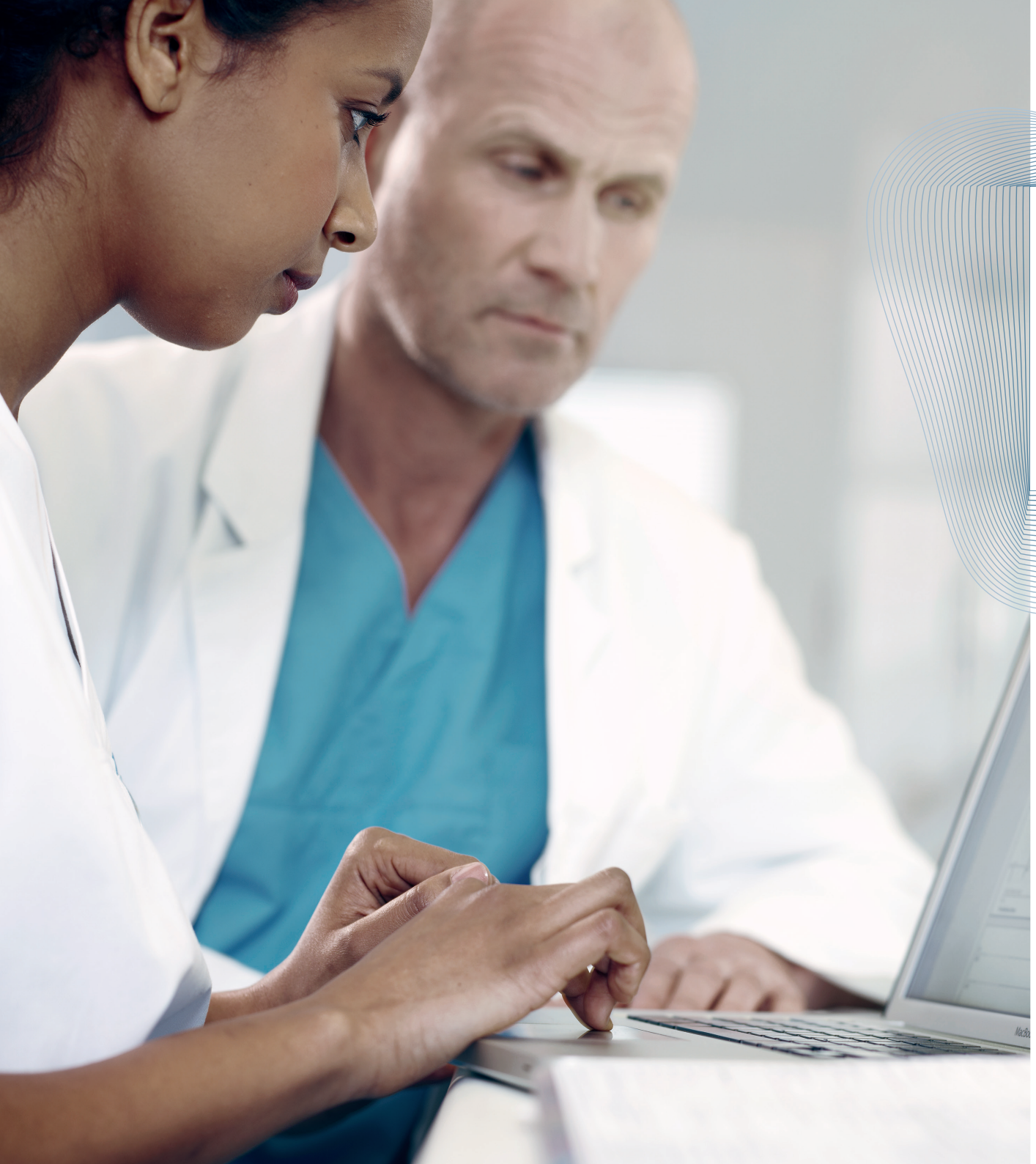
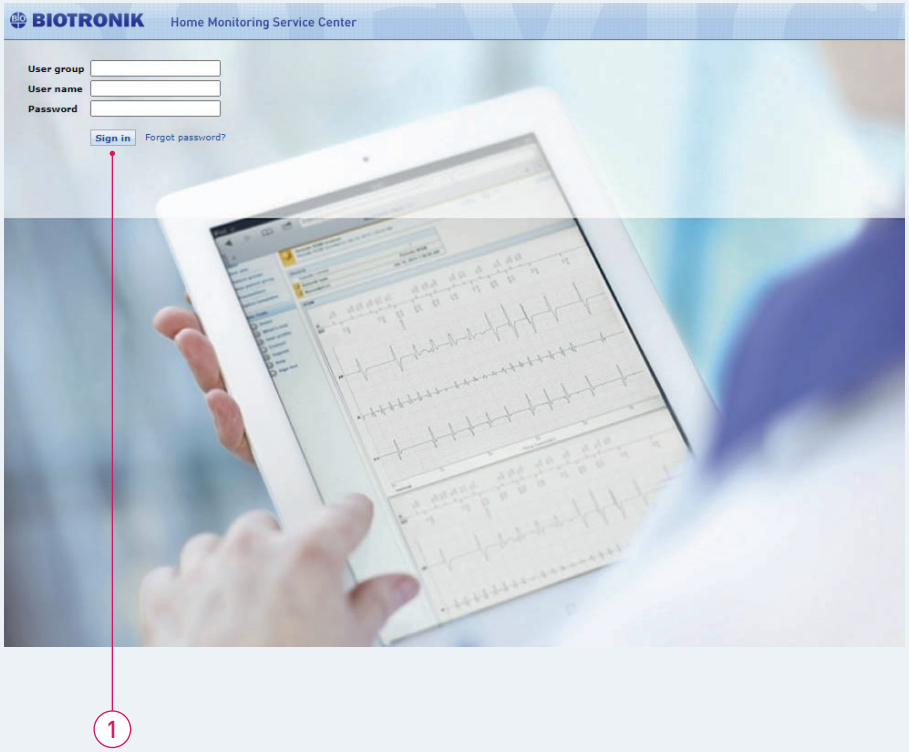
BIOTRONIK
Home Monitoring®
Step-By-Step Guide

