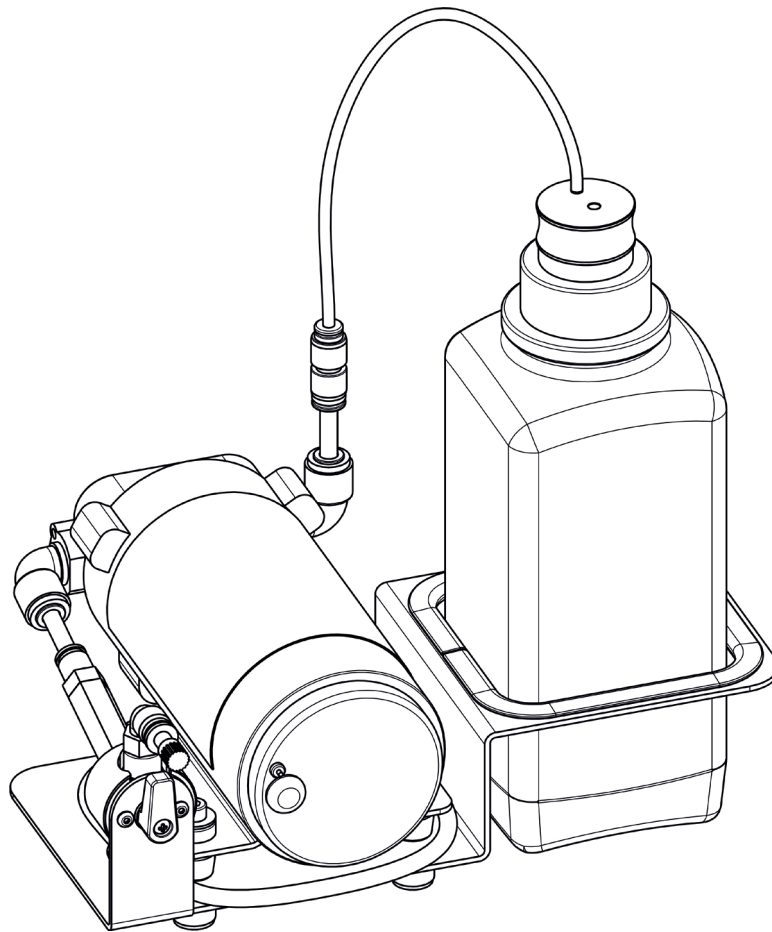


BR System

Instructions for use

EN

200004303 | 2024-09



eIFU:
www.metasys.com/downloads






METASYS

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| | Order number | | 200004303 |

If you would like to request a printed copy of the instructions for use, please contact us at ifu@metasys.com or use the order form at www.metasys.com/downloads. A hardcopy of the instructions for use will be made available to you free of charge and within seven calendar days of receipt of the request.

Translations

Translation of the original instructions for use

 **Tetras GmbH**
Sirius Business Park, Rupert-Mayer-Str. 44, 81379 Munich, Germany

Images

The images contained in these instructions for use are for reference and may differ from the actual appearance of the product.

1. Notes










































1.1. General instructions

METASYS can only guarantee the safety, reliability and performance of the dental device if the following instructions are adhered to:

- > The product is only to be used in accordance with the instructions for use.
- > During maintenance and service work (inspection, service, repair, replacement), only use original replacement parts.
- > All manufacturer specifications for the treatment units to which the device is connected must be observed.
- > After commissioning, complete the proof of installation and send this to METASYS in order to define the warranty period.
- > All maintenance and service work must be entered into the device logbook.
- > On request by an authorised technician, METASYS will provide all documentation that may be of use to technically qualified personnel during maintenance and service works
- > METASYS accepts no responsibility for damage that may arise due to external influences (defective installation), using incorrect information, improper use of the dental device, or maintenance and service works being carried out improperly.
- > The user must familiarise himself/herself with how to operate the dental device and ensure that the dental device is in good condition each time before operating it.

Important: Read the accompanying documents of the device carefully before installation, commissioning and use and keep them for the entire service life of the product!

