Message transmission time.

• **Itrevia, Iperia, Inventra, Intica and Ilivia ICDs:** These ICDs will try to send a recording for Event Messages once every 60 minutes for 3 attempts, or until the next IEGM is written to the device, then at the scheduled Home Monitoring transmission time.

Induced episodes and VT, SVT, or AT/AF monitoring zone episodes are no longer sent immediately upon event detection and are instead sent with the next Trend Message.

• Termination of VT/VF Episode
• Ongoing Atrial Monitoring Episode lasting longer than the programmed time (6, 12 or 18 hours)
• Ineffective ventricular maximum energy shocks

The following Event Messages are also supported and are only evaluated at the daily Trend Message transmission time:

• Atrial Therapy Episodes (Ilivia, Intica, Iperia, Itrevia, and Inventra only)
• Capture control failure
• Atrial and Ventricular ATM/VCC change to disable since the last successfully transmitted message
• Special Device Status
• Backup mode
• Shock impedance <20 ohm
• EOS
• ERI
• ICD therapy disabled
• Emergency brady active

### 4.6 Transmitted IEGMs and Hierarchy

Triggers can be programmed in an implant to create a recording for cardiac rates or rhythms (e.g., Ventricular Tachycardia, Atrial Tachycardia, Mode Switch). These recordings are not only stored on the implant, but may be transmitted to the Home Monitoring Service Center.

**Evia and Entovis Pacemakers:**

Periodic IEGMs are the only recordings transmitted to the Home Monitoring Service Center (HMSC) and are sent at the scheduled transmission time.

**Edora, Eluna and Etrinsa Pacemakers:**

These pacemakers only transmit one recording at the scheduled nightly transmission time using the following hierarchy:

1. Periodic IEGM
2. Bipolar lead failure recording
3. Unipolar lead failure recording
4. The last recorded High Atrial Rate (HAR), Mode Switch or High Ventricular Rate (HVR) episode recording prior to the scheduled Home Monitoring (HM) transmission time.
Illesto and Lumax ICDs:

- If a patient is not in range of his or her CardioMessenger (CM) before the scheduled HM transmission time, the last triggered IEGM prior to transmission is sent, regardless of type.
- Scheduled Periodic IEGMs take precedence and are transmitted rather than other recording types for that day.
- Multiple VT/VF or Ongoing atrial events can be sent to HMSC provided the patient is in range of the CM. These implants will try to send a recording for these events once every 72 minutes until the scheduled Home Monitoring transmission time.

Ilivia, Intica, Inventra, Iperia and Itrevia ICDs:

- If the patient is not in range of his or her CM before the scheduled HM transmission time, the following hierarchy is used during the patient’s nightly transmission:
  1. VT/VF episodes IEGMs
  2. Periodic IEGM
  3. High Atrial Rate IEGM
- Multiple VT/VF or Ongoing atrial events can be sent to HMSC provided the patient is in range of the CM that is connected to the HMSC. These implants will try to send a recording for these events once every 72 minutes until the scheduled Home Monitoring transmission time.

BioMonitor:

- BioMonitor models can generate recordings for Atrial Fibrillation, High Ventricular Rate, Bradycardia, Asystole, Periodic sECGs, and patient-activated triggers.
- BioMonitor can send the last triggered sECG prior to the HM transmission time, regardless of recording type. Scheduled Periodic sECGs take precedence over all other recordings.

BioMonitor2:

- BioMonitor 2 devices can send up to six sECG recordings each transmission time, with at least one of each of these triggered events: Atrial Fibrillation, High Ventricular Rate, Bradycardia, Asystole, Sudden Rate Drop, Patient Activated Events, and Periodic IEGMs.
- A scheduled Periodic IEGM will transmit the next day if six recordings transmit for that day.

The hierarchy of transmission for the six sECG recordings is as follows:

1. Most recent Patient triggered
2. Most recent Asystole
3. Most recent High Ventricular Rate (HVR)
4. Most recent Bradycardia
5. Most recent Sudden Rate Drop
6. Most recent Atrial Fibrillation (AF)
7. Next most recent Patient triggered
8. Next most recent Asystole
9. Next most recent High Ventricular Rate (HVR)
10. Next most recent Bradycardia
11. Next most recent Sudden Rate Drop
12. Next most recent Atrial Fibrillation (AF)
13. Next most recent Patient triggered
14. Next most recent Asystole
15. Pattern repeats
4.7 Sending a Test Message to a CardioMessenger Using the Programmer

The following describes the steps to successfully send a programmer-initiated test message to a CardioMessenger in office. Test messages are used to ensure the patient’s implant is paired and can successfully communicate with his or her CardioMessenger. Test messages should only be sent to the patient’s own CardioMessenger. Sending a test message to another CardioMessenger may result in difficulty in future communication with the patient’s monitor when returning home.

Once the programmer has successfully powered ON, verify that the date and time are correct. For more information on how to change the date and time on the programmer, please refer to the Programmer User Guide.

