Instructions for Use

Infinity Acute Care System

WARNING

For a full understanding of the performance characteristics of this medical device, the user should carefully read these Instructions for Use before use of the medical device.

Workstation Critical Care
and
Workstation Neonatal Care
Trademarks

Infinity®, Acute Care System™, and Medical Cockpit™ are trademarks owned by Dräger.

Definitions

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

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

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

**For Your Safety and that of Your Patients**  
- 4

**General WARNINGS and CAUTIONS**  
- 5

**Application**  
- 7

- Intended Use of Workstation Critical Care  
- 7

- Intended Use of Workstation Neonatal Care  
- 7

- Environment of Use  
- 7

**System Overview**  
- 8

**Technical Data**  
- 10

**EMC Declaration**  
- 10

**Index**  
- 15

**For Your Safety and that of Your Patients**  
- 4

**General WARNINGS and CAUTIONS**  
- 5

**Application**  
- 7

- Intended Use of Workstation Critical Care  
- 7

- Intended Use of Workstation Neonatal Care  
- 7

- Environment of Use  
- 7

**System Overview**  
- 8

**Technical Data**  
- 10

**EMC Declaration**  
- 10

**Index**  
- 15
For Your Safety and that of Your Patients

Strictly follow these Instructions for Use

**WARNING**
Any use of the medical device requires full understanding and strict observation of all portions of these Instructions for Use. The medical device is only to be used for the purpose specified under "Intended Use of Workstation Critical Care" and "Intended Use of Workstation Neonatal Care" on page 7 and in conjunction with appropriate patient monitoring (see page 5). Strictly observe all statements throughout these Instructions for Use and throughout all associated Instructions for Use and all statements on medical device labels.

**WARNING**
Do not use the medical device in an oxygen-enriched environment. The medical device is only suitable for use in rooms with adequate ventilation. Medical device malfunctions can increase the O2 concentration in the ambient air. Fire hazard.

**Safe connection with other electrical equipment**

**WARNING**
Electrical connections to equipment not listed in these Instructions for Use should only be made following consultation with the respective manufacturers of such equipment.

**Accessories**

**WARNING**
Only the accessories indicated on the List of Accessories Evita Infinity V500 9039085 or List of Accessories Babylog VN500 9039002 (1st edition or higher) have been tested and approved to be used with the medical device. Accordingly it is strongly recommended that only these accessories be used in conjunction with the specific medical device. Otherwise the correct functioning of the medical device may be compromised.

**Networking**

Device combinations approved by Dräger (see Instructions for Use of the individual devices or units) meet the requirements set forth by the following standards:
- IEC 60601-1 (EN 60601-1)
  Medical electrical equipment
  Part 1: General requirements for safety
- IEC 60601-1-1 (EN 60601-1-1)
  Medical electrical equipment
  Part 1-1: General requirements for safety
  Collateral standard: Safety requirements for medical electrical systems
- IEC 60601-1-2 (EN 60601-1-2)
  Medical electrical equipment
  Part 1-2: General requirements for safety
  Collateral standard: Electromagnetic compatibility; Requirements and tests

**Not for use in areas of explosion hazard**

**WARNING**
This medical device is neither approved nor certified for use in areas where combustible or explosive gas mixtures are likely to occur.
For Your Safety and that of Your Patients

– IEC 60601-1-4 (EN 60601-1-4)
  Medical electrical equipment
  Part 1-4: General requirements for safety
  Collateral standard: Programmable electrical
  medical systems

When Dräger devices or units are linked with other
Dräger or third-party devices and the resulting
combination is not approved by Dräger, the
operator is responsible for ensuring that the
resulting system meets the requirements set forth
by the above standards.
Follow Assembly Instructions and Instructions for
Use for each networked device.

Patient safety
The design of the medical device, the
accompanying literature, and the labeling on the
medical device take into consideration that the
purchase and use of the medical device are
restricted to trained professionals, and that certain
inherent characteristics of the medical device are
known to the trained operator. Instructions,
warnings, and caution statements are limited,
therefore, largely to the specifics of the Dräger
design.
This publication does not contain references to
various hazards which are obvious to a medical
professional and operator of this medical device, to
the consequences of medical device misuse, and
to potentially adverse effects in patients with
abnormal conditions. Medical device modification
or misuse can be dangerous.

