Instruction Manual
WD290

Article number: 10268-0068

Version: 001-03/08

Belimed

Infection Control

Inhaltsverzeichnis

1 Introduction

1.1 Before you read on

Your product meets high standards and is easy to operate. Nevertheless, please take time to read these instructions carefully. You will become familiarised with your product and be able to use it to its best.

1.2 Target group

These instructions are a component of the product and are intended for the owner, users, operators, as well as servicing personnel. They must be accessible for this group of persons.

1.3 Amendments

The text, graphics and data correspond to the technical status of the product at the time of going to print. Amendments in the sense of technical development remain reserved.

1.4 Symbols and references used

The following symbols and references to occupational safety used throughout the documentation are important to avoid harm to health and life.

DANGER!
There is an imminent risk to the life and health of persons.

WARNING!
There may be a risk to the life and health of persons.

CAUTION!
A situation for which there is a warning of damage to property and equipment.

NOTE
User tips and useful information on the best possible use of the equipment.

2 For your safety

With the EC Declaration of Conformity and the CE mark, we affiirm that this product complies with the basic health and safety requirements in accordance with Directive 93/42/EEC Annex II (see Chap. 18 "Conformity and certifications")

Hazards may still arise from the product if it is used incorrectly by inadequately trained personnel or not as intended.

2.1 Intended use

This product is exclusively approved for the uses stated in the instructions. Namely for central sterilisation, substerilisation in surgery, in hospitals, clinical laboratories and in industry.

2.2 Duty of care in handling the device

- Only use **original racks, spare parts and accessories**
- **Load the racks as intended** (see Chap. 8 "Loading and identifying racks")
- **Daily servicing work** on the device must be carried out regularly and in accordance with regulations (see Chap. 14 "Daily servicing and cleaning work")
- **Validation** of the programme parameters must be performed regularly (see Chap. 2.6 "Process validation")
- **Installation, deinstallation, servicing or modification** must only be carried out by persons authorised by Belimed
- In the case of**incorrectly installed, operated or maintained devices** all warranty claims are invalidated

2.3 Non-intended use

All other applications are considered as non-intended use.

Damages caused by operator error, non-intended use, failure to observe the instructions, operation by untrained personnel, unauthorised modifications and conversions without the written consent of the manufacturer, are not permitted and preclude the manufacturer's liability for the ensuing damage to property and personal injury.

2.4 Instruction of personnel

This product must only be used, maintained and repaired by authorised, trained and briefed personnel. This assumes that these instructions are read and understood.

Responsibilities and competencies in operation, servicing and maintenance must be clearly defined and observed.

2.5 Fields of application for the device

Cleaning and conditioning of:

- Surgical instruments
- Minimal-invasive instruments
- Instruments for anaesthesia and intensive care
- Baby bottles and teats
- Containers
- OP shoes
- Laboratory instruments from research and production
- Rigid endoscopes
- Eye instruments
- Neurosurgery

2.6 Process validation

The aim of process validation is to achieve a high level of safety in the reconditioning of medical devices in order to afford the operators and patients the greatest possible protection.

Process validation consists of:

a) **Type testing** / **factory testing**

b) **Process validation consisting of:**
   - IQ - Installation Qualification
   - OQ - Operational Qualification
   - PQ - Performance Qualification

c) **Routine testing** / **Annual requalification**
   (refer to appendix EN ISO 15883-1 November 2001, Chap. 6, Pages 35-37)

NOTE
Further information on process validation may be obtained from Belimed Customer Service.

CAUTION!
Validation must only be carried out by authorised persons!

Devices must only be operated with processes validated in accordance with regulations! Only use components (items to be washed, racks, programmes, chemicals) which have been validated together.

The safety of operators and patients may be compromised if the devices used are not validated in accordance with regulations.

3 Device description

3.1 Device unclean side (US)

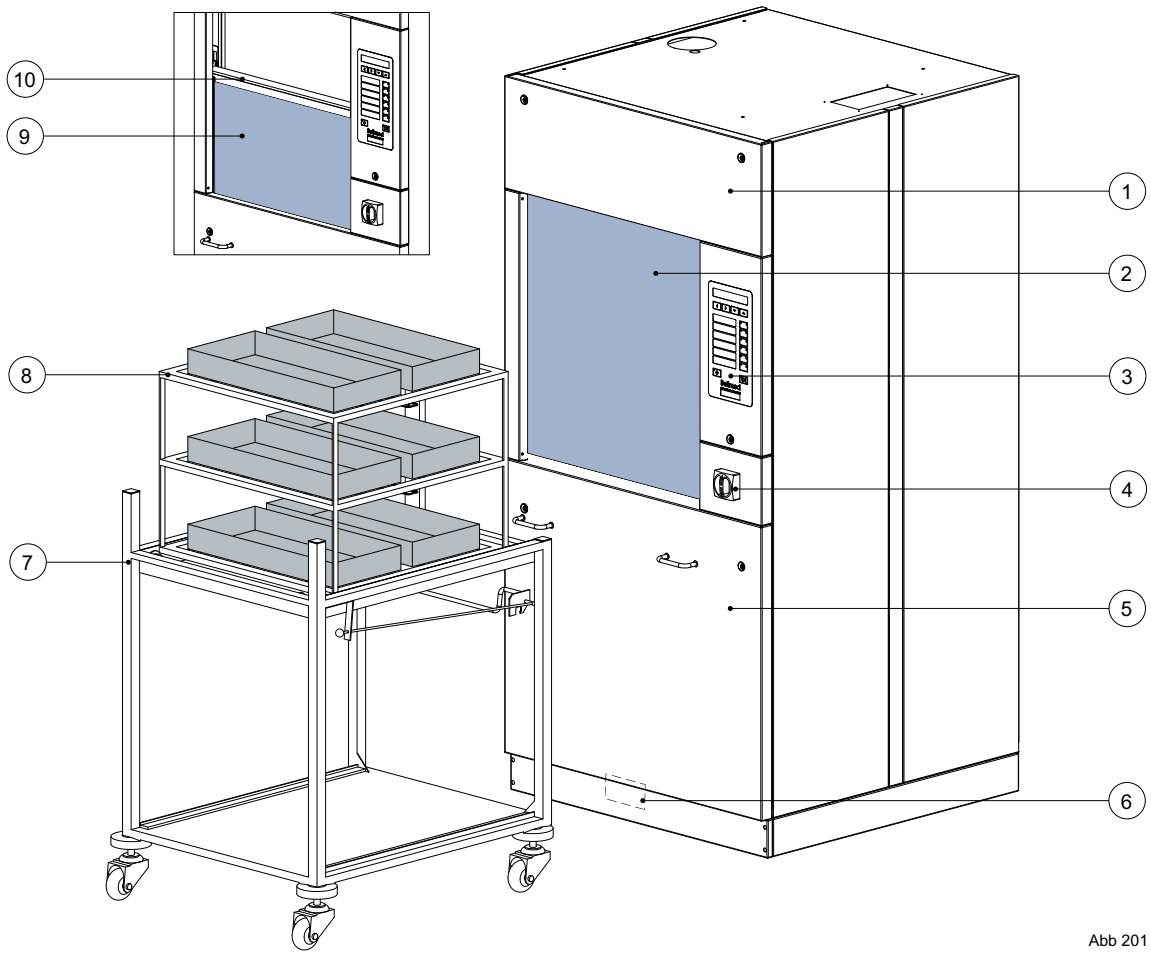
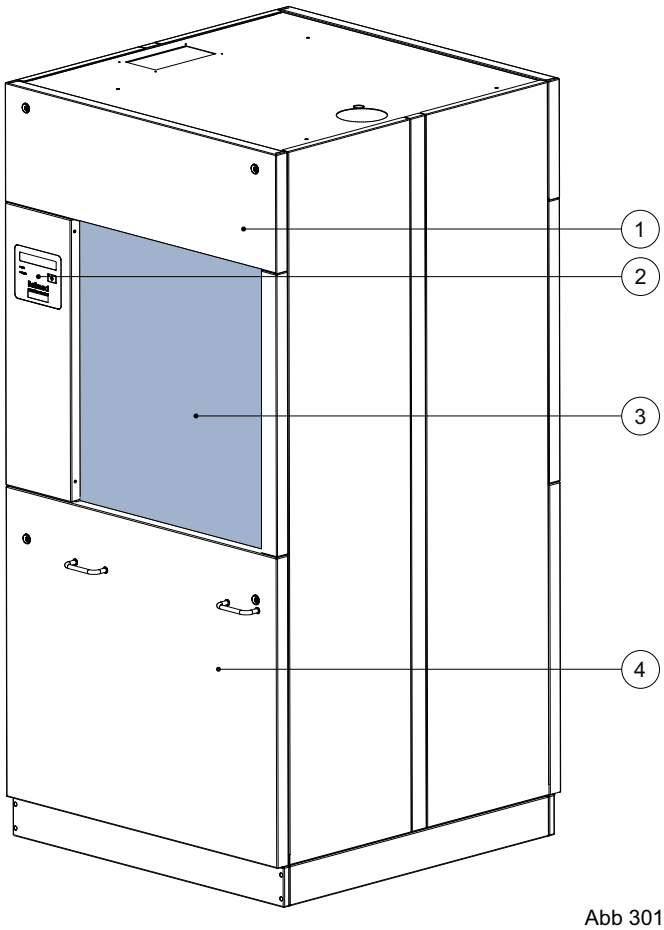