BIOTRONIK
excellence for life

Contents



Log in to Site

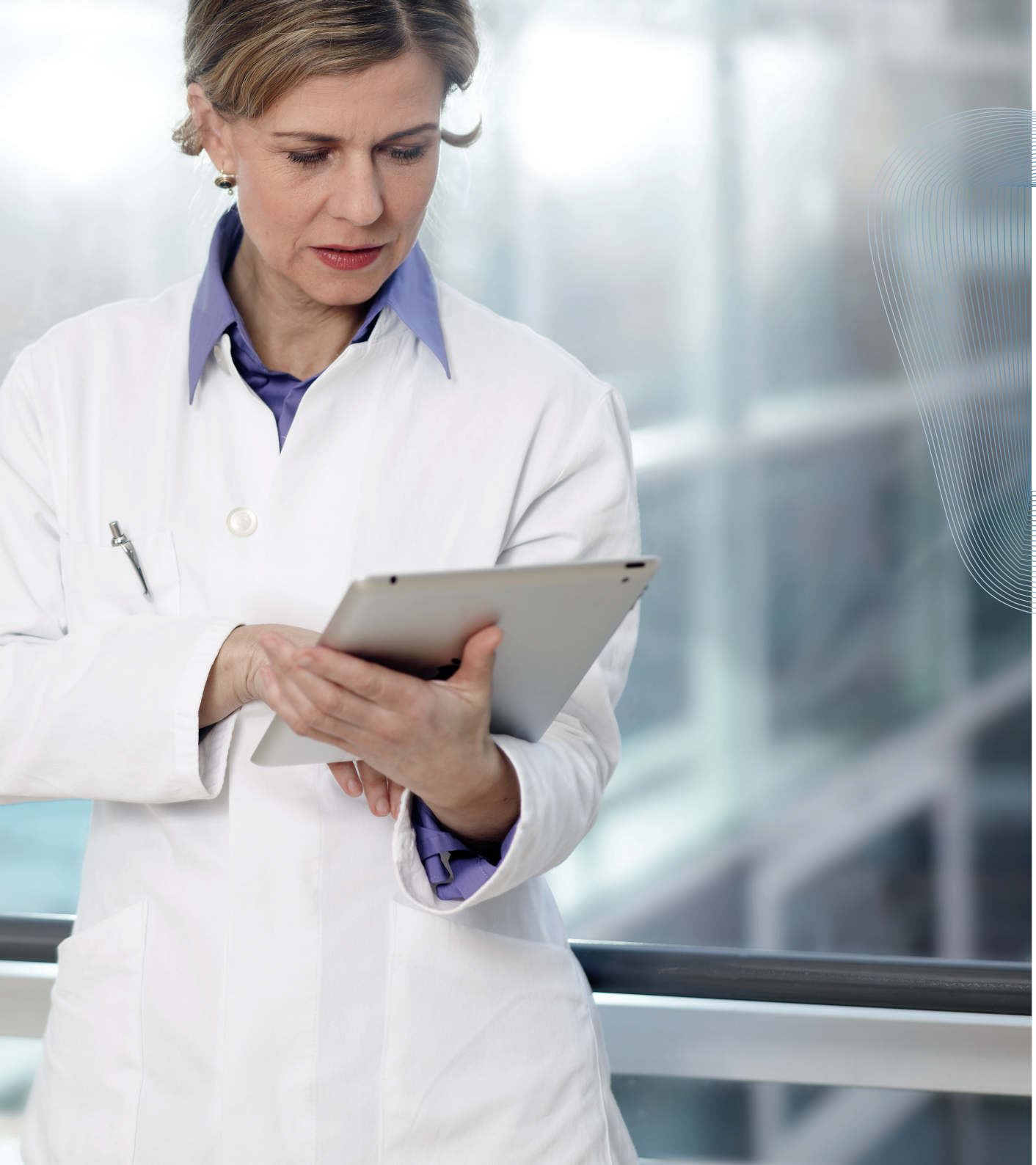


Log in to Site

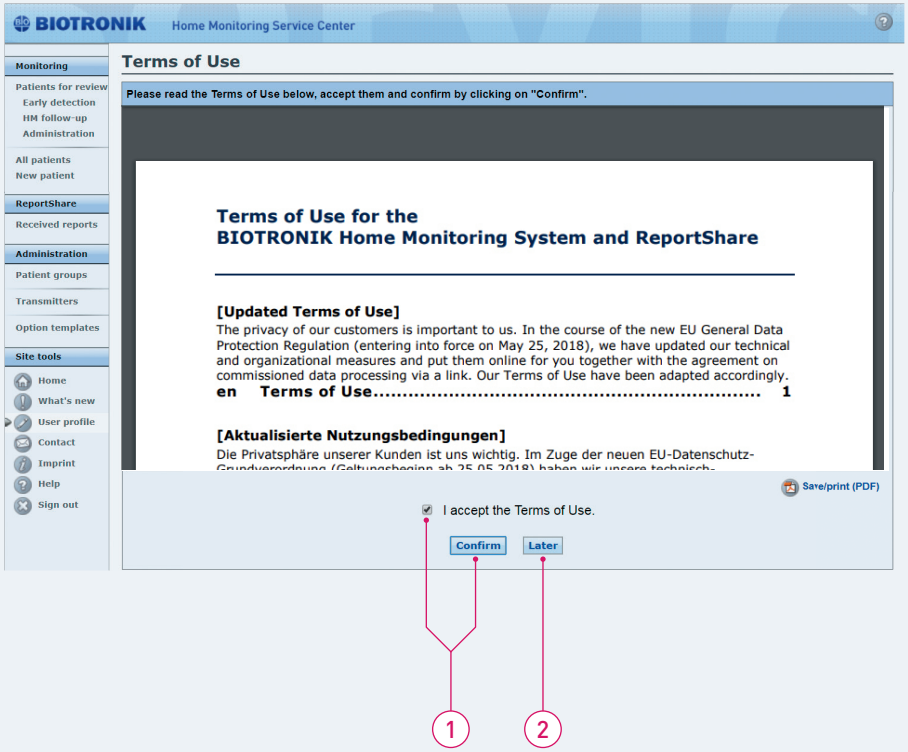
Please enter user group, user name and password.
All three items are case-sensitive.

- The password for new users will be sent by email as noted on the registration form.
- After successfully signing in to the system for the first time, you are prompted to change your password. The change password view opens automatically.

1 Click on “Sign in”.



Agree to Terms of Use



Agree to Terms of Use

After login for the first time, you are requested to agree to the terms of use.
Terms of use are available in five languages.

1 Accept the terms of use and continue.

2 Seven days after choosing „Later“, you will be requested to agree to the terms again.

How to Add a New Patient

Note:
Before adding a new patient verify that the device allows Home Monitoring, i.e. check that the device has the -T option and that Home Monitoring is activated on the device*.

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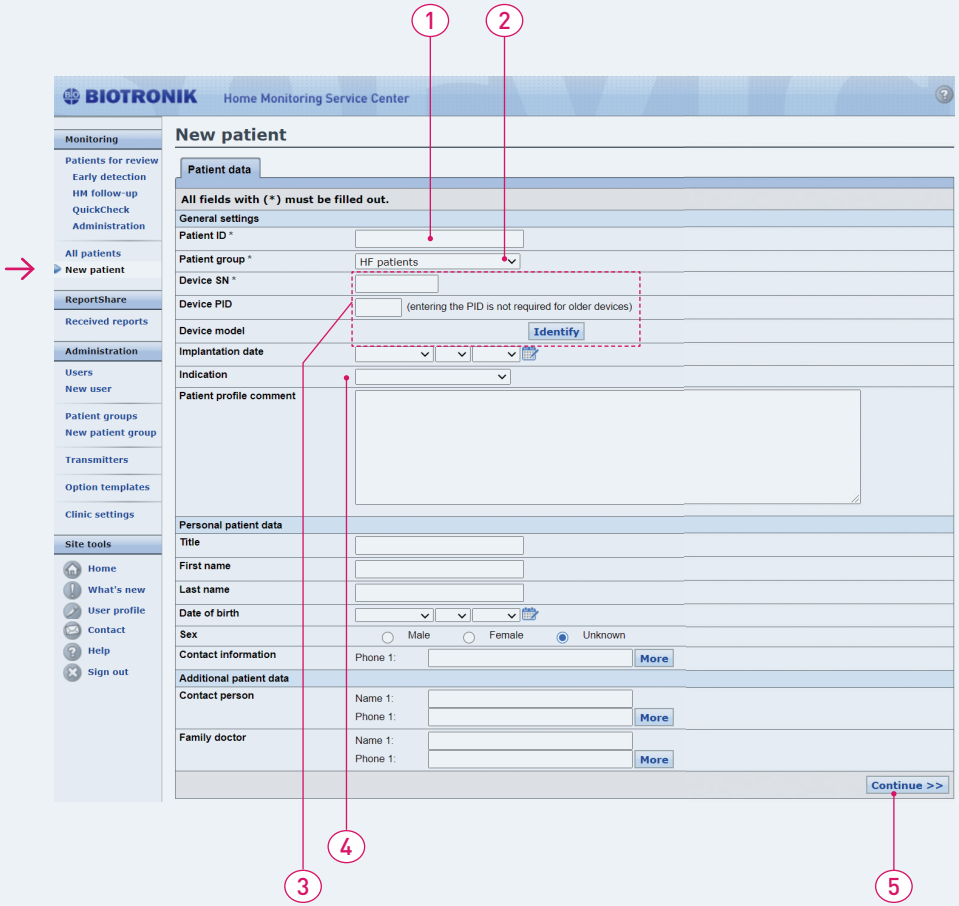
* For further details refer to the leaflet "Retrospectively Adding Patients to the Home Monitoring Service Center (HMSC)".



How to Add a New Patient

Enter basic patient data the first time you register a new patient:

1 Type a patient identifier code or record number.

2 Select the patient group to which the new patient should be assigned.

3 Type in the serial number and PID* of the device and click on "Identify".

4 Choose the indication.

5 Click here to continue.

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* A device PID is required for selected devices and is located on any BIOTRONIK programmer printout as well as on the sticker that comes with the device.

How to Configure Remote Scheduling

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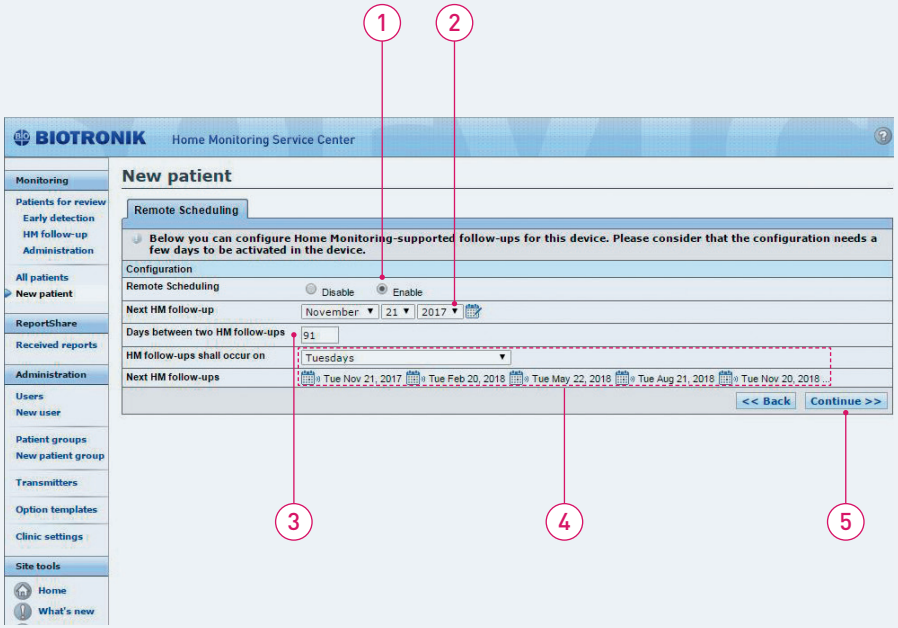
ONLY FOR SELECTED
DEVICES



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ONLY FOR SELECTED
DEVICES

How to Configure Remote Scheduling

With Remote Scheduling, you can set the transmission interval of Home Monitoring follow-ups via the Home Monitoring Service Center:

1 Click on "Enable" or "Disable" Remote Scheduling.

2 Set the date of the next Home Monitoring follow-up.

3 Set the minimum period of time that shall exist between two Home Monitoring follow-ups.

4 Select the day of the week when you would like to receive the Home Monitoring follow-up. The day to be selected depends on your clinic's organization.
→ Your next five scheduled Home Monitoring follow-ups will appear automatically. Note that further Home Monitoring follow-ups are scheduled beyond these dates without any further actions.

5 Click here to continue.

How to Change the Patient's Notification Options

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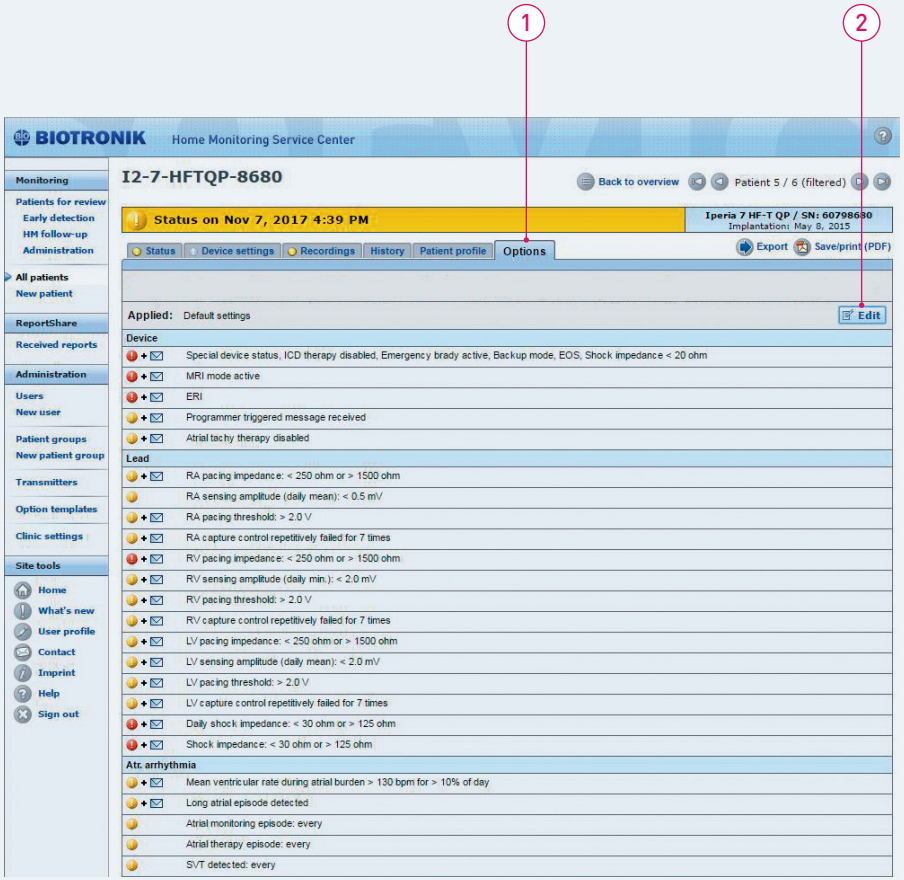

