

# Data module compact<sup>plus</sup>

Instructions for use

**en** English version 1.0



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# 1 About this document

## 1.1 Purpose


These instructions for use are part of the device and describe how to use the device safely and correctly.

- Read these instructions for use before using this device.
- Keep these instructions for use available near the device.
- Read and follow other applicable documents.

## 1.2 Scope of application

The Data module compact<sup>plus</sup> is intended for use only in a clinical and/or hospital environment. It is not suitable for use in home healthcare environment, ambulances or during air transportation.

## 1.3 Signs, symbols and tags


| Symbol  | Meaning   |
|---|---|
| •   | Prerequisite  |
| •   | Handling step: Follow the specified instructions.                     |
|  | Warning symbol, introduces a warning.                                 |
| Note:   | Information for a better understanding or to optimise work processes. |

# About this document

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## 1.4 Warnings

Various warnings are used in these instructions for use with the following meaning:

| Symbol   | Meaning  |
|--|--|
| <br>WARNING | Danger for people.<br>Non-compliance could lead to death or serious injuries.  |
| CAUTION  | Risk of damage or incorrect operation. Non-compliance could lead to material damage to the device or to incorrect operation. |

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## 1.5 Abbreviations

| Abbreviation | Meaning   |
|--------------|---|
| BCC          | Bedside Communication Controller (proprietary communication protocol for communication with a patient data management system) |
| CF           | Protection class for patient discharges (cardiac float)   |
| DHCP         | Communication protocol (Dynamic Host Configuration Protocol)  |
| DIN          | Deutsches Institut für Normung (German Institute for Standardization)   |
| EAP          | Extensible Authentication Protocol  |
| EMC          | Electromagnetic compatibility   |
| ESD          | Electrostatic discharge   |
| ETSI         | European Telecommunications Standards Institute   |
| FCC          | Federal Communications Commission   |
| GNU          | Free software license (general public license)  |
| HDMI         | Interface for digital image and audio transmission (High Definition Multimedia Interface)                                     |
| HF           | High frequency  |
| IEC          | International Electrotechnical Commission   |
| IEEE         | Institute of Electrical and Electronics Engineers   |

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# About this document












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| Abbreviation | Meaning  |
|--------------|--|
| IP address   | Internet Protocol address<br>(address for the identification of a network member)                                      |
| LAN          | Local area network   |
| LEAP         | Method for authenticating WLAN devices<br>(Lightweight Extensible Authentication Protocol)                             |
| LED          | Light Emitting Diode   |
| MAC          | Media access control (address for unique identification of a network member on the internet/intranet/hospital network) |
| Mini DIN 9   | 9-pin connection (serial interface for data communication)   |
| MR           | Magnetic resonance device  |
| PEAP         | Protected Extensible Authentication Protocol   |
| PSK          | Encryption method for wireless local networks (pre-shared key)   |
| QAC          | Disinfectant   |
| RJ-45        | Network connection for LAN cable   |
| RS-232       | Recommended standard for serial interfaces   |
| SNR          | Signal-to-noise ratio  |
| TKIP         | Security protocol for WLAN networks<br>(Temporal Key Integrity Protocol)   |
| TLS          | Protocol for the encryption of data transmissions<br>(Transport Layer Security)  |
| TTLS         | Protocol for the encryption of data transmissions<br>(Tunnelled Transport Layer Security)                              |
| USB          | Universal Serial Bus (interface for the connection of external devices)  |
| WEP          | Encryption method for wireless local networks<br>(Wired Equivalent Privacy)  |
| WLAN         | Wireless local area network  |
| WPA, WPA2    | Encryption methods for wireless local networks<br>(Wi-Fi protected access)   |

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# Symbols on the product and packaging

## 2 Symbols on the product and packaging

| Symbol  | Meaning   |
|---|---|
|    | Consult instructions for use  |
|    | Follow instructions for use   |
|    | Labelling of electric and electronic devices according to directive 2012/19/EC (WEEE) |
|    | CE marking  |
|    | Alternating current   |
|   | Catalogue number  |
|  | Batch number  |
|  | Serial number   |
|  | Date of manufacture (year-month-day)  |
|  | Manufacturer  |
|  | Humidity limitation   |

| Symbol   | Meaning   |
|--|---|
|   | Temperature limit                                     |
|   | Atmospheric pressure limitation                       |
|   | Not MRI safe  |
|   | Non-ionizing electromagnetic radiation (Wireless LAN) |
|   | Federal Communications Commission Registration        |
|  | Medical Device  |

# Intended use

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## 3 Intended use

The Data module compact<sup>plus</sup> is intended for use as the central interface for an individual patient bed for connecting the compact<sup>plus</sup> infusion system to an external IT system for data communication and alarm management. External IT systems can be connected via a network or via the connections provided on the Data module compact<sup>plus</sup> using accessories specified by B. Braun.

Therapeutic or diagnostic decisions must not be taken exclusively based on the data provided electronically by the Data module compact<sup>plus</sup>. In particular, interpreting the alarm data sent electronically by the Data module compact<sup>plus</sup> does not mean that the nursing staff no longer have to monitor the patient in their bed.

# Safety instructions

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## 4 Safety instructions

- Read the safety instructions before using the device and observe them.

### 4.1 General

- These instructions for use are part of the Data module compact<sup>plus</sup> and are a prerequisite for correct use.
- The instructions for use should be kept available near the Data module compact<sup>plus</sup> at all times.
- Only use the Data module compact<sup>plus</sup> if you have received training on its use and are familiar with it.
- If the device is dropped or subjected to external forces: stop using the device and have it tested by an authorised service workshop.
- Protect the device against moisture.
- Ensure that the electrical connections are undamaged and dry.
- No organisation system other than the Station compact<sup>plus</sup> may be used with the device. Devices from other B.Braun pump generations or from other manufacturers may not be used.

### 4.2 Testing after delivery

Check the delivery. Transport damage may occur even if the device has been carefully packaged.