- Interrogate the implanted device. Ensure Home Monitoring is programmed ON. Adjust the other parameter options for Home Monitoring transmissions at this time.
- Assure that the CardioMessenger is powered ON.
- Place the CardioMessenger no further away than six feet from the patient.
- The programmer will prompt to change the RF telemetry to PGH (programming head) when necessary if RF telemetry is enabled. To disable RF telemetry on the programmer and interrogate with wand head only to enable the ‘send test message’ feature, select the More tab, the the device tab (ie- the Ilivia tab for an Ilivia device). Select PGH for Telemetry. (RF Telemetry will automatically re-enable once the session with this device has ended.)
- Select the Status button on the programmer for Lumax 3 and 5 series implants (Figure 4-3). For later generation ICDs, pacemakers and BioMonitor models, select the Home Monitoring/ Diagnostics tab under Parameters (Figure 4-4).
- Next, select the Send Test Message button.
- For pacemakers the user will be prompted to remove the programming head from the implant for at least 30 seconds to allow the implant to send the Test Message. After at least 30 seconds have elapsed, place the programmer head back over the implant and tap the Interrogate button at the bottom of the screen. Alternatively, you may end the session and reintrrogate the device.
- For pacemakers the user will be prompted to remove the programming head from the implant for at least 30 seconds to allow the implant to send the Test Message. After at least 30 seconds have elapsed, place the programmer head back over the implant and tap the Interrogate button at the bottom of the screen. Alternatively, you may end the session and reintrrogate the device.
- If a transmission between an implant and CardioMessenger is successful, the Last Message / Message Created On field will update with the current date and time.
- If the Last Message field does not update, please contact the Customer Solutions Department at 1-800-547-0394 for additional assistance.
Figure 4-3 - The “Send test message” button is found on the Status screen for Lumax 3 and 5 series devices.

Figure 4-4 – The “Send test message” button is found on the Home Monitoring tab from the Parameters screen in all current pacemakers, ICDs, and BioMonitor models.

4.8 Resetting Home Monitoring Due to Non-transmission

If a BIOTRONIK pacemaker or Lumax 3 or 5 series ICD does not transmit for 60 days to Home Monitoring, the implant will go into Event Only transmission mode. This energy-conserving mode only transmits event reports. Daily trend messages are suspended. These devices require a Home Monitoring Reset to be performed on the implant via a programmer to restore normal transmission mode.
If these devices do not transmit for 90 days to Home Monitoring, the device status will change to Automatically Deactivated on the Home Monitoring website and the patient will be moved to the Deactivated list. Once Home Monitoring transmission is restored and the implant transmits again to Home Monitoring via their CardioMessenger, this status will return to Activated Monitoring status. The Options menu on the Home Monitoring website allows for alerts to be generated on the website prior to this occurring for non-transmission for a programmable length of time. The default alert is a yellow alert for non-transmission for 21 days to Home Monitoring.

Implants will continue to function as programmed, but communication to Home Monitoring must be restored by resetting Home Monitoring in clinic using a BIOTRONIK programmer.

These are the steps to perform a Home Monitoring reset on a BIOTRONIK implant:

- When the implant is interrogated in-office, Home Monitoring should be programmed OFF, the session with the implant ended, the implant reinterrogated, and Home Monitoring should be programmed ON again. Note that programming changes in pacemakers will clear any recordings or diagnostics, so care should be taken to save or print any of this information prior to making a programming change.
- Test messages should only be sent using the patient’s own CardioMessenger to verify the implant is successfully communicating. Please see section 4.7 for instructions on sending a test message using a BIOTRONIK programmer.

Please follow the same instructions above to restore the patient’s implant to active monitoring. The patient will automatically move back to an active monitoring state on the Home Monitoring Patient list. For assistance, please call the Customer Solutions Department at 1-800-547-0394.
Chapter 5: CardioMessenger Models and Setup

The CardioMessenger is designed to send daily reports to the Home Monitoring Service Center. This chapter describes the requirements for transmission, the available CardioMessenger models and setup, and finally the significance of indicator lights and symbols on the CardioMessenger models.

The following are basic requirements for successful Home Monitoring (HM) transmissions:

- The implant will transmit using the time automatically set in the implant by the programmer. Prior to programming the implant, check the programmer time in the upper right corner of the Start Screen and ensure it is accurate.
- The implant must have HM programmed ON.
- The implant’s serial number must be registered in the Home Monitoring Service Center website.
- The patient must have a CardioMessenger compatible with the implanted device.
- If the patient has a landline “TLine” CardioMessenger, an analog phone line must be used. Digital phone services (e.g., bundled phone/cable/internet, VoIP, etc.) are incompatible. However, a phone “digital filter” can be purchased and may help “TLine” CardioMessengers communicate over a bundled phone/cable/internet line.
- Cellular CardioMessengers rely on the T-Mobile network in the US. The CardioMessenger may work internationally, presuming there is cellular roaming coverage in partnership with Telekom Deutschland.
- The patient must be within six feet of the CardioMessenger during the daily programmed transmission time.
- At no time should patients use multiple CardioMessenger monitors.