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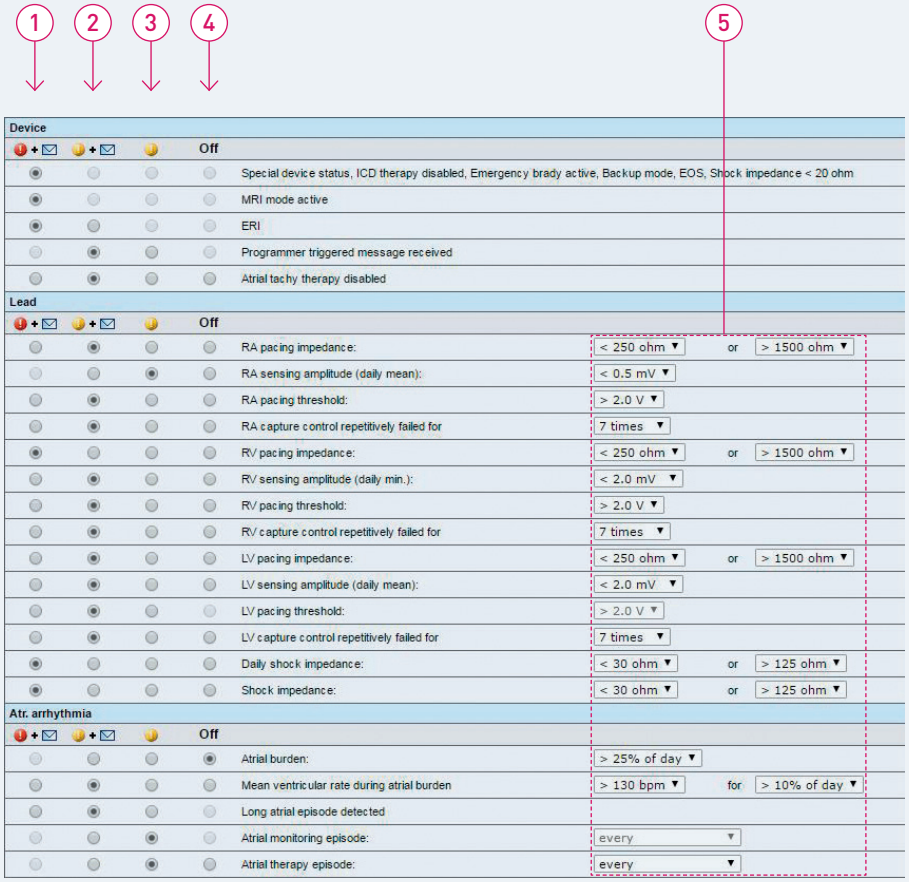
How to Change the Patient's Notification Options

After adding a new patient, the system will redirect you to the notification options. Click on "Edit" to see all options:

1 Options

2 Edit

The content of the "Options" tab depends on the device of the patient.



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How to Change the Patient's Notification Options

On the "Options" tab, select a notification parameter for each finding for each patient:

1  If this option is selected for a finding, the patient status becomes red and a notification is sent to the recipients specified for the patient's patient group.

2  If this option is selected for a finding, the patient status becomes at least yellow (if there is no "red" finding) and a notification is sent to the recipients specified for the patient's patient group.

3 If this option is selected for a finding, the patient status becomes at least yellow (if there is no "red" finding), but no notification is sent.

4  If this option is selected, the finding is switched off.

5 Adjust the parameters if desired.

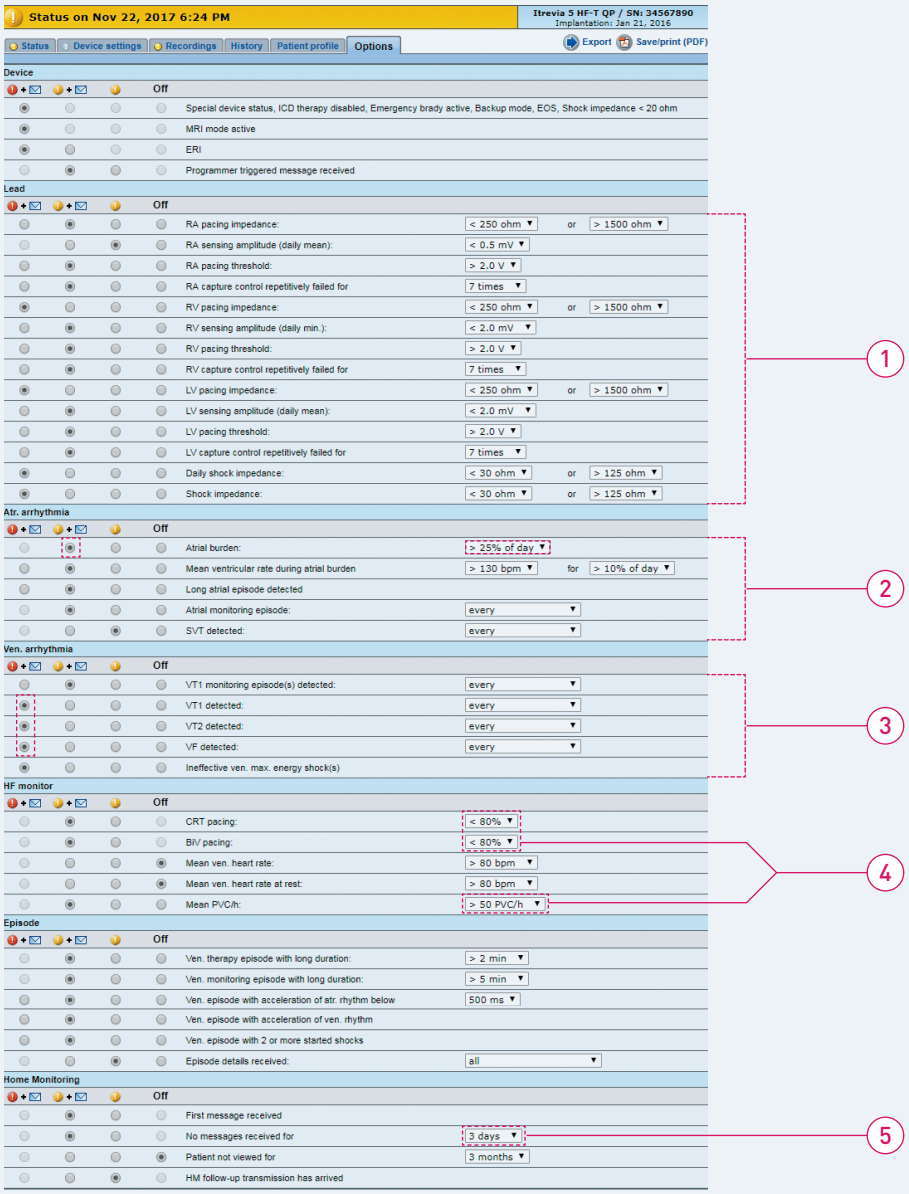
After applying, you can save the settings as a template for the device type.

The content of the "Options" tab depends on the devicet of the patient.

How to Change Notifications According to the IN-TIME Approach

2016 ESC Guidelines for diagnosis and treatment of acute and chronic heart failure:

Recommendations	Class	Level
Multiparameter monitoring based on ICD (IN-TIME approach) may be considered in symtomatic patients with HFrEF (LVEF ≤35%) in order to improve clinical outcomes.	IIb	B



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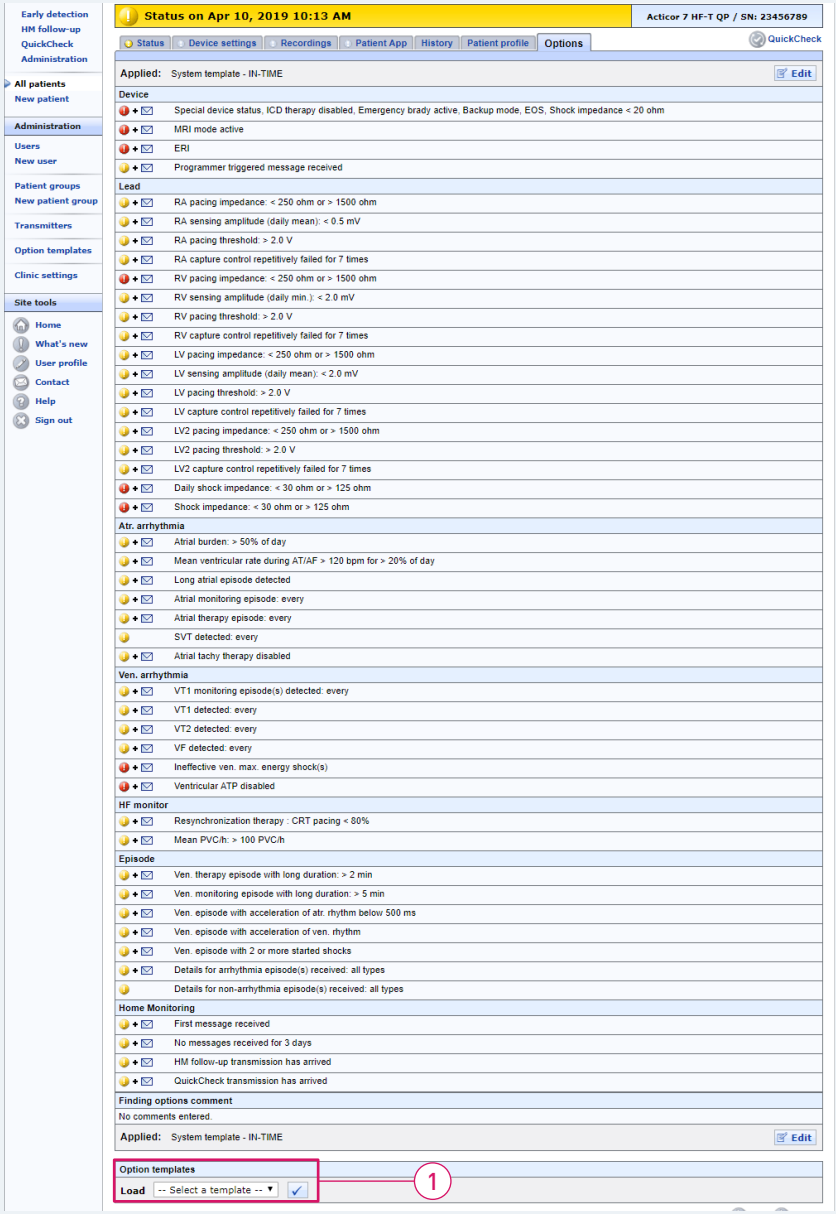
How to Change Notifications According to the IN-TIME Approach

