

MYTRONIC BOTTLE SYSTEM




Installation and operating instructions

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1 About this document

 These installation and operating instructions form part of the unit. Failure to comply with the instructions and information in these installation and operating instructions means that Mytronic will not be able to offer any warranty or assume any liability for the safe operation and the safe functioning of the unit.

The German version of the installation and operating instructions is the original manual. All other languages are translations of the original manual.

These installation and operating instructions apply to:

Mytronic Bottle System for built in unit
Order no.: 851.20.XX

Mytronic Bottle System for mounting on unit with mounting bracket
Order no.: 851.405.XX



Mytronic Bottle System for cup filler, mounting on unit with mounting bracket
Order no.: 851.605.XX

Mytronic Bottle System for cup filler, mounting on unit without mounting bracket
Order no.: 851.607.XX


1.1 Warnings and symbols

Warnings

The warnings in this document are intended to draw your attention to possible injury to persons or damage to machinery. The following warning symbols are used:

-  General warning symbol
-  Biohazard warning

The warnings are structured as follows:

 **Signal word**

Description of the type and source of danger

The possible consequences of ignoring the warning are described here.

> Follow these measures to avoid the danger.

The signal word differentiates between four levels of danger:

- **DANGER**
Immediate danger of severe injury or death
- **WARNING**
Possible danger of severe injury or death
- **CAUTION**
Risk of minor injuries
- **NOTICE**
Risk of extensive material/property damage

Other symbols

These symbols are used in the document and on or in the unit:

-  Note: e.g. specific instructions regarding efficient and cost-effective use of the unit.
-  Manufacturer
-  Order number
-  Serial number
-  Medical device
-  Health Industry Bar Code (HIBC)
-  Expiry date
-  CE labelling
-  Important information
-  Wear protective gloves
-  Wear protective goggles.
-  Use mouth and nose protection

1.2 Copyright information

All circuits, processes, names, software programs and units mentioned in this document are protected by copyright. The installation and operating instructions may not be copied or reprinted, either in full or in part, without written authorisation from Mytronic.

2 Safety

Mytronic has developed and designed the system in such a way that dangers are effectively ruled out if the unit is used in accordance with the intended use.

Despite this, the following residual risks can remain:

- Personal injury due to incorrect use/misuse
- Personal injury due to mechanical effects
- Personal injury due to lack of hygiene, e.g. infection

2.1 Intended Purpose

The Mytronic Bottle System is used to supply water to dental treatment units and in particular to the dental instruments connected to them.

2.2 Intended Use

Fill the Mytronic water bottle with a suitable solution. This can be a disinfection solution to prevent algae formation and to disinfect the waterways with drinking water or a suitable sterilising solution.

The system must be connected to a compressed air line as well as to the line supplying the treatment unit with water (see “6 Mounting”). The system may only be used with the supplied safety pressure regulator. The integrated stop valve enables the water bottle to be screwed in and out while the system is switched on.

2.3 Improper Use

Any other usage or usage beyond this scope is deemed to be improper. The manufacturer accepts no liability for damage resulting from improper usage. In such cases, the user/operator will bear the sole risk. Do not use any liquids or solids that are unsuitable for the Mytronic Bottle System.

2.4 Systems, connection with other devices

Additional devices connected with medical devices must be proven to conform with their corresponding IEC or ISO standards. All configurations must continue to comply with the standard requirements for medical systems (see IEC 60601-1).

Whoever connects additional devices to medical devices automatically becomes the system configurator and is responsible for ensuring that the system corresponds with the standard requirements for systems. Local laws take priority over the requirements outlined above.

2.5 General safety notes

- > Always comply with the specifications of all guidelines, laws, and other rules and regulations applicable at the site of operation for the operation of this unit.
- > Check the function, condition and fill level of the unit prior to every use.
- > Do not convert or modify the unit.
- > Comply with the specifications of the Installation and Operating Instructions.
- > The Installation and Operating Instructions must be accessible to all operators of the unit at all times.
- > When filling the water bottle, watch out for spilled liquids - danger of slipping.

2.6 Combining devices safely

Where applicable, the requirements for medical products have been taken into account in the development and construction of the device. As a result, this device is suitable for installation within medical supply equipment.

- > Where this device is integrated in other medical supply equipment, the requirements of European Union Medical Device Regulation (EU) 2017/745 and the relevant standards must be observed.

2.7 Specialist personnel

Handling

Unit operating personnel must ensure safe and correct handling based on their training and knowledge.

- > Instruct or have every operator instructed in handling the unit.

The following groups are not permitted to operate or use a commercially operated unit:

- People without the necessary experience and knowledge
- People with reduced physical, sensory or mental capabilities
- Children

Installation and repairs

- > All installation, resetting, alteration, extension and repair work must be carried out either by Mytronic personnel or by a suitably qualified person approved by Mytronic.

2.8 Essential performance characteristics

The unit does not have any essential performance characteristics as set out in IEC 60601-1 section 4.3. The unit complies with the requirements according to IEC 60601-1-2:2014 and DIN EN ISO 7494-2:2015-08.

2.9 Duty to report serious incidents


The operator/patient is required to report any serious incident that occurs in connection with the device to the manufacturer and to the competent authority of the Member State in which the operator and/or patient is established/resident.

2.10 Only use original parts


- > Only use accessories designated or approved by Mytronic.
- > Only use only original wear parts and replacement parts.

2.11 Storage and transport


The original packaging provides optimum protection for the unit during transportation.

 Mytronic will not accept any responsibility or liability for damage occurring during transportation due to the use of incorrect packaging, even where the unit is still under guarantee.

- > Only transport the unit in its original packaging.
- > Keep the packing materials out of the reach of children.

