

Instructions for use

Infinity[®] Gateway Suite

WARNING

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

**ADT Configuration Guide
Software VF9.0**

General information

Trademarks

The Dräger name and logo are registered trademarks of Dräger.

Infinity® is a registered trademark of Dräger.

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

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

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.
Rx only	Caution: 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.

Follow 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 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.

Intended application

The intended application of the Infinity Gateway software applications is data exchange between the Infinity network and the hospital network. This device is an active, reusable, and non-implantable medical device. It does not come into direct contact with the patient's body.

Contents

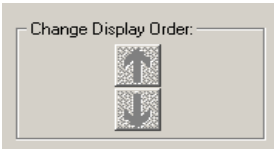
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Feature	Description	Maximum Character Length
Show	Controls whether an entry is displayed or hidden in Gateway.	N/A
String	Used to customize data lists for race, religion, etc.	16 (40 for allergy)
HIS Code	Used in the hospital information system to denote the particular race, religion, primary language, nationality, allergy, or ethnicity.	4
ADT Code	An internal code used between the HL7 server and Innovian. NOTE: Some ADT codes cannot be changed.	N/A
Change Display Order	Use to customize the order in which the selection is displayed in Innovian.	N/A

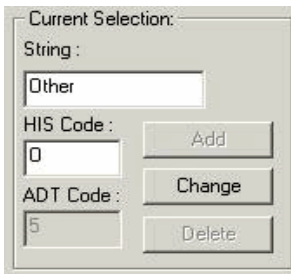
Change the display order

- 1 Select the entry you want to move.
- 2 Use the arrows to change the order in which the entry is displayed.



Change strings, HIS codes, and ADT codes

- 1 Select the entry to change.
- 2 Enter new text or codes into the **Current Selection** fields.
- 3 Click **Change**.



Show or hide entries

Select or deselect the check box to show or hide an entry respectively.

<input checked="" type="checkbox"/>	Show	String	HIS Code	ADT Code
<input checked="" type="checkbox"/>		Unknown	U	1
<input checked="" type="checkbox"/>		Caucasian	W	2

Select or deselect the check box next to **Show** to show or hide all of the entries; however, at final configuration, at least one entry must be set to **Show**.

<input checked="" type="checkbox"/>	Show
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These instructions for use only apply to
**Infinity® Gateway Suite ADT Configuration
Guide 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.



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3703518 – RI 02 en
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Edition: 3 – 2023-02
(Edition: 1 – 2019-03)



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