Abb 201

1 Door drive (behind the panel)
2 Wash compartment doors made of double-layer safety glass
3 Operating panel
4 Main switch (with EMERGENCY OFF function)
5 Service panel
6 Location type plate
7 Transfer trolley
8 Rack
9 Automatic wash compartment doors
10 Door safety switching strip

3.2 Device clean side (CS)



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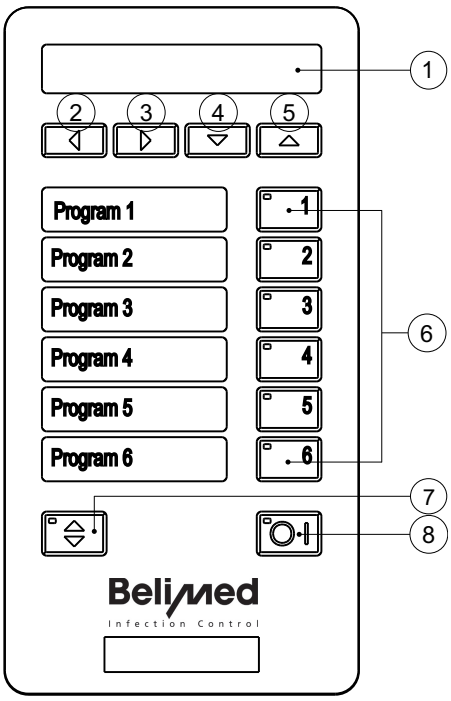
1 Door drive (behind the panel)
2 Operating panel with door button
3 Wash compartment doors made of double-layer safety glass
4 Service panel

3.3 Controller unclean side (US)



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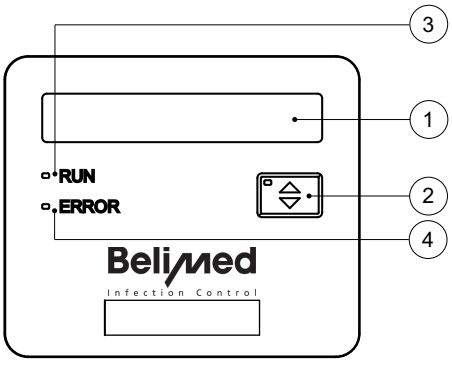
1) **Display**
   – With screensaver "***BELIMED INFECTION CONTROL"***; this means that this display automatically appears after approx. 1 h. Press any button, display *"Program ready"* appears again
2) **Cursor left**
   – Print operating data such as program formula and setup parameters
   – Self disinfection On/Off
   – IPD verification On/Off
3) **Cursor right**
   – Acoustic signal On/Off
4) **Cursor down**
   – Printer On/Off
5) **Cursor up**
   – Shift button Programs P7 - P12
6) **Program buttons**
   – Selection of Programs P1 - P6, with Shift P7 - P12
7) **Door button**
   – Opens/close door
8) **On/Off button**
   – Display batch number (press 4 seconds)

3.4 Controller clean side (CS)



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1) **Display**
   – With screensaver***BELIMED INFECTION CONTROL***; this means that this display automatically appears after approx. 1 h. Press any button, display *"Program ready"* appears again
2) **Door button**
   – Door opens/closes
3) **RUN**
   LED lit = In progress
4) **ERROR**
   LED lit = Fault
   (See Chap. 16 "Faults")

4 Pre-treating medical devices

4.1 Responsibility for pre-treatment

CAUTION!
Always observe the specifications from the medical device manufacturer!

The owner is responsible for pre-treatment of medical devices. The best possible washing results are only to be achieved with correct pre-treatment as intended.

Various treatments fix proteins and may contribute to preserving prion infectivity.

CAUTION!
The air bubbles in the foam prevent pressure building-up in the cleaning system and therefore the best possible contact between the cleaning agent and the items to be washed.

4.1.1 SOPs (Standard Operating Procedures)

The contents of the following criteria and specifications must be regulated:

- Product responsibility
- Transport routes and duration of waste disposal (time for soiling to dry in)
- Type of soiling (blood, ointments, bone meal...)
- Material properties and compatibility of the items to be washed (risk groups acc. to RKI Ordinance)
- Consideration of all operating instructions and reconditioning regulations for medical devices
- Necessary knowledge of the medical devices to be reconditioned
- Maintenance plan and regular inspections

Belimed recommends producing work instructions which describe the procedure within a working process.

4.2 Preparing medical devices

CAUTION!
Not all medical devices are suitable for mechanical reconditioning (see Chap. 2.5 "Fields of application for the device")

All inner and outer surfaces must be accessible for cleaning (open valves, taps, joint instruments...) Special caution is required for the lumen. Disassemble MIC or other complex instruments according to the manufacturer's specifications.

4.3 Pre-cleaning pre-treatment

Remove coarse soiling immediately after use. Dried-on blood or tissue reduces the effectiveness of cleaning.

4.3.1 Avoiding subsequent cleaning

Various treatments fix proteins and may contribute to preserving prion infectivity.

The following pre-treatment methods may cause impairments in subsequent washing:

- Pre-treatment with aldehydic disinfectants
- Pre-treatment with alcohol solutions
- Pouring antiseptic solutions on the items to be rinsed
- Aldehyde and alcohol vapours
- Heat pre-treatment

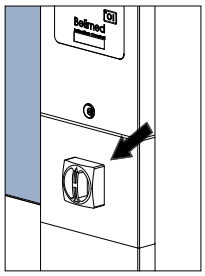
Small quantities of foam are permissible with manual cleaning in the immersion bath or ultrasonic cleaning.