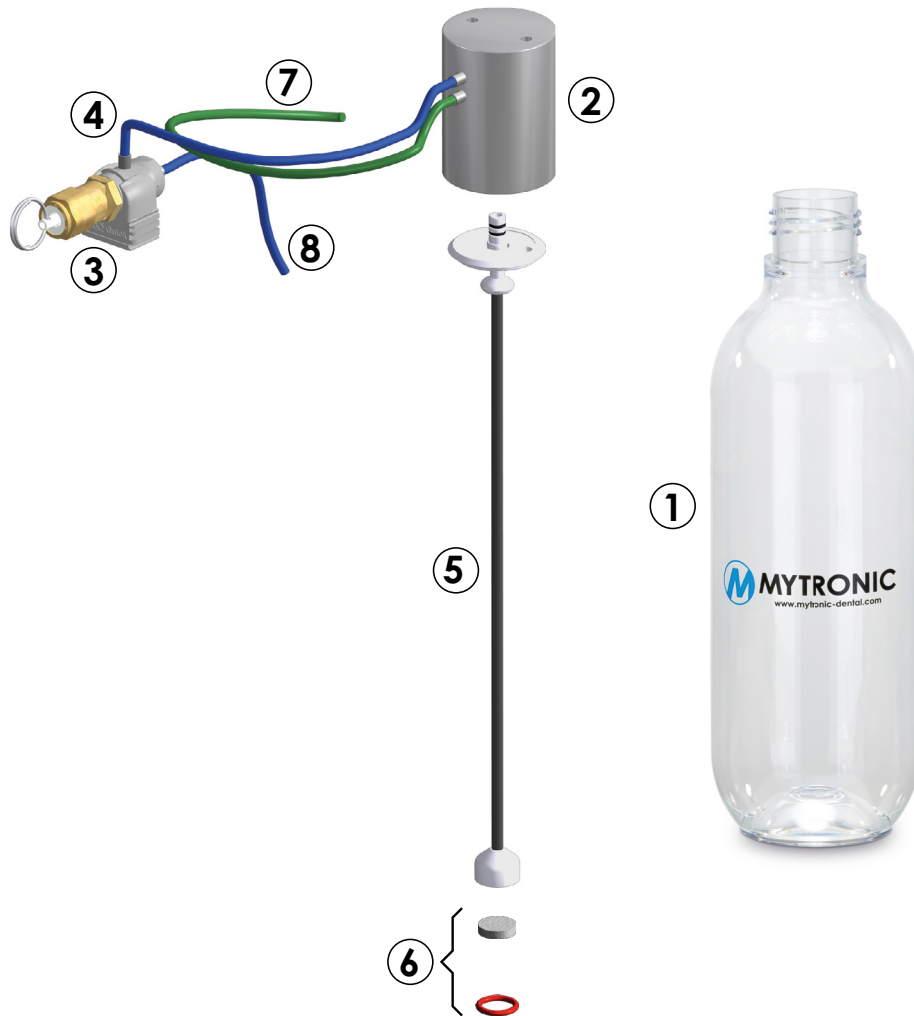
 The bottles are to be stored UV-protected when not in use.

2.12 Disposal

 The unit may be contaminated. Inform the waste management company so that they can take all necessary safety steps.

- > Prepare accessory parts before disposal, then dispose of according to local and national regulations.
- > If you have any questions about the correct disposal of parts, please contact your dental trade supplier.

3 Overview



- | | |
|---|--|
| 1 | Mytronic water bottle |
| 2 | Water bottle receptacle, mounting on unit without mounting bracket |
| 3 | Safety pressure regulator 2 bar for flexible hoses |
| 4 | Air hose water bottle receptacle < > safety pressure regulator |
| 5 | Riser pipe |
| 6 | Fine filter with fastening o-ring |
| 7 | Water hose to treatment unit |
| 8 | Air hose for compressed air supply |

For more items, see ["3.3 Accessories"](#)

3.1 Variants

3.1.1 Mounting on unit version with mounting bracket

The mounting on unit version is prepared for wall mounting.



Figure 2: Mounting on unit version with mounting bracket

3.1.2 Mounting on unit version without mounting bracket

The mounting on unit version without mounting bracket is prepared for mounting from below, on a table or worktop.

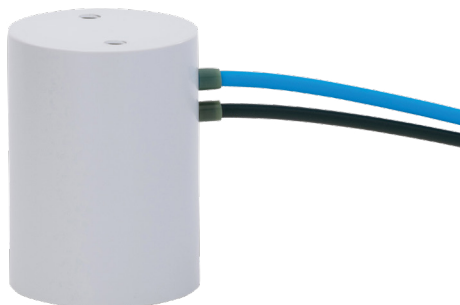


Figure 3: Mounting on unit version without mounting bracket

3.1.3 Built in unit version

The built in unit version is prepared for mounting from below, in a treatment unit.

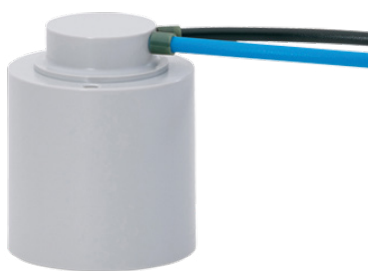


Figure 4: Built in unit version

3.2 Scope of delivery

The following items are included in the scope of delivery:

Mounting on unit version with mounting bracket

- Water bottle receptacle, mounting on unit
- Riser pipe with fine filter
- Pan-head screw M5x12 (2 pieces)
- PUR water hose green (IDxODxL/1.7 x 3.2 x 500 mm)
- PUR air hose (IDxODxL/1.5 x 3.45 x 500 mm)
- Safety pressure regulator 2.0 bar for flexible/fixed hoses
- Mounting bracket, stainless steel/white
- Installation and operating instructions

Mounting on unit version without mounting bracket

- Water bottle receptacle, mounting on unit
- Riser pipe with fine filter
- Pan-head screw M5x12 (2 pieces)
- PUR water hose green (IDxODxL/1.7 x 3.2 x 500 mm)
- PUR air hose (IDxODxL/1.5 x 3.45 x 500 mm)
- Safety pressure regulator 2.0 bar for flexible/fixed hoses
- Installation and operating instructions

Built in unit version

- Water bottle receptacle, mounting on unit
- Riser pipe with fine filter
- Pan-head screw M5x12 (2 pieces)
- PUR water hose green (IDxODxL/1.7 x 3.2 x 500 mm)
- PUR air hose (IDxODxL/1.5 x 3.45 x 500 mm) □ Safety pressure regulator 2.0 bar for flexible/fixed hoses
- Installation and operating instructions