Patient monitoring
The operators of the medical device are
responsible for choosing appropriate safety
monitoring that supplies adequate information on
medical device performance and patient condition.
Patient safety may be achieved through a wide
variety of means ranging from electronic
surveillance of medical device performance and
patient condition, to simple, direct observation of
clinical signs.
The responsibility for the selection of the best level
of patient monitoring lies solely with the medical
device operator.

Functional safety
The essential performance is described in the
associated Instructions for Use.

General WARNINGS and CAUTIONS

The following WARNINGS and CAUTIONS apply to
general operation of the device. WARNINGS and
CAUTIONS specific to subsystems or particular
features appear with those topics in later sections
of these Instructions for Use or in the Instructions
for Use of any Infinity unit or any other product
being used with this device.

**WARNING**
The medical device is intended for use in
health care facilities only. It must be operated
exclusively by qualified medical personnel
with specific training and experience in its
use, in order to provide immediate corrective
action in case of a malfunction.
For Your Safety and that of Your Patients

Note on EMC/ESD risk for the device function

General information on electromagnetic compatibility EMC/ESD pursuant to international EMC standard IEC 60601-1-2:

Electromedical devices are subject to special precautionary measures concerning electromagnetic compatibility (EMC) and must be installed and put into operation in accordance with the EMC information provided (see "EMC Declaration" on page 10).

Portable and mobile RF communications equipment can affect medical electrical equipment.

**WARNING**

Connector pins with an electrostatic discharge (ESD) warning sign should not be touched and no connections should be made between these connectors without implementing ESD protective measures. Such precautionary procedures may include antistatic clothing and shoes, the touch of a ground stud before and during connecting the pins or the use of electrically isolating and antistatic gloves. All staff involved in the above shall receive instruction in these ESD precautionary procedures.

Restriction of distribution

**CAUTION**

Federal Law (U.S.) restricts this device to sale by or on the order of a physician.
Application

Intended Use of Workstation Critical Care

The Infinity Acute Care System Workstations Critical Care consist of monitoring and control displays and additional therapy units. They are intended to be used as integrated, networked, and configurable workstations to provide critical care specific therapy.

The Infinity Acute Care System Workstations Critical Care are intended to be used by qualified and trained medical personnel.

Intended Use of Workstation Neonatal Care

The Infinity Acute Care System Workstations Neonatal Care consist of monitoring and control displays and additional therapy units. They are intended to be used as integrated, networked, and configurable workstations to provide specific therapy in neonatal intensive care.

The Infinity Acute Care System Workstations Neonatal Care are intended to be used by qualified and trained medical personnel.

Environment of Use

Suitable for stationary use in hospitals or hospital-like facilities or for intrahospital patient transport.

Restrictions may be applied in relation to the operational environment. Any such restrictions are indicated in the Instructions for Use of the specific units or devices that are components of the Workstations Critical Care or Neonatal Care Workstations. These restrictions must be observed.
System Overview

The modular workstations provide standardized care processes and procedures across all care areas. All functional units of a workstation can be used in different care environments. Workstations are configured to custom requirements. They consist of monitoring and control displays and additional units, devices, or accessories.

The Workstation Critical Care and Workstation Neonatal Care may consist of the following units:

A. Display unit
   - Infinity Medical Cockpit
   For a detailed description of the display unit, see Instructions for Use "Infinity Acute Care System: Infinity Medical Cockpits".

B. Ventilation unit
   - Evita Infinity V500
   For a detailed description of the ventilation unit, see Instructions for Use "Infinity Acute Care System: Evita Infinity V500".
   - Babylog VN500
   For a detailed description of the ventilation unit, see Instructions for Use "Infinity Acute Care System: Babylog VN500".

C. Trolley (optional)
   - Trolley 2 - 90 cm (35.43 inch)
   For a detailed description of the trolley, see Instructions for Use "Infinity Acute Care System: Evita Infinity V500" or Instructions for Use "Infinity Acute Care System: Babylog VN500".