Therefore, check that the device is complete and undamaged immediately after unpacking it. Do not use damaged devices or cables! Inform the service department.

### 4.3 Software

- Users are instructed to find out about the most recent changes to the device and its accessories after each software update.
- The integrated web interface of the Data module compact<sup>plus</sup> can be used to find out which software version is used.

### 4.4 Transport and storage

- Devices stored in temperature ranges below the defined operating conditions must be kept at room temperature for at least one hour before being powered on.

### 4.5 Set-up and start-up



**WARNING!** Defective devices must be disconnected from the mains immediately, removed from service and inspected by service personnel.

- Any serious incident that has occurred in relation to this product should be reported to B.Braun and the competent authority of the country in which the product is operated.
- The Data module compact<sup>plus</sup> may only be docked in a correctly assembled Station compact<sup>plus</sup> (see the Station compact<sup>plus</sup> instructions for use).
- The Data module compact<sup>plus</sup> and the Station compact<sup>plus</sup> mains connections must be kept dry and free of particles during docking.



# Safety instructions

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- Disconnect the Data module compact<sup>plus</sup> mains connection during docking, removal, or when changing the configuration.
- External surfaces must be disinfected when the device is to be used for a new patient.

## 4.6 Patient safety

- The user must be certain of the Data module compact<sup>plus</sup> functional reliability and that it is in good condition before using.
- Functional checks and safety checks must be performed separately for all additionally connected devices.
- Check and establish mains connection and additional plug connections.
- Observe the voltage information on the rating plate! (See section 9.1)

## 4.7 Operation

- Read the instructions for use for the pumps used and the Station compact<sup>plus</sup> carefully.

## 4.8 Safe handling

- All cable connections, pumps and Station compact<sup>plus</sup> must be disconnected before cleaning/disinfection.
- Close the cover caps of the Data module compact<sup>plus</sup> plug connections before cleaning.
- Make sure that the introductory training on the device is given by a B. Braun sales representative or another authorised person.

- Ensure that the device is properly positioned and secured, and that it is level in the Station compact<sup>plus</sup>.
- Make sure that the status LEDs light up during the self-test.
- Avoid mechanical effects on the device.
- Only connect the power cable once the system has been set-up.
- Do not operate the device near inflammable anaesthetics.

## 4.9 Safety Standards and informations

Data module compact<sup>plus</sup> satisfies all safety standards for medical electrical devices in compliance with IEC 60601-1:2005  
IEC 60601-1:2005 /AMD1:2012  
IEC 60601-1-6:2010  
IEC 60601-1-6:2010/AMD1:2013  
IEC 60601-1-8:2006  
IEC 60601-1-8:2006/AMD1:2012  
IEC 60601-1-12:2014  
IEC 60601-2-24:2012  
The EMC-limits (electro-magnetic compatibility) according to IEC 60601-1-2:2007 and IEC 60601-2-24:2012 are maintained.




**WARNING!** If the equipment is operated in the vicinity of other equipment which may cause high levels of interference (e.g. RF surgical equipment, nuclear spin tomography units, mobile telephones etc.), this equipment may be disturbed.


# Safety instructions


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Maintain the protective distances recommended by the manufacturers of these devices.

 **WARNING!** The use of this device adjacent to or stacked with other equipment has to be avoided. Nevertheless, if adjacent or stacked use is necessary, the Data module compact<sup>plus</sup> and the other devices have to be observed to verify normal operation in the configuration in which it will be used.


**Note:** A list of equipment with which the Data module compact<sup>plus</sup> has been tested in a stacked or adjacent configuration and with which stacked or adjacent use is permitted can be found in section 4.10.

 **WARNING!** The Data Module compact<sup>plus</sup> needs special precautions regarding EMC. The device must be set up, powered on and serviced in accordance with the EMC information in section 9. The safe distances and ambient/operation conditions specified in section 9 must be ensured and complied with.

 **WARNING!** Portable and mobile RF communications equipment can affect medical electrical equipment. Portable RF communications equipment (radio communications equipment) (including its accessories, e.g. antenna cables) should not be used closer to the Data module compact<sup>plus</sup> than the safe distance specified in section 9. Non-compliance could lead to a decrease in the device's performance.

- The Data module compact<sup>plus</sup> is used in a clinical and/or hospital environment. Users are physicians, nurses, BioMeds, pharmacists, IT staff and business management. Operators have to be trained according to the B. Braun training guidelines.
- All configurations must comply with system standard IEC 60601-1.
- The user must ensure that the system components have been correctly locked.
- Do not position the device above the patient or any other person.

## 4.10 Accessories

 **WARNING!** The use of accessories, transducers and cables other than those specified, with the exception of those sold by B. Braun Melsungen AG as replacement parts for internal components, may result in increased emissions or decreased immunity of the Data module compact<sup>plus</sup>.

- Only original replacement parts may be used.

Equipment, accessories, transducers and cables with which B. Braun Melsungen AG claims compliance with the requirements of the standards in section 4.9 and which are recommended:

- Perfusor® compact<sup>plus</sup> (8717030)
- Infusomat® compact<sup>plus</sup> (8717050)
- Infusomat® compact<sup>plus</sup> P (8717070)
- Station compact<sup>plus</sup> (8717141)
- Cover compact<sup>plus</sup> (8717145)
- Ethernetcable CAT6 or higher, maximum 20 m.

# Safety instructions

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**Note:** Special informations with regard to EMC are included in the separate instruction manuals for use for each relevant accessory.

## 4.11 Electrical connection

- Do not use the device if the plug has visible damage.
- Do not use the device if the electrical connection to the Station compact<sup>plus</sup> has visible damage.
- The power cable must be positioned so that it can be removed any time.
- The power and connection cables must be positioned so as not to present a trip hazard or hinder work with the Station compact<sup>plus</sup>.



### **WARNING! Risk of death from electric shock**

- Only use small quantities of cleaning fluids to clean the electrical plugs.



### **WARNING! Risk of death from electric shock**

- To prevent the risk of an electric shock, this device must only be connected to a mains power supply with a protective earth conductor and a residual current operated circuit breaker.

