



Instructions for Use

HeartX Viewer – Holter

Rev. 14 | EN

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Information about this Manual

This manual is published by
GETEMED Medizin- und Informationstechnik AG
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Germany.

The information in this manual applies to the Holter module of HeartX Viewer.

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Revision History

Version	Date	Description of Changes
01	23.07.2025	1st Edition
02	19.08.2025	2nd Edition Detail area for atrial fibrillation ECG strips for manual timepoints
03	01.09.2025	3rd Edition Detail area for atrial flutter
04	26.09.2025	4th Edition Heart Rate Variability
05	16.10.2025	5th Edition Heart Rate Variability - Detail view Switzerland REP-Label
06	06.11.2025	6th Edition Editing of all ECG events
07	09.12.2025	7th Edition Full disclosure view
08	28.04.2026	8th Edition Time Distance Measurement
10	22.06.2026	10th Edition Region list view and bulk delete/restore
11	16.07.2026	11th Edition Region deletion from the ECG display Manual report summary text
12	27.07.2026	12th Edition AFib and AFL regions marked in full disclosure view
13	05.08.2026	13th Edition Recording List CardioDay Export
14	17.08.2026	14th Edition AI-generated summary in the report dialog

Intended Use / Indication for Use

Intended Purpose

The HeartX Viewer is a software that is intended to analyze and/or display ECG data from a compatible ECG device and to allow direct diagnosis. The user is able to interpret visualized ECG data based on the analysis and measurement of the ECG data and to evaluate them diagnostically. The presentation of ECG data concerning zoom and amplitude can be set by the user.

Indications

Indication

The HeartX Viewer is indicated for the diagnostic evaluation of multi-channel ECGs in adult and pediatric patients, including but not limited to patients with conditions such as palpitations, syncope, chest pain, shortness of breath, or those who need to be remotely monitored at home to assess their current heart function, such as patients suffering from heart failure or other chronic conditions.

Contraindications

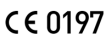
The HeartX Viewer is not a monitoring system for emergency situations and it is not indicated for patients whose clinical condition requires continuous monitoring of vital physiological parameters.

CE Conformity and Marking

Medical Device Conformity

The CE mark and the registration number of the Notified Body show that the medical device is in compliance with the essential requirements of Regulation (EU) 2017/745 (MDR).

Used Symbols

Symbol	Description
	The CE mark and the registration number of the Notified Body show that the medical device is in compliance with the essential requirements of Regulation (EU) 2017/745 (MDR).
	Manufacturer, Name and Address Refers to the name and address of the manufacturer.
	Indication of the company that distributes the medical device in the respective territory
	Identification of the country of manufacture of the products
	Medical Device Indicates that the product is a medical device.
	Follow Instructions for Use The symbol is displayed in the application and allows access to the instructions for use.
	Unique Device Identification
	GS1 Datamatrix Code (01) GTIN (10) LOT Number, (Version number) a.b.y.z (11) Production Date
	The instructions for use are embedded in the software and can additionally be accessed at the following URL: https://www.getemed.de/en/user-manuals
	Marking of the Swiss Authorized Representative.
	Open Settings
	Open Feedback Form

Safety Information

For safe operation with the HeartX Viewer, please observe the following precautions and notes. The terms "WARNING" and "CAUTION" are used in these instructions for use to indicate risks and the severity of a threat. A risk is defined as a source of possible injury to a person.

WARNING indicates a possible risk or unsafe procedure that, if not avoided, could result in death or serious injury.

CAUTION indicates a possible risk or unsafe procedure that, if not avoided, could result in minor injury or damage to the product or other items.

NOTICE indicates application notes or other useful information to ensure that you can use the product to its full extent.

Incident Reporting

Any serious incident related to the product must be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established. A serious incident is a malfunction of the product that leads to death or serious injury or could lead to death or serious deterioration of health.

Warranty and Service Information

If you notice an unexpected operating condition or unexpected incidents or if you need technical support, contact the manufacturer at the following address:

GETEMED
Medizin- und Informationstechnik AG
Oderstr. 77, 14513 Teltow, Germany
www.getemed.de

Required Hardware and Software

Category	Description
Client	Web browser Google Chrome, Safari or Mozilla Firefox Minimum requirements for the size of the browser window: Width: 1280 px Height: 750 px
Server	Docker environment 1 CPU core 2 GB RAM

Operating Concept

The application consists of two central views: the recording list and the analysis area. The analysis area is further divided into an overview area and a detail area.

Recording List

The list of all available recordings contains, among other things, the following information and actions:

- patient data, if available
- recording date and duration
- recording device used
- recording status
- button for opening the recording
- button for exporting the recording to CardioDay

CardioDay Export

The icon, color, and tooltip text indicate the export status:

- hourglass and rotating arrows: export in progress
- green or red icon: export completed successfully or with an error. The export can be started again.