### 5.1 CardioMessenger Types and Implant Compatibility

<table>
<thead>
<tr>
<th>CardioMessenger Type</th>
<th>Landline vs. Cellular</th>
<th>Device Compatibility</th>
</tr>
</thead>
<tbody>
<tr>
<td>CardioMessenger Smart Model # 401831</td>
<td>Only cellular capable</td>
<td>Pacemakers Evia to current ICDs Lumax to current</td>
</tr>
<tr>
<td>CardioMessenger II-S Model # 399729</td>
<td>Only cellular capable</td>
<td>Pacemakers Evia to current ICDs Lumax to current</td>
</tr>
<tr>
<td>CardioMessenger Type</td>
<td>Landline vs. Cellular</td>
<td>Device Compatibility</td>
</tr>
<tr>
<td>-------------------------------------------</td>
<td>-----------------------</td>
<td>----------------------------------------------------------</td>
</tr>
<tr>
<td>CardioMessenger II-S TLine Model # 399730</td>
<td>Only Landline Capable</td>
<td>Pacemakers Evia to current ICDs Lumax to current Estella pacemakers only work with this model</td>
</tr>
<tr>
<td>CardioMessenger II LLT Model # 399726</td>
<td>Landline &amp; Cellular Capable</td>
<td>Pacemakers Evia to current ICDs Lumax to current</td>
</tr>
<tr>
<td>CardioMessenger TLine Model # 358225</td>
<td>Only Landline Capable</td>
<td>Pacemakers prior to Evia and ICDs prior to Lumax</td>
</tr>
<tr>
<td>CardioMessenger LLT Model # 350939</td>
<td>Landline &amp; Cellular Capable</td>
<td>Pacemakers prior to Evia and ICDs prior to Lumax</td>
</tr>
<tr>
<td>CardioMessenger S TLine Model # 370329</td>
<td>Only Landline Capable</td>
<td>Pacemakers prior to Evia and ICDs prior to Lumax</td>
</tr>
<tr>
<td>CardioMessenger S Model # 370328</td>
<td>Only Cellular Capable</td>
<td>Pacemakers prior to Evia and ICDs prior to Lumax</td>
</tr>
</tbody>
</table>

Table 5-1
5.2 CardioMessenger Setup

5.2.1 Only Landline Capable Devices
CardioMessenger systems designated as “TLine” in the model name are only capable of landline communication. Follow the instructions below to set up the system:

- Place the CardioMessenger within six feet of where the patient will be at transmission time.
- Plug the power cord into the charging station on the side of the unit and an electrical outlet.
- Plug the phone cord into the #1 jack on the back of the CardioMessenger and the other end into an active telephone wall jack.
- A telephone can be plugged into the #2 jack if needed.

5.2.2 Landline and Cellular Capable Devices
CardioMessenger LLT and II LLT are capable of cellular and landline communication. If cellular coverage is poor or unavailable, set up the system for landline communication:

- Place the CardioMessenger in the charging base.
- Place the CardioMessenger and base within six feet of where the patient will be at transmission time.
- Plug the power cord into the charging station and an electrical outlet.
- Plug the phone cord into the #1 jack on the charging station and into an active telephone wall jack.
- A telephone can be plugged into the #2 jack, if needed.

5.2.3 Only Cellular Capable Devices
CardioMessenger S, II-S, and Smart models are capable of cellular only transmission. Follow the instructions below to set up the system:

- Place the CardioMessenger within six feet of where the patient will be at transmission time.
- Plug the power cord into the left side of the unit and an electrical outlet. For CardioMessenger Smart, plug the power cord into the micro USB plug on the right of the unit.

5.2.4 Indicator Lights and Symbols during Normal Operation
Based on CardioMessenger model, certain lights or indicators will illuminate when the system is correctly set up:

For CardioMessenger TLine, LLT, or II LLT normal light indicators will include:

- Call Request/ Telephone – OFF
- Information/ Book – OFF
- OK – Flashing green or temporarily yellow
- Battery – Solid yellow or solid green
- Charging Station – Solid green

For CardioMessenger S TLine, S, II-S TLine, or II-S normal light indicators will include:

- Call Request/ Telephone – OFF
- OK – Solid green

For CardioMessenger SMART, these symbols will appear during normal operation:

- Connected to Power and Charging or Battery Charge Level Icon
- OK Icon
5.2.5 Indicator Light and Symbol Troubleshooting

- If all indicator lights and symbols are off, ensure that the CardioMessenger Smart is receiving power. For CardioMessenger Smart, ensure the unit is turned on by pressing the power button on the side of the unit.
- If the OK light is yellow or the icon is on for CardioMessenger Smart, this indicates difficulty in communication with the Home Monitoring service. If the light is yellow for longer than 24 hours, contact the Customer Solutions department at 1-800-547-0394.
- If the “telephone” light illuminates or the telephone symbol appears for CardioMessenger Smart, this indicates the patient should call his or her physician because the clinician selected the “Request call back” button next to a patient’s transmitter serial number from the Transmitters list under the Administration menu on the Home Monitoring website.
Chapter 6: Quick Reference Guides

This chapter includes quick reference guides for commonly asked information about Home Monitoring features and devices. The last section of this chapter includes an alphabetical list of alert abbreviations and their clinical significance.