To be conform with the IN-TIME approach as recommended in the 2016 guidelines, make the following changes to the patient's notifications:

1	Device and Lead:	Standard
2	Atrial arrhythmias: Atrial burden:	Select all >25% of day
3	Ventricular arrhythmias:	Select all as red alerts
4	HF monitor:	CRT <80%, Mean PVC/h >100
5	Home Monitoring:	No message received for: 3 days

The content of the "Options" tab depends on the device of the patient.

Hindricks G et al., Implant-based multiparameter telemonitoring of patients with heart failure (IN-TIME): a randomised controlled trial. The Lancet 2014; 384(9943).
Ponikowski P et al., ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure. European Heart Journal 2016; 37, 2129-2200.



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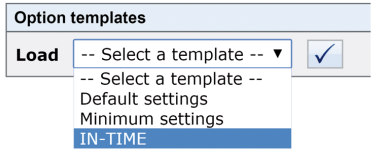
How to Change Notifications According to the IN-TIME Approach

The Acticor and Rivacor families feature the new IN-TIME template. This exclusive Home Monitoring alert template provides one-click access to IN-TIME protocol.

1 Go to the "Option templates" at the end of the page.

2 Choose the IN-TIME template from the drop-down and click the check mark button.



3 The IN-TIME alert setting is now displayed. Confirm the setting at the end of the page. Now, the IN-TIME template is active for this patient.

The content of the "Options" tab depends on the device of the patient.

How to Create a Template

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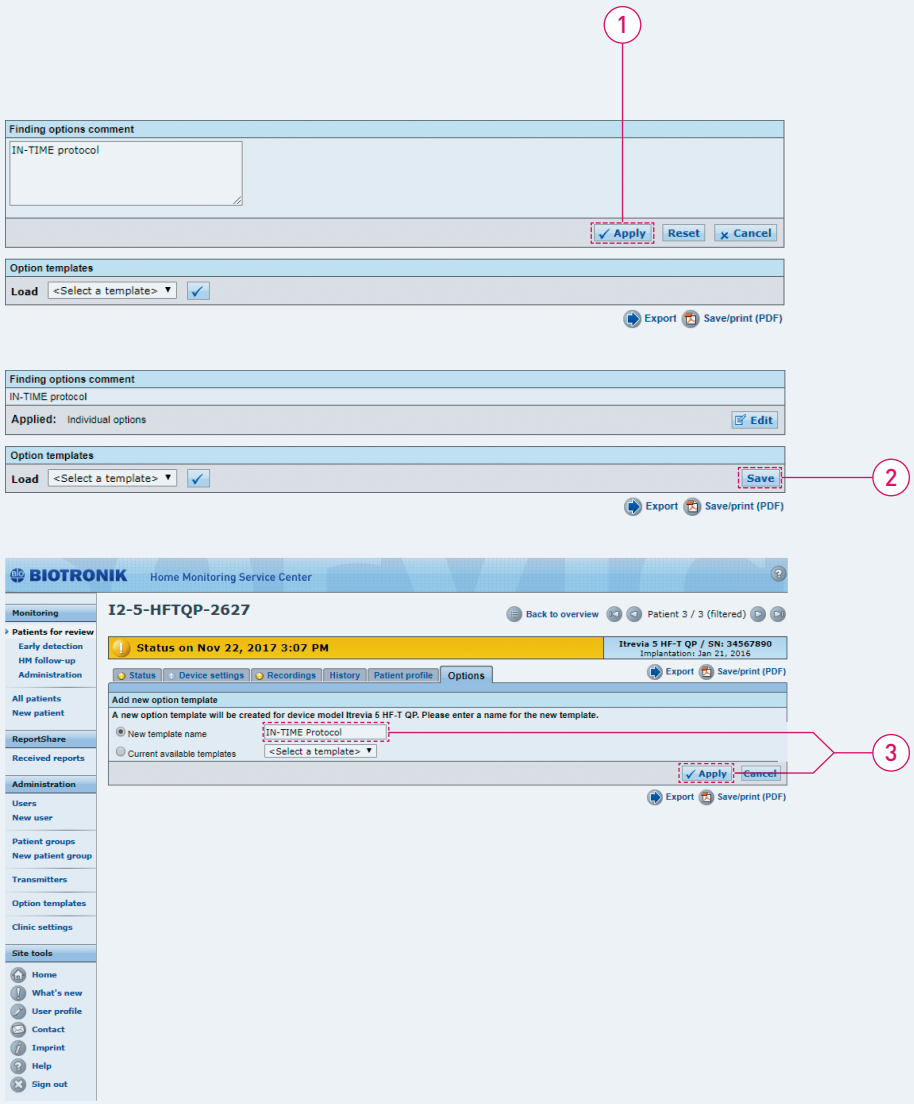
How to Create a Template

Save and rename edited notifications as a template

1 Apply the notifications after editing

2 Save the notifications as a template

3 Rename the template and apply



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How to Add a New User

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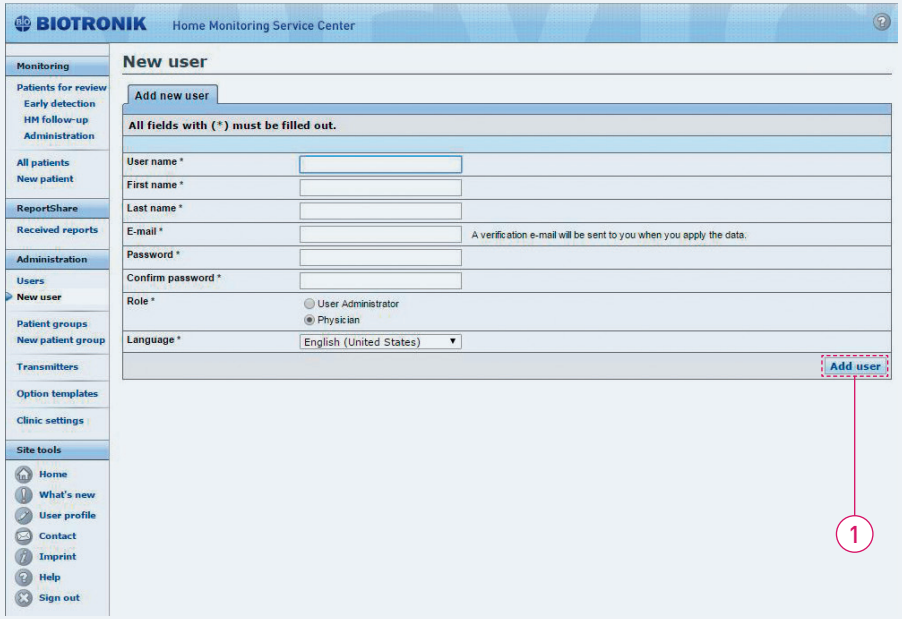

How to Add a New User

If you want to add a new user to your user group, simply fill out the appropriate fields, then indicate whether the user should be a user administrator or physician user.

- A user administrator can add new users and has essentially full access to all patient groups.
- Each group should have two user administrators to ensure that each administrator can substitute for the other.
- A physician user is granted access with or without the ability to change patients' settings by the user administrator.
- A user group should have a maximum of two administrators and up to 25 physician users. The numbers of administrators can be extended via request to BIOTRONIK Home Monitoring Customer Service Center.

1 Click here to add the user.

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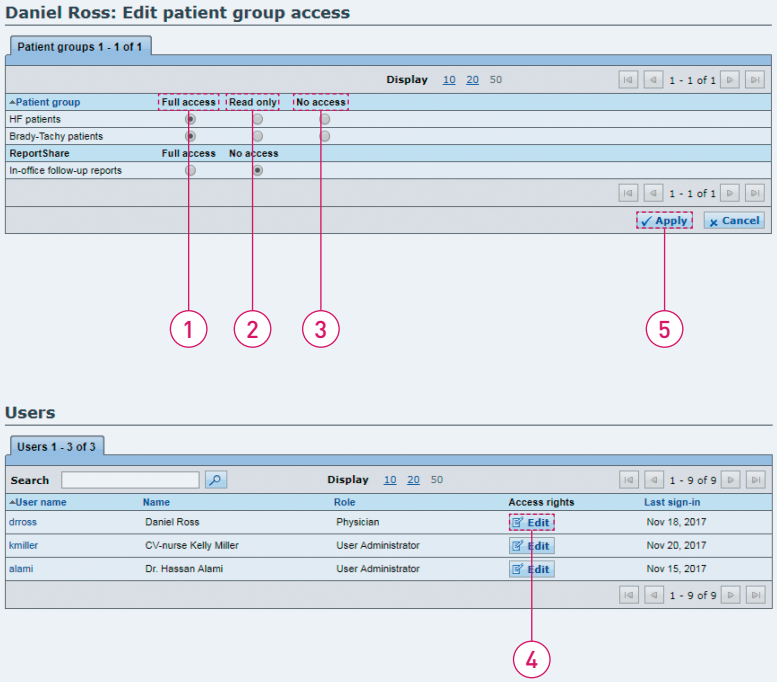

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How to Add a New User

After adding a user, the administrator has to define that user's access rights.