5 Preparing the device

WARNING!
Only operate the device if it is in a technically faultless condition! Damaged or defected components must be reported to the technical specialist.

After a prolonged period of disuse (approx. 1 week), the daily servicing work must be carried out to prepare the device (see Chap.14 "Daily servicing and cleaning work").

- ▶ Check the quantity of detergents (see Chap. 16 "Faults")
- ▶ Switch the device on at the main switch (Fig. 209) with the button. Four possible display texts may now appear



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Performing self-disinfection

(See Chap. 6 "Self-disinfection")

Display text:

```
Self-disinfection
Start
```

Program ready

Continue with program flow (see Chap. 7 "User identification")

Display text:

```
Program ready
```

Fault without process interruption

Rectify fault (see Chap. 16 "Faults")

Example display text:

```
Dosing device
Empty
```

Fault with process interruption

Report to the technical specialist

Example display text:

```
No pressure
Fault Code 110
```

6 Self-disinfection

6.1 Why self-disinfection?

Microorganisms form in the washing chamber, tubing and DI boiler after a prolonged period of disuse. Following thermal disinfection step, residues of dead bacteria on the medical device may constitute a risk for patients.

In the case of***active*** self-disinfection the owner is requested to perform self-disinfection after a programmed period (24 hours as standard) following the last program run.

NOTE
If there is no mains supply (mains switch OFF) the timer is not active, as the request for*"Self Disinfection Start"* always appears when active self-disinfection is switched on.

6.2 Starting self-disinfection

- ▶ Open the door with the button
- ▶ Slide in the empty rack

CAUTION!
Do not wash any items with the self-disinfection program! There is no cold pre-rinse. There is the risk of excessive foam formation and fixing proteins.

- ▶ Close the wash compartment door with the button
  - ▶ User identification (see Chap. 7 "User identification")

WARNING!
Do not touch the door or its surrounding paneling during the closing process. A crushing hazard exists.

If any objects are trapped between the panel and door, the technical personnel must be informed to rectify the problem.

- ▶ The device is ready to start

Display text:

```
Self Disinfection
Start
```

- ▶ Press any program button 1 to 6

Display text:

```
SD |_|                  13min
Desinf       A068        89°C
```

Legend:

SD |_| = program step status

13min = remaining run time

Desinf = program name

A068 = current A_0 value

89°C = temperature of rinsing agent or drying air

▶ **Procedure in case of faults:**

- ▶ If a fault occurs during operation, acknowledge with the button
- ▶ If the fault persists (see Chap. 16 "Faults")
- ▶ If the fault cannot be rectified, the technical specialist must be informed

DANGER!
If smoke is emitted or water escapes, immediately **turn off at the main switch** and isolate the device from the mains supply. Inform the technical specialist.

▶ The end of the program is indicated with an acoustic signal

Display text:

```
Program name
Correctly Finished
```

NOTE
For manual loading/unloading, unload the rack back to the US again at the end of the program. The CS door remains locked.

Self-disinfection is inactive for automatic loading/unloading.

7 User identification

The user must logon each time before using the device. The password identification is forwarded to the printer or the digital documentation system and assigned to the relevant batch.

Detection takes place via the operating panel or by means of barcode reader.

7.1 Identification via operating panel

▶ User identification is requested once the device is switched on.

```
User Name o No.?
--
```

▶ Inputting the identification number via the operating panel

NOTE
For input via the operating panel we recommend a list of numbers with the corresponding names (Example 1).

The identification number must lie within the range 11-65. Only the digits 1-6 can be used for a number. (Not possible: 17, 18, 19, 27, 28, 29....)

For an input of No. 0 or 66 *"No identification"* is output.

Example 1:

No.	**Name**
11	M. Smith
12	H. Jones
0	No Identification
66	No Identification

▶ Device ready

Display text:

```
Program ready
```

Display text for a prolonged period of disuse (see Chap. 6 "Self-disinfection"):

```
Self Disinfection
Start
```

7.2 Identification via barcode reader

▶ User identification is requested once the device is switched on.

Display text:

```
User Name o No.?
--
```

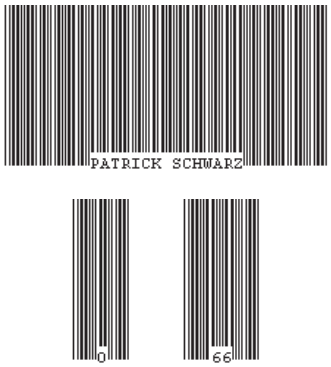
▶ Reading the barcode with the barcode reader

NOTE
The length of the name input is limited to 20 characters. If the no. 0 or 66 is read *"No identification"* is output (see Example 2)

Barcodes for name labels can be produced oneself from the Internet (free of charge). (*http://www.barcodemagic.com/barcodemagic.html*).

Display text:

Example 2:



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First name / **last name**

Heike Meyer

No Identification

0 / 66

▶ Program ready

Display text:

```
Program ready
--.--.----            --:--
```

Display text for a prolonged period of disuse (see Chap. 6 "Self-disinfection"):

```
Self Disinfection
Start
```

8 Loading and identifying racks

8.1 Loading racks

The loading of racks has a significant influence on the washing outcome. **For correct and intended loading it is absolutely necessary to follow the instructions supplied with the rack.**

DANGER!
Always wear protective goggles and gloves when handling the items to be washed. **Soiled items to be washed may cause infections!**

8.2 Rack identification

The rack identification is forwarded to the printer or the digital document system and assigned to the relevant batch.

Detection takes place via the operating panel or by means of barcode reader.

8.2.1 Rack identification via the operating panel

Display text:

```
Rack Name o No.?
--
```

▶ Inputting the identification number via the operating panel

NOTE
The identification number must lie within the range 11-65. Only the digits 1-6 can be used for a number. (Not possible: 17, 18, 19, 27, 28, 29....)

For an input of No. 0 or 66 *"No identification"* is output.

8.2.2 Rack identification via barcode

Display text:

```
Rack Name o No.?
--
```

▶ Read barcode

NOTE
The length of the name input is limited to 12 characters. If the no. 0 or 66 is read *"No identification"* is output (see Chap. 7.2 "Identification via barcode reader")

Barcodes can be produced oneself from the Internet (free of charge). (*http://www.barcodemagic.com/barcodemagic.html*).

9 Identification of batch content

The identification of batch content is forwarded to the printer or the digital documentation system and assigned to the relevant batch.

Detection takes place via the operating panel or by means of barcode reader.

9.1 Batch content identification via operating panel

Display text:

```
Read Content No.
No=--?
```

▶ Inputting the identification number via the operating panel

NOTE
The identification number must lie within the range 11-65. Only the digits 1-6 can be used for a number. (Not possible: 17, 18, 19, 27, 28, 29....)

For an input No. 66 *"No identification"* is output.

A maximum of 18 objects can be identified. **The same number cannot be input twice. Always complete input with 66**.

9.2 Batch content identification via barcode

Display text:

```
Quantity of Contents
--
```

▶ Reading the batch content with the barcode reader

NOTE
The reading process can be cancelled with the button. Always conclude with no. 66.

Reading is terminated after reaching a max. 18 batch contents.

NOTE
The length of the name input is limited to 12 characters. If the no. 0 or 66 is read *"No identification"* is output (see Chap. 7.2 "Identification via barcode reader")

Barcodes can be produced oneself from the Internet (free of charge). (*http://www.barcodemagic.com/barcodemagic.html*).

