

Instructions for use

# Infinity<sup>®</sup> Gateway Suite

**WARNING**

To properly use this medical device,  
read and comply with these  
instructions for use.

**Alarm History Database  
Software VF9.0**



## General Information

---

### Trademarks

---

The Dräger name and logo are registered trademarks of Dräger.

Infinity® is a registered trademark of Dräger.

Internet Explorer®, Microsoft®, Windows® operating system, Windows® 10, and Windows Server® 2016 and 2019, and Excel® are registered trademarks or trademarks of Microsoft Corporation in the United States and/or other countries.

### Open-source software

---

Dräger devices that use software may use open-source software, depending on their setup. Open-source software may be subject to different terms of license. Additional information regarding the open-source software used in this device is available at the following web page:

[www.draeger.com/opensource](http://www.draeger.com/opensource)

### User group requirements

---

The term "user group" describes the personnel responsible who have been assigned by the operating organization to perform a particular task on a product.

#### Duties of the operating organization

The operating organization must ensure the following:

- Every user group has the required qualifications (e.g., has undergone specialist training or acquired specialist knowledge through experience).
- Every user group has been trained to perform the task.
- Every user group has read and understood the relevant chapters in this document.

## User groups

### Clinical users

This user group operates the product in accordance with the intended use.

Users have medical specialist knowledge in the application of the product.

### Service personnel

This user group installs the product and performs the service activities.

Service personnel have specialist knowledge in software systems and applications. Service personnel also have experience in the servicing of medical devices.

Where product specific knowledge or tools are required, the service activities must be carried out by specialized service personnel. The specialized service personnel was trained by Dräger for these service activities on this product.

## Operating characteristics

---









### Classification









Classification Medical Device Europe

Class IIa

## Symbols

The following table lists the Infinity Gateway symbols. Additional information about the symbols is available on the following web page: [www.draeger.com/md-symbols](http://www.draeger.com/md-symbols)

Symbol	Description
	Read accompanying IFU for specific safety information.
	WEEE (Waste Electrical and Electronic Equipment) Do not dispose of at municipal collection points for waste electrical and electronic equipment. Dräger has authorized a company to collect and dispose of this device.
<b>Rx only</b>	<b>Caution:</b> Federal law restricts this device to sale by or on the order of a physician
	European Union Representative
	Device part number and revision
	Manufacturer
	Date of manufacture
	Complies with the European Medical Device Regulation (EU) 2017/745
	Complies with applicable EU regulations and directives

Symbol	Description
	Quantity
	China RoHS mark
	Unique Device Identifier, barcode
	Lot/batch number
	Medical device
	Importer
	Importer
	Revision index

# Safety

---

## Mandatory reporting of adverse events

---

Serious adverse events with this product must be reported to Dräger and the responsible authorities.

## Instructions for use

---

### **WARNING**

**Strictly follow these instructions for use. Any use of the software requires a full understanding and strict observation of all portions of these instructions. The software is only to be used for the purpose specified under "Intended use" on page 9 and in conjunction with appropriate patient monitoring. Observe all WARNING and CAUTION statements as rendered throughout this manual, and all statements on device labels.**

## Definitions

---

Certain paragraphs within these instructions are highlighted as WARNING, CAUTION or NOTE as follows:

### **WARNING**

**A WARNING statement provides important information about a potentially hazardous situation that, if not avoided, could result in death or serious injury.**

### **CAUTION**

A CAUTION statement provides important information about a potentially hazardous situation that, if not avoided, may result in minor or moderate injury to the user or patient or in damage to the equipment or other property.

### **NOTE**

A NOTE provides additional information intended to avoid inconvenience during operation.

## Connections to IT networks

---

Many medical devices manufactured by Dräger use networks to transmit patient data. Hospitals should refer to IEC 80001-1 before attempting to connect such medical devices to their IT networks.



## **Intended purpose**

---

## **Intended use**

---

The Infinity Gateway software applications are intended to provide clinicians with the capability of viewing patient data remotely via the Infinity network and for the data exchange of select clinical and administrative information between the Infinity network and the hospital network.

## **Indications**

---

The Infinity Gateway software applications are intended to provide clinicians with the capability of viewing patient data remotely via the Infinity network and for data exchange of select clinical and administrative information between the Infinity network and the hospital network.

## **Contraindications**

---

There are no known contraindications for the Infinity Gateway software applications.

## **Environments of use**

---

The Infinity Gateway software applications are intended for use in a healthcare environment.

## **Patient population**

---

The Infinity Gateway software applications are applicable to all patient populations.

This page has been left blank intentionally.

