getemed

Instructions for Use

HeartX Viewer – Holter

Rev. 2 | EN

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Information about this Manual

This manual is published by
GETEMED Medizin- und Informationstechnik AG
Oderstr. 77, 14513 Teltow,
Germany.

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

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

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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
CE 0197	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
	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 HeartX Viewer - Holter application is divided into two main 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:

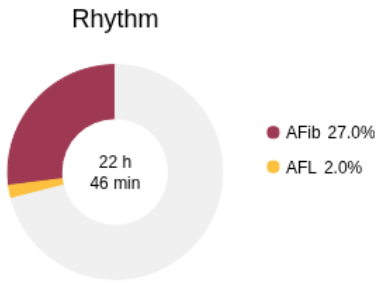
Ectopic Activity

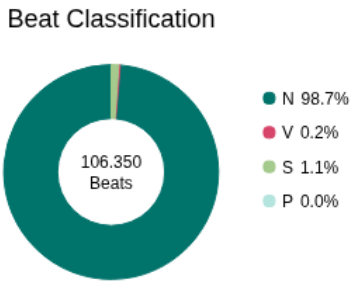
V Events	Distribution	Count
R-on-T	0.0%	0
VT	0.0%	0
V Run	0.0%	0
Triplet	0.0%	0
Couplet	0.9%	1
Bigeminy	8.7%	6
Isolated	90.4%	216

SV Events	Distribution	Count
SVT	2.8%	7
SV Run	6.2%	6
Triplet	4.6%	17
Couplet	4.1%	23
Bigeminy	5.8%	30
Isolated	76.4%	909

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.

Rhythm and Beat Distribution





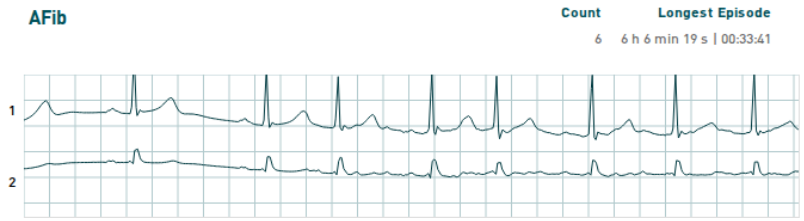
Donut Chart: Rhythm

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

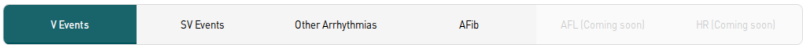


- **AFib**: Shows the number and the longest episode with timestamp
- **Ventricular Tachycardia**: Shows the number, the longest episode with timestamp, and the maximum heart rate
- **Pauses**: Shows the number, broken down by length over 2 s, 3 s, and 4 s including timestamp of the longest pause.

Detail Area

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

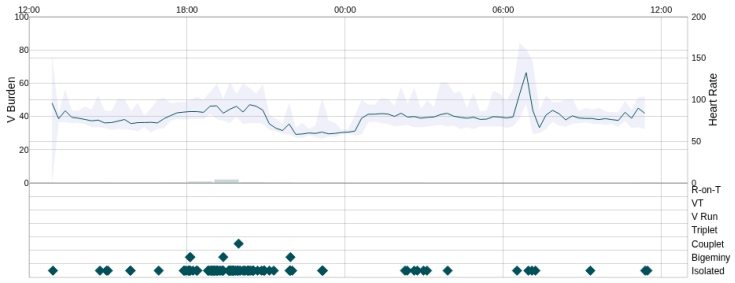
Category and Event Navigation



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, and AFib for atrial fibrillation. Additional tabs (AFL and HR) are already provided but currently without function; they therefore appear 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.

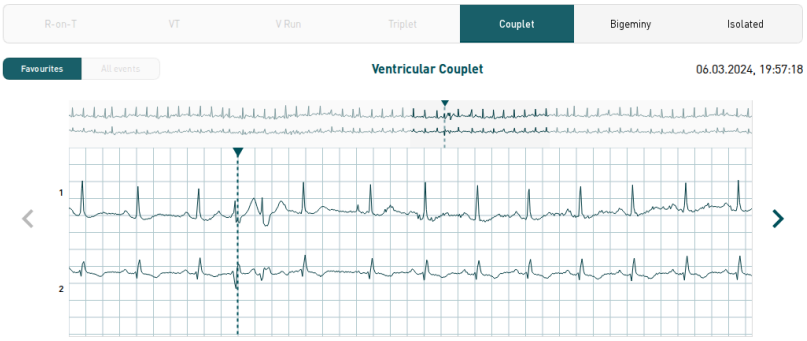
Directly below the curve area is an event timeline. Each marked point represents a single detected event. The event is identified by the legend on the right edge (e.g., VT, V-salvo, etc.). The horizontal alignment of all elements on the same time axis enables assignment of the events to the respective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

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

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 of the display, you first see the title of the currently selected event type, such as "Ventricular Couplet", followed by the timestamp of the event. To the right is a tab bar with the tabs "Favorites" and "All Events" – the latter is already provided but currently without function.

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.

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.

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
- Medical device information
- Help
- License information

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.

REF 79818021

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