Mounting on unit version, cup filler, with mounting bracket

- Water bottle receptacle, mounting on unit, cup filler
- Riser pipe with fine filter
- Pan-head screw M5x12 (2 pieces)
- PUR water hose green (IDxODxL/1.7 x 3.2 x 500 mm)
- PUR air hose (IDxODxL/1.5 x 3.45 x 500 mm)
- Safety pressure regulator 2.0 bar for flexible/fixed hoses
- Mounting bracket, stainless steel/white
- Installation and operating instructions

Mounting on unit version, cup filler, without mounting bracket

- Water bottle receptacle, mounting on unit, cup filler
- Riser pipe with fine filter
- Pan-head screw M5x12 (2 pieces)
- PUR water hose green (IDxODxL/1.7 x 3.2 x 500 mm)
- PUR air hose (IDxODxL/1.5 x 3.45 x 500 mm)
- Safety pressure regulator 2.0 bar for flexible/fixed hoses
- Installation and operating instructions

3.3 Accessories



NOTICE

Device malfunction or damage due to incorrect/missing accessories

Guarantee claims may become invalid as a result.

The water bottles can burst.

- > Only use Mytronic water bottles.
- > Only operate with a safety pressure regulator 2.0 bar.
- > Exchange water bottle after one year or 50 automatic treatments.
- > Damaged, scratched or opaque water bottles must be replaced immediately.



An overview of Mytronic water bottles is available in the online shop:
www.mytronic-dental.com

Water bottle with Mytronic logo, lasered	851,500.01
Water bottle with Mytronic logo, printed	851,500.02
Water bottle lid	.851.510



Other inscriptions on the water bottle are available on request.

Safety pressure regulator for flexible hoses	8101.59904.20.26.26
Safety pressure regulator for fixed hoses	8101.59904.20.S4.26



The safety pressure regulator for fixed hoses requires a hose with an outer diameter of 4 mm.

3.4 Wear parts and replacement parts

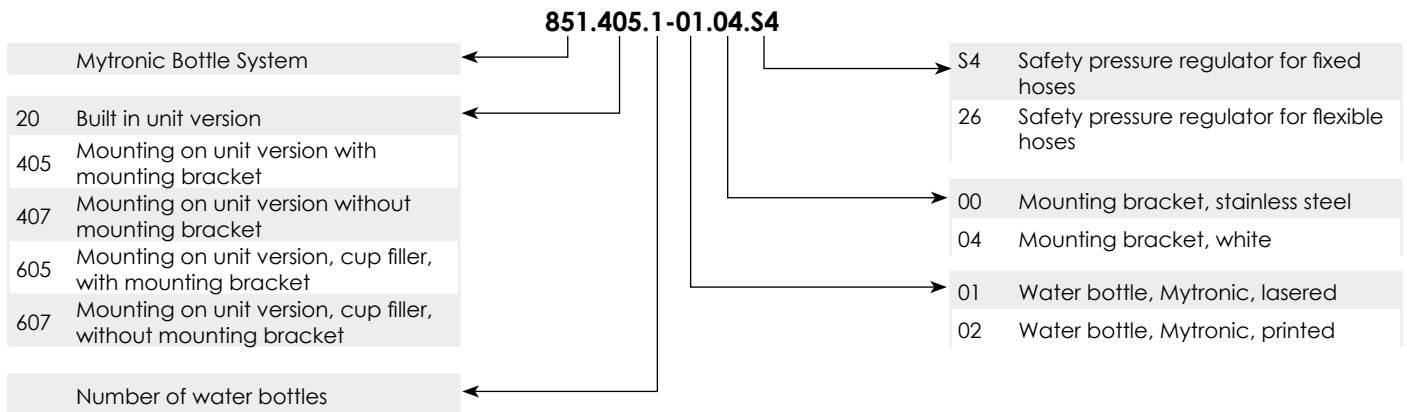
The following parts are subject to wear and tear, and should be replaced at regular intervals (see also "10 Maintenance"):

Riser pipe with fine filter	8101.85550.05
Fine filter	.350.722
Safety pressure regulator for flexible hoses	8101.59904.20.26.26
Safety pressure regulator for fixed hoses	8101.59904.20.S4.26



Information on spare parts is available in the online shop:
www.mytronic-dental.com

3.5 Order number key



If an optional article is not required, the order number can be as follows:

Mytronic Bottle System built in unit version with safety pressure regulator for flexible hoses
851.20.26

Order example:

Mytronic Bottle System mounting on unit version with white mounting bracket, water bottle with lasered Mytronic logo and safety pressure regulator for fixed hoses
851.405.1-01.04.S4

4 Technical data

Medical Device Class		
Mytronic Bottle System		Class 1
General technical data		
Dimensions (W x H x D)	cm	approx. 9 x 30 x 10
Weight	kg	approx. 0.5
Hose diameter		
PUR air hose blue (ID x OD x L)	mm	1.5 x 3.45 x 500
PUR water hose green (ID x OD x L)	mm	1.7 x 3.2 x 500
Water flow rate		
Standard variants	ml/min	approx. 760
Cup filler	ml/min	approx. 2155
Cup filler hose dimensions		
PUR air hose blue (ID x OD x L)	mm	1.5 x 3.45 x 500
PUR water hose green (ID x OD x L)	mm	3.0 x 4.5 x 500
Ambient conditions during operation		
Temperature	°C	+3 to +50
Relative humidity	%	5 to 95
Minimum connection pressure – air	bar	2
Maximum connection pressure – air	bar	6
Ambient conditions during storage and transport		
Temperature	°C	-20 to +70
Relative humidity	%	5 to 95
Atmospheric pressure	hPa	800 to 1200

4.1 Type plate

The type plate with the UDI code of the Mytronic Bottle System can be found on the back of the water bottle receptacle.

4.2 Evaluation of conformity

This unit has been subjected to a conformity assessment procedure in accordance with the current relevant European Union guidelines. This unit conforms to all relevant requirements.

5 Function

The unit is used to supply water to dental treatment units and in particular to the dental instruments connected to them.

The system must only be connected to a Mytronic water bottle.