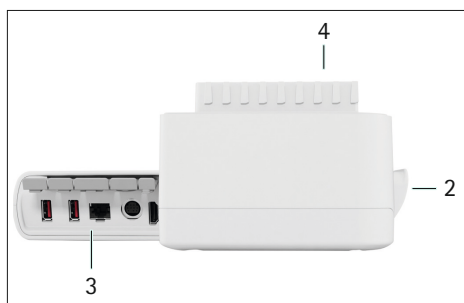
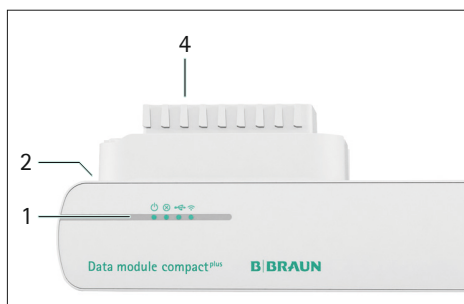
## 4.12 Maintenance

- Servicing and maintenance must only be performed by trained and qualified service personnel.

# Overview of functions

## 5 Overview of functions

The Data module compact<sup>plus</sup> allows external data communication for up to 18 pumps or six Station compact<sup>plus</sup> and supplies mains voltage for up to 12 pumps or four Station compact<sup>plus</sup>.



| No. | Name  |
|-----|---|
| 1   | LED operational status indicator (LED):   |
| 2   | Connection for power cable  |
| 3   | Connection panel with cover caps  |
| 4   | Connection mechanism for Station compact <sup>plus</sup> with integrated network and communication connection |

# Assembly

## 6 Assembly

- Station compact<sup>plus</sup> power cable removed
- Data module compact<sup>plus</sup> power cable removed
- Station compact<sup>plus</sup> mounted on a wall rail, infusion stand or vertical tube

### 6.1 Permitted Station compact<sup>plus</sup> and Data module compact<sup>plus</sup> combinations



A Data module compact<sup>plus</sup> ensures data communication for up to six Station compact<sup>plus</sup>. For this purpose, individual Station compact<sup>plus</sup> can be combined to create a pillar. Further information on the assembly and creation of individual pillars, as well as the permitted combinations, can be found in the instructions for use for the Station compact<sup>plus</sup>.

**CAUTION!** A pillar may consist of up to four Station compact<sup>plus</sup> and one Data module compact<sup>plus</sup>. A maximum of two pillars may be connected using one connecting cable. Connected pillars must not exceed the maximum of station compact<sup>plus</sup>. Each pillar must be completed with a Cover compact<sup>plus</sup>.

### 6.2 Station compact<sup>plus</sup> locking mechanism

In the case of a pillar with a maximum of four Station compact<sup>plus</sup>, the Data module compact<sup>plus</sup> is locked in place using the locking mechanism on the bottom Station compact<sup>plus</sup>.

The locking mechanism can be turned with a coin or a flat-headed screwdriver.

| Symbol  | Meaning  |
|---|--|
|  | Lock is open and the Data module compact <sup>plus</sup> can be docked/removed   |
|  | The lock is closed and the Data module compact <sup>plus</sup> is fixed to the Station compact <sup>plus</sup> . The red mark must be no longer visible. |

# Assembly

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**CAUTION!** The Data module compact<sup>plus</sup> is only correctly locked when the red marking on the Station compact<sup>plus</sup> is no longer visible.



## 6.3 Docking and removal of the Data module compact<sup>plus</sup>

In order to dock the Data module compact<sup>plus</sup> in the Station compact<sup>plus</sup>, please ensure that the Station compact<sup>plus</sup> is fixed to an infusion stand, a vertical tube or a wall rail (see the Station compact<sup>plus</sup> instructions for use).

When docking the Data module compact<sup>plus</sup>, please ensure that the power cable has been removed from the Station compact<sup>plus</sup> and Data module compact<sup>plus</sup>.

The Data module compact<sup>plus</sup> is assembled using the connection and locking mechanism on the underside of the Station compact<sup>plus</sup>. When operating a pillar with a maximum of four Station compact<sup>plus</sup> the Data module compact<sup>plus</sup> is fixed in place using the connection and locking mechanism on the bottom of the Station compact<sup>plus</sup> in the pillar.

In order to dock the Data module compact<sup>plus</sup>, the locking mechanism on the Station compact<sup>plus</sup> must be turned until the red mark is visible. The slot on the locking screw should then point to the opened lock symbol. The Data module compact<sup>plus</sup> is connected below the Station compact<sup>plus</sup> and fixed in place by the locking mechanism. The slot on the screw should point to the closed lock symbol.

To remove the Data module compact<sup>plus</sup>, the locking mechanism must be turned until the red mark is visible. The slot on the locking screw will then point to the opened lock symbol. When opening the locking mechanism, the Data module compact<sup>plus</sup> must be held securely and can then be separated from the Station compact<sup>plus</sup>. The locking mechanism on the Station compact<sup>plus</sup> should then be closed again. The slot on the screw should point to the closed lock symbol.

# Assembly

1. Open the locking mechanism on the bottom Station compact<sup>plus</sup>



2. Plug the Data module compact<sup>plus</sup> into the locking mechanism on the Station compact<sup>plus</sup> from below



3. Close the locking mechanism on the Station compact<sup>plus</sup>, until the red marking is no longer visible.



## 6.4 Connection to the mains power supply



### **WARNING! Risk of death from electric shock**

- The device must only be connected to a mains power supply with a protective conductor and a residual current operated circuit breaker.
- Connect the power cable with mains connection to the device.
- Position the power cable so that it does not present a trip hazard.
- Plug the power plug into the socket.
- The power cable must be positioned so that it can be removed any time.