1.2. Explanation of the symbols

| | | |
|--|---|--|
|  CE mark |  End device ready for operation |  Use eye protection |
|  Medical device |  Loudspeaker |  Use mouth and nose protection |
|  Item number |  Sound |  Unplug from mains |
|  Serial number |  Inclination / slope |  General warning sign |
|  Manufacturer |  Maximum installation altitude |  Warning of electrical voltage |
|  Date of manufacture |  Blower / fan |  Information |
|  Follow instructions for use |  On Off |  Download |
|  Follow instructions for use with reference to eIFU |  Separate collection of electrical/electronic equipment (WEEE) |  Do not cut |
|  Temperature limit |  Protective earthing |  Maintenance / service |
|  Caution / attention |  Protection class II |  Stop operation |
|  Beware of electric shock |  Applied part type BF |  Protect from heat / Protect from sunlight |
|  Humidity limit |  Applied part type B |  Protect from moisture / Store in a dry place |
|  Tank empty |  Responsible for the translation |  Fragile |
| |  Observe instructions for use |  Package orientation at the top |



Fault on end device



Use hand protection



Stacking limit n = (quantity)

CH **REP**

Name and address of the authorized representative's registered office in Switzerland



Unique identifier of a medical device



UDI marking with standard compliant HIBC data content

1.3. Copyright notice

All names and contents are protected by copyright. Distribution, duplication or alternative use of this document is only permitted with the written consent of METASYS Medizintechnik.

2. Intended use

The BR System is used for introduction of the GREEN&CLEAN BR in the water-bearing pipes of treatment units.

2.1. Indication

Not applicable.

2.2. Contraindication

Not applicable.

2.3. Target group

Trained technical staff.

3. Safety-related information

3.1. General safety-related information

All serious incidents related to the device must be reported to the manufacturer and the competent authority of the Member State where the user and/or the patient is resident.

3.2. Safety instructions

Assembly, modifications or repairs may only be carried out by authorised qualified personnel who guarantee compliance with the EN 60601-1 standard (international standard on Medical Electrical Equipment and Systems, in particular part 1: General requirements for basic safety).

The electrical installation must comply with the regulations of the IEC (International Electrotechnical Commission).

Medical devices should be handled with care with regard to electromagnetic compatibility. Special safety measures must therefore be taken.

The device is not suitable for operation in explosive areas or in flammable atmospheres.

3.3. Warnings

| | |
|------------------|--|
| Danger | Warning of a danger that will directly result in serious injury or death |
| Warning | Warning of a danger that can result in serious injury or death |
| Caution | Warning of a danger that can result in minor injury |
| Attention | Warning of a danger that can result in extensive damage to property |

4. Product description

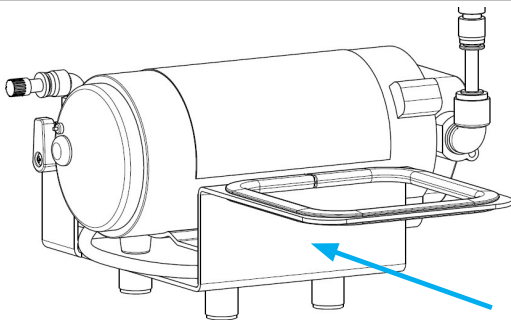
4.1. Product description

The BR System is used to introduce the product GREEN&CLEAN BR into the water-bearing pipes of the dental unit. In combination with GREEN&CLEAN BR, the BR System is used to sanitise the water-bearing pipes in the event of biofilm infestation. Existing biofilm is removed in 30 minutes.