Another function is to disinfect the waterways in the dental instrument, including the Mytronic Bottle System, and/or to remove and prevent algae growth, using a disinfectant solution in the water bottle. The water bottle is filled with the appropriate medium (drinking water or disinfection solution). The system is affixed to a compressed air line and to the line that provides the treatment unit with water and then fastened appropriately (see "6 Mounting"). Then the system is operational.

When unscrewing the water bottle, the attached compressed air line is blocked by a stop valve, which is re-opened when screwing in the bottle. This makes it easy to change bottles or to refill the water bottle while the unit is operational.



Figure 6: Water bottle

- | | |
|----------|--------------------------|
| A | Water bottle, screwed in |
| B | Water bottle, unscrewed |

6 Mounting

i Only qualified specialists or persons trained by Mytronic are permitted to mount, install and commission the system.

i For screwing in the water bottle, a space requirement of approx. 40 cm vertically downwards must be considered before assembly.

i The compressed air must be filtered with a 50 µm filter, in accordance with DIN EN ISO 7494 2:2015. The procurement of a suitable filter and the installation of the filter can be handled via specialist dental suppliers.

The water bottle receptacle can be fixed with or without a mounting bracket as follows:

- underneath a work top
- on the wall
- in a treatment unit

6.1 Water bottle receptacle, mounting on unit without mounting bracket

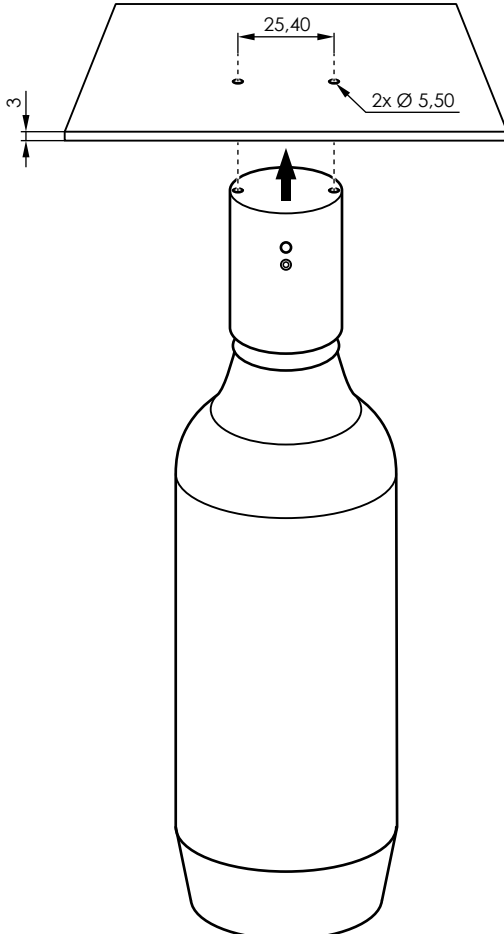


Figure 7: Mounting on unit

Assembly steps:

- > Drill 2 x holes \varnothing 5.5 mm in the panel.
- > Align the Mytronic Bottle System with the holes.
- > Fasten the Mytronic Bottle System with M5x12 screws.

i Installation example on a panel thickness of 3 mm.

6.2 Water bottle receptacle, mounting on unit with mounting bracket

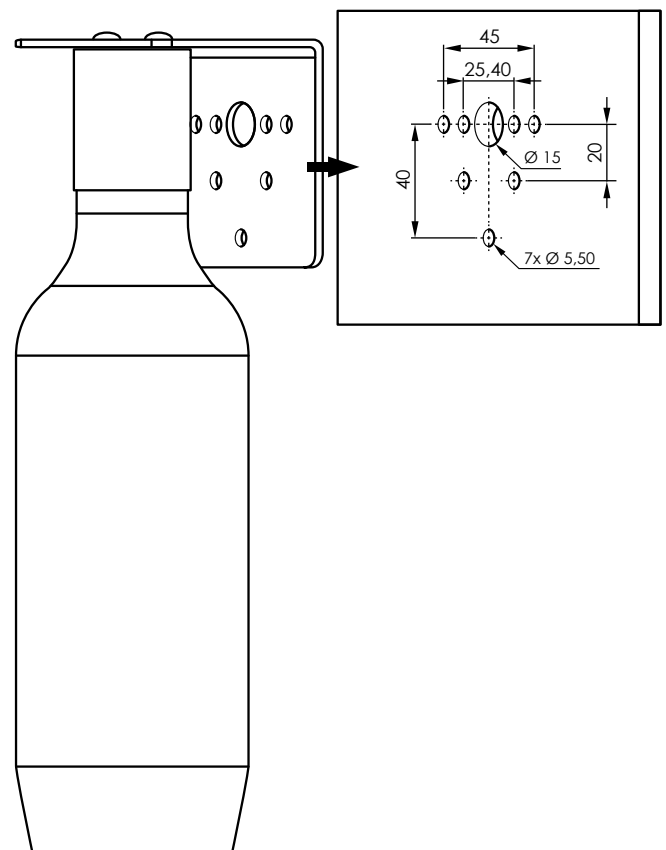


Figure 8: Mounting on unit with mounting bracket

Assembly steps:

- > Drill hole \varnothing 15 mm in panel.
- > Drill 7 x holes \varnothing 5.5 mm, with at least 3 of these in the panel and the mounting bracket is to be fixed using M5 pan-head screws.



All 3 holes should be positioned so that there is an even load distribution of the fastening.

- > Guide the air hose (blue) and water hose (green) through the \varnothing 15 mm hole.

6.3 Water bottle receptacle, built in unit



Figure 9: Built in unit

Assembly steps:

- > Drill a hole \varnothing 29.60 mm in the panel.
- > Drill 2 x holes \varnothing 4.3 mm in the panel.



All 3 holes must be on the same axis.

- > Insert the Mytronic Bottle System into the \varnothing 29.6 mm hole and align with the \varnothing 4.3 mm hole.
- > Fasten the Mytronic Bottle System with M4x12 screws.

6.4 Connect and lay the air hose



Observe the flow direction (IN > OUT) of the safety pressure regulator.