# Operation

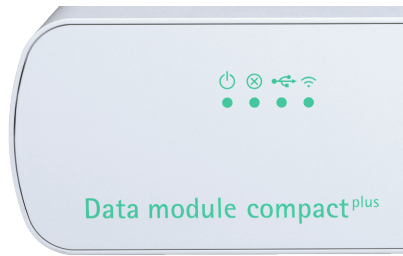
## 7 Operation

Plug the power cable in to switch on the Data module compact<sup>plus</sup>.  
 Pull the power cable out to switch off the Data module compact<sup>plus</sup>.



### 7.1 Data module compact<sup>plus</sup> status indicators















The Data module compact<sup>plus</sup> has four status indicators (LEDs) that indicate the current operating status.



| Symbol | Status LED      | Meaning   |
|--------|-----------------|---|
|        | OFF = OFF       | Mains power supply disconnected, Data module compact <sup>plus</sup> switched off     |
|        | ON = LIT UP     | Mains power supply active, Data module compact <sup>plus</sup> switched on            |
|        | OFF             | Start process completed, Data module compact <sup>plus</sup> ready for operation      |
|        | ON              | Start process active, Data module compact <sup>plus</sup> not yet ready for operation |
|        | FLASHING  (1Hz) | Update process active (e.g. software update)  |



# Operation

| Symbol   | Status LED  | Meaning  |
|--|---|--|
|   | FLASHING  (2Hz)    | Update process failed, fall back image active                            |
|   | FLASHING  (double) | Topology detection error, please check rack connection and configuration |
|   | FLASHING  (1 Hz)   | USB stick connected and processing completed, USB stick can be removed   |
|   | ON                 | Update has failed  |
|   | OFF                | No WLAN connection active  |
|   | ON                 | WLAN connection active   |
|  | FLASHING          | WLAN connection is being established                                     |

# Operation

## 7.2 Data communication interfaces

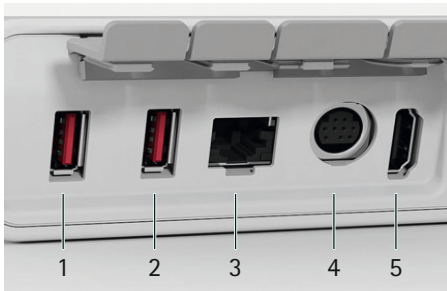
**⚠ WARNING!** Functional reliability is only guaranteed if accessories that have been approved, and therefore recommended by B. Braun Melsungen AG, are used.

The use of accessories, transducers or cables with medical electrical equipment and medical electrical systems other than those specified may result in increased emissions or decreased immunity of the medical electrical equipment or system.

**Note:** Recommended accessories are listed in section 4.10.

The Data module compact<sup>plus</sup> has a connection panel on the back for connecting external devices for the purpose of data communication. To protect liquid from getting into the connections, the connections are protected by cover caps. The data module compact<sup>plus</sup> has an integrated WLAN module for wireless network communication.

- Make sure that the cover caps of any connections not being used are completely closed.



| Connection | Meaning                             |
|------------|-------------------------------------|
| 1          | USB 2.0 (deactivated)               |
| 2          | USB 2.0 (deactivated)               |
| 3          | RJ-45 Ethernet<br>10/100/1000Mbit/s |
| 4          | Mini DIN 9 RS-232                   |
| 5          | HDMI (not in use)                   |

## 7.3 Standard data communication interface configuration

The Data module compact<sup>plus</sup> can be configured using an integrated web server. A new device has a default IP address for the RJ45 ethernet connection of **192.168.100.41**.

- Make sure that the configured IP address is only used once in your network.
- When using the WLAN function, we recommend using a dedicated VLAN/SSID for medical devices with a reserved bandwidth of 50 kb/s per Data module compact<sup>plus</sup>.
- When using the WLAN function, we recommend a signal strength of -65 dBm for the primary signal and a signal strength of -70 dBm for the secondary signal. The SNR (signal-to-noise ratio) should be  $15 \leq \text{dB}$ .
- When using the WLAN function, the encryption and authentication should be activated to secure the data connection.

# Operation

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| Parameter      | Setting     | As-delivered condition |
|----------------|-------------|------------------------|
| IP address LAN | Static      | 192.168.100.41         |
|                | DHCP        | -                      |
|                | Subnet mask | 255.255.255.0          |
|                | Gateway     | -                      |

## 7.4 Data module compact<sup>plus</sup> web interface


The Data module compact<sup>plus</sup> has an integrated web server that provides the "Data module compact<sup>plus</sup> web interface". The Data module compact<sup>plus</sup> web interface can be accessed via a standard web browser and is used for the technical configuration of the Data module compact<sup>plus</sup> interfaces and data protocols for the connection to the hospital's IT network.

Additional technical information on the configuration of interfaces and data protocols using the Data module compact<sup>plus</sup> web interface is available from B. Braun on request.


# Cleaning and maintenance

## 8 Cleaning and maintenance

- Power cable disconnected
- Data module compact<sup>plus</sup> removed from Station compact<sup>plus</sup>
- Cover caps on the connection panel to the rear of the unit are closed

 **WARNING!** Only use small quantities of cleaning fluids to clean the electrical plugs.

### 8.1 Cleaning and disinfecting the device

 **WARNING!** Risk of death from electric shock

- Disconnect the device from the mains power supply before cleaning

Clean the Data module compact<sup>plus</sup> with mild soap solution.

Do not use spray disinfectant on the mains connection.

**CAUTION!** Damage to the device

- The Data module compact<sup>plus</sup> must not be cleaned with cleaning agents that contain chlorine.

**Recommendation:** Disinfectants for wipe disinfection manufactured by B. Braun (e.g., Meliseptol). Allow the device to air dry for at least 1 min before operation. Do not spray into the openings on the device (openings for power input, interfaces, etc.). Observe all hygiene regulations!

Check the plug regularly for contamination (e.g., spilled liquids) and clean as required.