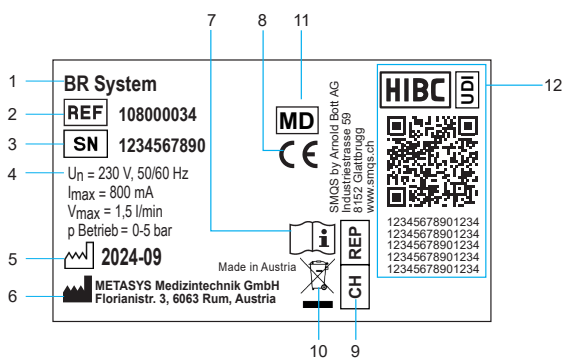
4.2. Technical data / performance data

| | |
|--------------------------|--------------------|
| Power supply | 230 V AC |
| Frequency | 50 / 60 Hz |
| Max. current consumption | 800 mA |
| Max. ambient temperature | 40 °C |
| Max. liquid flow rate | 1,5 l/min |
| Max. delivery pressure | 5,52 bar |
| Dimensions (H x W x D) | 240 x 252 x 200 mm |
| Class | MD class 1 |

4.3. Type plate



The type plate is located on the mounting plate near the recess for the chemical bottle.



Example picture

| | |
|----|--|
| 1 | Device description |
| 2 | Item number |
| 3 | Serial number |
| 4 | Connection data |
| 5 | Date of manufacture |
| 6 | Manufacturer |
| 7 | Follow instructions for use |
| 8 | CE mark |
| 9 | Name and address of the authorized representative's registered office in Switzerland |
| 10 | Separate collection of electrical/electronic equipment (WEEE) |
| 11 | Medical device |
| 12 | Unique identifier of a medical device, UDI marking with standard compliant HIBC data content |

4.4. Construction

The BR System consists of the mounting plate, the pump, the main switch and the connections for the water lines and the chemical bottle.

4.5. Functional description

The BR System is connected to the water inlet of the treatment unit. The pump then pumps the GREEN&CLEAN BR into the water-bearing pipes of the treatment unit. After a maximum exposure time of 30 minutes, the water inlet of the treatment unit is reconnected to the water mains. The waterbearing pipes are rinsed with fresh water until the liquid and the loosened dirt have been removed.





Please note that only GREEN&CLEAN BR may be used, as the device is designed for it!

5. Preparation for use




5.1. Transport and storage

The device is shipped in a cardboard box with bubble wrap.

This original packaging must be used for any onward and return transport. The device must always be transported and stored in an upright position. The device must be transported to the installation site in a completely packed state. After unpacking the device, check for completeness and possible transport damage.


| | | |
|---|---|--------------|
|  | Transport and storage temperature | 0 °C – 70 °C |
|  | Transport and storage humidity limitation | max. 80% |

5.2. Installation requirements


| | | |
|---|-----------------------|---------------|
|  | Operating temperature | 10 °C – 40 °C |
|  | Humidity limit | max. 70% |
|  | above sea level | ≤ 3000 m |

5.3. Installation, assembly and commissioning

5.3.1. Connecting to other devices

| | |
|---|--|
|  | When connecting the METASYS device to other devices or systems, hazards can arise. It must therefore be ensured that no hazards arise for the user or the patient and that the environment is not affected. The specifications of the manufacturer of the device or system to be connected must be observed. |
|---|--|

5.4. Electronics

| | |
|---|--|
|  | Before connecting to the mains, compare the rated voltage on the device type plate with the mains voltage. |
|---|--|

6. Use

6.1. Normal operation



Only intended for use by trained service technicians!

- 1 Read the instructions carefully before installation and commissioning!



- 2 Remove all water consumers from the dental unit (protection against clogging). Remove the sealing cap (black).



- 3 Insert the tube into the new GREEN&CLEAN BR bottle and press on the push-in cap.



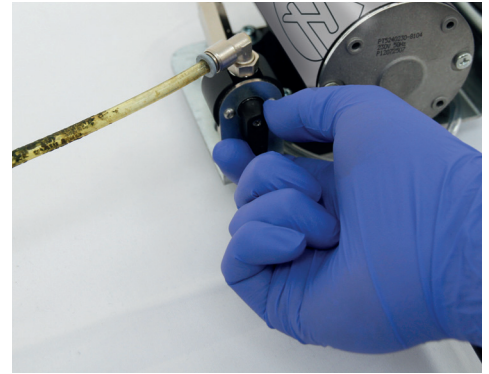
- 4 Remove the sealing plug (red).



