

Instructions for use

Controlled environment storage cabinet for processed thermolabile endoscopes

EDScab® 8H
EDScab® 8H-2

BMT Medical Technology s.r.o.
Cejl 157/50
602 00
Brno-Zábrdovice
Česká republika

CE

GTIN 8594203415133

TLP:GREEN

© BMT Medical Technology s.r.o.

The Instruction is protected by copyright law, the owner of the copyright being the company BMT Medical Technology s.r.o. The Instruction designed for personal use only and it is not allowed to make it available to public in any way, as a whole or in parts. Breach of the above stated regulations is considered to be a breach of the owner's copyrights.

Obsah

1 In general 7

1.1 Legend to the used symbols and safety warnings 7
1.2 Abbreviations 7
1.3 Information labels on the device 7

2 Security 8

2.1 Purpose and use 8
2.1.1 Purpose 8
2.1.2 Use 8
2.1.3 Drying and storage capacity 9
2.2 Lifetime of the device 9
2.3 Responsibility of the operator 9
2.3.1 Before commissioning 9
2.3.2 Operator training 9
2.3.3 Air quality 10
2.3.4 Noise emissions 10
2.3.5 Storage of adapter sets 10
2.3.6 Disposal 10
2.4 Service staff 11
2.4.1 Service staff – categories 11
2.4.2 Protected access 12
2.4.3 User permissions 12
2.5 Rules of conduct during operation 13
2.5.1 Personal protective equipment 13
2.5.2 Work on electrical equipment 13
2.5.3 Device maintenance 13
2.5.4 Power failure or main switch shutdown 13
2.6 Safety features of the device 13
2.6.1 Door blocking 13
2.6.2 Main switch 14
2.7 Maintenance and safety check 14
2.8 Standards, regulations and directives 15

3 Description of the device 16

3.1 Scope of application 16
3.2 Type label 16
3.3 Device design 18
3.3.1 Single door design 18
3.3.2 Two-door design 20
3.4 Technical description 20
3.4.1 Construction of the chamber 20
3.4.2 Chamber doors 21
3.4.3 Device location 21
3.4.4 Levelling the device 21
3.4.5 Control 21
3.4.5.1 MMM Smart HMI 22
3.4.5.2 Chamber illumination and light status indication 22
3.5 Technical equipment 22
3.5.1 Standard equipment 22

3.5.2 Air distribution . . . 22
3.5.3 Control and monitoring . . . 22
3.5.4 Drying – air parameters . . . 23
3.5.5 Service access . . . 23
3.5.6 Optional accessories . . . 23
3.5.6.1 Endo basket . . . 23
3.5.6.2 RFID cards printed (1pc) . . . 23
3.5.6.3 RFID cards unprinted (5pcs) . . . 23
3.5.6.4 Starter kit „Endoscope“ . . . 23
3.5.6.5 Starter kit „User“ . . . 23
3.5.6.6 Device-specific electric wiring documentation . . . 24
3.5.6.7 Marking of all conductors . . . 24
3.5.6.8 Supervision of construction preparations . . . 24
3.5.6.9 Valve for closing the air supply . . . 24
3.5.6.10 Left door for loading side . . . 24
3.5.6.11 Left door for unloading side . . . 25
3.5.6.12 Validation grommet for right door . . . 25
3.5.6.13 Validation grommet for left door . . . 25
3.5.6.14 Potential-free contact for alarm messages . . . 25
3.5.6.15 Restriction of air passage between loading and unloading side . . . 26
3.5.6.16 Stainless steel lining . . . 26
3.5.6.17 English plug . . . 26
3.5.6.18 Long open door signalling . . . 26
3.5.6.19 Language versions other than EN and DE . . . 26
3.5.7 Accessories supplied with EDScab® . . . 26
3.6 Adapter kit . . . 27
3.6.1 10-way connector . . . 27
3.6.2 Examples of connection adapters . . . 29
3.7 Electrical wiring and operating conditions . . . 30

4 User interface . . . 31

4.1 Loading and unloading side . . . 31
4.1.1 Main switch . . . 31
4.1.2 Display and touch screen . . . 32
4.1.2.1 Buttons and information . . . 32
4.1.3 Remote access via VNC . . . 33

5 Service . . . 34

5.1 Preparing the endoscope before drying . . . 34
5.2 Home screen . . . 38
5.3 Operator login and logout . . . 38
5.3.1 RFID login . . . 38
5.3.2 Login via menu . . . 39
5.4 Endoscope drying process – single-door version . . . 40
5.4.1 Preparation . . . 40
5.4.2 Login . . . 41
5.4.3 Endoscope reading . . . 41
5.4.3.1 Reading the endoscope via RFID . . . 41
5.4.3.2 Endoscope selection via the Menu . . . 42
5.4.3.3 Unspecified endoscope . . . 43
5.4.4 Connection of the adapter set on the shelf: . . . 44
5.4.5 Drying and storage phase . . . 45
5.4.6 Removing the endoscope: . . . 46

TLP:GREEN

5.5 Two-door design . . . 46
5.5.1 Inserting the endoscope . . . 46
5.5.2 Taking the endoscope out . . . 47
5.6 Door handling . . . 47
5.6.1 Door blocking . . . 47
5.6.1.1 Door opening . . . 48
5.6.1.1.1 Open door indication . . . 48
5.6.1.2 Automatic door unlocking . . . 48
5.7 Drying process . . . 49
5.7.1 Incorrect drying process . . . 49
5.7.2 Correct drying process . . . 50

6 Settings menu . . . 51
6.1 Creating, modifying and deleting users . . . 51
6.1.1 Permission Levels . . . 52
6.2 Add, change and delete an endoscope . . . 53
6.3 Date and time . . . 56
6.4 Display and touch screen . . . 57
6.4.1 Touch panel calibration . . . 57
6.5 LAN settings . . . 58
6.6 Cycle protocols . . . 59
6.6.1 Access via FTP . . . 59
6.7 Language . . . 61

7 Charts . . . 62

8 System information . . . 63

9 Faults . . . 64
9.1 Alarms . . . 64
9.2 Behaviour during the fault . . . 65
9.2.1 Alarm cancellation . . . 65
9.3 Action in case of special faults . . . 67
9.3.1 Power failure . . . 67
9.3.2 Emergency door opening . . . 67
9.4 Unsatisfactory drying result . . . 67

10 Maintenance . . . 69
10.1 Regular maintenance . . . 69
10.2 Maintenance agreement . . . 69
10.3 Cleaning the controls . . . 69
10.3.1 Touch screen . . . 69
10.3.2 Main switch . . . 70
10.4 Cleaning the outer surfaces and chamber of the device . . . 70
10.5 Maintenance of the adapter set . . . 71
10.6 Regular maintenance . . . 71
10.6.1 Daily . . . 71
10.6.2 As needed . . . 72
10.6.3 Quarterly . . . 73
10.6.4 Annually . . . 75

EDScab®

Possible device variants:

Business name	GTIN	Storage capacity [Flexible Endoscope]	Drying capacity	Number of doors
EDScab® 8H	8594203415133	8	3	1
EDScab® 8H-2	8594203415133	8	3	2

TLP:GREEN

1 In general

1.1 Legend to the used symbols and safety warnings

The following warning notices and symbols may be used in these instructions for use:



If not observed, there is a risk of injury!

WARNING

If not observed, there is a risk of damage to the device or the material being processed.



Indicates practical tips and important information for operating the device.

1.2 Abbreviations

Meaning of abbreviations		
PLC	Programmable Logic Controller	Programmable logic automatic machine
HMI	Human Machine Interface	User interface
RFID	Radio Frequency Identification	Standard for identification of persons and goods
PID	Piping and Instrumentation Diagram	Pipe connections and instrumentation

1.3 Information labels on the device

The following information labels may appear on the device:

	Risk of electric shock! Only appropriately qualified staff members are allowed to open.
	Protective earthing
	Wear safety glasses!
	Wear protective gloves!

2 Security

Please read these instructions for use carefully. Keep the instructions for use for future reference.