Substances from the groups of disinfectants listed below are approved, for normal cleaning according to the manufacturer's instructions:

| Group                                  | Active Substance   |
|--|--|
| Alcohols                               | 1-Propanol,<br>2-Propanol (Isopropanol),<br>Ethanol                    |
| QAC<br>(Quaternary ammonium compounds) | DDAC (Didecylidimethylammoniumchloride),<br>BAC (Benzalkoniumchloride) |
| Acids                                  | Citric Acid,<br>lactic acid,<br>acetic acid                            |
| Phenols                                | o-phenylphenol,<br>p-Chlor-m-cresol                                    |
| Peroxide                               | Hydrogen Peroxide,<br>Peracetic Acid,<br>Monoperoxyphthalhexahydrat    |
| Aldehydes                              | Glutaral,<br>Glyoxal,<br>Formaldehyde                                  |
| Alkylamines                            | N-(3-aminopropyl)-N-Dodecylpropan-1,3-Diamin,<br>Cocospopylendiamin    |

If you have any questions about the use of a particular disinfectant, please contact the manufacturer of the respective disinfectant.

**Note:** The use of unapproved cleaners and failure to follow the disinfection procedures and the manufacturer's recommended dilutions can result in an instrument malfunction.

# Cleaning and maintenance

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tion or product damage and could void the warranty.

- No pointed objects should be used for cleaning.

## 8.2 Maintenance and repair



**WARNING!** Risk of injury and/or malfunction from incorrect repair. The device does not contain any parts that the user can repair themselves.

- Do not repair defective devices independently.
- Send defective devices to B. Braun service.



**WARNING!** Risk of injury and/or malfunction from device modifications.

- Do not modify the device.

**Note:** Modifications and/or incorrect repair of medical devices can lead to a loss of guarantee/warranty claims and any authorisations.

- Replace damaged accessories with original accessories.

Regularly check, clean and disinfect the Data module compact<sup>plus</sup>. Check that the device is clean, intact and free of damage. Only use original replacement parts and accessories.

A safety check (SC) must be performed on the device every two years in accordance with the B. Braun checklist mentioned in the Service Manual. The service may only be performed by personnel who have received training from B. Braun.

## 8.3 Recycling the device

On-site disposal according to country-specific regulations. Old devices are taken back by B. Braun for disposal upon request.

## 8.4 Battery

The device is equipped with a modern lithium-ion battery that allows the device to shut down properly when it is disconnected from mains. The battery is charged by the device during mains operation.

- The battery should only be changed by a service technician.



**WARNING!** Risk from injury from the battery exploding or leaking.

- Do not open or burn the battery.

# Annex

## 9 Annex

### 9.1 Technical data

#### 9.1.1 Data module compact<sup>plus</sup>

| Parameter  | Value   |
|--|---|
| Operating conditions   |   |
| Temperature  | 5 °C ... 40 °C / 41 °F ... 104 °F   |
| Relative air humidity  | 30% ... 90% (without condensation)  |
| Atmospheric pressure   | 620 mbar ... 1060 mbar  |
| Storage conditions   |   |
| Temperature  | -20 °C ... 55 °C / -4 °F ... 131 °F   |
| Relative air humidity  | 20% ... 90% (without condensation)  |
| Atmospheric pressure   | 500 mbar ... 1060 mbar  |
| Dimensions (W x H x D)   | Approx. 243 x 92 x 235 mm   |
| Weight   | Approx. 1.2 kg  |
| Power supply   | Primary: 100 - 240 V ~<br>50 - 60 Hz  |
| Max. power consumption at  | 100 V      240V   |
| 4 Station compact <sup>plus</sup> with<br>pumps and Data module<br>compact <sup>plus</sup> | 455 VA      605 VA  |
| Classification (acc. to IEC 60601-1<br>and Regulation 2017/745 or acc. to<br>MDD/MDR)      | Type CF protection class I  |
| Class (MDD/MDR)  | I   |
| Type of protection   | IP 34 (protected against access with tools and<br>against water spray from any direction) |

# Annex

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| Parameter    | Value  |
|--------------|--|
| EMC          | DIN EN 60601-1:2006 (IEC 60601-1:2005)<br>DIN EN 60601-1-2:2007 (IEC 60601-1-2:2007)<br>DIN EN 60601-2-24:2015 (IEC 60601-2-24:2012) |
| Interfaces   | Cold device plug for mains voltage   |
| Safety check | Every 24 months  |

## Essential performance characteristics of the Data module compact<sup>plus</sup>

- None as defined by standard DIN EN 60601-1:2006 (IEC 60601-1:2005)

# Annex


## 9.1.2 Interfaces

| Parameter           | Value  |
|---------------------|--|
| Galvanic isolation  | External interfaces have galvanic isolation of 1.5 kV from the Data module compact <sup>plus</sup>   |
| USB interfaces      | 2 x USB 2.0 (deactivated)  |
| Ethernet interfaces | 1 x RJ45 with 10/100/1000Mbit/s  |
| Serial interfaces   | 1 x Mini DIN 9 RS-232  |
| HDMI interfaces     | HDMI type A (not in use)   |
| WLAN interfaces     | WiFi certificates:<br>Wi-Fi Alliance - 802.11a, 802.11b, 802.11g , 802.11n. WPA Enterprise, WPA2 Enterprise. Embedded Client Certification<br><br>Safety standards:<br>Wireless Equivalent Privacy (WEP)<br>Wi-Fi Protected Access (WPA)<br>IEEE 802.11i (WPA2).<br><br>Encryption:<br>Wireless Equivalent Privacy (WEP, RC4 Algorithm), Temporal Key Integrity Protocol (TKIP, RC4 Algorithm), Advanced Encryption Standard (AES, Rijndael Algorithm). Encryption key provisioning: Static (40 and 128 bit lengths). Pre-shared (PSK) dynamic: 802.1X Extensible Authentication Protocol. Types: EAP-TLS, EAP-TTLS, PEAP-GTC, PEAP-MSCHAPv2, PEAP-TLS, LEAP<br><br>Bandwidth 2.4 GHz: 20 MHz<br><br>Bandwidth 5 GHz: 20 MHz<br><br>Effective radiated power: ≤ 100 mW |