6.1 BIOTRONIK Devices and Release Dates

Home Monitoring features are often stated as being in a particular implant “and newer” implants. Below is a list of BIOTRONIK pacemakers and ICDs with release dates. Note that unless differentiated with “(HF-T),” a device name indicates that SR-T, DR-T, and HF-T versions of that model were released that year.

<table>
<thead>
<tr>
<th>Pacemakers</th>
<th>Release Year</th>
<th>ICDs</th>
<th>Release Year</th>
</tr>
</thead>
<tbody>
<tr>
<td>Edora</td>
<td>2017</td>
<td>Ividia / Intica</td>
<td>2017</td>
</tr>
<tr>
<td>Eluna / Etrinsa</td>
<td>2015</td>
<td>Iperia (HF-T)</td>
<td>2016</td>
</tr>
<tr>
<td>Entovis</td>
<td>2014</td>
<td>Iperia / Iforia / Inventra / Itrevia</td>
<td>2015</td>
</tr>
<tr>
<td>Estella</td>
<td>2011</td>
<td>Illesto / Iforia (HF-T)</td>
<td>2014</td>
</tr>
<tr>
<td>Evia (HF-T)</td>
<td>2012</td>
<td>Lumax 7 series</td>
<td>2012</td>
</tr>
<tr>
<td>Evia</td>
<td>2010</td>
<td>Lumax 5 series</td>
<td>2008</td>
</tr>
<tr>
<td>Cyllos</td>
<td>2005</td>
<td>Lumax 3 series</td>
<td>2006</td>
</tr>
<tr>
<td>Philos II</td>
<td>2004</td>
<td>Lumos</td>
<td>2005</td>
</tr>
</tbody>
</table>

6.2 Transmitted IEGMs and Hierarchy

This table describes an implanted device’s ability to transmit recordings to the Home Monitoring Service Center (HMSC). Recordings that are not transmitted can be read from the implant at follow-up.

Edora, Eluna and Etrinsa Pacemakers

- These pacemakers only transmit one recording at the scheduled nightly transmission time using the following hierarchy:
  1. Periodic IEGM
  2. Bipolar Lead failure recording
  3. Unipolar Lead failure recording
  4. The last recorded High Atrial Rate or Mode Switch, or High Ventricular Rate episode recording prior to the scheduled Home Monitoring (HM) transmission time
Evia and Entovis Pacemakers

- Periodic IEGMs are the only recordings transmitted to the HMSC and are sent at the scheduled transmission time.

Intica and Ilivia ICDs

- If the patient is not in range of their CM before the scheduled HM transmission time, up to 4 IEGMs can be transmitted with the nightly trend message. In this case, the most recent unset episode in every category will be sent using the following hierarchy (at most 2 IEGMs in each category will be sent to Home Monitoring):
  1. VT/VF with therapy episodes IEGMs
  2. AT/AF with therapy IEGMs
  3. Periodic IEGM, technical trigger
  4. AT/AF/VT/SVT without therapy
  5. nsVT
- Multiple VT/VF or Ongoing atrial events can be sent to HMSC provided the patient is in range of their CM which is connected to the HMSC. These implants will try to send a recording for these events once every 60 minutes for 3 attempts, then is transmitted at the scheduled HM transmission time.
- During the next monitoring interval an unsent ventricular therapy episode will be sent instead of the newest episode, as long as the unsent episode is newer than the last successfully sent episode. If there is an unsent ventricular therapy episode, the Periodic IEGM will be recorded and sent the following day.

Itrevia, Iperia and Inventra ICDs

- If the patient is not in range of their CM before the scheduled HM transmission time, the following hierarchy is used:
  1. VT/VF episodes IEGMs
  2. Periodic IEGMs
  3. High Atrial Rate IEGM
- Multiple VT/VF or Ongoing atrial events can be sent to HMSC provided the patient is in range of their CM which is connected to the HMSC. These implants will try to send a recording for these events once every 72 minutes until the scheduled HM transmission time.
- During the next monitoring interval an unsent ventricular therapy episode will be sent instead of the newest episode, as long as the unsent episode is newer than the last successfully sent episode. If there is an unsent ventricular therapy episode, the Periodic IEGM will be recorded and sent the following day.