WARNING	**Please respect the safety instructions! It is about your personal safety and the proper functioning of the device!**

Knowledge of the safety instructions and warnings listed here and their technically perfect implementation is a prerequisite for the safe, trouble-free and reliable operation and maintenance of the device described.

It is forbidden to make any changes to the device or its accessories, in particular to tamper with the safety features.

These instructions for use contain information on how to use the device in accordance with its intended purpose.

It is intended for persons authorised to operate the device, for persons responsible for the device, and for all persons involved in the installation, commissioning or maintenance of the device. See chapters 2.4, 2.5.

To make it more transparent, these instructions for use contain only instructions concerning the normal operation and regular maintenance. Only the essential principles of the device functioning are described here.

Please contact the manufacturer for further information.

2.1 Purpose and use

2.1.1 Purpose

The cabinet with controlled environment for drying and storage of disinfected thermolabile endoscopes (hereinafter referred to as the “EDScab®”) is designed for drying and storage of reusable, thermolabile flexible endoscopes in accordance with EN 16442:2015.

The equipment in question is intended for use in the healthcare sector (e.g. in medical equipment processing units, in medical practices, etc.).

2.1.2 Use

WARNING	**The EDScab® is primarily designed for drying endoscopes that have been washed and disinfected in a Uniclean PLE 3 washer, manufactured by MMM.**

The drying function of the EDScab® device may only be used for endoscopes belonging to the type test groups defined in Annex F (*Determination of type test groups of endoscopes*) of the DIN EN 16442 standard. The following types of endoscopes are examples of the above-mentioned type test groups:

- Gastroscopes
- Colonoscopes
- Duodenoscopes
- Bronchoscopes
- Ultrasound endoscopes

Prior to use, the operator is obliged to verify that the specific endoscope model is, according to the manufacturer’s instructions, suitable for drying and storage in controlled-environment cabinets.

The EDScab® device must not be used for endoscopes with a maximum permissible air inlet pressure of less than 150 kPa. During drying, medical compressed air with a pressure of up to 120 kPa is supplied to the endoscopes. To ensure thorough drying of the endoscopes, the air is pulsed during the initial phase of the drying process. During these pulses, the peak impulse pressure may temporarily reach up to 140 kPa. For this reason, it is essential to ensure that no endoscope is connected to the device that could be damaged by such pressure.

TLP:GREEN

WARNING

Only thermolabile flexible endoscopes that are specified by their manufacturer for this purpose can be machine dried.



The EDScab® device cannot be used for items and materials that are not explicitly listed in this chapter (2.1.2).

WARNING

Non-healthcare use is not envisaged.

2.1.3 Drying and storage capacity

Drying capacity:	3 endoscopes simultaneously
Storage capacity:	8 endoscopes simultaneously

2.2 Lifetime of the device

The expected lifetime of the device is 10 years (under normal operating conditions) provided that the prescribed regular maintenance is followed.

During the lifetime of the device, its properties and parameters will not be affected in such a way as to endanger the safety of patients, users or third parties.

Should you wish to use this device beyond the time interval specified above, please contact the manufacturer or an authorised service centre to assess the possibility of further use of the device with respect to its technical condition and maintenance possibilities.

2.3 Responsibility of the operator

WARNING

The operator is obliged to comply with the national laws and regulations in force at the place where the device is installed.

Any adverse event must be reported to the manufacturer and the competent authority of the Member State.

It is up to the operator to determine which legal provisions apply to the installation and operation of this device. These may differ from the information in these instructions for use!

2.3.1 Before commissioning

The operator must ensure that the following requirements are met:

- The device has been properly assembled, installed and set up by an authorized company.
- The persons responsible for the device and its operators have been properly trained.
- An operating permit has been granted (if required by national regulations).

2.3.2 Operator training

The operator of the device is responsible for ensuring that the authorised operator and the persons responsible for the device have been trained properly.

The personnel in charge of operation must be trained by a qualified person (e.g. BMT/MMM customer service) and familiarised with the operating instructions when the device is handed over at the latest.

The names of the persons responsible for operating the device and the persons responsible for the system (chap. 2.4) must be documented. If there is a change in personnel, the new users must be trained and familiarised with the instructions for use. A record of the training must be made.

The operator shall be responsible for establishing a code of practice that governs the organisation of the operation of the device within the organisation.



Any improper handling of the device or failure to respect the warnings can cause personal injury or damage to property.

2.3.3 Air quality

The air quality has a significant impact on the drying and storage outcome of endoscopes. The air provided by the operator shall therefore comply with the requirements of ISO 8573-1:2010 class 1.2.1.

The information on the required compressed air quality is given in the installation plan and the construction preparation drawing. As the supply of pressurised air is subject to quality fluctuations during operation, the operator must regularly check the supplied pressurised air.

2.3.4 Noise emissions

The average noise level of the device during drying and storage is less than 50 dB. The noise level was measured according to EN 61010.

2.3.5 Storage of adapter sets

See 3.6. When storing adapter sets, please observe the following rules:

- Store adapter sets hanging.
- Do not store them in direct sunlight.
- Store at 10 to 90 °C.

2.3.6 Disposal

The operator is responsible for eco-friendly disposal of the device, its components, packaging and accessories in accordance with local regulations in force.

LEGAL GUIDELINES FOR OPERATORS:

Disposal of device components
Local regulations concerning the device disposal must be observed.

Disposal of device
The device must not be disposed of with normal household waste („unsorted municipal waste“). The device must be disposed of separately, see also „Disposal of device components“ above.

Return of old device
The operator has the option to return the old device to the manufacturer. MMM Group will carry out its professional disposal.

TLP:GREEN

Privacy policy

If personal data have been stored in the device, they must be deleted by the operator under its own responsibility before the device is to be disposed or returned.

If you have any questions about the eco-friendly disposal of the device, its individual components or the return of old devices, please contact the MMM Group customer service:

GUIDELINES FOR EU OPERATORS

- Under European Directive 2006/66/EC, used batteries and accumulators must be disposed of at a municipal collection point or returned to the manufacturer.
- European Directive 2012/19/EU on waste electrical and electronic equipment (WEEE Directive) is also in force.
- Personal data are subject to the EU General Data Protection Regulation (GDPR, Regulation (EU) 2016/679).

2.4 Service staff

WARNING

This device may only be operated by persons who have the necessary training or knowledge and experience.

Untrained persons must not operate the device.

The device has a user management system allowing you to configure the permissions of individual operators individually.

2.4.1 Service staff – categories

The intended users of the product are trained employees of the institution where the product is operated in accordance with its purpose.

Authorised operator
The operator of the device must be instructed by a specialist (e.g. MMM Group customer service) on the correct use of the device in accordance with the instructions for use.

Improper handling of the device or failure to respect the warnings can cause personal injury or property damage.

Responsible person
The operator must designate an employee who is responsible for the device. The name of the responsible person must be documented.

When the device is handed over by the manufacturer, the responsible person will receive the following accessories:

- Technical documentation
- Emergency door opener

The person responsible must acknowledge the delivery of the accessories by his/her signature.

Expert
The term „expert“ as used in this manual refers to persons who:

- Based on their professional education, they are able to perform the assigned tasks.
- Thanks to their experience, they are able to reliably and correctly perform the tasks entrusted to them.
- They are committed to continuing education and keep abreast of the state of the art in the field.
- They are able to independently recognise possible dangers and avoid potential threats.
- They are able to take responsibility for their work by observing applicable safety regulations.

This includes in particular MMM Group customer service or persons or companies authorised by MMM Group.

2.4.2 Protected access

The access to device control is password protected. This prevents any unauthorized access to process parameters and security settings.

Individual operators have different permissions to operate the device depending on the user group to which they are assigned.

By default, the operators performing normal day-to-day operations have limited access to the device controls.

2.4.3 User permissions

The preset users and their permissions:

Level	Name	Service	Permissions:
1	USER	Authorised user	E.g. insertion and removal of the endoscope, error confirmation, display of alarm history, configuration of basic parameters.
2	SUPERVISOR	Responsible person	Permissions for user + configuration of advanced parameters.
3	ADMIN	Responsible person/expert	System administration, access to all parameters
4	MMM	Expert, MMM Group Customer Service	System administration, access to all parameters

These permissions and their dependent actions can only be performed after the user has logged in.