- 5 Connect the water inlet hose of the dental unit to the BR System.



6 Open the inlet tap.



7 Switch on the BR System.



8 As soon as the purple liquid emerges at the consumers, switch the device off again.



9 Close the inlet tap.



10 Disconnect the water inlet hose of the dental unit from the BR System.
Remove the push-in cap from the GREEN&CLEAN BR bottle, replace the sealing plug and close the bottle with the bottle cap.



- 11 Contact time: 30 minutes.
At the end of the exposure time, run all water consumers until clear water comes out.



6.2. Error messages



Assembly, modifications and repairs may only be carried out exclusively by authorised specialist personnel (see 3.2. Safety instructions)! For further information and assistance in carrying out repairs, retrofitting, fault analyses, etc., the METASYS technical customer service is also available!

| Error message | Possible cause | Countermeasures |
|---|---|---|
| Water leaking from the connection | Hose not connected correctly (not pressed in enough) | Check the hose connections for leaks. If necessary, press the hose firmly into the respective connection. |
| The device draws no/little disinfectant from the GREEN&CLEAN BR bottle. | Line blocked | Check the hose for foreign objects and remove them. |
| No chemicals are coming out of the BR System. | Ball valve closed | Ensure that the ball valve is open during the cleaning process. |
| | The unit to be cleaned generates back pressure (e.g. through a closed valve). | Ensure that the unit is not generating any back pressure. |
| | The GREEN&CLEAN BR bottle is empty. | Replace the used GREEN&CLEAN BR bottle with a new one. |

7. Care and maintenance

7.1. Replacing consumables

- 1 Remove the empty GREEN&CLEAN BR bottle from the device.
- 2 Pull the push-in cap (incl. tube) out of the bottle
- 3 Insert the tube into the new GREEN&CLEAN BR bottle and press on the push-in cap.
- 4 Place the bottle back in the device.



For information on use and safety instructions, see the GREEN&CLEAN BR instructions for use.

8. Decommissioning

8.1. Disassembly



Warning:

Remove from power source before disassembly!



Warning:

Risk of contamination: To avoid infection, wear personal protective equipment (hand, eye, nose and mouth protection) and disinfect and clean the device!

If it is necessary to return the device to the depot or to METASYS, the original METASYS packaging must be used. Before packing the METASYS device to be transported, clean and disinfect it. Possible openings where residual fluids could escape must be closed.

8.2. Recycling and disposal



The device may be contaminated! Advise the disposal company of this so that appropriate precautions can be taken. Parts that are contaminated with amalgam, such as sieves, filters, hoses, etc., must also be disposed of in accordance with the national regulations.

Untampered plastic parts of the device can be recycled as normal plastics. The integrated electronic components (including circuit board) are to be disposed of as electronic waste. Metal parts are to be disposed of as scrap metal.

Alternatively, the device can be returned to the manufacturer for proper disposal. Before packing the METASYS device to be transported, clean and disinfect it. Possible openings where residual fluids could escape must be closed. The original METASYS packaging must be used for shipping.

The proof of installation and the device logbook must be kept for 5 years after the device has been disposed of.

9. Annex

9.1. Order numbers and scope of delivery

| Order number (new) | Order number (previous) | Designation | Scope of delivery |
|--------------------|-------------------------|-----------------|--|
| 108000034 | 40050501 | BR System, 230V | Device with instructions for use, 1 x GREEN&CLEAN BR 1000 ml |

9.1.1. Accessories, service kits, collection containers and spare parts

Consumables

| Order number (new) | Order number (previous) | Designation |
|--------------------|-------------------------|-----------------------------------|
| 122000002 | 60040300 | GREEN&CLEAN BR 1000 ml, 2 bottles |

9.2. Warranty conditions

METASYS grants a guarantee of 12-36 months for specific products (duration of guarantee depends on the product according to the information in the current price list).