Ilesto and Lumax ICDs

- If a patient is not in range of their CardioMessenger (CM) before the scheduled HM transmission time, the last triggered IEGM prior to transmission is sent regardless of type. Also, in this case, scheduled Periodic IEGMs take precedence and are transmitted rather than other recording types for that day.
- Multiple VT/VF or Ongoing atrial events can be sent to HMSC provided the patient is in range of their CM which is connected to the HMSC. These implants will try to send a recording for these events once every 72 minutes until the scheduled HM transmission time.

BioMonitor 2 and BioMonitor

- BioMonitor models can generate recordings for atrial fibrillation, high ventricular rate, bradycardia, sudden rate drop, asystole, Periodic sECG recordings, and patient-activated triggers.
- BioMonitor will send one sECG per day to Home Monitoring, in order of priority (highest to lowest): Patient trigger, Asystole, HVR, Bradycardia, Atrial fibrillation, Periodic trigger. If the patient does not transmit for this monitoring interval, the sECG scheduled to transmit will not resend on the following day.
BioMonitor 2 devices can send up to six sECGs each transmission time, with at least one of each of the following categories, in order of priority (highest to lowest): Most recent patient trigger, Asystole, HVR, Bradycardia, Sudden rate drop, Atrial fibrillation (BioMonitor 2 AF only), Next most recent event. The Periodic trigger will send only if no event sECG occurred during the current daily monitoring interval (and will not be repeated the following day). If the patient does not transmit for this monitoring interval, the sECG scheduled to transmit will not resend on the following day.

6.3 Periodic IEGM Transmission and Programming

Periodic IEGMs provide clinicians a 30-second recording only viewable on the Home Monitoring Service Center. These recordings are transmitted with the normal daily trend message and can be scheduled to transmit on a cyclic basis (e.g., 30, 60, 90 days, etc.) or on up to five specific dates. This guide describes the differences in programmability by product family.

Evia and Entovis Pacemakers
- Changes to Periodic IEGM Transmissions must be programmed on the device.
- Periodic IEGMs can be programmed to transmit on a cyclic basis.
- After the 5 dates have been utilized, new dates must be programmed for Periodic IEGM transmission on the implant via the programmer.

Eluna and Etrinsa Pacemakers
- Changes to Periodic IEGM Transmissions must be programmed on the device itself and cannot be programmed through the Home Monitoring Service Center.
- Periodic IEGMs can be programmed to transmit on a cyclic basis OR specific date selections.

Edora Pacemakers
- Changes to Periodic IEGM Transmissions must be programmed on the Home Monitoring Service Center on the “Patient profile” tab and “Remote Scheduling” sub-tab.
- Periodic IEGMs can be programmed to transmit on a cyclic basis OR specific date selections.

Lumax ICDs
- Changes to Periodic IEGM Transmissions must be programmed on the device itself and cannot be programmed through the Home Monitoring Service Center.
- In Lumax 3 and 5 series device can be programmed to transmit on a cyclic basis. Lumax 7 devices can either transmit on a cyclic basis or specific date selections.

Ilesto, Inventra, Iperia, Itrevia, Intica and Ilivia ICDs
- Changes to Periodic IEGM Transmissions must be programmed on the Home Monitoring Service Center on the “Patient profile” tab and “Remote Scheduling” sub-tab.
- A custom number of days cyclic interval may be programmed OR specific date selections.

BioMonitor and BioMonitor 2
- Changes to Periodic sECG Transmissions must be programmed on the device itself and cannot be programmed through the Home Monitoring Service Center.
- Biomonitor can be programmed to transmit on a cyclic basis.
- Biomonitor 2 can either transmit on a cyclic basis or specific date selections.
### 6.4 Patient Status Finding Descriptions

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Finding</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1stMsg</td>
<td>First message received</td>
<td>The patient has successfully set up their CM system and successfully transmitted their first message. This message is now available for review by the clinician.</td>
</tr>
<tr>
<td>ABurd</td>
<td>Atrial burden – above limit</td>
<td>The percentage of time that the patient met the criteria for atrial tachycardia was greater than 25% of the day or longer than 6 hours.</td>
</tr>
<tr>
<td>A-Epis</td>
<td>Atrial therapy episode</td>
<td>A new atrial therapy episode is detected</td>
</tr>
<tr>
<td></td>
<td>Long atrial episode/ mode switching episode detected (ongoing at end of mon. interv.)</td>
<td>An ongoing atrial episode is detected at the time of transmission whose duration is above the duration that has been programmed in the device</td>
</tr>
<tr>
<td>A-Mon</td>
<td>Atrial Monitoring episode</td>
<td>A new atrial monitoring episode is detected</td>
</tr>
<tr>
<td>Asys</td>
<td>Number of asystole episodes per day – above limit</td>
<td>The number of asystole episodes per day is above the set limit</td>
</tr>
<tr>
<td>AT</td>
<td>Number of atrial arrhythmia episodes per day - above limit</td>
<td>The number of atrial tachyarrhythmia episodes per day is above the set limit</td>
</tr>
<tr>
<td>AtrOff</td>
<td>Atrial tachytherapy disabled</td>
<td>Atrial therapy has been switched off by the device.</td>
</tr>
<tr>
<td>Backup</td>
<td>Backup mode active</td>
<td>Electromagnetic interference has caused the device to revert into a safe mode with pre-programmed parameters.</td>
</tr>
<tr>
<td>Brady</td>
<td>Number of bradycardia episodes per day</td>
<td>The number of bradycardia episodes per day is above the set limit.</td>
</tr>
<tr>
<td>DetOff</td>
<td>Ven. Detection Off</td>
<td>VT/VF Therapy disabled</td>
</tr>
<tr>
<td>EBrady</td>
<td>Emergency Brady Active</td>
<td>Emergency brady pacing mode is active</td>
</tr>
<tr>
<td>EOS</td>
<td>EOS</td>
<td>Device is EOS</td>
</tr>
</tbody>
</table>