Example:

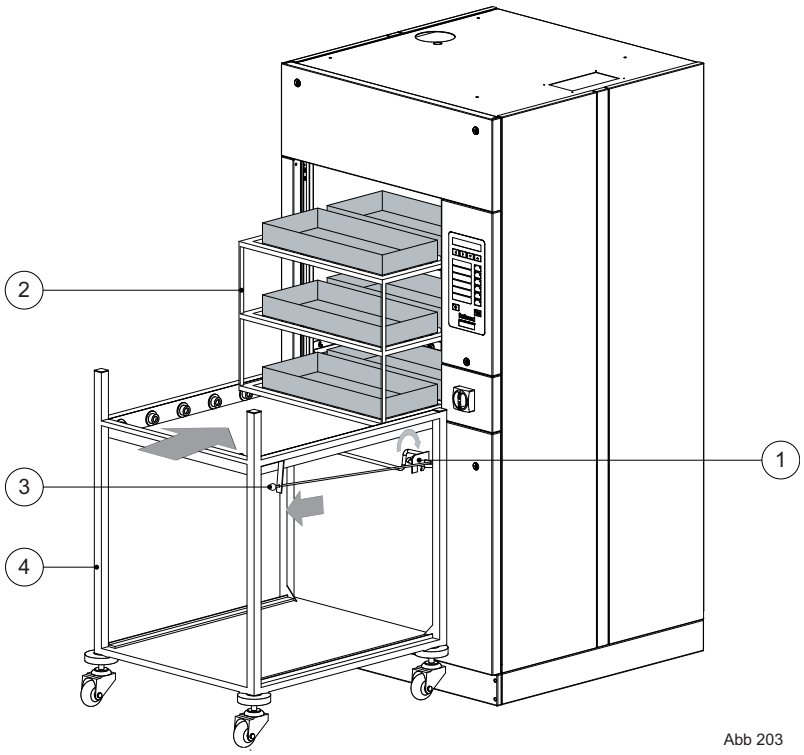
Abb 227

10 Loading from the unclean side

DANGER!
Always wear protective goggles and gloves when loading. **Soiled items to be washed may cause infections!**

10.1 Manual loading

▶ Attach the transfer trolley with the loaded rack to the device (Fig. 203 Pos. 1)



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1 Attachment and detachment hook
2 Rack
3 Locking hook
4 Transfer trolley

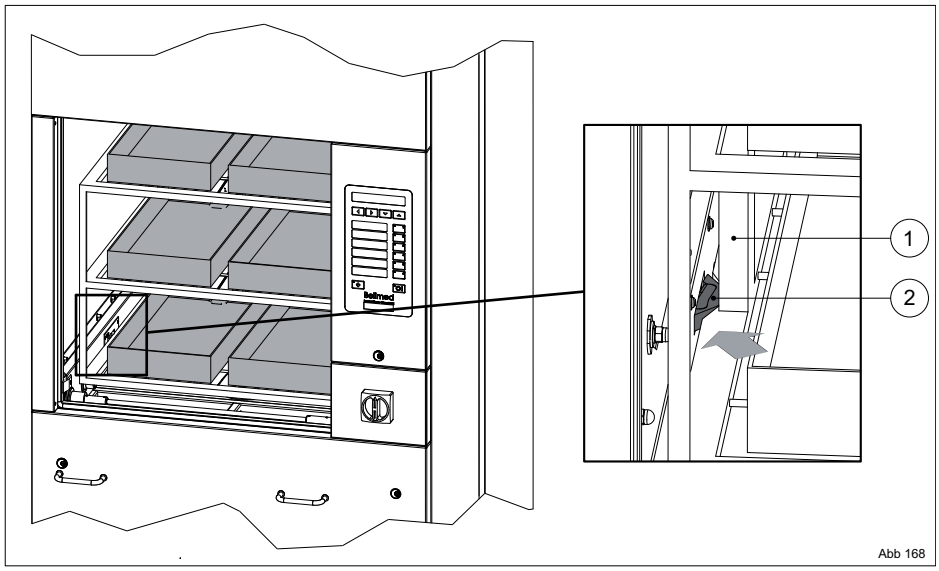
▶ Open the washing compartment with the button

▶ Slide the loaded rack into the washing chamber (Fig. 203)

- Rack docking must coincide with the device docking
- The rack has to lock into the guide (Fig. 168)

CAUTION!
Sharp or pointed objects may fall down when sliding the rack. This can cause injuries.

The rinsing arms must not be blocked by too high objects or objects protruding downwards. Check rotation by hand!



1 Rack
2 Rack downholder

▶ Close the washing compartment with the button

WARNING!
Do not touch the door or its surrounding panel during the closing process. A crushing hazard exists.

If any objects are trapped between the panel and door, the technical personnel must be informed to rectify the problem.

▶ The device is ready to start.

```
Program ready
dd.mm.20yy              hh:mm
```

NOTE
Check that the date and time are correct. This is important for the batch documentation. Report discrepancies to the technical specialist!

10.2 Automatic rack station (optional)

For correct and intended operation and servicing it is absolutely necessary to follow the instructions supplied wit the automated rack station.

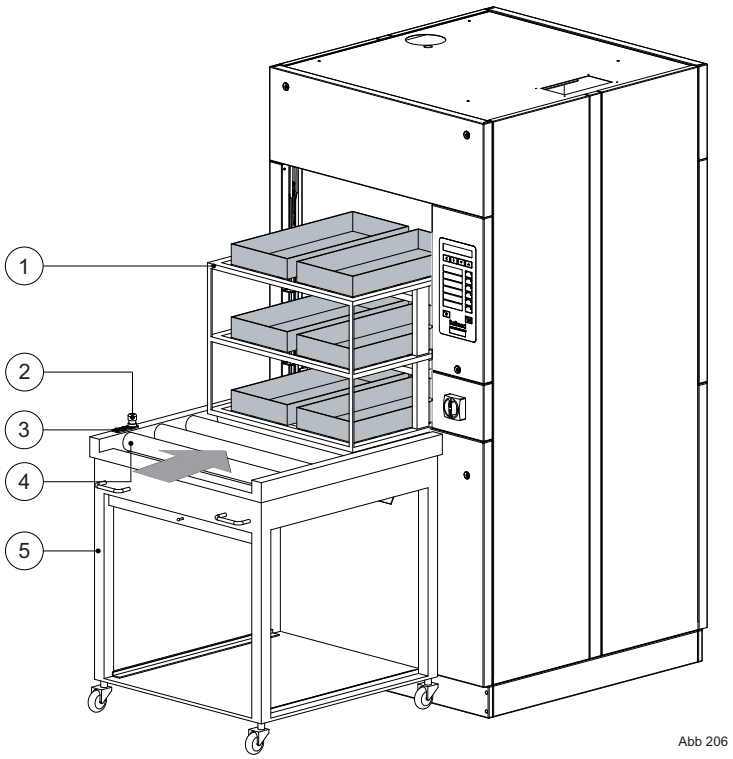


Abb 206

1 Rack
2 Rack station Emergency Stop
3 Rack station operating buttons
4 Automatically driven rollers
5 Rack station

11 Washing and disinfection

11.1 General information

WARNING!
Only operate the device with the original metal paneling! Uncontrolled escape of water due to a burst pipe or split tubing can cause scalding. Only remove the metal panel once the device is isolated from the mains supply.

11.2 Washing, disinfecting

▶ Press the required button 1 to 6

This step proceeds automatically for automated program recognition (optional)

NOTE
In the case of *"automatic program recognition"* check the items to be washed against the program name!