This screen pops up automatically.

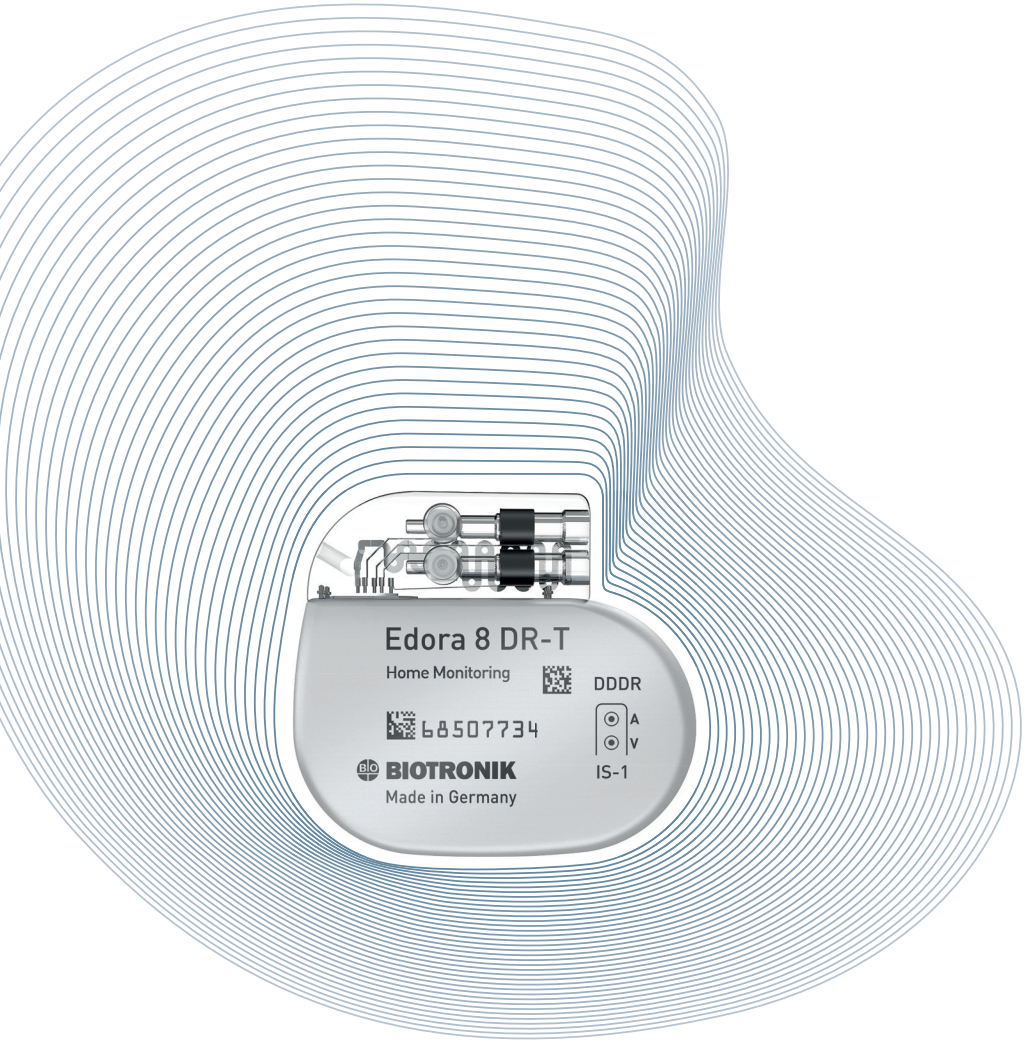
1 User gains full access to the designated patient group.

2 User can only view patient data, but cannot change any settings or acknowledge a finding.

3 User will not be able to see any patients within this group.

4 The administrators can at any time change the access rights of a user by editing the patient group access.

5 Click the "Apply" button.



How to Add a New Patient Group

ONLY ADMINISTRATORS ARE ENABLED TO CREATE A NEW PATIENT GROUP.

EVERY USER WITH FULL ACCESS TO THIS PATIENT GROUP CAN ADD A PERSONAL NOTIFICATION MODE.

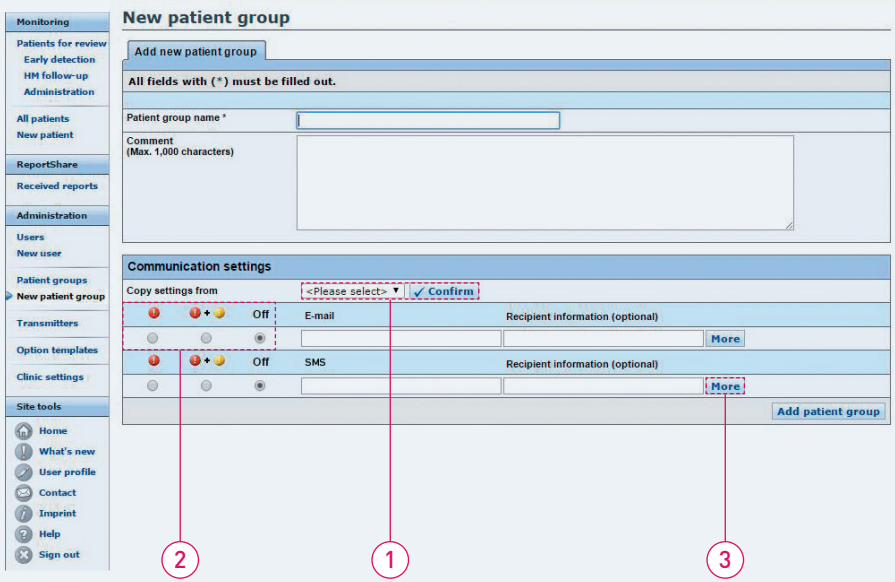
How to Add a New Patient Group

If you would like to add a new patient group to your user group, you simply fill out the form and specify the desired notification modes.

1 You can simply reuse the preestablished notification modes from an existing group.

2 Or, you can select the desired communication settings according to the color-coded finding.

3 Add more options for email or SMS if desired.



ONLY ADMINISTRATORS ARE ENABLED TO CREATE A NEW PATIENT GROUP.

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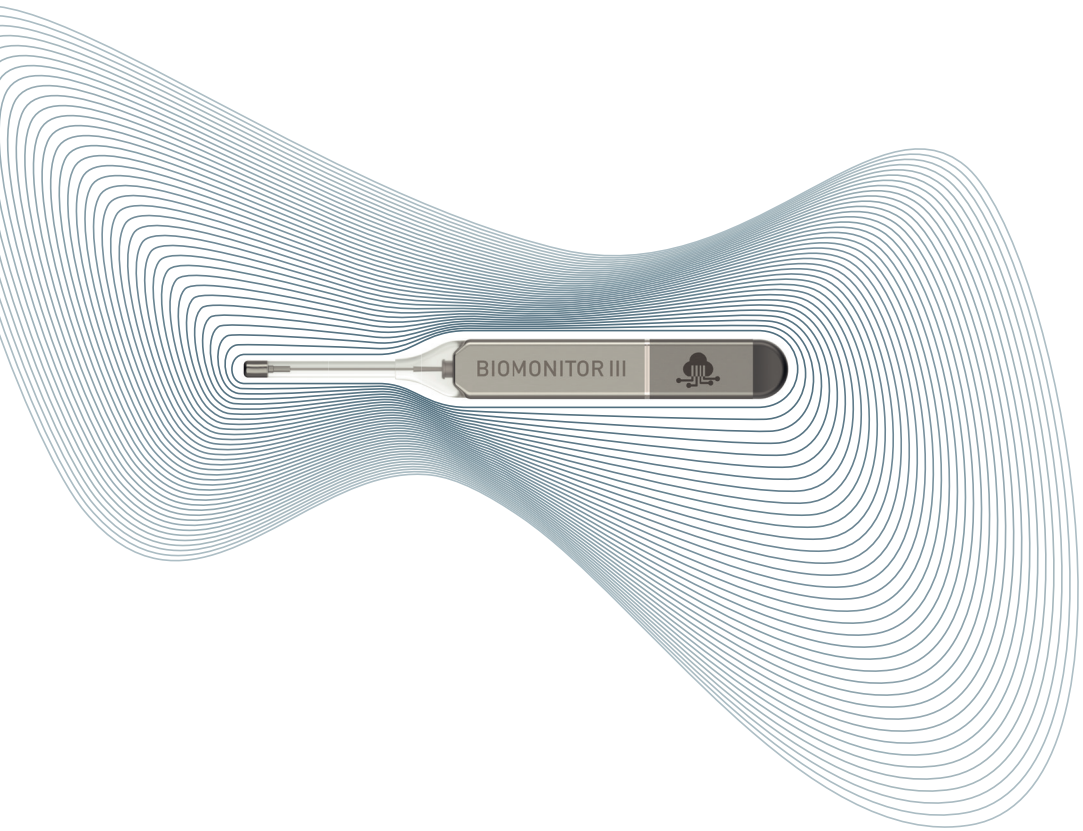
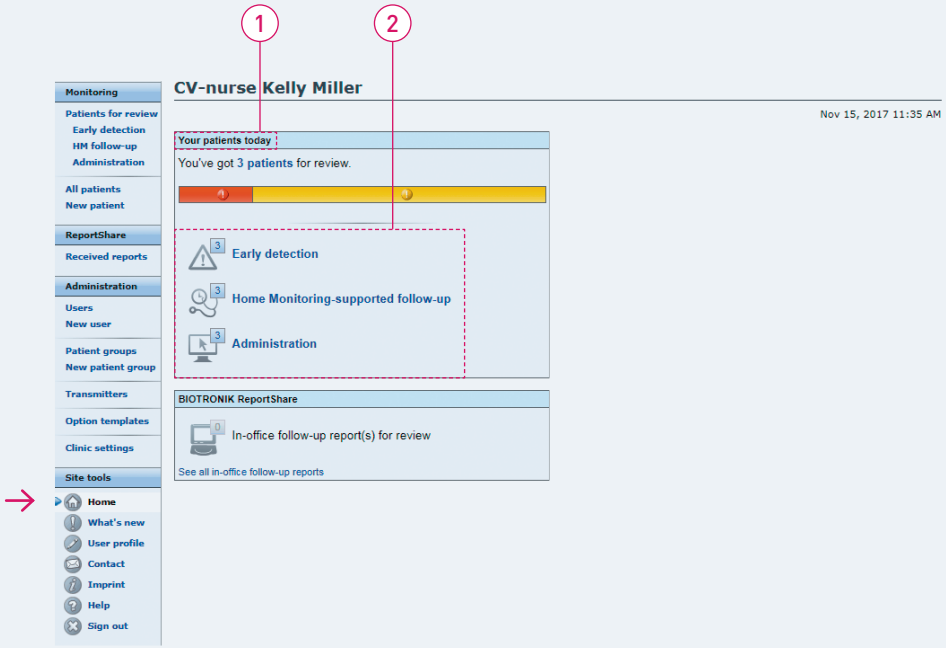