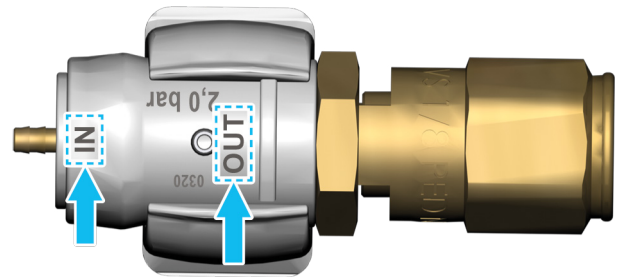


Figure 10: Safety pressure regulator

Assembly steps:

- > Measure the required length of the air hose between the safety pressure regulator (IN) and the connection to the compressed air supply (e.g. in the floor socket).
- > Shorten the air hose to the required length.
- > Connect the air hose to the input (IN) of the safety hose regulator.
- > Connect the air hose to the compressed air supply and secure with a hose safety device.
- > Measure the required length of the air hose between the safety pressure regulator (OUT) and the water bottle receptacle.
- > Shorten the air hose to the required length.
- > Connect the air hose to the output (OUT) of the safety pressure regulator.



Check the safety pressure regulator after installation and once a year. If it blows off, pull the ring.

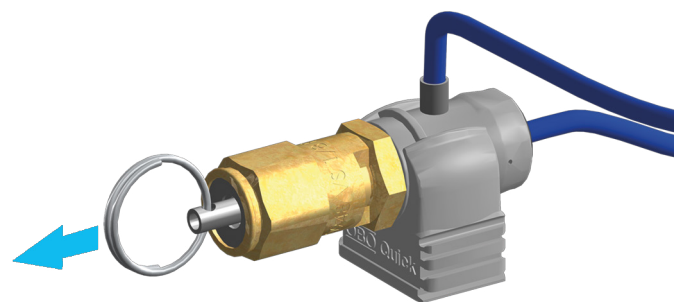


Figure 11: Safety pressure regulator ring

6.5 Connect and lay the water hose

- > Measure the required length of the water hose between the water bottle receptacle and the connection to the water supply (e.g. in the treatment unit).
- > Shorten the water hose to the required length.
- > Thread the hose safety devices on to the water hose.
- > Connect the water hose to the water supply and secure with a hose safety device.

7 Handling

7.1 Initial use

- > Clean the Mytronic Bottle System before initial use (see "8 Disinfection and cleaning").

7.2 Operating tips

- > Insert the riser pipe into the water bottle.
- > Place the water bottle in the water bottle receptacle.
- > Turn anti-clockwise approx. ½ turn and tighten gently.
The pressure is mounted automatically.



Figure 12: Mounting the water bottle

- > Insert riser pipe in the water bottle [A]
- > Screw in the water bottle [B]

8 Disinfection and cleaning



WARNING

Health hazard due to contaminated unit

Contaminated units can cause infections.

- > Clean and disinfect the Mytronic Bottle System before working on the unit.
- > Wear suitable personal protective equipment when working (e.g. impermeable gloves, protective goggles and mouth and nose protection).



NOTICE

Device malfunction or damage due to incorrect cleaning and disinfecting agents

Guarantee claims may become invalid as a result.

- > Do not use any foaming agents, e.g. household cleaning agents or instrument disinfectants.
- > Do not use abrasive cleaners.
- > Do not use agents containing chlorine.
- > Do not use any solvents like acetone.



NOTICE

Device malfunction or damage due to damaged/worn water bottles

Guarantee claims may become invalid as a result.

The water bottles can burst.

Water bottles are subject to operational wear and tear and have a limited service life*.

- > Exchange water bottle after one year or 50 automatic treatments.
- > Damaged, scratched or opaque water bottles must be replaced immediately.

* The expiry date is lasered on the bottom of the water bottle, along with the corresponding pictogram.

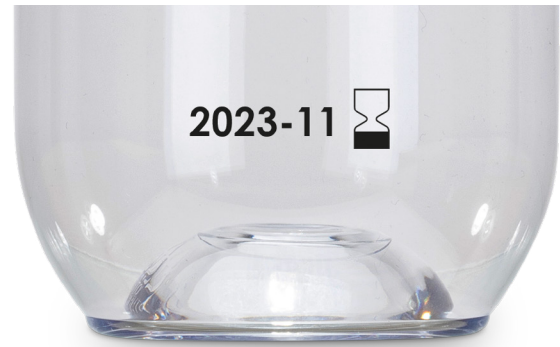


Figure 13.: Expiry date

Mytronic recommends:

- For continual disinfection of procedural water and water supply lines: Alpron* solution
- For cleaning and disinfection of waterways: Bilpron* solution
- For cleaning and disinfection of water bottles: BC-San 100* solution
- For cleaning and disinfection of external surfaces, water bottles and threads: FD 366 sensitive top wipes Disinfection of sensitive surfaces and FD 366 sensitive Disinfection of sensitive surfaces, ready-to-use solution**

Only these products have been tested by Mytronic.

* Alpron, Bilpron and BC-San 100 are products from Alpron Medical GmbH.

** FD 366 sensitive top wipes and FD 366 sensitive Disinfection of sensitive surfaces, ready-to-use solution, are products from DÜRR DENTAL SE.

8.1 Procedural water disinfection

Drinking water can be mixed with Alpron for use on patients. This ensures consistent water quality.

- > Detailed information can be found in the Alpron operating instructions.

8.2 Daily after the end of treatment



The bottle contents must be changed every day, otherwise there is a risk of contamination.

The following are required for cleaning:

- ✓ Non-foaming disinfectant/cleaning agent that is compatible with the materials.
- > Clean the water bottle with hot water (≤ 90 °C) and a cleaning brush.

Cleaning and disinfecting surfaces

- > Regularly clean and disinfect surface and thread of the water bottle and water bottle receptacle, e.g. with FD 366 sensitive top wipes.

8.3 Once or twice a week/break-time preservation

The following are required for cleaning:

- ✓ Non-foaming disinfectant/cleaning agent that is compatible with the materials.
- > Rinse the water bottle with hot water.
- > Clean the water bottle with a cleaning brush or in the washer-disinfector.
- > Fill the water bottle with Bilpron according to the manufacturer's instructions and flush all the lines. Detailed information can be found in the Bilpron operating instructions.
- > Fill the empty water bottle with BC-San 100 according to the manufacturer's instructions and close with a screw cap, if available.