▶ Program flow

Display text:

```
P2|____|                13min
Wash                     36°C
```

P2|____| = program step status

13min = remaining run time

Wash = current step

36 °C = temperature of washing agent or drying air

▶ **Procedure in case of faults:**

- ▶ If a fault occurs during operation, acknowledge with the 01 button
- ▶ If the fault persists (see Chap. 16 "Faults")
- ▶ If the fault cannot be rectified, the technical specialist must be informed

DANGER!
If smoke is emitted or water escapes, immediately **turn off at the main switch** and isolate the device from the mains supply. Inform the technical specialist.

▶ The end of the program is indicated with an acoustic signal

Display text:

```
Program name
Correctly Finished
```

12 Unloading from the clean side

- ▶ Attach the transfer trolly to the device
- ▶ Open the CS washing compartment door with the button.
- ▶ Remove the washed items (Fig. 204)

CAUTION!
The washed items and washing chamber are hot! Always wear protective goggles and gloves when unloading.

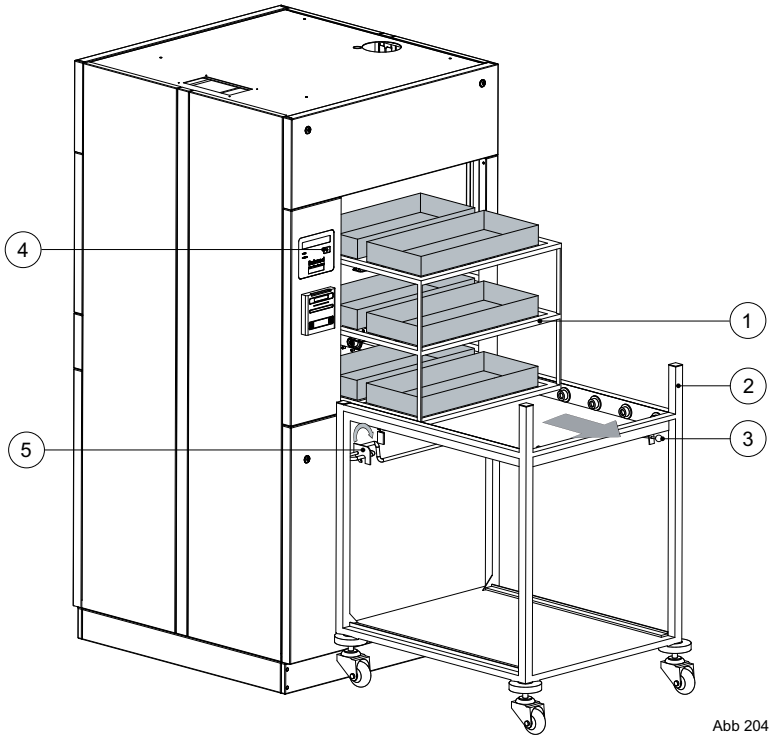


Abb 204

1 Rack
2 Transfer trolley
3 Unlocking lever
4 CS door button
5 Attachment and detachment hook

- ▶ Open the CS washing compartment door with the button
- ▶ On the display appears "*Program ready*"
- ▶ Visually inspect the results of cleaning. *In the case of washed items that are unclean, repeat washing with the same program!*

CAUTION!
There must be no more soiling (incrustations, depositions) visible.

- ▶ Detach the transfer trolley with the lever (Fig. 204 Pos. 3)
- ▶ Washed items ready for further processing

13 Switching off the device

▶ Switch off the device after use

CAUTION!
Switch off the device with the button .

For servicing, switch off the device at the main switch (see Chap. 14.1 "Servicing in general").

NOTE
If the device is switched off at the main switch, the controller is also no longer active. Consequently, the water level is not checked and, in the case of a broken valve, water can overflow.

14 Daily servicing and cleaning work

14.1 Servicing in general

The owner is responsible for carrying out servicing and cleaning work.

DANGER!
Switch off at the main switch prior to all servicing work.

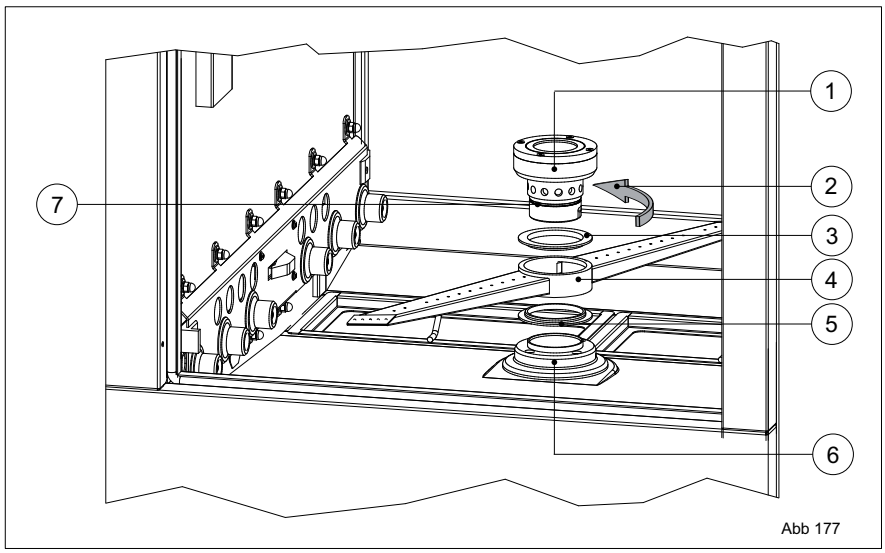
Only carry out servicing and cleaning work with safety goggles and gloves! Soiling residues can cause infections!

CAUTION!
Never spray the device for cleaning. The device is not water-jet-proof.

Only use chrome steel cleaning agents or surface disinfectants for cleaning the outside of the device. **No solvents!**

14.2 Servicing the bottom washing arm

WARNING!
Pointed or sharp objects can cause injuries when washing the device.



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1 Clamping fixture
2 Direction for loosening
3 Top bearing yoke
4 Bottom washing arm
5 Bottom bearing yoke
6 Supporting bearing
7 Sealing O-ring for clamping fixture

- ▶ Twist the clamping fixture (Fig. 177 Pos. 1) counter-clockwise and pull it upwards
- ▶ Disassemble the remaining components acc. to Fig. 177
- ▶ Check the seal on the clamping fixture (Fig. 188 Pos. 7) for damage

- ▶ Check the washing arm (Fig. 177 Pos. 4) for clogged nozzles and clean as required
- ▶ Clean the bearing yokes (Fig. 177 Pos. 2+5), check for wear and replace as required

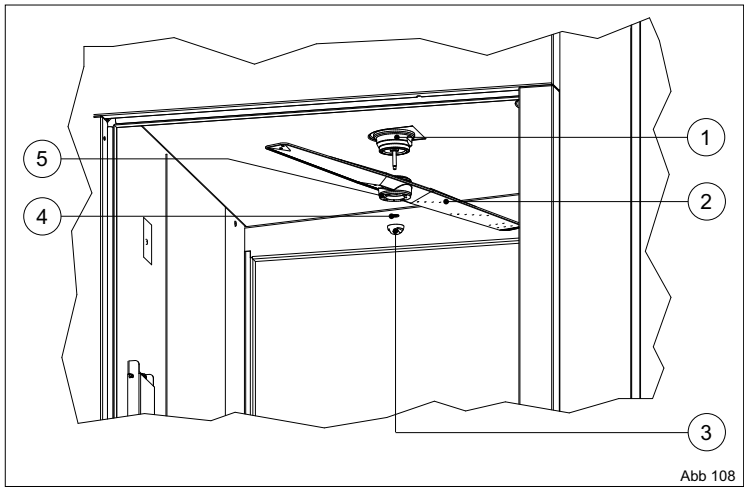
  Replacement criteria: Score marks or deep scratches
- ▶ Reassemble components

CAUTION!
Rinsing nozzles upwards!