After a defined period of inactivity, the operator can be automatically logged out. See 6.1.

TLP:GREEN

2.5 Rules of conduct during operation

2.5.1 Personal protective equipment

To increase the safety of the operator, the device is equipped with a number of safety features. Nevertheless, operators and service personnel may be injured by improper or unauthorized operation.



Operations staff:

When loading and unloading the chamber, wear gloves, work clothes and protective equipment prescribed for the workplace.



Service staff:

If necessary, appropriate protective and safety measures must be taken.

2.5.2 Work on electrical equipment



Risk of electric shock!

Work on electrical parts of EDScab® device maybe carried out only by qualified persons trained by MMM Group.



Risk of electric shock!

When working on electrical parts of the device (e.g. changing parts), turn off the main switch and disconnect the mains supply from the socket.

2.5.3 Device maintenance

Maintenance work (see 10) may only be carried out by qualified personnel (see 2.4).

2.5.4 Power failure or main switch shutdown

In the event of a power failure, the device is in a safe condition. The pressurized air will be shut off, the fans will be stopped, the lights and screens will be turned off. The door will remain as it was before the outage. For emergency opening and closing of the door see chapter 9.3.2.



In the case of a two-door enclosure, one door must always remain closed during a power failure (main switch off).

The device manufacturer does not recommend to open the door to the loading compartment.

2.6 Safety features of the device

2.6.1 Door blocking

The door cannot be opened without an operator logged in. In addition, in the two-door version the doors at the loading and unloading side cannot be opened at the same time.

Forced door opening is forbidden!

Emergency door opening in case of ongoing drying and storage is prohibited!

If the device is in a faulty condition, only the door on the loading side of the device can be opened.

Two-door version:

Emergency door opening is only permitted in unavoidable cases and only on the loading side!

There is a risk of contamination of the clean side!

2.6.2 Main switch

The main switch is located at the top of the unit to the left of the control panel, see „2“, Fig. 4.



Fig. 1

In case of danger or when working on the device (e.g. repairs, maintenance, etc.), turn off the main switch and disconnect the mains supply from the socket.

The main switch must be freely accessible!

The access to the device must not be blocked by other objects!

Do not store endoscopes inside the device when the device is switched off with the main switch.

2.7 Maintenance and safety check

The regular and professional inspection as well as the maintenance is a prerequisite for a seamless operation of your device. We therefore recommend that you conclude an inspection and maintenance contract.

TLP:GREEN

Maintenance and safety checks may only be carried out by qualified persons (see chapter 2.4). Only persons appropriately authorised by the manufacturer may perform the device repairs.

Worn and spare parts can only be replaced with genuine components.

The manufacturer disclaims any liability for damage to the device or injury to persons in connection with the device if the device has been repaired or maintained by unauthorized persons.

The maintenance and servicing of the device must comply with the countryspecific regulations.

Please note that in the event of a loss related to the operation of the device, insurance companies may not cover the claim if no maintenance has been carried out.

Maintenance of the device can be carried out mainly from the loading side. However, repairs can be made from both sides.

Access to the device from the side is not required for maintenance.

Validity of the warranty

Maintenance and safety checks at the prescribed intervals during the warranty period are a prerequisite for any warranty claims.

2.8 Standards, regulations and directives

The device has been designed and manufactured in accordance with applicable standards, directives and legal norms. See Declaration of Conformity.

WARNING

Note to the EU:

In accordance with the EU Declaration of Conformity, this device complies with the relevant European regulations and carries the CE marking.

WARNING

Other standards referred to in the regulations listed above, which may be only partially applicable, are not listed separately.

3 Description of the device

This description is a general description of the device and its function.

The specific technical data of this device can be found in the technical data sheet, the installation plan and on the type label located on the device.

3.1 Scope of application

The device (EDScab®) is designed for the storage and drying of reusable thermolabile flexible endoscopes (see chapter 2.1), which are commonly used in healthcare facilities.

3.2 Type label

The type label is located in the superstructure:



Fig. 2

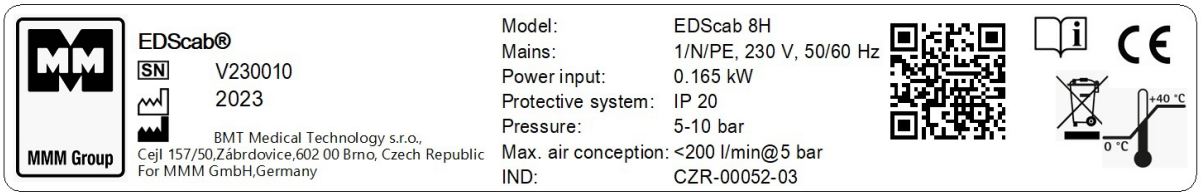


Fig. 3

TLP:GREEN

Explanation:

	Manufacturer		CE mark with identification number (example)
	Type		Disposal (WEEE Recycling)
	Serial number		Follow the instructions for use.
	Date of manufacture	IND	Device identifier
	Lower and upper humidity limits		Lower and upper temperature limit

3.3 Device design

3.3.1 Single door design



Fig. 4

(1) Touch panel
(2) Main switch
(3) Superstructure
(4) Door
(5) RFID reader
(6) Endoscope shelf

⚠ The shelf is fitted with a stop and it cannot be fully extended.

(7) Endo basket

⚠ Handle the basket carefully with respect to the optics of the endoscope.

(8) 10-pin connector socket

TLP:GREEN

(9) Fans
(10) HEPA filter
(11) Seals
(12) Anchoring point
(13) LED lighting

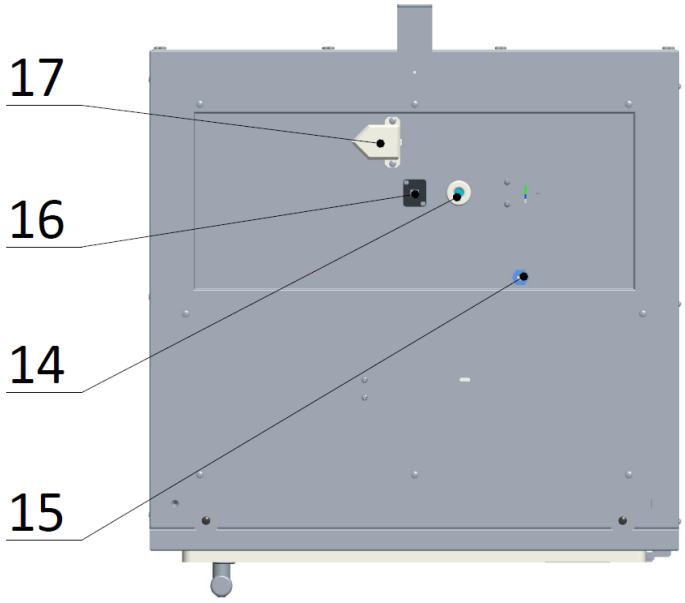


Fig. 5

(14) Mains supply
(15) Pressure air connection
(16) Ethernet
(17) Exhaust of moist air

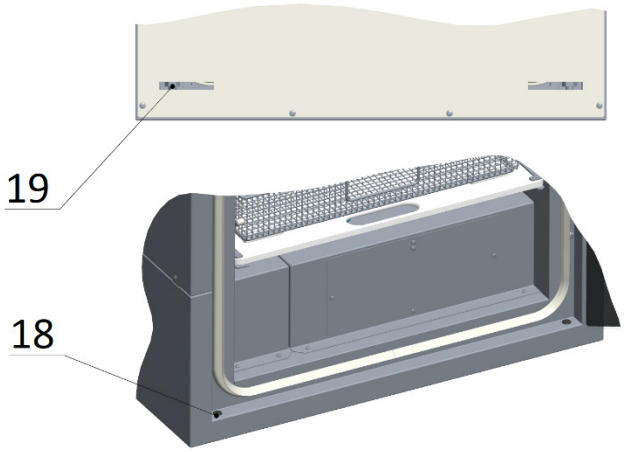


Fig. 6

(18) Feet on the door side
(19) Feet on the back cover side

3.3.2 Two-door design

The two-door design has doors on both the loading and unloading sides. The door control logic prevents contamination of the environment on the unloading side by possible sources of contamination from the loading side.