How to Review a Patient

Patients for Review

Quick View Report

Acknowledge Function



How to Review a Patient

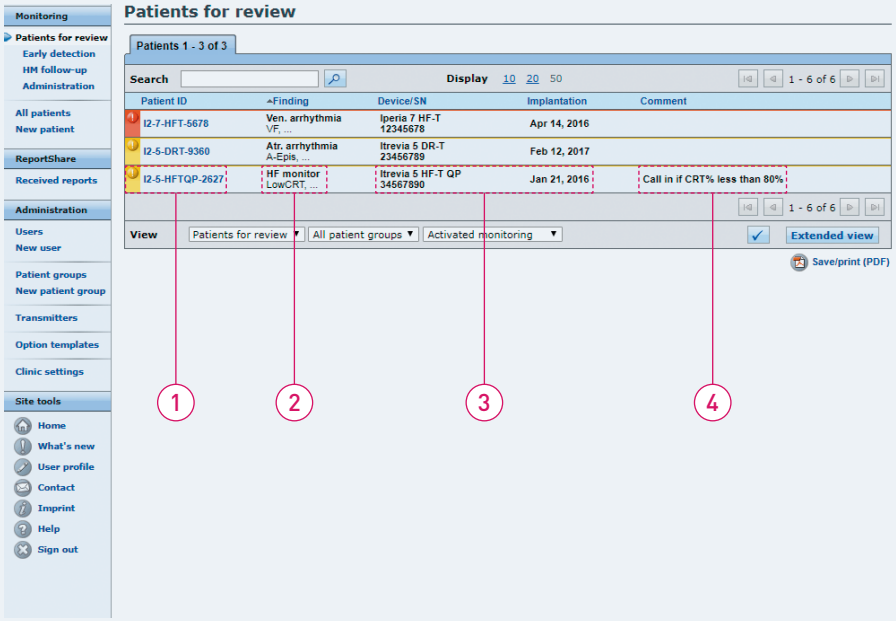
After signing in to the Home Monitoring Service Center, the workflow assist feature is displayed automatically.

1 The "Your patients today" section informs you about the general status of your patients.

2 Click on specific options to review and acknowledge your patients' findings:

- The "Early detection" link displays only those patients who have at least one new clinically relevant and device-related finding, such as ventricular fibrillation (VF) or ventricular tachycardia (VT) detected.
- The "Home Monitoring-supported follow-up" link displays only those patients for whom a trigger for a Home Monitoring-supported follow-up has been received (Home Monitoring follow-up transmission has arrived).
- The "Administration" link displays only those patients who have at least one new administrative finding (e.g., first message received, no message received).

If you receive a notification via email stating that a finding has been detected for a certain patient, you may use these links in the email to sign in quickly.



How to Review a Patient

The “Patients for review” list shows only those patients requiring attention for

- Early detection
- Home Monitoring-supported follow-up
- Administration

The color code or status helps you to differentiate the clinical priorities.

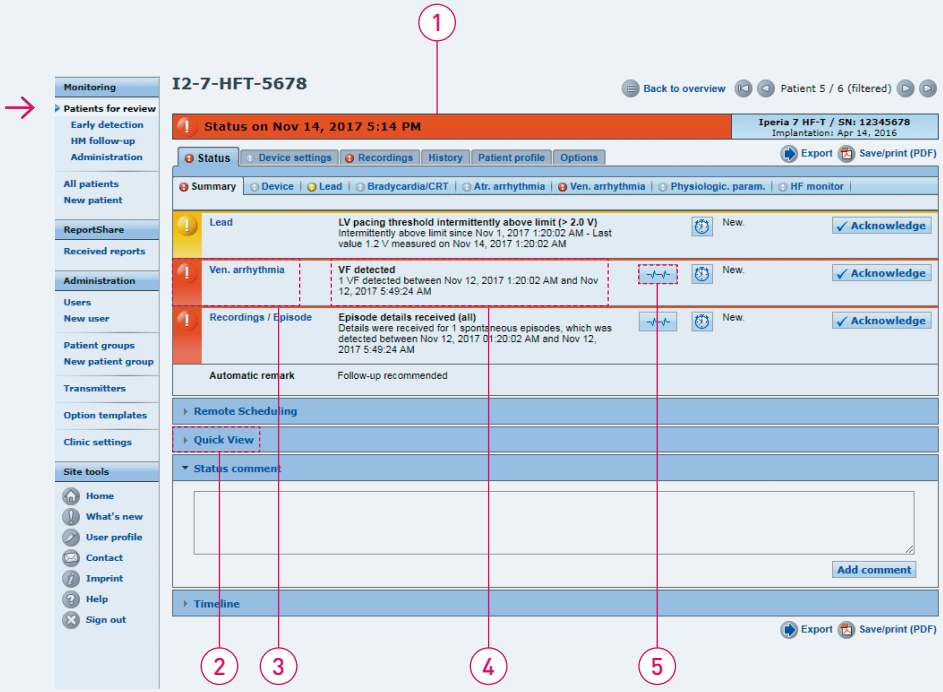
1 Patient ID

2 Main finding

3 Device and implantation date

4 Previous comments added by a user

Click on the **patient ID** to focus on the finding.



How to Review a Patient

By clicking on a patient's ID code, you can review his/her clinical status summary

1 Patient status

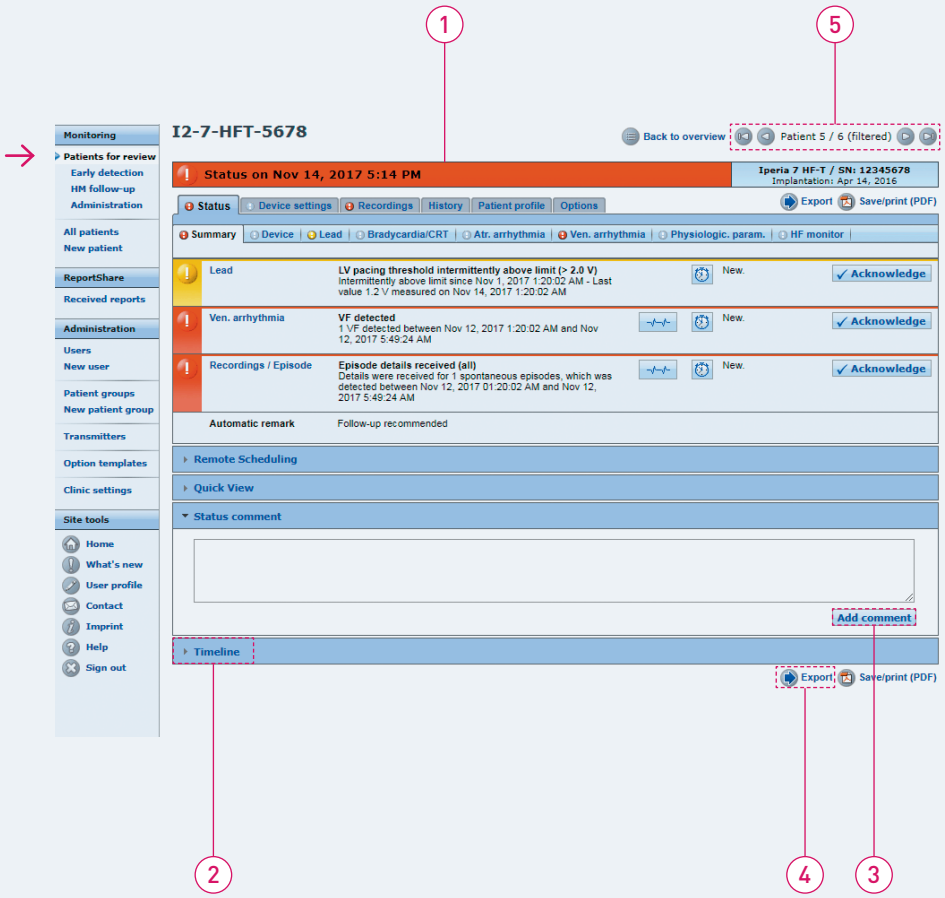
2 By clicking on "Quick View", you can review a comprehensive summary of clinically relevant information on one page.

3 Finding overview with link to finding details

4 Summary text of finding

5 Display recordings details (type of the episode* and possibly transmitted IEGM)

* Episode parameters depend on the device model of the selected patient.