# Annex

## Wi-Fi Certifications

| Regulatory Domain    | Certifications   | Certification ID   |
|----------------------|--|--|
| ETSI                 | EN 300 328 v1.8.1<br>EN 301 893 v1.7.1<br>EN 60950-1:2006<br>+ A11:2009 + A1:2010 + A12:2011<br>EN 62311:2008<br>EN 301 489-1 v1.9.2<br>EN 301 489-17 v2.2.1   | N/A  |
| FCC                  | Modular Approval<br>15 Subpart B (Class B)<br>15.247 Subpart C (DTS)<br>15.407 Subpart E (DFS)   | SQG-WB45NBT  |
| Industry Canada (IC) | RSS-210 Issue 8<br>RSS-Gen Issue 3   | 3147A-WB45NBT  |
| MIC (Japan)          | STD-T71<br>Article 2 Item 19, Category WW<br>(2.4GHz Channels 1-13)<br>Article 2 Item 19-2, Category GZ<br>(2.4GHz Channel 14)<br>Article 2 Item 19-3 Category XW<br>(5150-5250 W52 & 5250-5350 W53) |  R 201-140137 |
| KC (Korea)           |  | MSIP-CRM-LAI-WB45NBT   |

# Annex

## Wi-Fi Specifications

| Feature                    | Description   |
|----------------------------|---|
| Wi-Fi Data Rates Supported | 802.11a (OFDM): 6, 9, 12, 18, 24, 36, 48, 54 Mbps<br>802.11b (DSSS, CCK): 1, 2, 5.5, 11 Mbps<br>802.11g (OFDM): 6, 9, 12, 18, 24, 36, 48, 54 Mbps<br>802.11n (OFDM, HT20, MCS 0-7): 6.5,13,19.5, 26, 39,52, 58.5, 72.2 Mbps<br>7.2,14.4, 21.7, 28.9,43.3, 57.8, 65 Mbps   |
| Modulation                 | BPSK @ 1, 6, 6.5, 7.2 and 9 Mbps<br>QPSK @ 2, 12, 13, 14.4,18, 19.5 and 21.7 Mbps<br>CCK @ 5.5 and 11 Mbps<br>16-QAM @ 24, 26, 28.9, 36, 39 and 43.3 Mbps<br>64-QAM @ 48, 52, 54, 57.8, 58.5, 65, and 72.2 Mbps   |
| 2.4 GHz Frequency Bands    | ETSI: 2.4 GHz to 2.483 GHz    MIC: 2.4 GHz to 2.495 GHz<br>FCC: 2.4 GHz to 2.483 GHz    KC: 2.4 GHz to 2.483 GHz  |
| 2.4 GHz Operating Channels | ETSI: 13 (3 non-overlapping)    MIC: 14 (4 non-overlapping)<br>FCC: 11 (3 non-overlapping)    KC: 13 (3 non-overlapping)  |
| 5 GHz Frequency Bands      | ETSI<br>5.15 GHz to 5.35 GHz (Ch 36/40/44/48/52/56/60/64)<br>5.47 GHz to 5.725 GHz (Ch 100/104/108/112/116/120/124/128/132/136/140)<br>FCC<br>5.15 GHz to 5.35 GHz (Ch 36/40/44/48/52/56/60/64)<br>5.47 GHz to 5.725 GHz (Ch 100/104/108/112/116/120/124/128/132/136/140)<br>5.725 GHz to 5.85 GHz (Ch 149/153/157/161/165)<br>MIC (Japan)<br>5.15 GHz to 5.35 GHz (Ch 36/40/44/48/52/56/60/64)<br>5.47 GHz to 5.725 GHz (Ch 100/104/108/112/116/120/124/128/132/136/140)<br>KC<br>5.15 GHz to 5.35 GHz (Ch 36/40/44/48/52/56/60/64)<br>5.47 GHz to 5.725 GHz (Ch 100/104/108/112/116/120/124)<br>5.725 GHz to 5.825 GHz (Ch 149/153/157/161) |
| 5 GHz Operating Channels   | ETSI: 19 non-overlapping    MIC: 19 non-overlapping<br>FCC: 24 non-overlapping    KC: 19 non-overlapping  |

# Annex

## 9.1.3 Possible configurations with dimensions

| System  | W [mm]<br>approx. <sup>1)</sup> | H [mm]<br>approx. | D [mm]<br>approx. <sup>1)</sup> | Weight [kg]<br>approx. |
|---|---------------------------------|-------------------|---------------------------------|------------------------|
| 1x Station compact <sup>plus</sup><br>1x Cover compact <sup>plus</sup><br>1x Data module compact <sup>plus</sup>  | 320                             | 445               | 235                             | 4.8                    |
| 2x Station compact <sup>plus</sup><br>1x Cover compact <sup>plus</sup><br>1x Data module compact <sup>plus</sup>  | 320                             | 770               | 235                             | 8.1                    |
| 3x Station compact <sup>plus</sup><br>1x Cover compact <sup>plus</sup><br>1x Data module compact <sup>plus</sup>  | 320                             | 1,100             | 235                             | 11.5                   |
| 4x Station compact <sup>plus</sup><br>1x Cover compact <sup>plus</sup><br>1x Data module compact <sup>plus</sup>  | 320                             | 1,430             | 235                             | 14.8                   |
| 1x Station compact <sup>plus</sup><br>1x Cover compact <sup>plus</sup><br>1x Data module compact <sup>plus</sup><br>3x Infusion pump compact <sup>plus</sup>  | 510                             | 445               | 306                             | 11.7                   |
| 2x Station compact <sup>plus</sup><br>1x Cover compact <sup>plus</sup><br>1x Data module compact <sup>plus</sup><br>6x Infusion pump compact <sup>plus</sup>  | 510                             | 770               | 306                             | 21.9                   |
| 3x Station compact <sup>plus</sup><br>1x Cover compact <sup>plus</sup><br>1x Data module compact <sup>plus</sup><br>9x Infusion pump compact <sup>plus</sup>  | 510                             | 1,100             | 306                             | 32.1                   |
| 4x Station compact <sup>plus</sup><br>1x Cover compact <sup>plus</sup><br>1x Data module compact <sup>plus</sup><br>12x Infusion pump compact <sup>plus</sup> | 510                             | 1,430             | 306                             | 42.3                   |

<sup>1)</sup> The maximum dimensions are defined by the maximum space required by the system.