It does not have any anchoring point because it is intended to be installed in the wall.

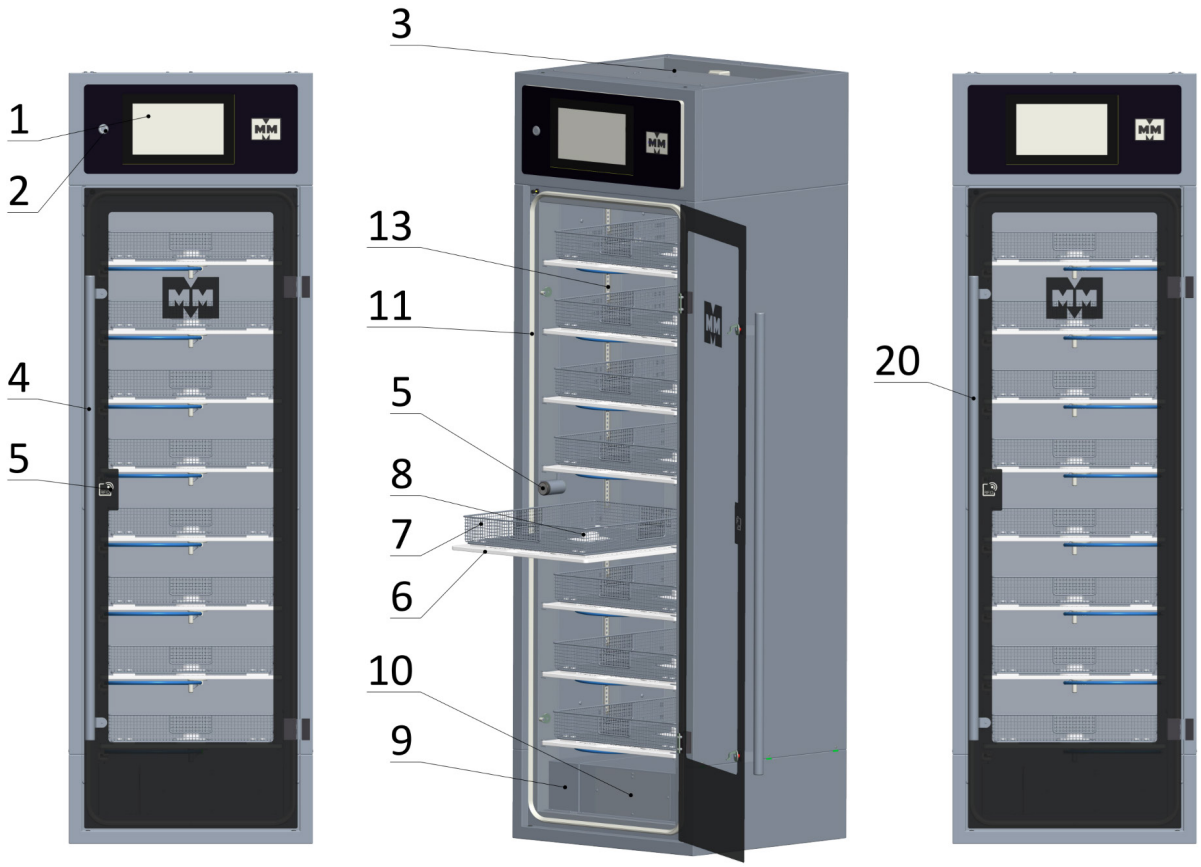


Fig. 7

(20) Unloading side

3.4 Technical description

3.4.1 Construction of the chamber

Welded chamber made of CrNi steel, material No. 1.4404 (AISI 316L). Hygienic high quality finish in 2B (smooth, matt).

The chamber is equipped with guides for inserting 8 shelves. A sieve with one endoscope can be placed on each shelf and the endoscope can be connected to the air supply using the appropriate connector.

External dimensions of the device:	600 × 1900 × 567 mm (W × H × D)
Internal dimensions of the chamber:	456 × 1509 × 546 mm (W × H × D)
Dryer chamber volume:	390 litres

TLP:GREEN

3.4.2 Chamber doors

Hinged doors made of laminated safety glass, silicone sealing, pneumatically operated locking mechanism.

The loading and unloading doors are closed manually. When closed and lightly pressed, the doors is secured by a pneumatic mechanism.

3.4.3 Device location

The device can stand alone or it can be placed with the same devices right next to each other without gaps. If the device is located in a corner of the room, a gap of at least 100mm must be maintained be-tween the side of the device and the wall to allow the doors to be opened sufficiently. The single door version of the device must be anchored to the wall in the room using the included anchoring kit. The back side of the device should be 0–50 mm from the wall of the room to which the device will be anchored. Place the device on the desired location and mark the place for a hole in the wall to be drilled. Drill a hole according to the dowel used. The dowel supplied is designed for normal masonry, for special masonry the type of dowel must match.

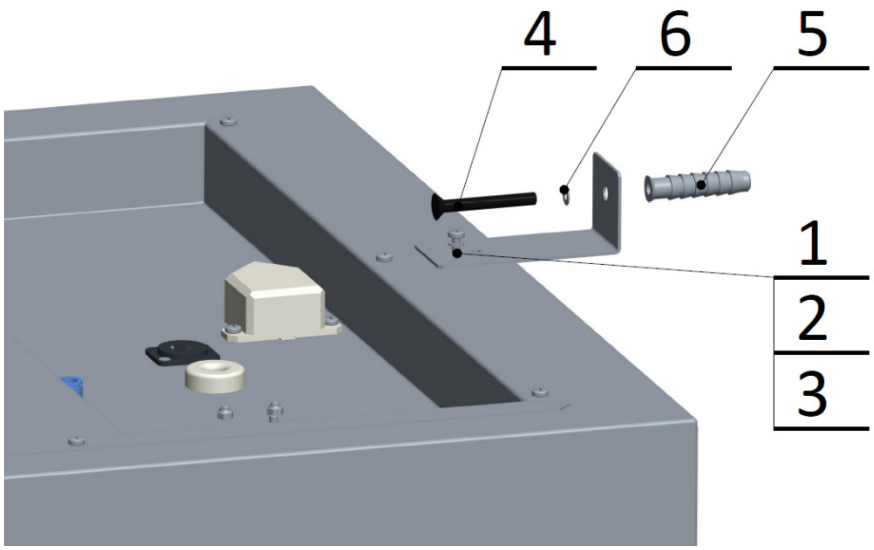


Fig. 8

a) Drill a hole in the solid wall and insert the dowel (5).
b) Attach the fixing set (1), (2), (3) to the device.
c) Anchor the device to the wall using the supplied screw (4) and washer (6).

3.4.4 Levelling the device

When installing the device, the four hidden feet must be adjusted due to uneven floor conditions. The feet on the loading side are adjusted with a size 5 Allen key after the rubber caps are removed. The other two feet can only be adjusted from the back side using a size 17 hex key. See Fig. 6. In the case of the two-door version, all four feet are adjusted in the same way as on the loading side, using a size 5 Allen key.

3.4.5 Control

The control is based on a programmable logic controller (PLC). The device operation is fully automatic, the parameters of the drying process, such as pressure and time, can be adjusted and protected by an access code.

The device has connectivity via Ethernet. The performed operating cycles are recorded in the integrated memory. Capacity up to 25,000 cycles.

The AC and DC electronics are housed in a slide-out module at the top of the device. Electronics storage provides a clear layout and easy service access.

3.4.5.1 MMM Smart HMI

The machine is operated via a 10“ graphic display with a touch panel on the loading (or unloading) side. The MMM smart HMI offers a user-friendly design, easy-to-understand graphic buttons and a seamless representation of all processes in graphical and simple text form. It provides access to process control menus, device parameters and maintenance information.