How to Review a Patient

The status summary gives you the chance to:

1 See the patient status.

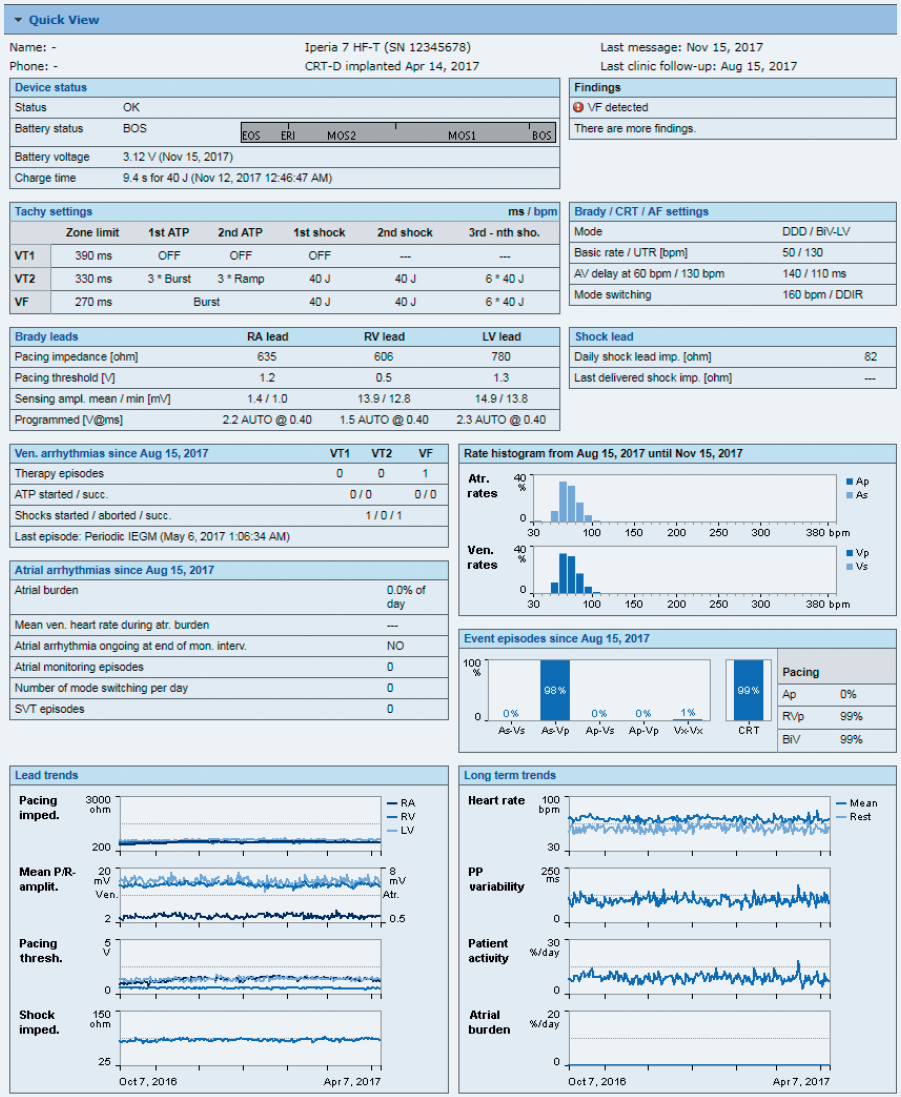
2 Consult a patient timeline, which allows you to see a 90-day history of the findings.

3 Add specific comments about newly acknowledged findings.

4 Export to EHR (electronic health record) system. (EHR DataSync must be configured by the administrator in clinical settings.)*

5 To review the next patient, click on the arrow.

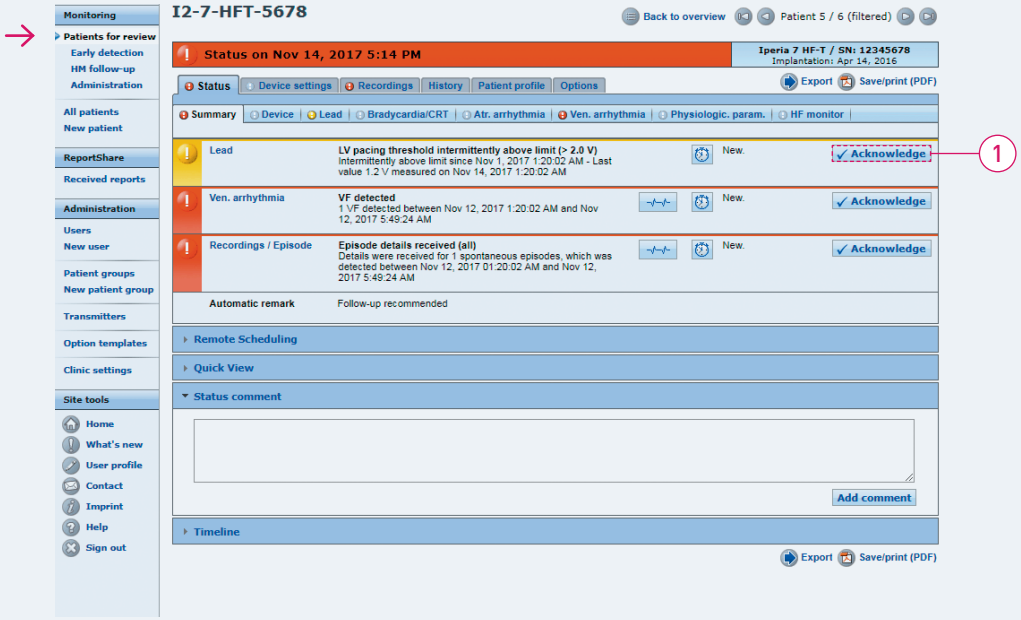
* Note for customers in the United States: Export feature available. Must be activated. Contact BIOTRONIK representative to initiate.



How to Review a Patient

The Quick View provides a fast and easy review of all relevant patient and device data at a glance.

- Device status
- Findings
- Tachy settings
- Brady/CRT/AF settings
- Brady leads
- Shock lead
- Ventricular arrhythmias
- Rate histogram
- Atrial arrhythmias
- Event episodes
- Lead trends
- Long term trends



How to Review a Patient

When reviewing the clinical status of a patient, you can acknowledge findings:

By acknowledging a finding:

- Some immediately turn white because the underlying condition is over.
- Others may remain colored if the condition still requires additional measurements to confirm that the finding is resolved. For example: A finding of threshold measurement requires that the finding is solved before it turns white.

To acknowledge a finding, you need full access to the patient's corresponding group.
You can view all acknowledged findings in the patient history.

1 Click here to acknowledge findings.
Acknowledged findings can be unacknowledged.

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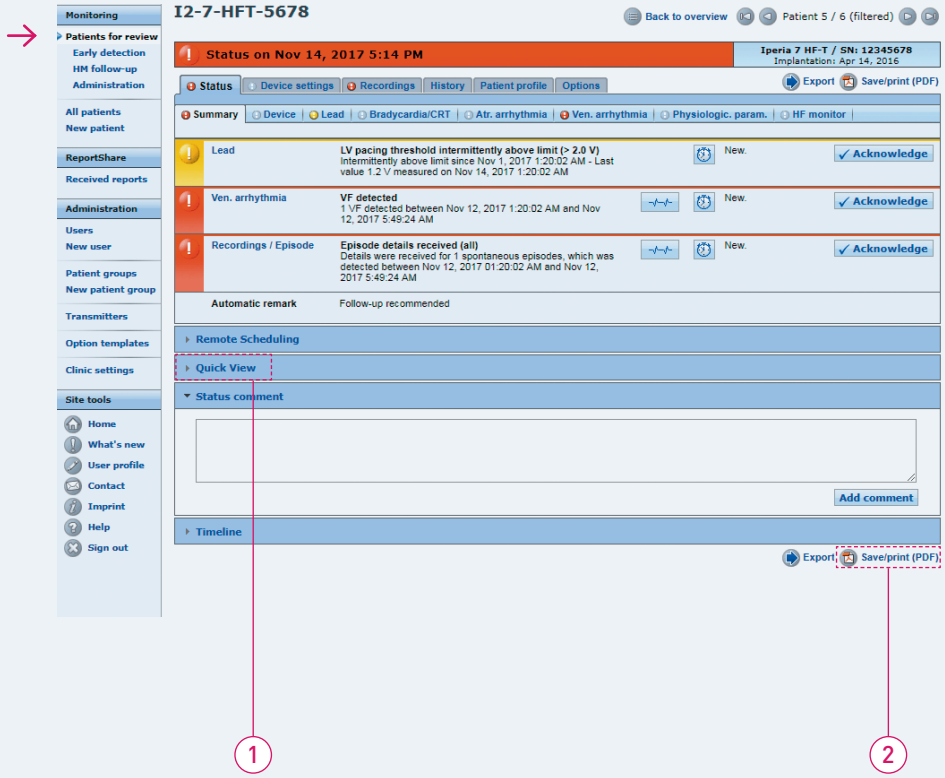
Printing and Exporting

Quick View

Optional Selection

Export Function

CONFIGURATION AND ACTIVATION OF EHR DATASYNC EXPORT FUNCTION IS RESTRICTED TO ADMINISTRATORS ONLY

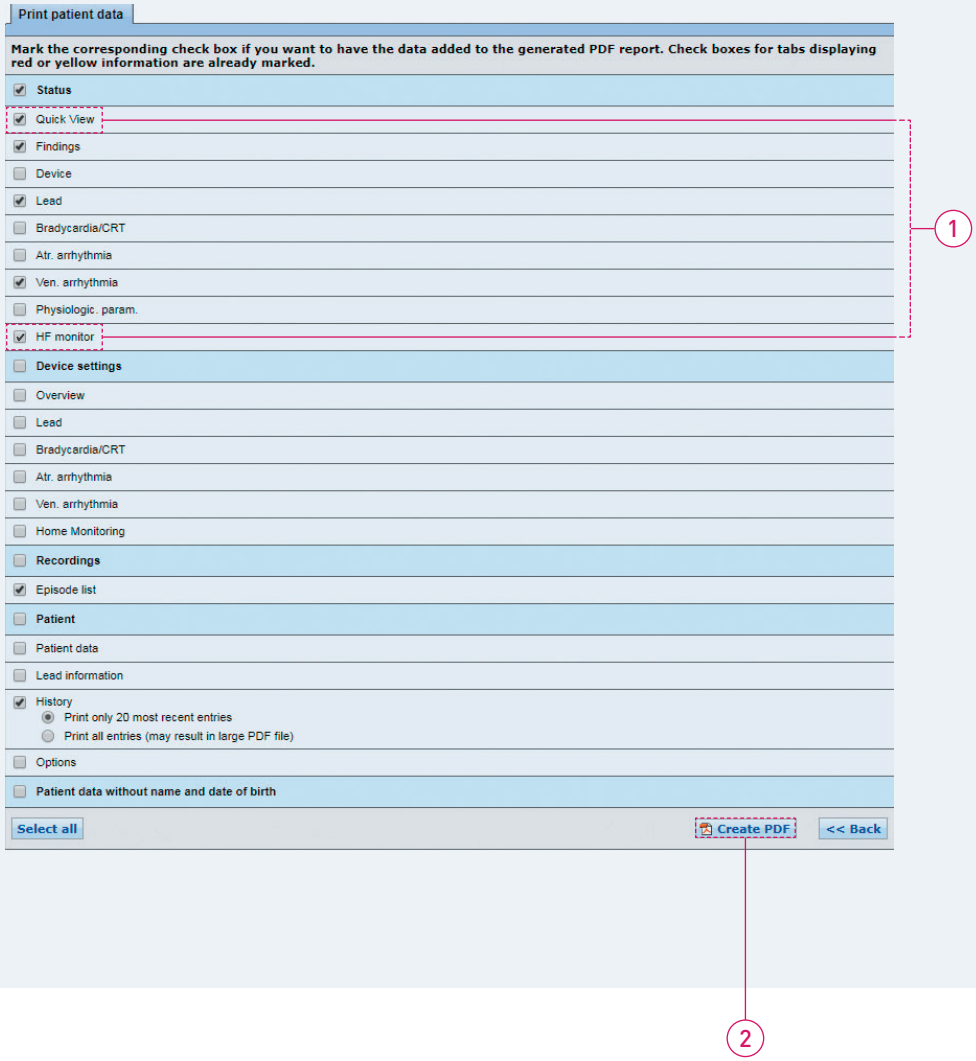


Printing and Exporting

For every patient, you are able to print selected summary reports or save them as pdf files.