### Details for arrhythmia episode received

- **Epis**
  - Invoked if details for an arrhythmia episode have been received.
  - Details for non-arrhythmia episode received
  - Invoked if details for a non-arrhythmia episode have been received.
  - Episode details received
  - A finding is invoked if episode details have been received.

### Episode/ Recording details received

- **Epis/Rec**
  - Invoked if an IEGM was received.

### Device is ERI

- **ERI**
  - Device is ERI
<table>
<thead>
<tr>
<th>Finding Code</th>
<th>Description</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>HighVp</td>
<td>Ventricular pacing (RVp) – above limit</td>
<td>Right ventricular pacing percentage is above the set limit</td>
</tr>
<tr>
<td>HM-FU</td>
<td>HM follow-up transmission has arrived</td>
<td>HM follow-up transmission has reached the home monitoring service center</td>
</tr>
<tr>
<td></td>
<td>Patient not viewed for time period – above limit</td>
<td>The patient data has not been viewed for the set number of months</td>
</tr>
<tr>
<td>HR</td>
<td>Number of high rate episodes per day – above limit</td>
<td>The number of high rate episodes per day is above the set limit.</td>
</tr>
<tr>
<td>HR-AB</td>
<td>Mean ventricular rate during atrial burden above set value</td>
<td>The ventricular rate is above the set limit</td>
</tr>
<tr>
<td>HR-MSw</td>
<td>Mean ventricular rate during mode switching – out of range</td>
<td>The ventricular rate during a mode switch is above a set limit for a set amount of time</td>
</tr>
<tr>
<td>HVR</td>
<td>Dur. of longest ven. epis. above limit</td>
<td>A finding is invoked if the duration of the longest ventricular episode is above the set limit.</td>
</tr>
<tr>
<td></td>
<td>High ven. rate episode</td>
<td>A finding is invoked if the number of high ventricular rate episodes (HVR) per day is above the set limit.</td>
</tr>
<tr>
<td></td>
<td>HVR duration longer than limit</td>
<td>A finding is invoked if the duration of the longest HVR episode is above the set limit.</td>
</tr>
<tr>
<td>InMaxJ</td>
<td>Ineffective ven. max. energy shock(s)</td>
<td>The maximum energy shock has been ineffective</td>
</tr>
<tr>
<td>Lead</td>
<td>Lead check</td>
<td>The automatic lead check of the pacing lead fails</td>
</tr>
<tr>
<td></td>
<td>Pacing impedance – out of range</td>
<td>The measured impedance is outside the set range</td>
</tr>
<tr>
<td></td>
<td>Sensing amplitude (daily mean) – below limit</td>
<td>The mean sensing amplitude is below the set limit</td>
</tr>
<tr>
<td>LeadLV</td>
<td>BiV impedance &lt; 300 ohm or &gt; 3000 ohm</td>
<td>A finding is invoked if the measured impedance is below 300 or above 3000 ohm.</td>
</tr>
<tr>
<td></td>
<td>LV ATM or capture control disabled</td>
<td>A finding is invoked if capture control has been disabled automatically.</td>
</tr>
<tr>
<td></td>
<td>LV impedance &lt; 200 ohm or &gt; 3000 ohm</td>
<td>A finding is invoked if the measured impedance is below 200 or above 3000 ohm.</td>
</tr>
<tr>
<td></td>
<td>LV impedance out of range</td>
<td>A finding is invoked if the measured impedance is outside the set range.</td>
</tr>
<tr>
<td></td>
<td>LV lead failure detected</td>
<td>A finding is invoked if the automatic lead check in the ventricle fails.</td>
</tr>
<tr>
<td></td>
<td>LV pacing threshold above limit</td>
<td>A finding is invoked if the left ventricular pacing threshold is above the set limit.</td>
</tr>
<tr>
<td></td>
<td>LV sensing amplitude below limit</td>
<td>A finding is invoked if the sensing amplitude is below the set limit.</td>
</tr>
<tr>
<td></td>
<td>LV thresh. safety margin below limit</td>
<td>A finding is invoked if the difference between the pacing threshold and the programmed pacing output is less than the set limit.</td>
</tr>
</tbody>
</table>
### Patient Status Finding Descriptions