# Contents

---

<b>General Information</b> . . . . .	3
Trademarks . . . . .	3
Open-source software . . . . .	3
User group requirements . . . . .	3
Duties of the operating organization . . . . .	3
User groups . . . . .	4
Operating characteristics . . . . .	4
Classification . . . . .	4
Symbols . . . . .	5
<b>Safety</b> . . . . .	7
Mandatory reporting of adverse events . . . . .	7
Instructions for use . . . . .	7
Definitions . . . . .	7
Connections to IT networks . . . . .	8
Indications for use . . . . .	8
Intended use . . . . .	8
Intended operator . . . . .	8
Intended patient population . . . . .	8
Intended use environment . . . . .	9
<b>Alarm History Database</b> . . . . .	13
Client requirements . . . . .	13
Accessing the Alarm History Database . . . . .	13
For US government users . . . . .	14
Accessing the instructions for use . . . . .	14
Logging into the Alarm History Database . . . . .	14
Session timeout . . . . .	16
Exporting Alarm History data . . . . .	16
Using Alarm History data . . . . .	18
Storing Alarm History data . . . . .	18
Logging off . . . . .	19

This page has been left blank intentionally.

# Alarm History Database

---

The Alarm History Database is a web-based application that captures and maintains a history of Infinity patient monitor alarms on a Gateway server, and is configurable from 1 to 52 weeks (defaulted to 28 weeks). The Alarm History Database does not support SDC-only devices.

## Client requirements

---

Before you can use your PC to access the web-based Alarm History Database, your PC must meet the following requirements:

- Your PC must have one of the following installed:
  - Windows 10 64-bit
  - Windows Server 2016 or 2019 Standard
- Your PC must have the following installed:
  - Internet Explorer 11 or Microsoft Edge in IE Mode
- An Alarm History Database license: purchased, enabled, and available on the Infinity Gateway Server
- A web server installed on your network and accessible by your PC
- An available Gateway server on the network, which can be accessed locally or remotely and is configured for use by the Alarm History Database application
- A signed certificate for the client installed on the Gateway server to allow the Alarm History Database to make an https connection (recommended by Dräger).

## Accessing the Alarm History Database

---


Access the Alarm History Database by the following URL, where the <server\_name> is the Gateway PC server name:

```
//<server_name>/webviewer/alarmhistory/InfinityGatewayLogon.html
```

**NOTE**

Depending on the configuration of IIS and the Alarm History Database in the Infinity Gateway configuration, access can be through HTTP or HTTPS.

## Accessing the instructions for use

To view the *Instructions for use* in a browser window, click the  symbol in the top upper right of the screen (refer to the following figure).



## Logging into the Alarm History Database

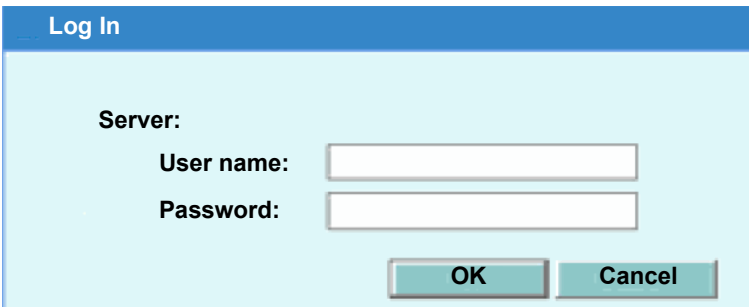
---

### NOTE

A group named AlarmHistory must exist on the Infinity Gateway. Users will not be allowed to log into the Alarm History Database unless they are members of the AlarmHistory group on the Infinity Gateway Server.

When the Infinity Gateway login page is loaded, a login page appears as shown in the following screen.

- 1 Enter your **User name**.
- 2 Enter your **Password**.
- 3 Click **OK**.



The Infinity Alarm History Database is an information technology tool and is intended for the gathering of alarm information from the Infinity network. The receipt of alarms cannot be guaranteed. The Alarm History Database is not intended to influence clinical decisions.

### NOTE

A note appears in the web page footer area if the server fails to return any language information when a language request has been made by the client.

After a successful login, the following screen appears:

Select the date to include in the export:

**Start date:**

**End date:**

Select monitoring units:

Collect all available monitoring units  
 Collect only selected monitoring units

Do not collect    Collect

Do not export alarms that have no alarm grade.

Feature	Description
Start date	Earliest date from which recorded alarms are included in the report.
End date	Latest date from which recorded alarms are included in the report.
Collect all available monitoring units	A monitoring unit is a grouping of patient monitors. Your biomed can help identify what monitoring unit covers the beds you are responsible for.
Collect only selected monitoring units	
Do not export alarms that have no alarm grade.	When a Gamma patient monitor is used, it is possible to get false alarms with an alarm grade of <b>None</b> . This option will remove these alarms from the exported report.

## Session timeout

---

If the system is configured for a session timeout due to inactivity, a message displays at the bottom of the browser as the system approaches this limit. This message states that the session is about to expire due to inactivity and provides the time remaining (in minutes) before you will be logged out of the application. If the system expires, repeat the log in procedure. To avoid the timeout and continue the session, click anywhere within the browser window.

## Exporting Alarm History data

---

The Alarm History report contains a list of all alarms received by the Gateway during the selected time period for the selected monitoring units.

Complete the following steps to select start and end dates for data collection and to select monitoring units for alarm history data.