- ▶ Check the rotation of the washing arm

14.3 Servicing the top washing arm

The washing arm must be checked daily and clogged nozzles cleaned.



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1 Washing arm
2 Top washing arm
3 Dome nut
4 Slide ring
5 Rotor bearing

DANGER!
Switch off at the main switch prior to all servicing work.

Only carry out servicing and cleaning work with safety goggles and gloves!
Soiling residues can cause infections!

- ▶ Loosen dome nut (Fig. 108 Pos. 3)

NOTE
Do not lose the washer (Fig. 108 Pos. 4)!

- ▶ Disassemble components (Fig. 108)
- ▶ Check the washing arm (Fig. 108 Pos. 2) for clogged nozzles and clean as required
- ▶ Check the rotor bearing (Fig. 108 Pos. 5) for wear and replace as required

Replacement criteria: Score marks or deep scratches

- ▶ Reassemble components
- ▶ Check the rotation of the washing arm

14.4 Cleaning the surface sieve and coarse sieve

DANGER!
Switch off at the main switch prior to all servicing work.

Only carry out servicing and cleaning work with safety goggles and gloves!
Soiling residues can cause infections!

- ▶ Remove surface sieve (Fig. 96 Pos. 4) and clean as required
- ▶ Remove coarse sieve (Fig. 96 Pos. 3) and clean as required

CAUTION!
The tank heating elements can be very hot!

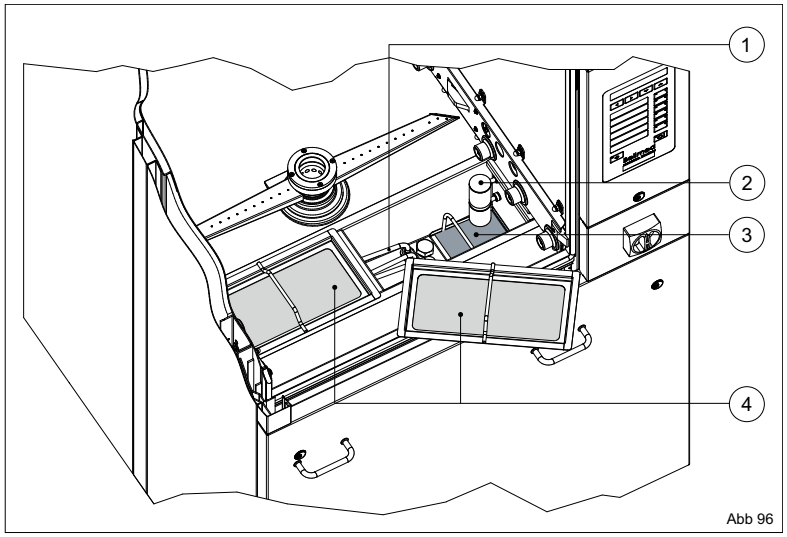


Abb 96

1 Tank heating elements
2 Level float
3 Coarse sieve
4 Surface sieve

- ▶ Removing foreign bodies from the washing compartment
- ▶ Reinsert the coarse sieve correctly
- ▶ Reinsert the surface sieve correctly

CAUTION!
Never rinse without the surface sieve and coarse sieve!

15 Device fails to clean properly

15.1 Checking the device

- Is the right program selected for the items to be washed?
- Do the washing arms rotate? (See Chap. 14 "Daily servicing and cleaning work")
- Are the washing arms correctly installed? (See Chap. 14 "Daily servicing and cleaning work")
- Are the washing arm nozzles clogged? (See Chap. 14 "Daily servicing and cleaning work")
- Are the suction and intermediate sieves clogged or absent? (See Chap. 14.4 "Cleaning the surface sieve and coarse sieve")
- Does the trolly dock to the device properly? (See Chap. 14.2 "Servicing the bottom washing arm")
- Are the waste water and media connections correctly established? (See Chap. 5 "Preparing the device") ***The checks are to be performed by the technical specialist!***

15.2 Checking dosing

- Is there sufficient cleaning agent in the containers? (See Chap. 16.1 "Fault text without process interruption")

15.3 Checking rack loading

- Are the items to be washed properly loaded on the trolley provided for this purpose? (See Chap. 8 "Loading and identifying racks")
- Are the washing nozzles on the rack clogged? (See Chap. 8.1 "Loading racks")
- Is the rack inserted correctly? (See Chap. 10.1 "Manual loading")
- Have the items to be washed been proberly pre-treated? (See Chap. 4 "Pre-treating medical devices")

16 Faults

16.1 Fault text without process interruption

Fault text display	Cause	Remedy
`Doser _ _ _ _` `Empty`	Doser container is empty. Empty indicator float incorrectly fitted or defective.	1) Fit a new canister 2) Pull the empty indicator lance out of the empty canister and correctly insert it into the new canister. 3) Activate the washing program with the button ***Caution!*** ***Always use protective goggles and gloves when refilling the detergents!***
`Program Recognition` `Fault Code 118`	The rack position in the washing chamber is not correct. Reed sensor for *"automatic program recognition"* is defective.	Pull out the rack and slide it in again. Inform the technical specialist.
`Door Interlock` `Select Pr again`	If the program is interrupted with the button the washing compartment door remains locked.	New program can be selected.
`Probe Difference` `Is too Large`	Difference between the monitoring probe and the regulating probe is too large (+- 2°C).	New program can be selected. Inform the technical specialist immediately. Recalibrate the probes at least at 80°C.
`Replace Filter`	The sterile filter for drying is clogged.	Inform the technical specialist immediately.
`Periodical Service`	Servicing promt after the specified batch number. (Generally every 1500 batches)	New program can be selected. Initiate service call from contractual partner.
`Exhaust facility defective`	Building exhaust facility failure.	New program can be selected. Inform the technical specialist immediately.
`Peak Load Block`	The building peak load management has blocked the device as a load.	A new program cannot be selected. Wait until it is enabled once again.
`No Communication` `Documentation system`	Connection to PC for batch recording is interrupted.	New program can be selected. Re-establish the connection between the device and PC for batch recording.

16.2 Fault text with process interruption

WARNING!
Report fault text with process interruption to the technical specialist immediately. Under no circumstances continue working with the device!

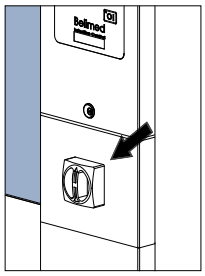
Fault texts with process interruption appear during the program flow. The fault code and the cause of the fault blink alternately on the display (exception Fault Code 101).

Example:

```
Leakage Pan
Fault Code 112
```

16.3 Device does not run

- Is the device switched on at the main switch? (Fig. 209)



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- Are the fuses intact? (inspection by the technical specialist)
- Are the washing compartment doors correctly locked? (See Chap. 5 "Preparing the device")
- Fault code on the display? (See Chap. 16 "Faults")

17 Options

17.1 Modem connection

If a modem is installed, the device can be linked with the Belimed Service Centre. Inform the Service Centre before activating the modem (see Chap. 20 "Organisation Belimed AG".