A water bottle that is filled with BC-San 100 solution must not be connected.

Detailed information can be found in the BC-San 100 operating instructions.

9 Reprocessing

9.1 Risk analysis and categorisation

A risk analysis and categorisation of medical products often used in dentistry must be performed before their reprocessing by the operator. Comply with all national directives, standards and specifications such as, for example, the "Recommendations from the Commission for Hospital Hygiene and Infection Prevention".

Accessories of the medical device are also subject to reprocessing.

Classification recommendation given proper use of the product: semi-critical B.

Semi-critical medical device

A medical product that comes into contact with mucous membranes or pathologically affected skin. The operator is responsible for correct classification of the medical products, defining the reprocessing steps and performing the reprocessing.

9.2 Preparation process in accordance with EN ISO 17664

- > The reprocessing procedure after each treatment is carried out according to the reprocessing procedure established by EN ISO 17664.

Important information!

The reprocessing notes in accordance with EN ISO 17664 have been independently tested by Mytronic for the preparation of the device and its components for their reuse.

The person conducting the reprocessing is responsible for ensuring the reprocessing performed using the equipment, materials and personnel achieves the desired results. This requires validation and routine monitoring of the reprocessing process. Any deviation from the procedures described following by preparation staff is solely the responsibility of the personnel in terms of effectiveness and the possible adverse consequences.

Frequent reprocessing has little effect on the device components. The end of the product life cycle is especially influenced by the amount of wear and tear or damage resulting from its use. The use of soiled, contaminated and damaged components is at the sole responsibility of the person performing the reprocessing and the operator.

The reprocessing method was validated as follows:

- **Pre-cleaning**
 - FD 366 sensitive top wipes
 - Cleaning brush
- **Manual cleaning**
 - FD 366 sensitive top wipes
 - FD 366 sensitive ready-to-use solution
 - Cleaning brush
- **Manual disinfection**
 - FD 366 sensitive top wipes
 - Bilpron
 - BC-San 100 (only for the water bottle)
- **Automatic cleaning and disinfection**
 was performed in accordance with EN ISO 15883 with tested efficacy.
 - Cleaning agent: Neodisher MediClean Forte
 - Washer-disinfector: PG 8535 (Miele)
 - Programmes: "Cleaning without neutralisation" and "THERMAL DESotro"
 - Cleaning/disinfection temperature: 90 °C
 - Cleaning/disinfection time: 5 minutes

– **Cleaning brush**

Bottle brush with silicone bristles

- Bristle material: silicone
- Brush head: Ø 60 mm
- Temperature resistance up to 300 °C
- Brush length: 350 mm





Example:

Culinaris bottle brush, sterilisable, anthracite REF 227721

General information

- > Comply with all national directives, standards and specifications for the cleaning, disinfection and sterilisation of medical products as well as the specific specifications for dental practices and clinics.
- > When selecting the cleaning and disinfecting agents to be used, observe the specified information (see "Manual cleaning, intermediate rinsing, disinfection, final rinse, drying" and "Automatic cleaning, intermediate rinsing, disinfection, final rinse, drying").
- > Comply with the concentrations, temperatures, residence times and post-rinsing specifications issued by the manufacturer of the cleaning and disinfectant agent.
- > Only use cleaning agents that are non-protein-fixing, aldehyde-free and display material compatibility with the product.
- > Only use disinfectants that are aldehyde-free and display material compatibility with the product.
- > Do not use any rinse aid (danger of toxic residue on the components).
- > Only use freshly-produced solutions.
- > Only use distilled or deionised water (not sterile water) with a low bacterial count (at least drinking water quality) that is free from facultative pathogenic microorganisms (e.g. legionella bacteria).
- > Use clean, dry, oil and particle-free compressed air.
- > Do not exceed temperatures of 93 °C.
- > All devices used (e.g. ultrasonic bath, cleaning and disinfection device (washer-disinfector)) must be regularly serviced and inspected.

9.3 Preparation at the operating location

-  Wear protective gloves
-  Wear protective goggles.
-  Use mouth and nose protection
-  Use protective clothing



WARNING

Risk of infection from contaminated products.

Risk of cross contamination

- > Prepare the product correctly and promptly before its first use.

- > Thoroughly wipe down the exterior surfaces of all components with cleaning wipes to remove coarse organic and inorganic soiling:
 - one cleaning wipe for the small components, e.g. the individual parts of the riser pipe and
 - two cleaning wipes for larger components, e.g. the water bottle.
- > Note the action time of the cleaning agent.
- > Protect the unit from contamination when transporting it from the treatment chair to the reprocessing location.

9.4 Manual cleaning, intermediate rinsing, disinfection, final rinse, drying

A disinfectant or combined cleaning and disinfectant agent is required for manual disinfection. It must have the following properties:

- ✓ Proven effectiveness (VAH or European standards) For more information, see *“General information”*.

Cleaning

- > Thoroughly wipe riser pipe and water bottle receptacle as well as their threads with cleaning and disinfection wipes (non-protein-fixing/aldehyde-free, see *“General information”*), until all contamination has been removed.
- > Wipe water bottle with cleaning and disinfection wipes, clean inner surfaces and thread with cleaning brush and cleaning and disinfecting solution, to remove all dirt.
- > Comply with the reaction times of the cleaning and disinfecting agents (see *“General information”*).
- > If you notice any further contamination, brush all surfaces completely with a cleaning brush and cleaning and disinfecting agent.

Intermediate rinsing

After the action time prescribed by the manufacturer:

- > Rinse all components under running water (temperature < 35 °C) for at least 1 minute.



Figure 14: Riser pipe

- > Unscrew the water bottle from the water bottle receptacle [A].
- > Remove the riser pipe from the water bottle receptacle [B].