Analysis Area

The analysis area of the HeartX Viewer - Holter application is divided into two areas that enable efficient analysis of Holter data:

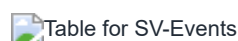
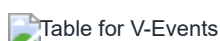
1. **Overview Area** (left): Provides statistical summaries and visualizations of Holter data
2. **Detail Area** (right): Enables detailed viewing and analysis of specific ECG events

This division follows the overview/detail principle, where the overview area provides an overview of the data, while the detail area enables deeper analysis.

Overview Area

The overview area on the left side of the HeartX Viewer - Holter application contains the following elements:

Ectopic Activity



In the overview area, the ectopic activities are displayed in two tables arranged one below the other – first the V-events with frequency and percentage, then the SV-events in the same form.

Heart Rate Variability

The Poincaré plot shows the intervals between consecutive heartbeats (RR intervals) in a scatter representation.



In the detail view, the Poincaré plot is shown together with the N-N histogram and the heart rate variability statistics.

Rhythm and Beat Distribution



Donut Chart: Rhythm

The rhythm donut chart shows the percentage of atrial fibrillation (here: 27.0%) and atrial flutter (here: 2.0%) relative to the analysis duration.

Donut Chart: Beat Classification

The beat classification donut chart shows the distribution of individual beats and provides an overview of all detections. Normal beats (N), ventricular beats (V), supraventricular beats (S), and paced beats (P) are always displayed.

Event Summaries



- **AFib:** Shows the number and the longest episode with timestamp
- **Ventricular Tachycardia:** Shows the number, the longest episode with timestamp, and the maximum heart rate
- **Pauses:** Shows the number, broken down by length over 2 s, 3 s, and 4 s including timestamp of the longest pause.

Detail Area

The detail area on the right side of the HeartX Viewer - Holter application enables detailed analysis of specific events:

Category and Event Navigation



Events can be accessed in the application via a two-level tab bar. In the first level, you select a primary tab: V-events for ventricular events, SV-events for supraventricular events, Other Arrhythmias for other rhythm disorders, AFib for atrial fibrillation, and AFL for atrial flutter. An HR tab is planned but currently without function; it therefore appears grayed out. In the example shown, the primary tab "V-events" is active.

The second navigation bar contains the secondary tabs for the selected event type. For ventricular events, these include VT, V-salvo, etc.; non-occurring types are automatically deactivated. If you switch to SV-events, analogous sub-tabs appear (e.g., SVT, SV-salvo, etc.). This way, you can access any desired event category with one click, without having to navigate through additional menus.

Event Histogram



In the upper area of the diagram, two curves are superimposed: The shaded bars show the load profile of ventricular (V-) or supraventricular (SV-) events as percentage per hour, while the line parallel to it shows the course of the heart rate (right y-axis). This allows you to see in which time periods the event load correlates with the heart rate.

Directly below the curve area is an event timeline. Each marked point represents a single detected event. The event is identified by the legend on the right edge (e.g., VT, V-salvo, etc.). The horizontal alignment of all elements on the same time axis enables assignment of the events to the respective load and heart rate profiles.

For atrial fibrillation and atrial flutter, only the load profile and heart rate are displayed.

Region List View

For AFib and AFL, you can switch between histogram and list view. The list shows each region with start time, end time, duration, and status. Multiple regions can be selected and deleted or restored together. Clicking a row opens the selected region at the start time.

Deleted regions remain available in the list and can be restored before saving the changes. They are excluded from the active region values shown in the application.

ECG Strips for Manual Timepoints

By clicking on a position in the histogram, you open the ECG strip at exactly that timepoint. This allows you to examine events or individual timepoints in detail.

ECG Display



Header Area

In the header area, you see the title of the selected event on the left (e.g., "Ventricular Bigeminy") with the event date and time beneath it. To the right is a toolbar: use the star icon to add or remove the favorite marking. The "Full view" icon (square with arrow pointing outward) opens the full disclosure ECG. In this view, detected AFib and AFL regions are marked with a dotted line and a colored "AFib" or "AFL" label; hovering over a region shows its start time, end time, and duration. On the far right is the filter control with the options "Favourites" and "All events", where you choose whether to display all detected ECG events or only those marked as favorites.

ECG Visualization

The ECG display is structured as an overview/detail view:

Overview area (top): shows the complete signal course with a highlighted window that marks the currently visible section.