17.1.1 Activating the connection

Display text	Description
`Program ready` `XX.XX.XXXX  12:00`	In standby mode press the button for 4 seconds
`Password ?` `___`	Press the button for 4 seconds
`Remote Support` `Initialize Modem`	Modem connection is established
`Remote Support` `Not Connected`	Modem connection could not be established
`Remote Control` `Connected`	Modem connection is established. Device is remote controlled

17.2 Independent measurement data acquisition IPD

With automatic verification, the ongoing process is interrupted with the relevant error message. The function can be switched on and off from the operating panel. For function *"On"* a process interruption follows, for *"Off"* only a text on the display.

Activation:

▶ Device must be on the status

```
Program ready
dd.mm.20yy              hh:mm
```

▶ Press the button 3 times until *"Verification On/Off"* appears

```
Process Verification
               On
```

▶ Use the button to switch between *"On"* or *"Off"*

17.3 Tank heating manually switchable

17.3.1 Function

The selection switch (Fig. 231 Pos.3) is used to switch between electrical heating E (Fig. 231 Pos. 2) for the washing chamber and steam heating D (Fig. 231 Pos.1).

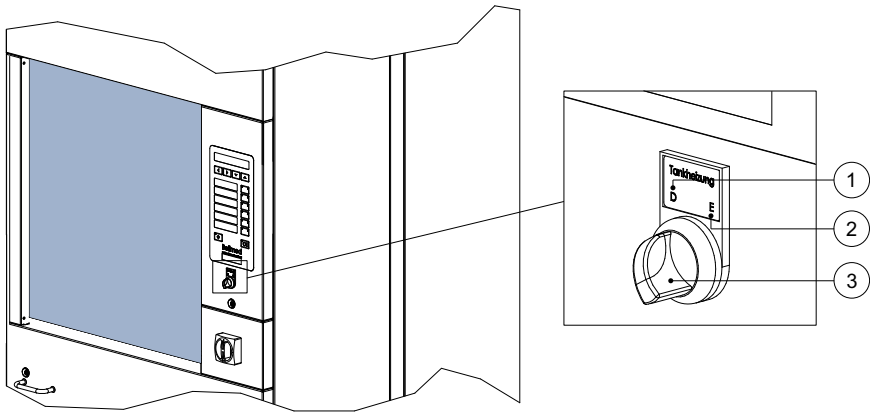

Abb 231

1 Steam heating
2 Electrical heating
3 Manual selection switch

17.3.2 Operation

▶ Fault 161 or 162 appears

```
No heat
Fault Code 161
```

```
No heat
Fault Code 162
```

▶ Acknowledge fault with door button

▶ Manual switching with the selection switch (Fig. 231 Pos. 3) from electrical heating (Fig. 231 Pos. 2) to steam heating (Fig. 231 Pos. 1)

▶ Restart program

CAUTION!
If the same fault still occurs after switching to steam, the technical specialist must be informed immediately (see Chap. 16.2 "Fault text with process interruption")

17.4 Built-in printer CS / US

17.4.1 Function

The built-in printer allows operating data, such as process steps and error messages, to be recorded and printed out.

NOTE
The function of the built-in printer is the same for both built-in versions CS/ US.

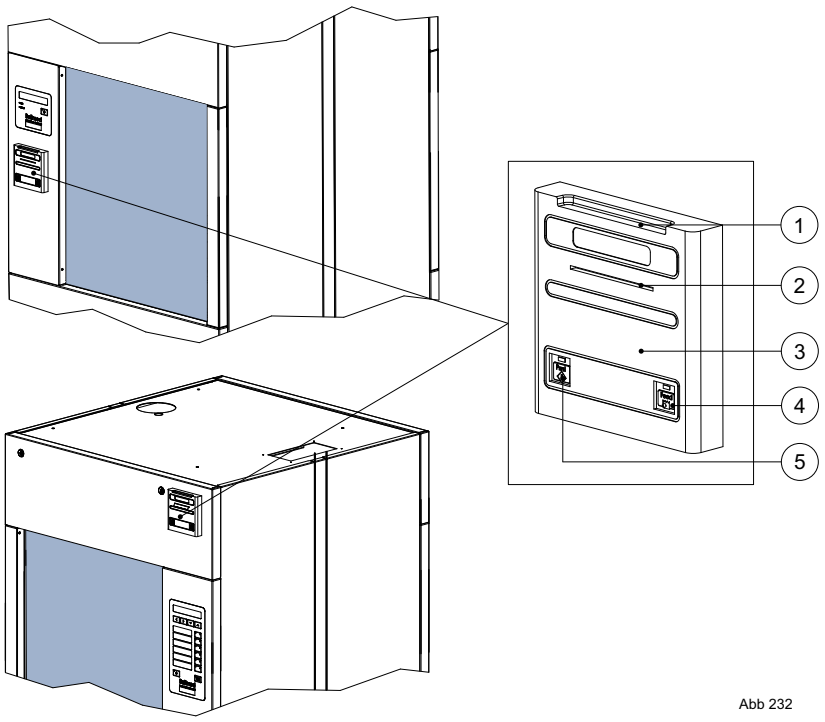

Abb 232

1 Recess lid opens upwards
2 Paper slit
3 Costom built-in printer
4 Paper feed button
5 Print button (not active)

17.4.2 Operation

- ▶ Display text *"Program ready"*
- ▶ Activate printer with the 4 button

  All program steps, faults and program interruptions are now recorded and printed out
- ▶ Archiving printed data
- ▶ Use the 2 button and the 5 button to print out operating data

  Operating data = program formulas, setup data
- ▶ Deactivate the printer with the 4 button

17.4.3 Changing paper rolls

- ▶ Open up the lid on the recess (Fig. 232 Pos. 1)
- ▶ Replace roll acc. to brief instructions on the inside of the lid
- ▶ Close lid. Feed paper through the paper slit (Fig. 232 Pos. 2)
- ▶ Printer ready for operation again

17.5 Emergency stop CS

17.5.1 Function

If necessary, an ongoing process can be interrupted on the clean side with the additional emergency stop.

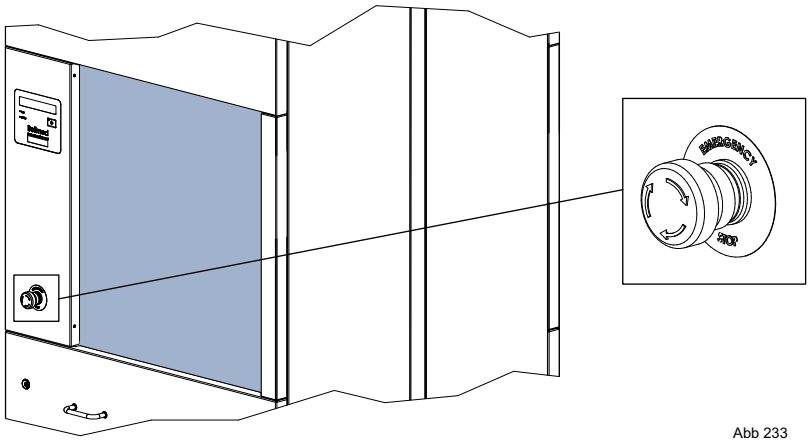

Abb 233

17.5.2 Operation

If a problem occurs during a process, implement the following steps without delay:

- ▶ Press the emergency stop (Fig. 233)
- ▶ The ongoing process is interrupted immediately
- ▶ Rectify fault (see Chap. 16 "Faults")
- ▶ Restart program