3.4.5.2 Chamber illumination and light status indication

For easy visual control, the drying phase is indicated by coloured LED lighting on the individual shelves.

Colour	Meaning
White	Door open
Blue	Drying in progress
Green	Drying completed – storage
Yellow	Notice that the storage time is close to the maximum allowed value.
Red	Fault

3.5 Technical equipment

3.5.1 Standard equipment

- Hinged doors made of laminated safety glass
- Chamber made of CrNi steel, material No. 1.4404 (AISI 316L).
- Sheet metal chassis made of ground CrNi steel sheet

3.5.2 Air distribution

- Pressure medical air inlet from above, 1x solenoid valve (YV0), flow meter, inlet filter (FILA).
- The air circulating inside the chamber is filtered by HEPA filter H13 (FIL1).
- 1x solenoid valve for air supply to each shelf
- 1x solenoid valve for air supply to the chamber
- Air is supplied to the endoscope through one monitored inlet, from which it is then distributed to all channels of the endoscope.

3.5.3 Control and monitoring

- 10“ colour display with touch panel
- B&R programmable logic automatic machine
- Pull-out module with electronics
- Colour LED indication of the drying process, 5 colours.
- Ethernet interface 10/100 Mbit/s
- Temperature monitoring, PT100 sensor.
- MMM Smart HMI (Human Machine Interface) with different levels of access permissions, password protected.
- Protocols for individual endoscopes stored in the chamber.
- Possibility to preset values of some variables (pressure, time).
- Easy portability of individual parameter sets to another device.
- Central database with parameter sets for different types of endoscopes.
- Operator login and endoscope type identification using RFID technology.

TLP:GREEN

3.5.4 Drying – air parameters

- Air according to ISO 8573-1:2010, class 1.2.1 is used for internal and external drying.
- The air circulating inside the chamber is filtered by HEPA filter H13.

3.5.5 Service access

Maintenance of the device is primarily performed from the loading side.

The device also requires service access from the side.

If the EDScab® is operated as a single door, an adequate access for maintenance must be provided (see installation plan).

3.5.6 Optional accessories

3.5.6.1 Endo basket

Mat. number	Description	Valid for:
010621499	Wire basket into which the endoscope is inserted	➢ EDScab® 8H ➢ EDScab® 8H-2

3.5.6.2 RFID cards printed (1pc)

Mat. number	Description	Valid for:
010623769	ENDOSKOP – RFID	➢ EDScab® 8H ➢ EDScab® 8H-2
010623770	User – RFID	

3.5.6.3 RFID cards unprinted (5pcs)

Mat. number	Description	Valid for:
010623767	ENDOSKOP – RFID	➢ EDScab® 8H ➢ EDScab® 8H-2
010623768	User – RFID	

3.5.6.4 Starter kit „Endoscope“

Mat. number	Description	Valid for:
010623648	Starter packet „Endoscope“	➢ EDScab® 8H ➢ EDScab® 8H-2

3.5.6.5 Starter kit „User“

Mat. number	Description	Valid for:
010623649	Starter packet „User“	➢ EDScab® 8H ➢ EDScab® 8H-2

3.5.6.6 Device-specific electric wiring documentation

Mat. number	Description	Valid for:
010626584	Customer electric wiring documentation + PID	➢ EDScab® 8H ➢ EDScab® 8H-2

Creation of electric wiring documentation and pipe interconnections for a specific device configuration.

3.5.6.7 Marking of all conductors

Mat. number	Description	Valid for:
010626583	Marking of conductors and electrical components	➢ EDScab® 8H ➢ EDScab® 8H-2

Marking of all conductors in the electronics module.



Each conductor has its own specific marking, with the marking of the beginning and end of each conductor being identical. This guarantees the documentation to be clear, without the possibility of confusion.



Optional accessory Device-specific electric wiring documentation is assumed.

3.5.6.8 Supervision of construction preparations

Mat. number	Description	Valid for:
010636897	Consultation before installation. Preparation of the pressure air supply.	➢ EDScab® 8H ➢ EDScab® 8H-2

Consultation during the preparation of a pressurized air supply:

3.5.6.9 Valve for closing the air supply

Mat. number	Description	Valid for:
010626580	Air valve	➢ EDScab® 8H ➢ EDScab® 8H-2

3.5.6.10 Left door for loading side

Mat. number	Description	Valid for:
010626576	Left door	➢ EDScab® 8H ➢ EDScab® 8H-2

TLP:GREEN

3.5.6.11 Left door for unloading side

Mat. number	Description	Valid for:
010626577	Left door	➢ EDScab® 8H-2

3.5.6.12 Validation grommet for right door

Mat. number	Description	Valid for:
010626578	Grommet R	➢ EDScab® 8H ➢ EDScab® 8H-2

For loading side only

3.5.6.13 Validation grommet for left door

Mat. number	Description	Valid for:
010626579	Grommet L	➢ EDScab® 8H ➢ EDScab® 8H-2

Pouze pro nakládací stranu

3.5.6.14 Potential-free contact for alarm messages

Mat. number	Description	Valid for:
010626581	BMS	➢ EDScab® 8H ➢ EDScab® 8H-2

The potential-free contact is led to a connector at the top of the device, it can be connected to a voltage of up to 24V/1A. It is used to implement a remote alarm (in Anglo-Saxon countries it is referred to as a BMS relay – Building Management System relay) - i.e. by remote wiring, which is interrupted by the builtin relay of the potential-free contact, information about a fault is transmitted to other premises than the one in which the device is located. In the normal state, the relay is closed (1-2). When a fault occurs, the relay disconnects (2-3). The relay disconnects in all error conditions reported on the display.

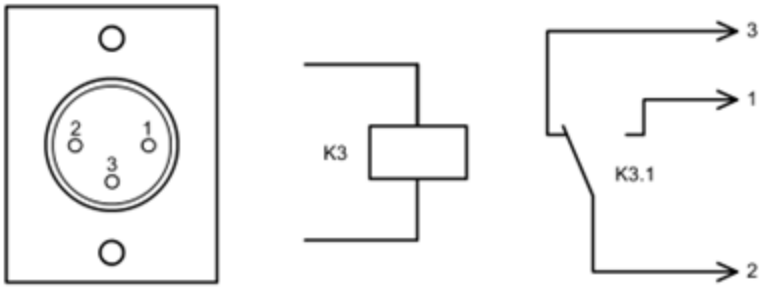


Fig. 9

3.5.6.15 Restriction of air passage between loading and unloading side

Mat. number	Description	Valid for:
010626582	BIOSEAL	➢ EDScab® 8H-2

The solution consists of additional stainless steel cladding panels including a full-circuit seal.

WARNING

The pressurisation system in the rooms must be designed to guarantee a higher air pressure on the unloading side.

3.5.6.16 Stainless steel lining

Mat. number	Description	Valid for:
010636896	Docking the extension into the ceiling of the room, around the device, etc.	➢ EDScab® 8H ➢ EDScab® 8H-2

3.5.6.17 English plug

Mat. number	Description	Valid for:
010124557	Electrical plug	➢ EDScab® 8H ➢ EDScab® 8H-2

3.5.6.18 Long open door signalling

Mat. number	Description	Valid for:
010636895	Buzzer	➢ EDScab® 8H ➢ EDScab® 8H-2

If the door is opened for too long, an audible alarm will sound.

3.5.6.19 Language versions other than EN and DE

Mat. number	Description	Valid for:
010636894	Language version of the user interface	➢ EDScab® 8H ➢ EDScab® 8H-2

3.5.7 Accessories supplied with EDScab®

- Emergency door opener
- Anchoring set
- Shelf inductive sensor covers

TLP:GREEN

3.6 Adapter kit

The adapter set consists of a 10-pin connector plug and color-coded hoses with individual adapters. The 10-pin connector plug is connected to the 10-pin connector socket on the device shelf (see 5.4). The individual adapters are connected to the endoscope, see Fig. 10. The colour of the hose indicates the channels to which the adapter is to be connected. Each adapter set has a label with a unique identifier.