D. Gas supply unit GS 500 (optional)
   For a detailed description of the gas supply unit, see Instructions for Use "Infinity Acute Care System: Evita Infinity V500" or Instructions for Use "Infinity Acute Care System: Babylog VN500".

E. Optional
The Workstation Critical Care and Workstation Neonatal Care may also be combined with a:

**F** Nebulizer
For a detailed description, see the Instructions for Use of the device used.

**G** Humidifier
For a detailed description, see the Instructions for Use of the device used.

**H** Other Dräger and third-party devices and accessories (see List of Accessories Evita Infinity V500 or List of Accessories Babylog VN500).
Technical Data

EMC Declaration

General information

When using wireless networking, be aware that the system operates at 2.4 GHz range. Other equipment, even if compliant with CISPR emission requirements, could interfere with reception of wireless data. When selecting new wireless systems (e.g., cell phones, pager systems, cordless phones, etc.) for use in installations where wireless networking is used, care should always be used to ensure that operating frequencies are compatible. For example, selecting cordless phones that operate at 2.4 GHz will likely cause difficulty with the phones and networking components. Low-level signals such as ECG are particularly susceptible to interference from electromagnetic energy. While the equipment meets the testing described below, it will not ensure perfect operation, the ‘quieter’ the electrical environment the better. In general, increasing the distance between electrical devices decreases the likelihood of interference.

NOTE

Detailed radio frequency characteristics: 2412 to 2472 MHz, direct-sequence spread spectrum (DSSS) IEEE 802.11b compliant, limited to 100 mW. Applicable to both access points and client adaptors. When used with 802.15.1 wireless, the device will transmit with the following characteristics: 2400 to 2485 MHz, Frequency Hopping Spread Spectrum (FHSS), limited to 2.5 mW. See the documentation that accompanies the wireless products for further details.

The EMC declaration applies to the Workstation Critical Care and Workstation Neonatal Care.

The EMC conformity of medical devices includes the use of the external cables and accessories (see List of Accessories 9039085 or 9039002).

The medical device should not be used adjacent to or stacked with other equipment; if adjacent or stacked use is inevitable, the medical device should be observed to verify normal operation in the configuration in which it will be used. In any case observe the Instructions for Use of the other devices.
Electromagnetic emissions

The medical device is intended for use in the electromagnetic environment specified below. The user should assure that it is used in such an environment.

<table>
<thead>
<tr>
<th>Emissions</th>
<th>Compliance according to</th>
<th>Electromagnetic environment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Radio frequency emission (CISPR 11)</td>
<td>Group 1</td>
<td>The medical device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.</td>
</tr>
<tr>
<td></td>
<td>Class A</td>
<td>The medical device is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.</td>
</tr>
<tr>
<td>Harmonic emissions (IEC 61000-3-2)</td>
<td>Not applicable</td>
<td>Not applicable because the RF emissions comply with Class A.</td>
</tr>
<tr>
<td>Voltage fluctuations/flicker (IEC 61000-3-3)</td>
<td>Not applicable</td>
<td>Not applicable because the RF emissions comply with Class A.</td>
</tr>
</tbody>
</table>

Information regarding electromagnetic emissions (IEC 60601-1-2, table 201)
Electromagnetic immunity

The medical device is intended for use in the electromagnetic environment specified below. The user should assure that it is used in such an environment.

<table>
<thead>
<tr>
<th>Immunity against</th>
<th>IEC 60601-1-2 test level</th>
<th>Compliance level (of Workstation Critical Care and Workstation Neonatal Care)</th>
<th>Electromagnetic environment</th>
</tr>
</thead>
</table>
| Electrostatic discharge / ESD (IEC 61000-4-2) | Contact discharge: ±6 kV | ± 2, 4, 6 kV | Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
| | Air discharge: ±8 kV | ± 2, 4, 8 kV, except interfaces bearing an ESD symbol 📜 |
| Electrical fast transient / bursts (IEC 61000-4-4) | Power supply lines: ±2 kV | ±2 kV | Mains power quality should be that of a typical commercial or hospital environment.
| | Longer input / output lines: ±1 kV | ±1 kV |
| Surge on AC mains lines (IEC 61000-4-5) | Common mode: ±2 kV | ±2 kV | Mains power quality should be that of a typical commercial or hospital environment.
| | Differential mode: ±1 kV | ±1 kV |
| Power frequency magnetic field (50/60 Hz) (IEC 61000-4-8) | 3 A/m | 3 A/m | Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment. |
### Technical Data

