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## Instructions for Use

### HeartX Viewer – Holter

Rev. 6 | 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.

HeartX is a trademark of GETEMED.

Other company or product names mentioned here are trademarks of their respective owners.

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## Revision History

| Version | Date       | Description of Changes                                                                 |
|---------|------------|----------------------------------------------------------------------------------------|
| 01      | 23.07.2025 | 1st Edition                                                                            |
| 02      | 19.08.2025 | 2nd Edition<br>Detail area for atrial fibrillation<br>ECG strips for manual timepoints |
| 03      | 01.09.2025 | 3rd Edition<br>Detail area for atrial flutter                                          |
| 04      | 26.09.2025 | 4th Edition<br>Heart Rate Variability                                                  |
| 05      | 16.10.2025 | 5th Edition<br>Heart Rate Variability - Detail view<br>Switzerland REP-Label           |
| 06      | 06.11.2025 | 6th Edition<br>Editing of all ECG events                                               |

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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**

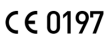
The HeartX Viewer is not a monitoring system for emergency situations and it is not indicated for patients whose clinical condition requires continuous monitoring of vital physiological parameters.

# 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                                                                                                                                                                                              |
|-------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|    | 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<br>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<br>Indicates that the product is a medical device.                                                                                                                                        |
|  | Follow Instructions for Use<br>The symbol is displayed in the application and allows access to the instructions for use.                                                                                 |
|  | Unique Device Identification                                                                                                                                                                             |
|  | GS1 Datamatrix Code<br>(01) GTIN<br>(10) LOT Number, (Version number) a.b.y.z<br>(11) Production Date                                                                                                    |
|  | The instructions for use are embedded in the software and can additionally be accessed at the following URL: <a href="https://www.getemed.de/en/user-manuals">https://www.getemed.de/en/user-manuals</a> |
|  | 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.

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# 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](http://www.getemed.de)

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# Required Hardware and Software

| Category | Description                                                                                                                                          |
|----------|------------------------------------------------------------------------------------------------------------------------------------------------------|
| Client   | Web browser Google Chrome, Safari or Mozilla Firefox<br>Minimum requirements for the size of the browser window:<br>Width: 1280 px<br>Height: 750 px |
| Server   | Docker environment<br>1 CPU core<br>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

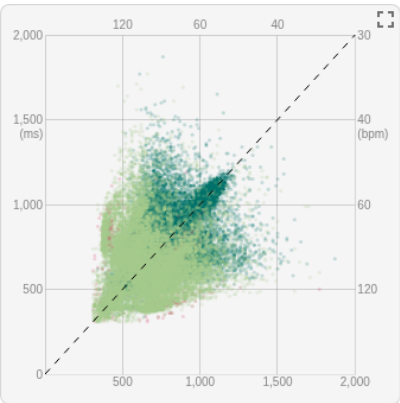
| V Events | Distribution | Count |
|----------|--------------|-------|
| R-on-T   | 0.0%         | 0     |
| VT       | 0.0%         | 0     |
| V Run    | 0.0%         | 0     |
| Triplet  | 0.0%         | 0     |
| Couplet  | 0.9%         | 1     |
| Bigeminy | 8.7%         | 6     |
| Isolated |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

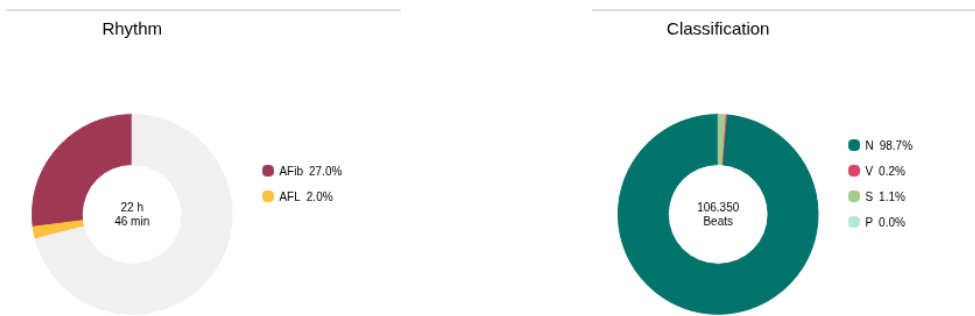
### Heart Rate Variability

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

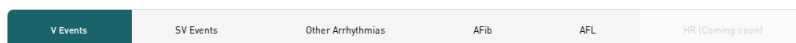


- **AFib:** Shows the number and the longest episode with timestamp
- **Ventricular Tachycardia:** Shows the number, the longest episode with timestamp, and the maximum heart rate
- **Pauses:** Shows the number, broken down by length over 2 s, 3 s, and 4 s including timestamp of the longest pause.

### Detail Area

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

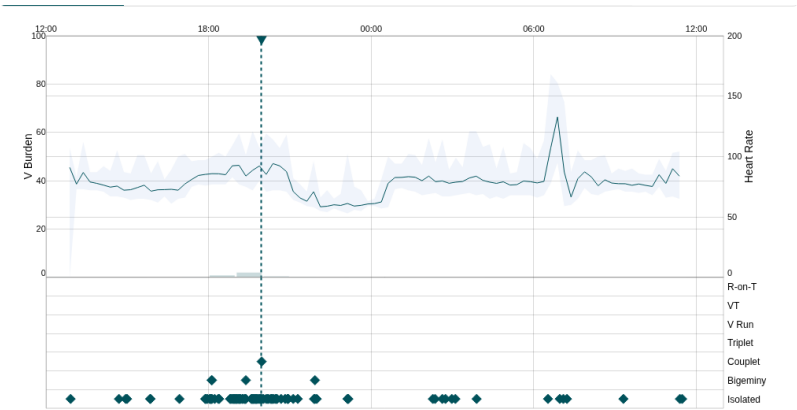
### Category and Event Navigation



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.

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 see the title of the currently selected event type, such as "Ventricular Couplet", followed by the timestamp of the event. The ECG event is marked as a favorite by the highlighted star button. To the left of it is a toggle with the labels "Favorites" and "All Events" to switch between all and favorite ECG events.

## 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.

## 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.

When you save the selection, a new PDF report is created. The 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
- 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.

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# 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 <a href="mailto:hotline@getemed.de">hotline@getemed.de</a> to reset your account. |

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