# Annex

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## 9.2 Notes and manufacturer's declaration on electromagnetic compatibility



**WARNING!** In Order to meet with the following compliance levels, only original accessories and replacement parts may be used. Otherwise, there may be increased emissions or decreased device immunity.

If the device is used in a system involving other devices (e.g. electro-surgery), this system should be checked to ensure correct operation of the system.

The device may be interfered by other devices, even if these other devices comply with CISPR emission requirements.

**CAUTION!:** The device is unsafe to use in proximity to Magnetic Resonance Imaging (MRI) equipment. The device must not be used near a Magnetic Resonance Imaging unit without protection.

**Note:** The following guidelines may not be applicable in all situations. Electromagnetic wave propagation is affected by the absorptive and reflective qualities of the surrounding structures, objects and people.

# Annex

## 9.2.1 Electromagnetic interference emissions

The Data module compact<sup>plus</sup> system is designed for use in the electromagnetic environmental conditions described below. Customers or users of the Data module compact<sup>plus</sup> or its components should ensure that the system is being operated in such an environment.

| Emission measurements                               | Compliance                                   | Electromagnetic environment – Guidelines  |
|---|--|---|
| RF emission as per CISPR 11                         | Group 1 / Class B (see Note 1/ Note 2 below) | <p>The Data module compact<sup>plus</sup> uses RF energy for its internal functions only. As such, its RF emissions rate is very low and it is unlikely to interfere with nearby electronic equipment.</p> <p><b>Note:</b> The WiFi in the Data module compact<sup>plus</sup> (2.4 and 5 GHz/≤ 100 mW) can interfere with devices in the vicinity. Please observe the required minimum distances.</p> |
| Voltage fluctuations / flicker as per IEC 61000-3-3 | Conforms                                     | The Data module compact <sup>plus</sup> and its components are intended for use in all establishments (including residential areas and similar) directly connected to a public power grid that also supplies buildings used for residential purposes as described by other manufacturers.   |
| Harmonic emissions according to IEC 61000-3-2       | Not applicable                               |   |

**Note 1:** The limits for interference emissions are measured with individual components as well as with the maximum set-up (fully equipped compact<sup>plus</sup> system).

**Note 2:** If Class A equipment is attached to the compact<sup>plus</sup> system, the compact<sup>plus</sup> system will become Class A too. This equipment/system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the compact<sup>plus</sup> system or shielding the location.

# Annex

## 9.2.2 Electromagnetic immunity


The Data module compact<sup>plus</sup> is designed for use in the electromagnetic environmental conditions described below. Customers or users of the Data module compact<sup>plus</sup> or its components should ensure that the system is being operated in such an environment.

| Immunity tests   | Test level<br>IEC 60601-1-2<br>IEC 60601-2-24   | Compliance level | Electromagnetic environment - Guidelines   |
|--|---|------------------|--|
| Electrostatic discharge (ESD) as per IEC 61000-4-2             | <b>Contact discharge</b><br>IEC 60601-1-2:<br>±6 kV   | ±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 %. |
|  | IEC 60601-2-24:<br>±8 kV  | ±8 kV            |  |
|  | <b>Air discharge</b><br>IEC 60601-1-2:<br>±8 kV   | ±8 kV            |  |
|  | IEC 60601-2-24:<br>±15 kV   | ±15 kV           |  |
|  | At ±4 kV, ±6 kV and ±8 kV contact discharge and ±8 and ±15 kV air discharge WiFi may be influenced.<br>At ±8 kV and ±15 kV air discharge topology errors may occur. |                  |  |
| Electrical fast transients / bursts according to IEC 61000-4-4 | For power cables<br>±2 kV   | ±2 kV            | Mains power quality should be that of a typical commercial or hospital environment.  |
|  | For input and output cables<br>±1 kV  | ±1 kV            |  |

# Annex

| Immunity tests  | Test level<br>IEC 60601-1-2<br>IEC 60601-2-24                 | Compliance level                     | Electromagnetic environment - Guidelines   |
|---|---|--------------------------------------|--|
| Surges as per IEC 61000-4-5   | Differential mode voltage and at ethernet cable<br>$\pm 1$ kV | $\pm 1$ kV                           | Mains power quality should be that of a typical commercial or hospital environment.  |
|   | Common mode voltage<br>$\pm 2$ kV                             | $\pm 2$ kV                           |  |
| Voltage dips, brief supply voltage interruptions and fluctuations according to IEC 61000-4-11 | < 5 % UT for 1/2 period (> 95 % dip)                          | Conforms without interference        | Mains power quality should be that of a typical commercial or hospital environment. If the user of the Data module compact <sup>plus</sup> requires continued operation during power mains interruptions, it is recommended that the Data module compact <sup>plus</sup> be powered from an uninterruptible power supply or a battery. |
|   | 40 % UT for 5 periods (60 % decline)                          | Conforms without interference        |  |
|   | 70 % UT for 25 periods (30 % decline)                         | Conforms without interference        |  |
|   | < 5 % UT for 5 s (> 95 % dip)                                 | Conforms, Data module may switch off |  |
| Magnetic field at supply frequency (50/60 Hz) as per IEC 61000-4-8                            | 3 A/m   | 30 A/m                               | <p><b>Note:</b><br/>UT is the AC mains voltage prior to test level application.</p> <p>Power frequency magnetic fields should be at levels characteristics of a typical location in a typical commercial or hospital environment.</p>  |