1 By clicking on “Quick View”, you are able to see, save and print a summary report of the patient.

2 Click on “Save/Print (PDF)” to select and print the desired patient information.



Printing and Exporting

Select any additional categories to be printed or saved. Red and yellow alert categories are automatically selected

1 For example, select Quick View or HF monitor to directly see a one-page summary report of a patient.

2 Click here to create a PDF.

Quick View Report

Quick View - Nov 15, 2017

To: CV-Nurse Kelly Miller

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Name: -
Patient ID: 12-7-HFT-5678
DOB: -
Phone: -
Iperia 7HF-T (SN12345678)
CRT-D implanted Apr 14, 2017
Last message: Nov 15, 2017
Last clinic follow-up: Aug 15, 2017

Device status	
Status	OK
Battery status	BOS
Battery voltage	3.12 V (Apr 7, 2017)
Charge time	9.4 s for 40 J (Nov 12, 2017 12:46:47 AM)

Findings
VF detected
There are more findings.

Tachy settings	Zone limit	1st ATP	2nd ATP	1st shock	2nd shock	3rd - nth sho.
VT1	390 ms	OFF	OFF	OFF	---	---
VT2	330 ms	3 * Burst	3 * Ramp	40 J	40 J	6 * 40 J
VF	270 ms	Burst		40 J	40 J	6 * 40 J

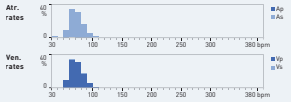
Brady / CRT / AF settings	
Mode	DDD / BiV-LV
Basic rate / UTR [bpm]	50 / 130
AV delay at 60 bpm / 130 bpm	140 / 110 ms
Mode switching	160 bpm / DDIR

Brady leads	RA lead	RV lead	LV lead
Pacing impedance [ohm]	635	606	780
Pacing threshold [V]	1.2	0.5	1.3
Sensing ampl. mean / min [mV]	1.4 / 1.0	13.9 / 12.8	14.9 / 13.8
Programmed [V@ms]	2.2 AUTO @ 0.40	1.5 AUTO @ 0.40	2.3 AUTO @ 0.40

Shock lead	
Daily shock lead imp. [ohm]	82
Last delivered shock imp. [ohm]	---

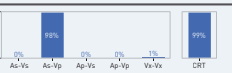
Ven. arrhythmias since Dec 16, 2016	VT1	VT2	VF
Therapy episodes	0	0	1
ATP started / succ.	0 / 0		0 / 0
Shocks started / aborted / succ.	1/0/1		
Last episode: Periodic IEGM (Mar 6, 2017 1:06:34 AM)			

Rate histogram from Dec 16, 2016 until Mar 6, 2017



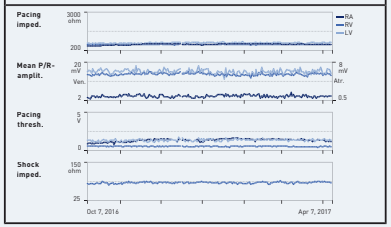
Atrial arrhythmias since Dec 16, 2016	
Atrial burden	0.0% of day
Mean ven. heart rate during atr. burden	---
Atrial arrhythmia ongoing at end of mon. interv.	NO
Atrial monitoring episodes	0
Number of mode switching per day	0
SVT episodes	0

Event episodes since Dec 16, 2016

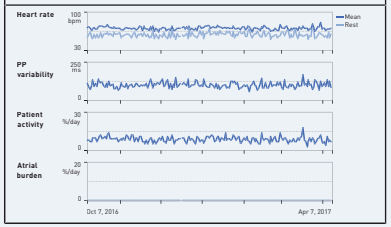


Pacing	
Ap	0%
RVp	99%
BiV	99%

Lead trends



Long term trends



Technical Services:
Tel.: +49 30 68905 - 2440
Fax: +49 30 68905 - 2941

Date:

Signature:

1/1

One Page Summary Status Report

Status report - N 15, 2017

To: CV-Nurse Kelly Miller

BIOTRONIK excellence for life

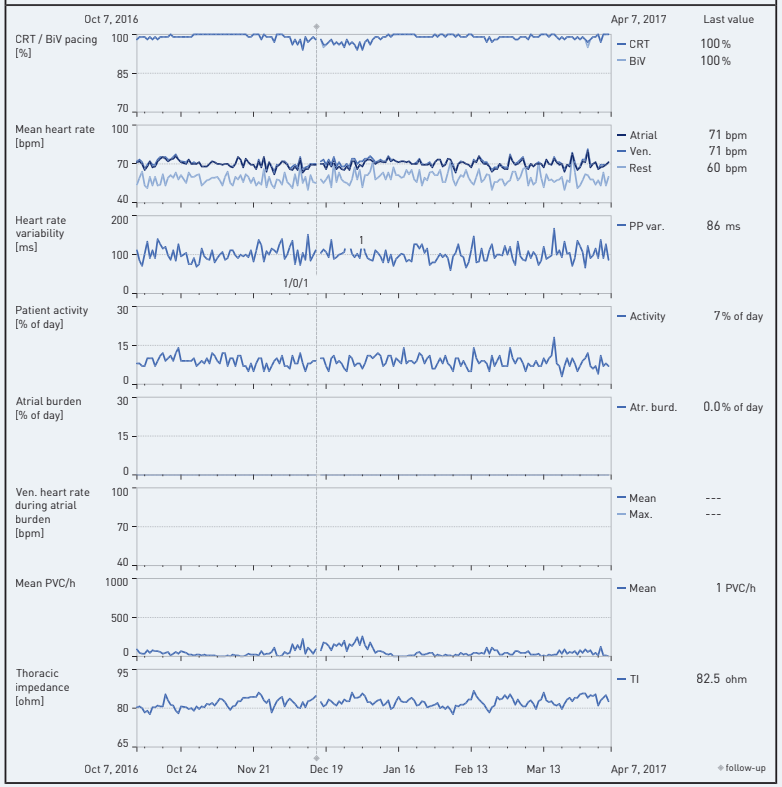
Name: -
Patient ID: 12-7-HFT-5678
DOB: -
Phone: -
Iperia 7HF-T (SN12345678)
CRT-D implanted Apr 14, 2017
Last message: Nov 15, 2017
Last clinic follow-up: Aug 15, 2017

Status - HF monitor:

Device status Nov 15, 2017	
Device status	OK
Battery status	OK (BOS)
Pacing mode	DDD (BiV-LV first)

Arrhythmias since Aug 15, 2017	VT1	VT2	VF	AMon
Episodes	0	0	0	0
ATP started / succ.	0 / 0		1	-
Shocks started / aborted / succ.	1 / 0 / 1			-

Long term trends

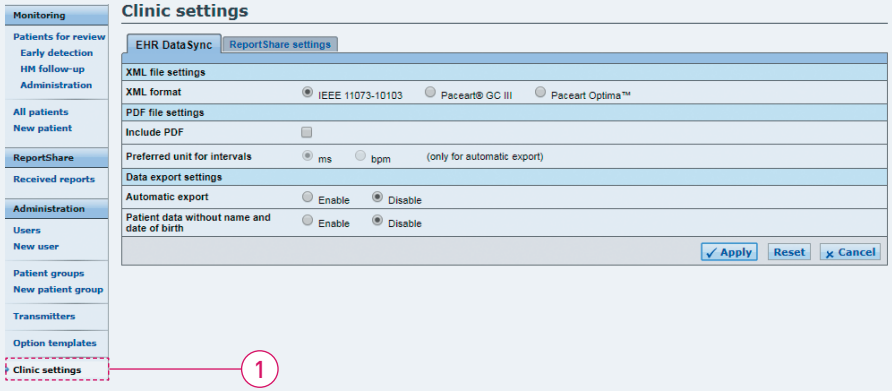


Technical Services:
Tel.: +49 30 68905 - 2440
Fax: +49 30 68905 - 2941

Date:

Signature:

1/1



Printing and Exporting

Via the EHR DataSync, data can be integrated into software systems (e.g., Paceart®) or directly to your hospital EHR system.[1]

1 Configure and activate EHR DataSync in the "Clinic settings" tab.

2 Users have the option to manually[2] initiate the export of data for a single patient to the clinic's EHR system.

CONFIGURATION AND ACTIVATION OF EHR DATASYNC EXPORT FUNCTION IS RESTRICTED TO ADMINISTRATORS ONLY

1 Contact your local BIOTRONIK representative for more information on EHR DataSync
2 Upon request, customers from the United States are able to activate automatic export function.
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BIOTRONIK Home Monitoring®
Step-By-Step Guide

For a more detailed explanation, click on the online help function.
If you have any questions regarding other functions of this application, click on "Help" in the field "Site tools" to access the online help.
A contextsensitive help function relating to the currently viewed page can be opened with the "Help" symbol.

If you wish to send an email to the BIOTRONIK Home Monitoring Customer Service Center, please click on "Contact."
Our email address is healthservices@biotronik.com.

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