18 Conformity and certifications

KONFORMITÄTSERKLÄRUNG
DÉCLARATION DE CONFORMITÉ
DECLARATION OF CONFORMITY

Belimed AG
Dorfstrasse 4
CH-6275 Ballwil

Name und Adresse des Herstellers/ Nom et adresse de fabricant/ Name and address of the manufacturer

Wir erklären in alleiniger Verantwortung, dass der Reinigungs- und Desinfektionsautomat
Nous déclarons sous notre propre responsabilité que l'automate de lavage et de désinfection
Under our sole responsibility we herewith declare that the washer and disinfectors

Typ: **WD 290** Serien-Nr.: **99812...** **99813...** **99814...**

nach Anhang IX der Richtlinie 93/42/EWG, als ein Medizinprodukt der Klasse IIA eingestuft wird und gemäss der Bestimmungen der Richtlinien
est conforme, selon l'annexe IX de la directive 93/42/CEE sur les dispositifs médicaux de la classe IIA, aux directives des normes
according to annex IX of directive 93/42EEC, is rated as a médical device of class IIA and under the terms of reference

93/42/EWG; 73/23/EWG; 89/336/EWG
93/42/CEE; 73/23/CEE; 89/336/CEE
93/42/EEC; 73/23/EEC; 89/336/EEC

mit den folgenden harmonisierten Normen, nationalen Normen oder normativen Dokumenten übereinstimmt.
selon les normes harmonisées, les normes nationales ou autres documents normatifs suivants.
is confirm with the following harmonised standards, national standards or other normative documents.

Sicherheit	**DIN EN 61010-1**: 94-03; **EN 61010-1**: 93-04; **EN 61010-1/A2**: 95-07
	DIN EN 61010-2-045: 2002-05; **EN 61010-2-045**: 2000-12
	IEC 61010-1: 1990-09: am1 1992-09; am2 1995-06
EMV	**EN 61326**: 1997; A1: 1998; A2: 2001; A3: 2003; IEC 61326: 2002
SVGW	**W/TPW 106:** 2000-05, **EN 61770**
DVGW	**DIN 1988-4:** 1988-12
Typenprüfung	nach **prEn ISO 15883-1**:2003

Konformitätsbewertungsverfahren
Procédure d'évaluation de la conformité
Conformity assessment procedure
Nach 93/42 EWG, Anhang II
(Vollständiges Qualitätssicherungssystem)

Konformitätsbewertungsstelle
Organisme notifié
Notified Body
CE 0044 TÜV NORD

Prüfzeichen
Label de test
Test characters
DVE GS SVGW SSIGE DVGW

Ballwil, 3. Januar 2006
Ort Datum / Lieu date /Place date

E. Moser
Geschäftsleiter
Belimed AG
Name und Funktion/ Nom et fonction/ Name and function

Verteiler: Intranet
Erstellt/geändert MA/AH
Datum: 03 01 06

Ueberprüft/genehmigt MA
Datum: 03 01 06
Kopie unterliegt nicht dem Aenderungsdienst

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19 Glossary

Authorised persons	Approval for special persons, especially the issuance of rights, for third-party usage as applicable.
Operators	Persons who load the device and perform simple washing and servicing work.
Loading	Collective term to describe all items, devices and materials that are inserted into a washing/disinfection device for the purpose of treatment in a cycle.
Intended use	Use of the device in accordance with the information provided in the user information.
Boiler	Closed vessel in which water is heated indirectly by the flow of a heated medium by means of a heat exchanger at a pressure higher than atmospheric pressure.
Disinfection	Reduction in the number of viable microorganisms on a product to a predefined level suitable for its continued handling or use.
Performance qualification	System with which the process cycle can be interrupted or modified depending on requirements; illustrative and documenting evidence that the device, as it is installed and operated according to the operating procedures, works durably in accordance with the predefined criteria and therefore products are obtained that fulfil their definitions, i.e. the washing/disinfection device delivers products that are cleaned and disinfected according to the required standard.
Error, error message	State of a unit in which it is incapable of fulfilling the required function, whereby the functionality caused by servicing or other planned actions or the absence of external resources is excluded.
Hazard	Potential source of damage.
Device	Aggregate of parts or assemblies combined together, of which at least one is movable with the corresponding drive elements, control and energy circuits joined together for a specific application, especially for processing, treatment, transporting or packaging of a material.
Device for continuous operation	Device that automatically transports for loading through each individual process cycle.
Glove	Alkali and acid resistant glove
Installation qualification	Illustrative and documenting evidence that the device has been equipped and installed in accordance with the relevant definitions.
CW	Cold water
Medical devices	All individual or interconnected instruments, apparatuses, device materials or other objects including the software used for he proper function of the medical device that are determined by the manufacturer for use on persons for the following purposes: • identification, prevention, monitoring, treatment or alleviation of diseases; • Identification, monitoring, treatment, alleviation or compensation of injuries or disabilities; • examination, replacement or modification of the anatomical structure or of a physiological process; • contraception, and their proper main function in or on the human body is neither achieved by pharmacological, immunological nor metabolic means, but whose mode of action may be supported by these means.
Washing	Removal of contamination from the surface to be washed with an aqueous medium with or without process chemicals depending on requirements.

Washing/ disinfection device	Device for washing and disinfecting medical products and other objects used in the areas of medicine, dental medicine, pharmaceuticals and veterinary medicine. *Note: Device types are excludes that are designed specifically to wash cloths or other laundry. Definitions for devices intended for sterilisation or termed as "sterilisers" are specified in other standards , e.g. in EN 285.*
Washing/ disinfection device for instruments	Washing/disinfection device intended for washing and disinfecting loads containing surgical instruments, anaesthetic accessories, containers, devices, glass devices and similar objects.
Two-door washing/ disinfection device	Washing/disinfection device with separate doors for loading and unloading.
Risk	Combination of the probability of occurrence of damage or the extent of damage.
RKI	The task assigned to the**R**obert **K**och**I**nstitute includes both the observation of occurrence of diseases and the relevant health hazards for the population, as well as the deriving and scientifically establishing the required measures for effective protection of the health of the population.
CS	Clean side
Protective goggles	Alkali and acid resistant fully closed protective goggles
Safety	Term for a state free of unjustifiable risks or impairment or seen as being free of hazards.
SOP	**S**tandard **O**perating **P**rocedure is a document describing the approach within an operational working process. Frequently recurring workflows are described in texts and provided for the person implementing the task.
Controller	Installation that controls the washing/disinfection device step-by step through the required phases of the process cycle(s) or the process according to the defined process parameters.
Fault	Identification by the automated controller that the prescribed process variable for the process cycle of the washing/disinfection device are not adhered to.
Tank	Container permanently installed in the washing/disinfection device to store solutions consumed during the process.
Technical specialist	Technical specialist responsible for performing simple service and maintenance work on the device.
Door	Mechanism for closing and sealing the chamber.
US	Unclean side
Validation, process validation	Documented procedure for achieving, recording and interpreting the required results to demonstrate that a procedure always agrees wit the prescribed specifications.
Lock, locked	Mechanical, electrical or other type of mechanism having the purpose of preventing the execution of hazardous device functions under defined conditions.
Verification	Affirmation by providing objective proof that the defined requirements have been fulfilled [EN ISO 9000:2000]
DI water	Deionised or demineralised or fully demineralised water (H2O) without the minerals (salts, ions) occurring in normal spring water and mains water.
Rack	Mechanism for the correct loading and washing of items.
Washing chamber	The part of the washing/disinfection device in which the load is treated. *Note: Steam generator, piping, e.g. drains and connections, from which the chamber is separated, are not included.*
WW	Warm water

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21 Notes