The guarantee covers all material faults that more than negligibly affect the function of the device. The guarantee does not cover damages caused by incorrect or improper handling as well as normal wear. Furthermore, the guarantee does not apply to the replacement of the amalgam collection container or to fragile parts such as glass, plastic, hoses, filters, condensate filters or membranes. Any incurred working and travel times are excluded from the warranty.

In order to determine the validity of the guarantee, the installation proof accompanying the device must be returned to METASYS immediately after proper assembly has taken place. In this case the warranty period begins with commissioning. In the event of installation without returning the installation proof to METASYS, any warranty claim is forfeited. Installation and return of installation proof must be completed within 24 months from the date of sale from METASYS.

Furthermore, any warranty claims of the customer expire if only one of the following circumstances arises, regardless of whether the circumstances arise for the customer of METASYS or a later owner or operator:

- > Improper installation, operation, maintenance or transport of the device. If METASYS parts have to be returned, the original METASYS packaging must be used for shipping. Prior to packaging and shipping, the METASYS device must be cleaned and disinfected. Any openings where residual fluids could leak must be closed.
- > Installation and return of installation proof have not been completed in the aforementioned 24 months.
- > Failure to send the Installation Proof to METASYS.
- > Installation and use of non-original METASYS parts.
- > Installation of the device by personnel who are neither trained nor authorized by METASYS.
- > Occurrence of damages through improper handling and operation or use of unapproved cleaning and/or disinfecting material, as well as non-compliance with the instructions for use.
- > Execution of repairs by unauthorised repair shops or unauthorised personnel.
- > Failure to comply with the prescribed maintenance intervals. Maintenance must be carried out 11-12 / 23-24 / 35-36 months after installation of the respective METASYS item.
- > Missing entries in the Equipment Logbook regarding the installation as well as prescribed servicing by technicians trained by METASYS.
- > Failure to take reasonable immediate measures to avoid further damages in the event of a malfunction.
- > Shipping of devices or components to METASYS without proper accompanying paperwork, in particular without error description or invoice for the purchase of the device.
- > Failure to provide visual images (photos, video clips ...) of the METASYS item complained about, as well as of its installation situation and ambient conditions.

METASYS reserves the right to demand the documentation supplied with the device to check the maintenance intervals for the assertion of warranty claims. The processing of warranty claims takes place exclusively according to the following method:

In the event of malfunctions, the device must be opened by an authorized technician, the relevant component taken out and sent to METASYS unopened and cleaned. The customer sends the device or component in question to METASYS at his own expense. METASYS checks whether there is a warranty claim. METASYS will repair the device or component if it is cost-effective. The customer is charged for the costs incurred for the repair, but not the replacement parts covered by the guarantee. The consignment of the device or component to METASYS always represents a repair order for METASYS. For cost estimates for the repair of returned devices, a processing fee* is charged if the warranty period has expired or no warranty case exists. For products inspections only without any cost estimates a processing fee* can be charged. When sending the device or component to METASYS, an error description with all importation information about the device must always be included. The customer of METASYS may only provide payment in advance after consultation with METASYS. Only the affected component is to be sent in (smallest possible unit). If contaminated, intact parts are sent to METASYS without technical necessity, METASYS is entitled to destroy them without separate payment. The new part corresponding to the part to be destroyed is only delivered after a separate order and invoice. In any case, METASYS has the right to handle the guarantee through credit note or the return of new parts without conducting repairs. Guarantee services do not result in an extension of the

warranty period nor do they initiate a new warranty period. The warranty period for installed replacement parts ends with that for the originally delivered device. The METASYS customer is obligated to make his customer aware of the conditions regarding the warranty processing. The statutory warranty rights of the customer remain unaffected.

* The current warranty conditions and fees can be found in the current METASYS price list.

9.3. Change history

| Revision | Date | Description |
|-----------|------------|----------------|
| 200004303 | 26.09.2024 | Newly created. |

Corrected various spelling and translation errors.



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Subject to printing and setting errors!