<table>
<thead>
<tr>
<th>LeadRA</th>
<th>Finding Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>P-wave amplitude &lt; 50% safety margin</td>
<td>A finding is invoked if the measured value of the P-wave amplitude is below 50% of the safety margin.</td>
</tr>
<tr>
<td>RA ATM or capture control disabled</td>
<td>A finding is invoked if the atrial capture control became disabled automatically.</td>
</tr>
<tr>
<td>RA impedance &lt; 200 ohm or &gt; 3000 ohm</td>
<td>A finding is invoked if the measured impedance is below 200 or above 3000 ohm.</td>
</tr>
<tr>
<td>RA impedance &lt; 300 ohm or &gt; 3000 ohm</td>
<td>A finding is invoked if the measured impedance is below 300 or above 3000 ohm.</td>
</tr>
<tr>
<td>RA impedance out of range</td>
<td>A finding is invoked if the measured impedance is outside the set range.</td>
</tr>
<tr>
<td>RA lead failure detected</td>
<td>A finding is invoked if the automatic lead check in the atrium fails.</td>
</tr>
<tr>
<td>RA sensing amplitude below limit</td>
<td>A finding is invoked if the mean sensing amplitude is below the set limit.</td>
</tr>
<tr>
<td>RA threshold above limit</td>
<td>A finding is invoked if the difference between the pacing threshold and the programmed pacing output is above the set limit.</td>
</tr>
<tr>
<td>RA threshold measurement failed</td>
<td>A finding is invoked if the threshold measurement for the capture control feature failed for the set number of times.</td>
</tr>
<tr>
<td>LeadRV</td>
<td></td>
</tr>
<tr>
<td>RV ATM/ACC disabled</td>
<td>A finding is invoked if the ATM [Active Threshold Monitoring] or the ACC [Active Capture Control] has been disabled by the device.</td>
</tr>
<tr>
<td>RV capture control disabled</td>
<td>A finding is invoked if capture control has been disabled automatically.</td>
</tr>
<tr>
<td>RV impedance &lt; 200 ohm or &gt; 3000 ohm</td>
<td>A finding is invoked if the measured impedance is below 200 or above 3000 ohm.</td>
</tr>
<tr>
<td>RV impedance &lt; 300 ohm or &gt; 3000 ohm</td>
<td>A finding is invoked if the measured impedance is below 300 or above 3000 ohm.</td>
</tr>
<tr>
<td>RV impedance out of range</td>
<td>A finding is invoked if the measured impedance is outside the set range.</td>
</tr>
<tr>
<td>RV lead failure detected</td>
<td>A finding is invoked if the automatic lead check in the ventricle fails.</td>
</tr>
<tr>
<td>RV pacing threshold above limit</td>
<td>A finding is invoked if the right ventricular pacing threshold is above the set limit.</td>
</tr>
<tr>
<td>RV sensing amplitude below limit</td>
<td>A finding is invoked if the minimum sensing amplitude is below the set limit.</td>
</tr>
<tr>
<td>RV thresh. safety margin below limit</td>
<td>A finding is invoked if the difference between the pacing threshold and the programmed pacing output is less than the set limit.</td>
</tr>
<tr>
<td>RV threshold above limit</td>
<td>A finding is invoked if the difference between the pacing threshold and the programmed pacing output is above the set limit.</td>
</tr>
<tr>
<td>R-wave amplitude &lt; 50% safety margin</td>
<td>A finding is invoked if the measured value of the R-wave amplitude is below 50% of the safety margin.</td>
</tr>
<tr>
<td>LeadV</td>
<td></td>
</tr>
<tr>
<td>Ven. sensing amplitude below limit</td>
<td>A finding is invoked if the mean sensing amplitude is below the set limit.</td>
</tr>
<tr>
<td>LowBiV</td>
<td></td>
</tr>
<tr>
<td>BIV pacing</td>
<td>The BIV pacing percentage recorded is below the set limit.</td>
</tr>
<tr>
<td>LowCRT</td>
<td></td>
</tr>
<tr>
<td>CRT pacing - below limit</td>
<td>The percentage of CRT pacing is below the set limit.</td>
</tr>
<tr>
<td>Memory</td>
<td></td>
</tr>
<tr>
<td>Available episode memory bins</td>
<td>The device’s memory is almost full. The device is able to store the given number of further episodes. To empty the memory, clear the stored recordings.</td>
</tr>
<tr>
<td>MRI</td>
<td></td>
</tr>
<tr>
<td>MRI mode active</td>
<td>Device is in MRI mode</td>
</tr>
<tr>
<td>Patient Status Finding Descriptions</td>
<td></td>
</tr>
<tr>
<td>------------------------------------</td>
<td></td>
</tr>
<tr>
<td><strong>MSw</strong></td>
<td>Number of mode switching per day - above limit</td>
</tr>
<tr>
<td></td>
<td>Duration of mode switching per day – above limit</td>
</tr>
<tr>
<td><strong>NoMsg</strong></td>
<td>No messages received for time period – above limit</td>
</tr>
<tr>
<td><strong>NoView</strong></td>
<td>Patient not viewed for time period – above limit</td>
</tr>
<tr>
<td><strong>P-IEGM</strong></td>
<td>Periodic IEGM</td>
</tr>
<tr>
<td><strong>ProgM</strong></td>
<td>Programmer Triggered Message</td>
</tr>
<tr>
<td><strong>PatMsg</strong></td>
<td>Patient message received</td>
</tr>
<tr>
<td><strong>PtTrig</strong></td>
<td>Number of patient triggered recordings above limit</td>
</tr>
<tr>
<td><strong>PVC</strong></td>
<td>Mean PVC per hour above limit</td>
</tr>
<tr>
<td><strong>S-Imp</strong></td>
<td>Shock impedance out of range</td>
</tr>
<tr>
<td></td>
<td>Daily shock impedance – out of range</td>
</tr>
<tr>
<td></td>
<td>Shock impedance &lt;20 ohms</td>
</tr>
<tr>
<td><strong>Status</strong></td>
<td>Special Device Status</td>
</tr>
<tr>
<td><strong>SVT</strong></td>
<td>SVT detected</td>
</tr>
<tr>
<td><strong>V-Epis</strong></td>
<td>Long ven. monitoring episode</td>
</tr>
<tr>
<td></td>
<td>Long ven. therapy episode</td>
</tr>
<tr>
<td></td>
<td>Long ven. episode</td>
</tr>
<tr>
<td></td>
<td>Number of ven. episodes above limit</td>
</tr>
<tr>
<td></td>
<td>Ven. epis. with 2 or more deliv. shocks</td>
</tr>
<tr>
<td></td>
<td>Ven. epis. with 2 or more started shocks</td>
</tr>
<tr>
<td></td>
<td>Ven. epis. with accel. of atr. rhythm</td>
</tr>
<tr>
<td></td>
<td>Ven. epis. with accel. of ven. rhythm</td>
</tr>
<tr>
<td></td>
<td>Ven. episode with ATP time-out</td>
</tr>
<tr>
<td><strong>VF</strong></td>
<td>Ven. episode with ven. acceleration</td>
</tr>
<tr>
<td>Patient Status Finding Descriptions</td>
<td></td>
</tr>
<tr>
<td>------------------------------------</td>
<td></td>
</tr>
<tr>
<td><strong>V-HR</strong></td>
<td>Mean ven. heart rate above limit</td>
</tr>
<tr>
<td><strong>V-HR</strong></td>
<td>Mean ven. heart rate at rest above limit</td>
</tr>
<tr>
<td><strong>VT1</strong></td>
<td>VT1 detected</td>
</tr>
<tr>
<td><strong>VT1Mon</strong></td>
<td>VT1 monitoring episode(s) detected</td>
</tr>
<tr>
<td><strong>VT2</strong></td>
<td>VT2 detected</td>
</tr>
</tbody>
</table>
6.5 CardioMessenger Types and Compatible Devices