<table>
<thead>
<tr>
<th>Immunity against</th>
<th>IEC 60601-1-2 test level</th>
<th>Compliance level (of Workstation Critical Care and Workstation Neonatal Care)</th>
<th>Electromagnetic environment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Voltage dips and short interruptions on AC mains input lines (IEC 61000-4-11)</td>
<td>Dip &gt;95 %, 0.5 periods</td>
<td>&gt;95 %, 0.5 periods</td>
<td>Mains power quality should be that of a typical commercial or hospital environment. If the user of the Workstation Critical Care and Workstation Neonatal Care requires continued operation during power mains interruptions, it is recommended that the Workstation Critical Care and Workstation Neonatal Care be powered from an uninterruptible power supply or a battery.</td>
</tr>
<tr>
<td></td>
<td>Dip 60 %, 5 periods</td>
<td>60 %, 5 periods</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Dip 30 %, 25 periods</td>
<td>30 %, 25 periods</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Dip &gt;95 %, 5 seconds</td>
<td>&gt;95 %, 5 seconds</td>
<td></td>
</tr>
<tr>
<td>Radiated RF (IEC 61000-4-3)</td>
<td>80 MHz to 2.5 GHz: 10 V/m for life-supporting functions 3 V/m for non-life-supporting functions</td>
<td>10 V/m</td>
<td>Recommended separation distance from portable and mobile RF transmitters with transmission power PEIRP to the Workstation Critical Care and Workstation Neonatal Care including its lines: (1.84 m x √PEIRP)¹</td>
</tr>
<tr>
<td>Conducted RF (IEC 61000-4-6)</td>
<td>150 kHz to 80 MHz within ISM bands: 10 V for life-supporting functions 3 V for non-life-supporting functions</td>
<td>10 V</td>
<td>Recommended separation distance from portable and mobile RF transmitters with transmission power PEIRP to Workstation Critical Care and Workstation Neonatal Care including its lines: (1.84 m x √PEIRP)¹</td>
</tr>
<tr>
<td></td>
<td>150 kHz to 80 MHz: 3 V outside of ISM bands ²</td>
<td>3 V</td>
<td></td>
</tr>
</tbody>
</table>

¹ For PEIRP the highest possible “equivalent isotropic radiated power” of the adjacent RF transmitter has to be inserted (value in Watt). Also in the vicinity of equipment marked with the symbol interference may occur. Field strengths from fixed, portable or mobile RF transmitters at the location of the equipment should be less than 3 V/m in the frequency range from 150 kHz to 2.5 GHz and less than 1 V/m below 150 kHz or above 2.5 GHz.

²
Technical Data

2) ISM bands in this frequency range are: 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; 40.66 MHz to 40.70 MHz.

Information regarding electromagnetic emissions (IEC 60601-1-2, tables 202, 203, and 204)