# Annex

| Immunity tests                                       | Test level<br>IEC 60601-1-2<br>IEC 60601-2-24   | Compliance level   | Electromagnetic environment - Guidelines  |
|--|---|--|---|
| Conducted RF interference according to IEC 61000-4-6 | <p>IEC 60601-1-2:<br/>150 kHz to 80 MHz<br/>3 V<sub>RMS</sub> outside and<br/>10 V<sub>RMS</sub> in ISM<br/>frequency bands</p> <p>IEC 60601-2-24:<br/>150 kHz to 80 MHz<br/>10 V<sub>RMS</sub></p> | <p>10 V<sub>RMS</sub><br/>150 kHz to<br/>80 Mhz<br/>in all<br/>frequency<br/>bands</p>                             | <p>Do not use portable radio communications equipment closer to the Data module compact<sup>plus</sup> (including connection cables) than the recommended safe distance calculated using the appropriate equation for that frequency.<br/><b>Recommended safe distance: <math>d = 1.2 \sqrt{P}</math></b></p>   |
| Radiated RF interference according to IEC 61000-4-3  | <p>10 V/m<br/>80 MHz to 2.5 GHz</p>   | <p>10 V/m<br/>80 MHz to<br/>6 GHz<br/><br/>Between<br/>2.4 GHz and<br/>2.9 GHz<br/>WiFi may be<br/>influenced.</p> | <p>The field strength should be lower than 10 V/m</p> <p><math>d = 1.2 \times \sqrt{P}</math> <sup>1)</sup><br/>80 MHz to 800 MHz</p> <p><math>d = 2.3 \times \sqrt{P}</math> <sup>1)</sup><br/>800 MHz to 2.5 GHz</p> <p>Field strengths from stationary RF transmitters should be below the compliance level for all frequencies, based on an on-site test.</p> <p>Interference is possible in the vicinity of equipment that has the following symbol.</p>  |

<sup>1)</sup> With P as the maximum rated power of the transmitter in watts (W) according to the transmitter manufacturer specifications and d as the recommended safe distance in metres (m).



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**Note:** The deviating test values derived from IEC 60601-2-24 are labelled in the table. However, these test values allow one outage, while the test values according to IEC 60601-1-2 do not allow any outages.

The compliance levels for ISM frequency bands between 150 kHz and 80 MHz and in the 80 MHz to 6 GHz frequency range are designed to minimise the likelihood of mobile/portable communications equipment causing interference if accidentally brought into the patient area. For this reason the additional factor 10/3 is used when calculating the recommended safe distances in these frequency ranges.

Field strengths emitted from stationary transmitters (such as base stations for cordless telephones and land mobile radio devices, amateur radio stations, or AM and FM radio and television broadcasts) theoretically cannot be predicted exactly. Consider conducting a study of the site to determine electromagnetic environmental conditions as regards stationary transmitters. If the measured field strength in the area the Data module compact<sup>plus</sup> is being used in exceeds compliance levels, monitor the Data module compact<sup>plus</sup> to ensure that it is functioning properly. If abnormal performance is observed, additional measures may be necessary, e.g., changing the device's location or facing it in a different direction.

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## 9.2.3 Recommended safe distances between portable and mobile RF telecommunications equipment and the Station compact<sup>plus</sup> including the Data module compact<sup>plus</sup>

The Data module compact<sup>plus</sup> is designed for use in an electromagnetic environment in which emitted RF disturbances are controlled. Customers or users of the Data module compact<sup>plus</sup> or its components can help prevent electromagnetic interference by complying with the minimum distances between portable and mobile RF telecommunications devices (transmitters) and the Data module compact<sup>plus</sup> and its components, as recommended below in accordance with the maximum output power of the communication device.

**Note:** The higher value applies at 80 MHz and 800 MHz.

**Note:** For transmitters whose rated power is not specified in the table above, the distance can be determined using the equation for the relevant column. P is the transmitter's rated power in W according to the manufacturer's specifications.

**Note:** A factor of 10/3 is used to calculate the recommended safe distance of transmitters in the frequency range between 80 MHz and 2.5 GHz, in order to reduce the probability of a mobile communication device used unintentionally in the patient area causing a fault.

| Transmitter rated power in W | Safe distance according to transmitter frequency m |                         |                          |
|------------------------------|--|-------------------------|--------------------------|
|                              | 150 kHz to 80 MHz 1.2√P                            | 80 MHz to 800 MHz 1.2√P | 800 MHz to 2.5 GHz 2.3√P |
| 0.01                         | 0.12   | 0.12                    | 0.23                     |
| 0.1                          | 0.38   | 0.38                    | 0.73                     |
| 1                            | 1.2  | 1.2                     | 2.3                      |
| 10                           | 3.8  | 3.8                     | 7.27                     |
| 100                          | 12   | 12                      | 23                       |

# Annex

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Version 2, June 1991

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# Annex

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## 9.4 Ordering data

### 9.4.1 compact<sup>plus</sup> product family

| Name                                 | Order number |
|--------------------------------------|--------------|
| Perfusor® compact <sup>plus</sup>    | 8717030      |
| Infusomat® compact <sup>plus</sup>   | 8717050      |
| Infusomat® compact <sup>plus</sup> P | 8717070      |

### 9.4.2 compact<sup>plus</sup> accessories

| Name                                | Order number |
|-------------------------------------|--------------|
| Station compact <sup>plus</sup>     | 8717141      |
| Cover compact <sup>plus</sup>       | 8717145      |
| Data module compact <sup>plus</sup> | 8717160      |
| Interface cable RS232 (Cross-over)  | 8713237      |
| Interface cable RS232 (1:1)         | 8713238      |



**Manufacturer:**  
**B. Braun Melsungen AG**  
34209 Melsungen  
Germany  
Tel +49 (0) 56 61 71-0  
[www.bbraun.com](http://www.bbraun.com)

**Sales:**  
**B. Braun Melsungen AG**  
Hospital Care division  
34209 Melsungen  
Germany  
Tel: +49 (0) 56 61 71-0  
Fax: +49 (0) 56 61 71-20 44  
[www.bbraun.com](http://www.bbraun.com)

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