Example of an adapter kit:

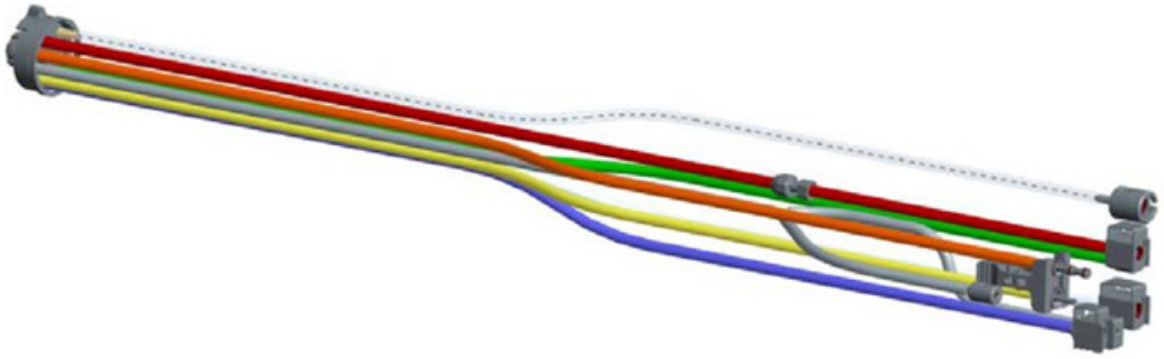


Fig. 10

The unused channels on the 10-way connector are blinded with plugs.

3.6.1 10-way connector

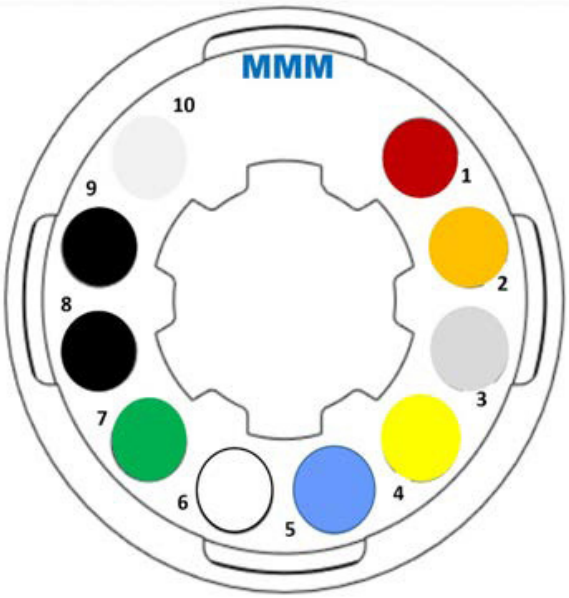
Channel layout				
	Channel		Channel	
Channel for tightness testing	10		1	Bioptic channel 1
Not used	9		2	Bioptic channel 2
Not used	8		3	Air channel
Albaran bridge channel	7		4	Suction channel
Rinsing channel	6		5	Water channel

Fig. 11
Example of channel layout on a 10-way connector

Examples of individual endoscope channel connections:

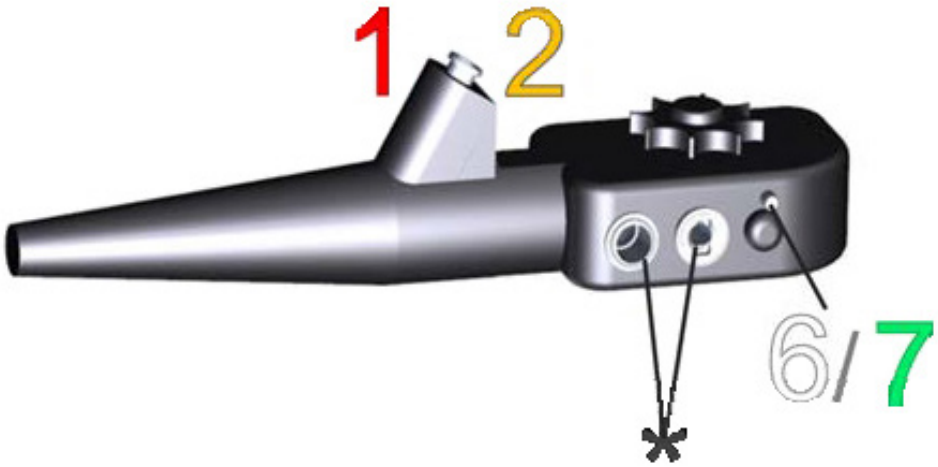


Fig. 12

1	Bioptic channel 1
2	Bioptic channel 2
6	Rinsing channel
7	Albaran bridge channel

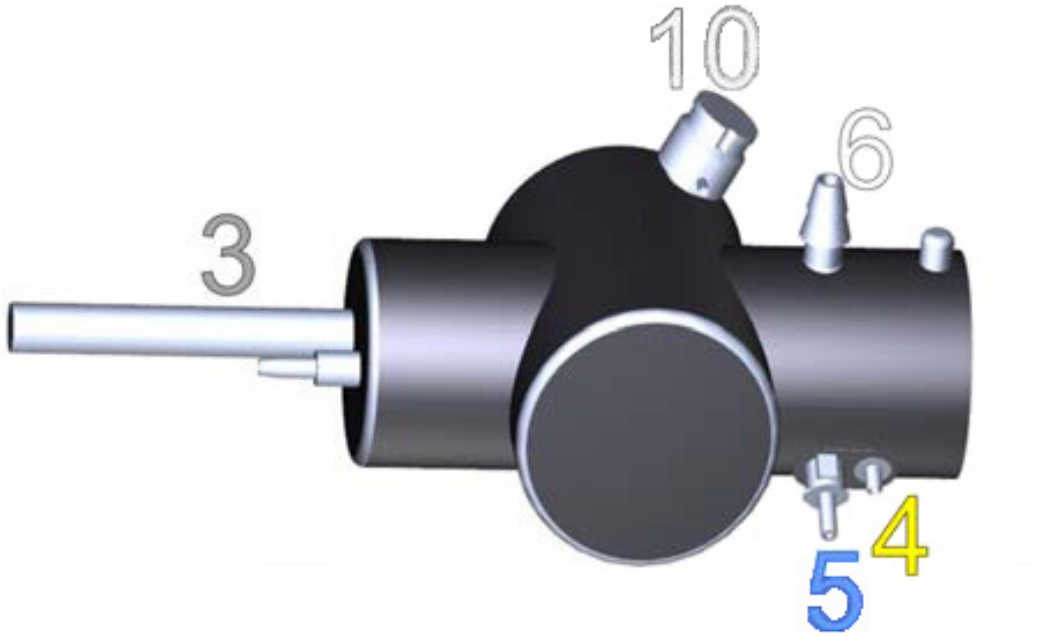


Fig. 13

3	Air channel
4	Suction channel
5	Water channel
6	Rinsing channel
10	Tightness testing channel

TLP:GREEN

Follow the endoscope manufacturer‘s instructions for use!

The description of the connection positions of the individual channels of the endoscope mentioned above is only illustrative. Please refer to the instructions for use of the respective endoscope for the exact location of the individual channel connections.

3.6.2 Examples of connection adapters

Adapter with spring lock  **Fig. 14**	➢ Connection and disconnection is done by compressing the spring. ➢ Check that the adapter is firmly and correctly fitted. The adapter must not be able to be disconnected without the lock being deliberately released.
Adapter with bayonet lock  **Fig. 15**	➢ The connection is made by pushing and turning. ➢ Check that the adapter is firmly and correctly fitted. The adapter must not be able to be disconnected without the lock being deliberately released.
Adapter with pin lock  **Fig. 16**	➢ The connection (disconnection) is made by pressing the upper parts of the adapter together. ➢ Check that the adapter is firmly and correctly fitted. The adapter must not be able to be disconnected without the lock being deliberately released.