Current pacemakers, ICDs, and BioMonitor models use the CardioMessenger described below. Note that pacemakers released prior to Evia and ICDs prior to Lumax use a different set of CardioMessenger models described in Chapter 4.

<table>
<thead>
<tr>
<th>CardioMessenger Types and Compatible Devices</th>
<th>Landline vs. Cellular</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>CardioMessenger Type</strong></td>
<td></td>
</tr>
</tbody>
</table>
| **CardioMessenger Smart**                    | Cellular Only Model #: 401831  
                                           | Serial Number: 647XXXXX |
| **CardioMessenger II-S**                     | Cellular Only Model #: 399729  
                                           | Serial Number: 483XXXXX |
| **CardioMessenger II-S TLine**               | Landline Only Model #: 399730  
                                           | Serial Number: 480XXXXX  
                                           | Estella pacemakers only work with this CardioMessenger model |
| **CardioMessenger II LLT**                   | Landline and Cellular Model #: 399726  
                                           | Serial Number: 471XXXXX |
### 6.6 CardioMessenger SMART Icons

<table>
<thead>
<tr>
<th></th>
<th>Icon</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td><img src="image" alt="OK" /></td>
<td>Operation icon</td>
</tr>
</tbody>
</table>
| 2 | ![Call Back](image) | Call back icon                       
|   |     | See Call Back Function               |
| 3 | ![Information](image) | Information icon                     
|   |     | Error Resolution                     |
| 4 | ![Battery](image)   | The battery icon is always displayed with 1-3 bars according to the charging status |
| 5 | ![Battery & Plug](image) | When the CardioMessenger is connected to the power supply brick and charging, a battery icon with a small power plug is displayed. |
Chapter 6
BIOTRONIK Home Monitoring® Reference Guide

This page intentionally left blank