Disinfect

- > Wipe and disinfect the riser pipe and water bottle receptacle, as well as their threads, with cleaning and disinfecting agent (non-protein-fixing/ aldehyde-free, see *"General information"*).
- > Wipe and disinfect the exterior surface of the water bottle with cleaning and disinfecting wipes.
- > Fill the water bottle with Bilpron, connect it to the Mytronic Bottle System and flush all the lines. Detailed information can be found in the Bilpron operating instructions.
- > Fill empty water bottles that are not connected to the unit with BC-San 100 then close. Detailed information is available in the BC-San 100 operating instructions.
- > Note the action time for the disinfectant.

Final rinse

After the action time prescribed by the manufacturer:

- > Rinse all components under running water (temperature < 35 °C) for at least 1 minute.

Drying

- > If necessary, re-dry components in a clean location using a hygienic, lint-free cloth.
- > Dry the components with compressed air in a clean location.
- > Store empty water bottles with the opening facing downwards – observe drying time of 4 hours.

9.5 Automatic cleaning, intermediate rinsing, disinfection, final rinse, drying

Selection of the washer-disinfector

Automatic cleaning and disinfection requires a washer-disinfector with the following properties and validated processes:

- Corresponds to and tested in accordance with EN ISO 15883
- Inspected programme for thermal disinfection (A0 value ≥ 3000 or min. 5 minutes at 93 °C)
- Programme is suitable for the components and provides sufficient rinsing cycles (see also *"General information"*).

Selection of the machine cleaning agents and disinfectants

The following properties are required:

- Material compatibility with the product
- Corresponds with the manufacturer's specifications of the CD

For further information, see: *"General information"*.

Automatic cleaning and disinfecting



When arranging the parts in the washer-disinfector, make sure there are no areas missed by rinsing.



Observe the drying time for the water bottle of min. 4 hours.

- > Attach water bottle to suitable holders in the washer-disinfector.

9.6 Check for function

- > After the end of the cleaning and disinfection cycle, check the components for any residual soiling and residual moisture. If necessary, repeat the cycle after the drying time.
- > If necessary, replace any damaged parts, see *"3.3 Accessories"*.
- > Insert the riser pipe in the water bottle receptacle, screw in the water bottle and check the system for leaks.
- > The components should be packaged as soon as possible after drying and checking.

10 Maintenance

All maintenance work must be performed by a qualified expert or by one of our service technicians.



WARNING

Health hazard due to contaminated unit

Contaminated units can cause infections.

- > Clean and disinfect the Mytronic Bottle System before working on the unit.
- > Wear suitable personal protective equipment when working (e.g. impermeable gloves, protective goggles and mouth and nose protection).



10.1 Replacing the fine filter

Replace the fine filter 1 x per year.



NOTICE

Device malfunction or failure during operation without fine filter

Working without a fine filter creates the risk that particles will settle in the pipes in unsuitable locations and hinder efficient function.

- > Before screwing in the water bottle, ensure that the fine filter is placed correctly and secured with the o-ring.

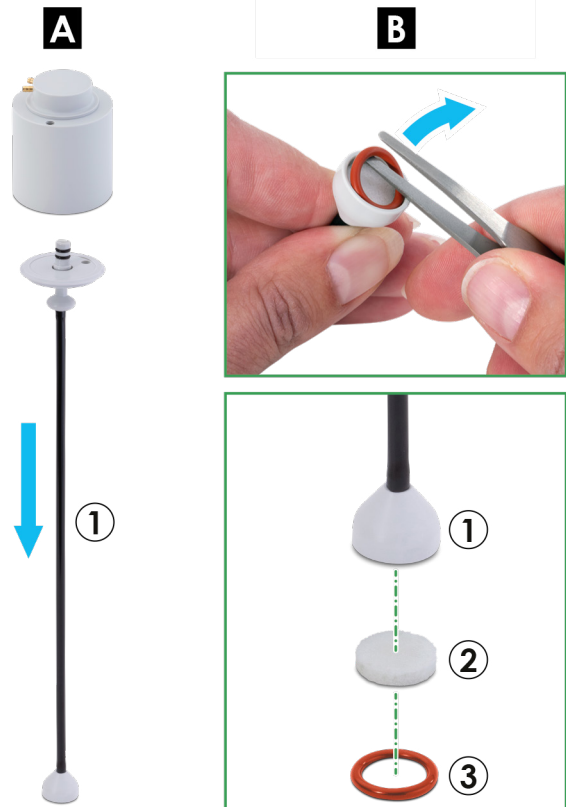


Figure 15: Replacing the fine filter

1	Riser pipe
2	Fine filter
3	O-ring

- > Pull the riser pipe out of the water bottle receptacle [A].
- > Carefully remove the o-ring and fine filter with blunt tweezers [B].
- > Insert a new fine filter and secure with an o-ring.

Fine filter (10 pieces)

..... Order number 350722

O-ring ID 11.0 x 2.0 mm NBR70 (10 pieces)

..... Order no.: 9329.11.0x2.0.SIL

10.2 Replacing the riser pipe

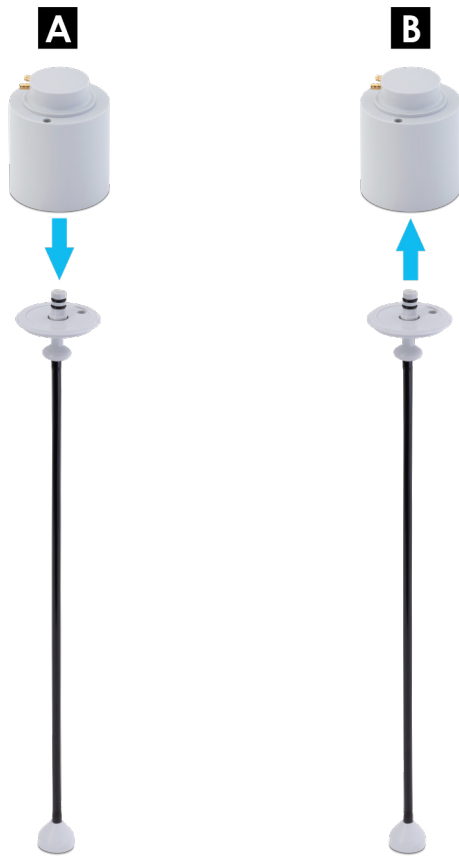


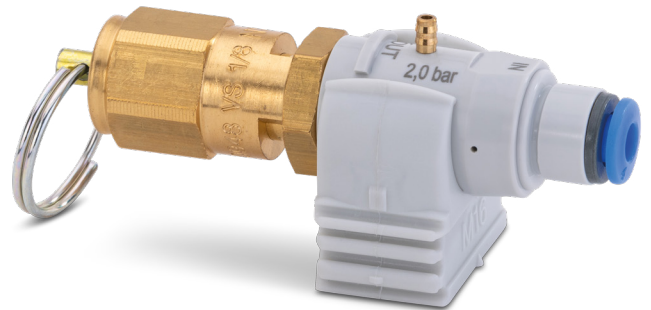
Figure 16: Replacing the riser pipe

- > Remove the riser pipe [A].
- > Insert a new riser pipe [B].