Detail area (bottom): provides an enlarged, precise view of the marked section. The window in the overview area can be moved via drag and drop to jump to other signal segments. The RR interval labels shown above the strip can be clicked once to switch between RR intervals in milliseconds and heart rate in bpm.

Time Distance Measurement



Hold down the Shift key and click two points in the ECG strip to measure the time distance. A horizontal measurement line with endpoint markers is shown between the selected positions, and the measured distance is displayed in milliseconds. Completed measurements remain visible until another ECG strip is opened.

Beat Selection and Relabeling

Every detected beat is marked above the waveform with a letter showing its current classification: N (normal), S (supraventricular), V (ventricular), J (junctional), B (bundle branch block), or P (paced). A beat marked as an artifact is shown as a dot (•) instead of a letter, since it is excluded from the RR-interval calculation; the interval before and after an artifact beat is combined into a single value spanning the real beats on either side of it.

When an ECG strip opens, the beat closest to the event's marked timepoint is automatically selected and highlighted. You can change the selection at any time:

- Click a beat to select only that beat, replacing any previous selection. Clicking the only currently selected beat again deselects it.
- Hold Ctrl (Cmd on Mac) and click additional beats to add or remove individual beats from the selection, even if they are not next to each other.
- Click and drag across a section of the strip to select every beat within that range in a single motion. A highlighted band follows the pointer while dragging to show the section that will be selected. Hold Ctrl (Cmd on Mac) while dragging to add the beats in that section to the current selection instead of replacing it.

Selected beats are shown with a highlighted background. Both selection gestures are ignored while the Shift key is held, so they never interfere with the time distance measurement described above.

With one or more beats selected, press one of the following keys to relabel all selected beats at once:

Key	Beat type
N	Normal
S	Supraventricular
V	Ventricular
J	Junctional
B	Bundle branch block
P	Paced
. (period)	Artifact

The beat label above the waveform and any affected RR-interval labels update immediately. When exactly one beat was selected, the selection automatically advances to the next beat after relabeling, so you can keep pressing a classification key to quickly relabel a run of consecutive beats without reselecting each one. This automatic advance does not occur when multiple beats were relabeled at once.

Event Navigation

Below the ECG curves, arrow buttons are available that allow you to jump to the previous or next event. Once the last event of a category is reached, the system automatically switches to the first event of the next type; if no further events are available, the navigation buttons are grayed out and thus inactive.

Event Editing

By default, the favorite ECG events are displayed when opening. Favorites are marked with a star in the event header. Clicking on the filled star removes the favorite marking. Conversely, you can mark an ECG event as a favorite by clicking on the star. It then appears in the favorites list until you save the selection.

ECG events can also be deleted or restored with the delete/restore button in the event header. For AFib and AFL regions, the same button deletes or restores the selected region. Deleted items remain visible when the corresponding "Deleted" filter is selected and can be restored before saving.

Saving Changes and Report Summary

When you save your changes, a new PDF report is generated.

Clicking "Create Report" opens the Summary dialog, where you can enter an optional diagnosis summary for the report. You can enter up to 1000 characters, and a character counter shows the remaining number of characters while you type.

Alternatively, you can click "Generate with AI" to have an AI-generated summary drafted from the recording's current analysis. The generated text appears in the Summary field and remains fully editable. A note below the field reminds you that AI-generated text may contain mistakes and must be reviewed and corrected before saving. Generating a summary by itself does not save anything or create a report.

If you close the dialog by clicking "Cancel", the entered text is preserved and is displayed again the next time the Summary dialog is opened.

When you confirm the dialog, the diagnosis summary is saved together with the selected event and region changes and is included in the newly generated PDF report.

If you leave the Summary field empty, the report will contain an empty Summary section.

Report creation can take up to ten minutes. You can close the application during this time. After completion, you will receive an email notification.

Settings

The settings can be accessed via the gear icon in the upper right corner of the application. After opening, a dialog with five tabs appears:

- User profile information
- Language setting
- IEM Integration
- Medical device information
- Help
- License information

IEM Integration

To integrate IEM Flow with HeartX Management, an access token needs to be created. Navigate to the IEM Integration tab in the settings dialog and click the "Create Token" button.



IEM Integration Settings

The system will generate an access token file that will be automatically downloaded to your device. Import this file into IEM Flow to establish the connection between the two systems.

UUID

Each ECG automatically receives a UUID (Universally Unique Identifier) that is displayed in the address bar of your browser and in the ECG PDF report; it uniquely identifies the dataset throughout all processing steps and serves as a reference for inquiries.

Troubleshooting

Error	Possible Cause	Troubleshooting
You have forgotten your password and cannot log in.	-	You can reset your password in the login window.
You have lost your second factor and cannot log in.	-	Contact hotline@getemed.de to reset your account.

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