<table>
<tr><td>Screw adapter

Fig. 17</td><td>➢ Connection by screwing.
➢ Check that the adapter is firmly and correctly fitted. The adapter must not be able to be disconnected without the lock being deliberately released.</td></tr>
<tr><td>Adapter - plug

Fig. 18</td><td>➢ Plug the adapter all the way in.</td></tr>
<tr><td>Adapter with key

Fig. 19</td><td>WARNING
Reduced cleaning performance!
The key on the adapter (green arrow) must be oriented against the white mark on the endoscope.
➢ Plug in the adapter.
➢ Check that the adapter is firmly and correctly fitted. The adapter must not be able to be disconnected without the lock being deliberately released.</td></tr>
</table>

3.7 Electrical wiring and operating conditions

Voltage system		1x 230V/ 50(60) Hz
Mains voltage fluctuations	%	± 10
Protection class against dangerous contact		I
Outer circuits separation		double insulation
Device fork type		CEE-7/VII, IEC-83/CH,16 A/250 V
Length of feeding cable	mm	3000
Socket protection	A	min. 16
Disconnecting the device		Switch off the device by pressing the mains switch and pulling the power cord out of the socket.
Protection according to EN 60529		IP 20
Overvoltage category according to (IEC 664 – EN 61010)		II at pollution 2
Device protection		Jistič 1492-SPM3C160,16 A,C
Max. device input	W	165
Max. current consumption of the device	A	0,89
Noise level of the whole device	dB	≤ 50
Ambient temperature	°C	+5 až +40
Max. relative humidity at 31 °C	%RH	80
Max. altitude	m above sea level	3000

Note:
All specifications apply in an empty chamber with the ambient temperature of 20-22 °C and supply voltage of 230V ± 10%.

TLP:GREEN

When drying endoscopes inside the EDScab®, the ambient and supply air temperature must be at least 20 °C.

4 User interface

4.1 Loading and unloading side



Fig. 20

4.1.1 Main switch

The on/off button is used to switch the device on/off. The button is located on the loading side of the device, to the left of the operating display, see »2« Fig. 20. Switching off the device is possible at any working stage of the device, there is no risk of damage to the device. If the device is switched off during the drying or storage phase, temporary data may be lost and the phases must be repeated.

Turning on
After switching the device on with the on/off button, the control electronics start. The start-up sequence and automatic fan check will take place. The device is then ready for operation.

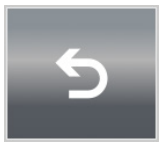
Shutdown
The device is switched off with the on/off button. Switching the appliance off with the on/off button is possible no matter what stage of drying the appliance is currently in.

Complete and safe disconnection from the mains is only achieved by pulling the plug of the mains cord out of the socket!

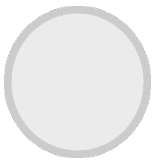
4.1.2 Display and touch screen

4.1.2.1 Buttons and information

Buttons are only active if the desired action is enabled!

Buttons:		
	User login/logout	Each action requires user to be logged in. If no user is logged in, the message »Nobody« will be displayed.
	Manual endoscope selection	Displays a list of endoscopes that can be processed in the device.
	Setting	
	Confirm the selected action	
	Open/close the door	
	Arrows	Navigation within the menu
	Save	
	Back	Back to previous menu

TLP:GREEN

Information:	
	Date/Time
	Loading the endoscope using RFID
	Position not used
	Warning: The storage time of the endoscope will soon exceed the permitted limit.
	An endoscope has been placed in the device (adapter connected), but it has not been identified (i.e. neither RFID reading nor selection from the endoscope list has been performed; see 5.4). In the row corresponding to the relevant endoscope, the warning »UNASSIGNED« is displayed.
	Drying in progress
	Drying successfully completed. Storage is in progress.
	There was an error in the process.

4.1.3 Remote access via VNC

Graphical access to the EDScab® device is possible via the VNC (Virtual Network Computing) protocol, which enables remote connection to the graphical user interface over a computer network. To establish the connection, a VNC client application capable of connecting to the device must be installed.

Access to the device via VNC allows the user to view the device screen and, where applicable, also to edit it from a remote PC.

Two authorization levels are available for VNC access to the device. The first level allows the user to view the screen only. The second level also allows remote control of the screen. When accessing the device using the second authorization level, individual user menus can be edited via the keyboard and mouse of the remote PC.

To establish a VNC connection, the password corresponding to the respective authorization level must be entered into the VNC client located on the same network. The client must also know the IP address of the device and port 5901. For some clients, it is necessary to set the colour depth to 256 colours (medium).

5 Service

The drying (or storage) process is fully automatic, it is monitored and regulated by the control unit using pressure, relative humidity and temperature sensors and actuators.

Endoscopes to be processed in the EDScab® must first undergo machine washing and disinfection.

The EDScab® is designed for drying endoscopes that have been

washed and disinfected in a Uniclean PLE 3 washer manufactured by MMM. The endoscope that has been processed in this washer is stored in the MMM Endo basket, the individual channels of the endoscope are connected to the MMM adapter set.

The EDScab® device can only be used for endoscopes that have been washed and disinfected in a washer that ensures that the endoscope channels are checked to be passable.

The endoscope channels must be rinsed with pressurised air at the end of the washing cycle in the washer to expel the residual water.

WARNING

The activities described in the following text may only be carried out by trained personnel.

5.1 Preparing the endoscope before drying

The MMM endo basket is referred to hereinafter as the „basket“.

Use disposable sterile gloves when handling the basket. Avoid direct contact with the endoscope.

TLP:GREEN

Manual pre-drying is necessary before the actual machine drying:

- To remove excessive water from the surface of the basket and endoscope, shake the basket gently.

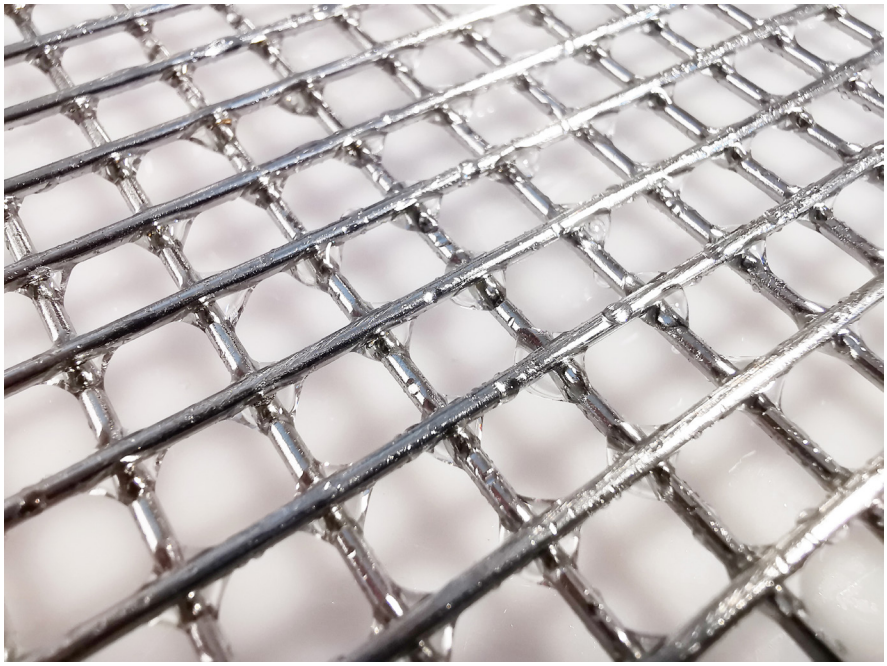


Fig. 21

- After removing excessive water, the basket can be dried with a pressurized air gun according to ISO 8573-1:2010, class 1.2.1. Place the endoscope basket on sterile absorbent material.