- 1 Click the calendar symbol in the **Start date** field.
- 2 Select the desired date to begin alarm capture.
- 3 Click the calendar symbol in the **End date** field.
- 4 Select the desired date to end alarm capture.
- 5 Click **Collect all available monitoring units** to automatically move all available monitoring units to the **Collect** box.

You can highlight individual monitoring units in the **Collect** box and move these to the **Don't collect** box. You may also highlight individual monitoring units in the **Don't collect** box and move these to the **Collect** box.



- 6 Click **Export** to request the Infinity Gateway web server to export data from the Alarm History Database. The file will be saved in your browser's default download folder. This will export a tab separated text file with a filename formatted as follows:

***AlarmHistoryData-<start\_date>-<end\_date>.txt***

Where **<start\_date>** is the start date of the requested alarm data, and **<end\_date>** is the end date of the requested alarm data. The dates are formatted as: MM\_DD\_YYYY.

#### **NOTE**

This operation may take some time for databases with a large number of alarm entries.

#### **NOTE**

If no monitoring units are selected, or start and end dates are not filled in, then one or both of the following message appears in the footer area of the web page:

***No monitoring unit is selected.***

***Error: Export start and end date must be entered.***

Output includes the following:

- Alarm history data for the server <server name>
- Number of monitoring units
- Start date for the alarm history data report
- End date for the alarm history data report

<b>Column</b>	<b>Description</b>
local_time	The local time is taken from the Gateway server at the time the entry is written.
bed_label	Alarming monitor
pat_ID	Patient ID
mon_unit	Monitoring unit (network group to which monitor belongs)
care_unit	Care unit to which the monitor belongs
alarm_grade	Alarm Grade (HIGH, MEDIUM, or LOW)
alarm_state	Alarm State (ACTIVE, REACTIVE, SILENCED, LATCHED)
alarm_message	Alarm Message
param_id	Parameter Label
param_value	Parameter Value
param_uom	Parameter Units of measure
param_upper_lim	Parameter Upper Limit
param_lower_lim	Parameter Lower Limit

Column	Description
onset_tick	Time of alarm, in proprietary format, from monitor
alarm_duration	Alarm Duration
change_time (UTC)	Time of alarm, in UTC (Coordinated Universal Time), from the Gateway server at the time the entry is written.
change_tick	Time of alarm state change, in proprietary format, from monitor
aborted	Indicates how the alarm condition was cleared: <ul style="list-style-type: none"> <li>● 0: Acknowledged – indicates the alarm was acknowledged at bedside</li> <li>● 1: Timeout – no updates were received for this alarm for 10 seconds</li> <li>● 2: Shutdown – when the service is shutdown all alarms are cleared</li> </ul>

## Using Alarm History data

---

The resulting text file can now be imported into a tool for further analysis. One such tool you can use is Microsoft Excel. Import the text file into Excel as follows:

- 1 Open Excel.
- 2 Select **File > Open**.
- 3 Search for text files in the folder designated for web downloads.
- 4 Follow the Text Import Wizard and select **Delimited** as file type, and **Tab** as the delimiter.
- 5 Analyze the imported data.

### NOTE

The format of cells containing the date and time may need to be adjusted to see all data.


## Storing Alarm History data

---

The Alarm History Database can be configured during setup to collect alarm history for up to one year in one week increments. Only data collected in the configured period of time is stored. Once past the configured time, the data older than the configured time is deleted. Dräger recommends that you regularly export alarm history data and save it for long-term storage, as required by your institution.

## Logging off

---

To log off the Alarm History Database, click the  symbol in the top upper right of the screen (refer to the following figure).



This page has been left blank intentionally.

This page has been left blank intentionally.

This page has been left blank intentionally.






These instructions for use only apply to **Infinity Gateway® Suite Alarm History Database VF9.0** with the Serial No.:

If no Serial No. has been filled in by Dräger, these instructions for use are provided for general information only and are not intended for use with any specific machine or unit.



Distributed in USA by

 **Draeger Medical Systems, Inc.**  
3135 Quarry Road  
Telford, PA 18969-1042  
U.S.A.  
 (215) 721-5400  
(800) 4DRAGER  
(800 437-2437)  
FAX (215) 723-5935  
 <http://www.draeger.com>

 **Draeger, Inc.**  
3135 Quarry Road  
Telford, PA 18969-1042  
U.S.A.  
 (215) 721-5400  
(800) 4DRAGER  
(800 437-2437)  
FAX (215) 723-5935  
 <http://www.draeger.com>

 **Drägerwerk AG & Co. KGaA**  
 Moislinger Allee 53 – 55  
23542 Lübeck  
Germany  
 +49 451 8 82-0  
FAX +49 451 8 82-20 80  
 <http://www.draeger.com>

3703556 – RI 03 en  
© Drägerwerk AG & Co. KGaA  
Edition: 3 – 2023-02  
(Edition: 1 – 2019-03)



Dräger reserves the right to make modifications to the equipment without prior notice.