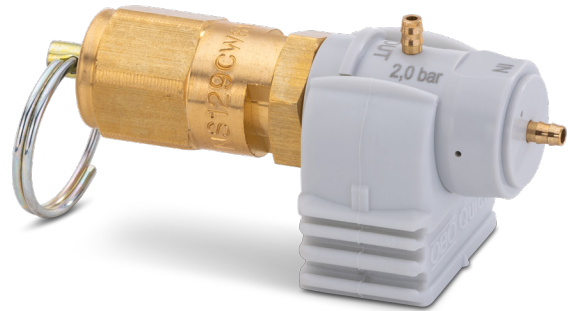
Riser pipe (1 piece)
 Order no. 8101.85550.05

10.3 Replacing safety pressure regulator

- > Remove hose safety devices with small diagonal pliers.
- > Carefully remove the hoses from the nipple using small diagonal pliers.
- > For a fixed hose: Press the blue sleeve of the hose connection in the opposition direction to the pulling direction, and pull out the hose.
- > Replace the safety pressure regulator.
- > Thread the hose safety device onto the hoses.
- > Mount the hoses on the nipple and slide the hose safety device over the connection.
- > For a fixed hose: Insert the hose into the connection.




Safety pressure regulator for fixed hoses
 (1 piece). Order no.: 8101.59904.26.S4



Safety pressure regulator for flexible hoses
 (1 piece). Order no.: 8101.59904.26.26

11 Tips for operators and service technicians

 Any repairs exceeding usual routine maintenance must be carried out by suitably qualified personnel.



WARNING

Infection due to contaminated unit



Contaminated units can cause infections.

> Clean and disinfect the Mytronic Bottle System before working on the unit.



> Wear suitable personal protective equipment when working (e.g. impermeable gloves, protective goggles and mouth and nose protection).



Error	Possible cause	Solution
Low water flow rate	Fine filter blocked in the riser pipe	> Replace the fine filter.
	Blockage in the riser pipe	> Remove and clean riser pipe.
	Blockage in the PUR hose	> Remove and clean the PUR hose, replace if necessary.
	Kink in the PUR hose	> Reposition the PUR hose.
No water flow	Blockage in the riser pipe	> Remove and replace riser pipe.
	Blockage in the PUR hose	> Remove and replace the PUR hose.
	No pressure	> Switch on the compressed air supply. > Screw in the water bottle as far as it will go, to open the stop valve.
Fluids leakage from the bottle system	PUR hose is not attached correctly	> Reconnect the PUR hose with a hose safety device.
Air blows off audibly	Bottle not completely screwed in	> Turn bottle to screw in completely.
	Safety valve blows off	> Pull the ring of the safety valve to vent.

12 Manufacturer



Hersteller/Manufacturer:

Mytronic GmbH

In den Ensterwiesen 7

61276 Weilrod

Germany

Tel.: +49 6083 95989-0

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info@mytronic-dental.com

13 Handover record

This document confirms that a qualified handover of the medical device has taken place and that appropriate instructions have been provided for it. This must be carried out by a qualified adviser for the medical device, who will instruct you in the proper handling and operation of the medical device.

Product name	Order number (REF)	Serial number (SN)

- Visual inspection of the packaging for any damage
- Unpacking the medical device and checking for damage
- Confirmation of the completeness of the delivery
- Instruction in the proper handling and operation of the medical device based on the operating instructions

Notes:

Name of person receiving instruction:

Signature:

Name and address of the qualified adviser for the medical device:


Date of handover:

Signature of the advisor for the medical device:

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14 Bottle documentation

This log documents the specified replacement of the water bottle of this medical device. Exchange water bottle after one year or 50 automatic treatments.

 Perform a preparation cycle before using a new water bottle for the first time.

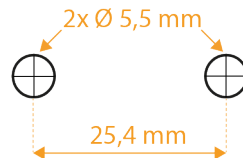
Area used in	Expiry date on the water bottle	Date of initial use	Type of preparation	Disposal date / notes
			<input type="checkbox"/> Automatic <input type="checkbox"/> Manual	
			<input type="checkbox"/> Automatic <input type="checkbox"/> Manual	
			<input type="checkbox"/> Automatic <input type="checkbox"/> Manual	
			<input type="checkbox"/> Automatic <input type="checkbox"/> Manual	
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			<input type="checkbox"/> Automatic <input type="checkbox"/> Manual	

Cleaning and disinfecting agents used:

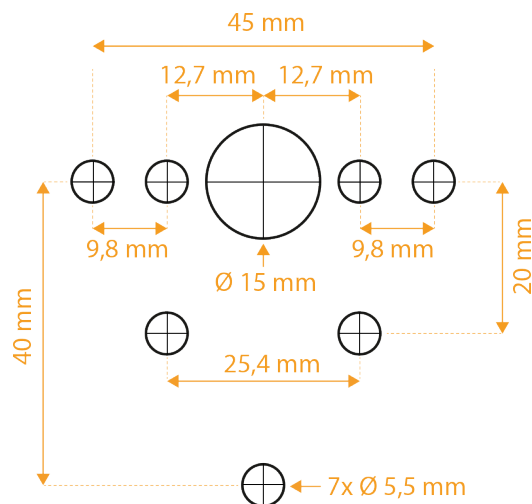
Bohrschablonen

15 Drilling templates

15.1 Mounting on unit version without mounting bracket



15.2 Mounting on unit version with mounting bracket



15.3 Built in unit version