Recommended separation distances

<table>
<thead>
<tr>
<th>Max. PEIRP (W)</th>
<th>150 kHz to 2.5 GHz</th>
<th>all other frequencies</th>
<th>Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.001</td>
<td>0.06 m (0.20 ft)</td>
<td>0.17 m (0.56 ft)</td>
<td></td>
</tr>
<tr>
<td>0.003</td>
<td>0.10 m (0.33 ft)</td>
<td>0.30 m (0.98 ft)</td>
<td></td>
</tr>
<tr>
<td>0.010</td>
<td>0.18 m (0.59 ft)</td>
<td>0.55 m (1.80 ft)</td>
<td></td>
</tr>
<tr>
<td>0.030</td>
<td>0.32 m (1.05 ft)</td>
<td>0.95 m (3.12 ft)</td>
<td>e.g., WLAN 5250 / 5775 (Europe)</td>
</tr>
<tr>
<td>0.100</td>
<td>0.58 m (1.90 ft)</td>
<td>1.73 m (5.68 ft)</td>
<td>e.g., WLAN 2440 (Europe), Bluetooth</td>
</tr>
<tr>
<td>0.200</td>
<td>0.82 m (2.69 ft)</td>
<td>2.46 m (8.07 ft)</td>
<td>e.g., WLAN 5250 (outside Europe)</td>
</tr>
<tr>
<td>0.250</td>
<td>0.91 m (2.99 ft)</td>
<td>2.75 m (9.02 ft)</td>
<td>e.g., DECT devices</td>
</tr>
<tr>
<td>1.000</td>
<td>1.83 m (6.00 ft)</td>
<td>5.48 m (17.98 ft)</td>
<td>e.g., GSM 1800- / GSM 1900- / UMTS mobile telephones, WLAN 5600 (outside Europe)</td>
</tr>
<tr>
<td>2.000</td>
<td>2.60 m (8.53 ft)</td>
<td>7.78 m (25.52 ft)</td>
<td>e.g., GSM 900 mobile telephones</td>
</tr>
<tr>
<td>3.000</td>
<td>3.16 m (10.37 ft)</td>
<td>9.49 m (31.14 ft)</td>
<td></td>
</tr>
</tbody>
</table>

Information regarding separation distances
(IEC 60601-1-2, tables 205 and 206)
## Index

<table>
<thead>
<tr>
<th>A</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Accessories</td>
<td>4</td>
</tr>
<tr>
<td>Application</td>
<td>7</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>C</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Caution</td>
<td>2</td>
</tr>
<tr>
<td>definition</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>D</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Display unit</td>
<td>8</td>
</tr>
<tr>
<td>Distribution</td>
<td>6</td>
</tr>
<tr>
<td>Restriction of</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>E</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Electrical equipment, connections with other</td>
<td>4</td>
</tr>
<tr>
<td>Electromagnetic emissions</td>
<td>11</td>
</tr>
<tr>
<td>Electromagnetic immunity</td>
<td>12</td>
</tr>
<tr>
<td>EMC Declaration</td>
<td>10</td>
</tr>
<tr>
<td>Emissions, electromagnetic</td>
<td>11</td>
</tr>
<tr>
<td>Environment of Use</td>
<td>7</td>
</tr>
<tr>
<td>Essential performance</td>
<td>5</td>
</tr>
<tr>
<td>Explosion hazard, areas of</td>
<td>4</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>F</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Functional safety</td>
<td>5</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>H</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Humidifier</td>
<td>9</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>I</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Immunity, electromagnetic</td>
<td>12</td>
</tr>
<tr>
<td>Infinity Medical Cockpits</td>
<td>8</td>
</tr>
<tr>
<td>Intended Use</td>
<td>7</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>N</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Nebulizer</td>
<td>9</td>
</tr>
<tr>
<td>Networking</td>
<td>4</td>
</tr>
<tr>
<td>Note</td>
<td>2</td>
</tr>
<tr>
<td>definition</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>P</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient monitoring</td>
<td>5</td>
</tr>
<tr>
<td>Patient safety</td>
<td>5</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>S</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Separation distances, recommended</td>
<td>14</td>
</tr>
<tr>
<td>System Overview</td>
<td>8</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>T</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Technical Data</td>
<td>10</td>
</tr>
<tr>
<td>Trolley 2 - 90 cm</td>
<td>8</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>V</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Ventilation unit</td>
<td>8</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>W</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Warning</td>
<td>2</td>
</tr>
<tr>
<td>definition</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>W</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Warnings and Cautions, General</td>
<td>5</td>
</tr>
</tbody>
</table>
Directive 93/42/EEC concerning Medical Devices

Manufacturer:

Dräger Medical GmbH
Molslinger Allee 53 – 55
D-23542 Lübeck
Germany
+49 451 8 82-0
FAX +49 451 8 82-20 80
http://www.draeger.com

Distributed in the U.S. by

Draeger Medical, 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

As of 2015-08:
Dräger Medical GmbH changes to
Drägerwerk AG & Co. KGaA