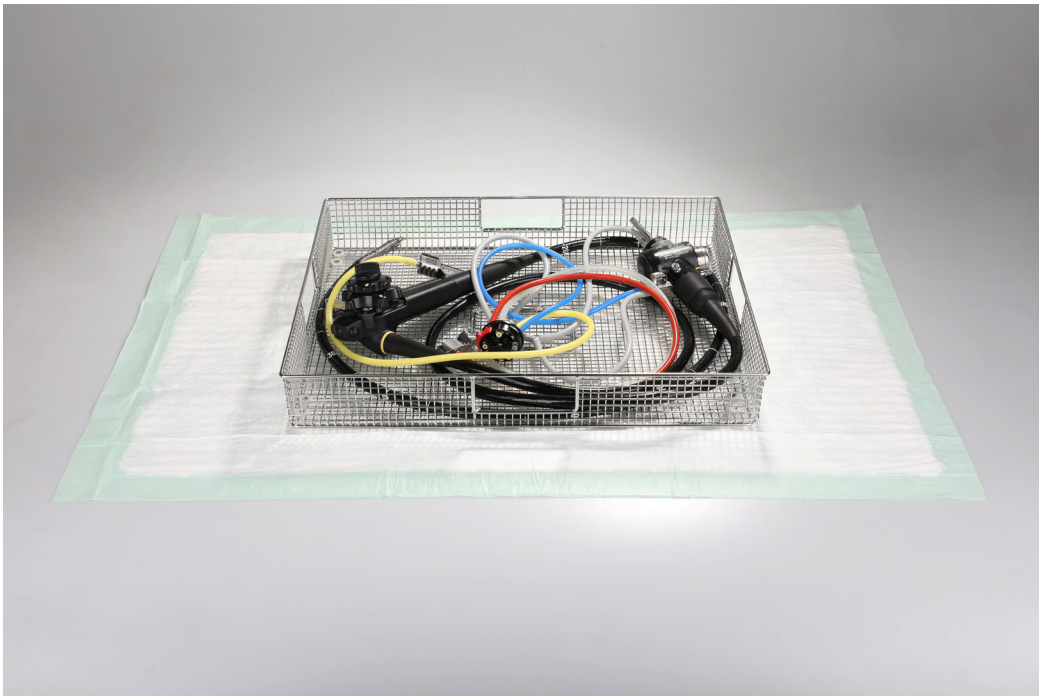


Fig. 22

- Use an air gun to dry the slots between the endoscope controls, also focus on the junction areas of the endoscope parts and the adapter set, these parts are particularly prone to trapping moisture. Make sure that the outer surface of the endoscope is completely dry.



Fig. 23

When preparing the endoscope before drying, follow the handling instructions given by the endoscope manufacturer.

The endoscope must be declared by the manufacturer as suitable for machine drying.

Preparation before drying must ensure that all channels of the endoscope are freely passable and that nothing obstructs the passage of drying air.

TLP:GREEN

Spread the endoscope evenly in the basket before inserting it into the EDScab® in a staggered manner to minimize overlapping parts.

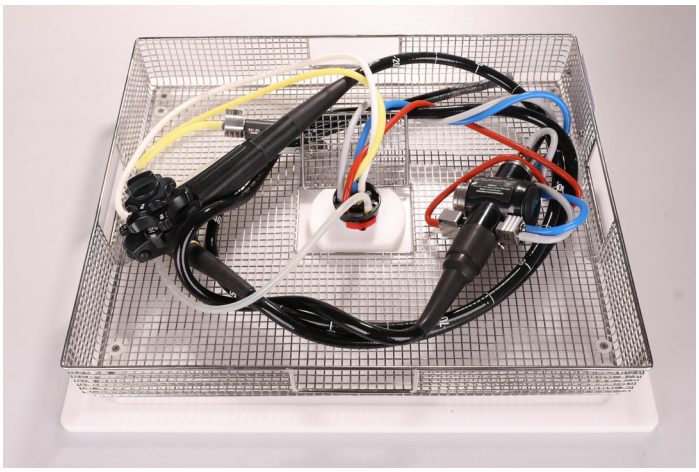


Fig. 24
Incorrect placement of the endoscope

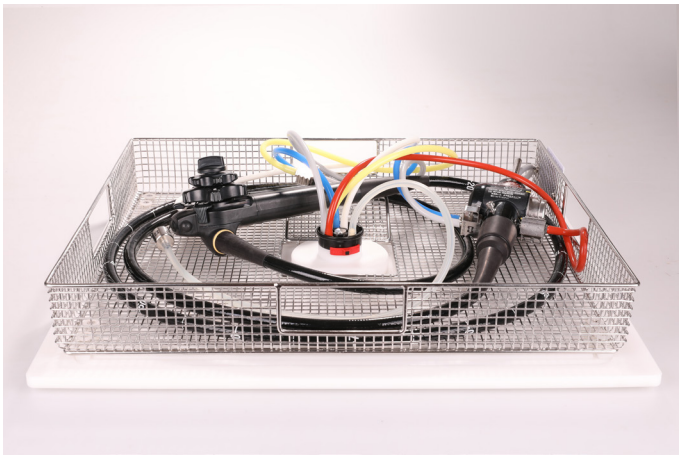


Fig. 25
Correct placement of the endoscope

It is necessary to leave a sufficient gap between everything that is stored in the basket and what is mounted on the next shelf above the basket. This prevents damage to the endoscope, adapter or instrument components when sliding the shelf in and out.



Fig. 26

The total volume of residual water on the surface and in the channels of an endoscope before inserting into the EDScab® and starting the machine drying must not exceed 30 millilitres.

For optimal drying efficiency, place the endoscopes in the EDScab® when the relative humidity in the chamber is lower than 40%.

The EDScab® allows drying of a maximum of 3 endoscopes simultaneously.

5.2 Home screen

It provides the basic information about the processes involved. See also 4.1.2.1.

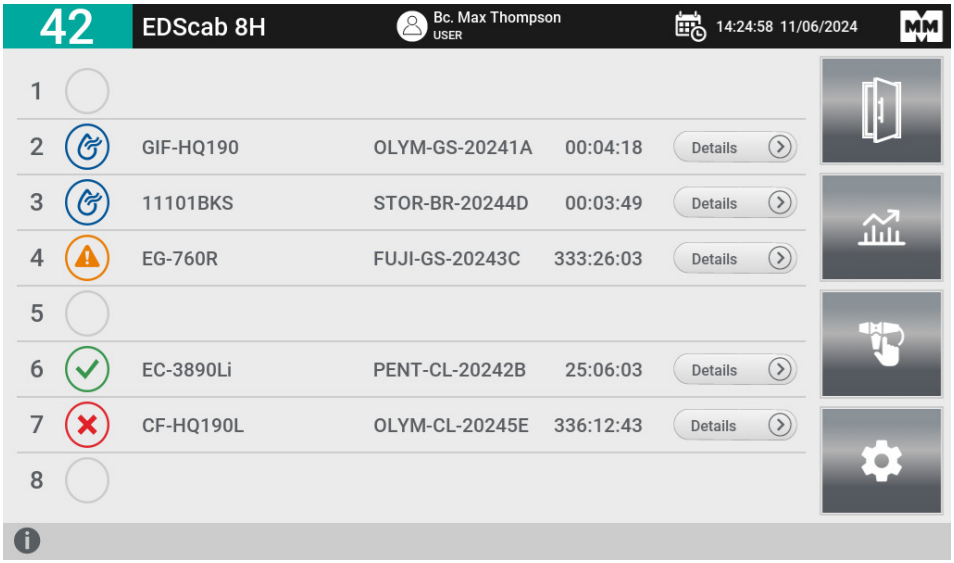


Fig. 27

5.3 Operator login and logout

A user login is always required to operate the device.

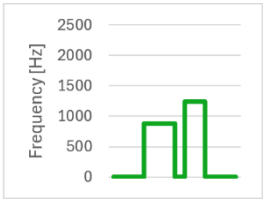
5.3.1 RFID login

- Place the RFID card close to the RFID reader.
- The user logs in automatically.
- The top bar displays the user‘s name and his permission level.

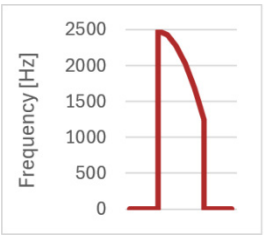
TLP:GREEN

Operator login via RFID is indicated acoustically and visually.

Successful login: green flashing lights + 2 × beeps (low and medium tone)



Unsuccessful login: yellow flashing lights + 1 × beep (high tone)



5.3.2 Login via menu

The login menu is activated using the button on the top bar.

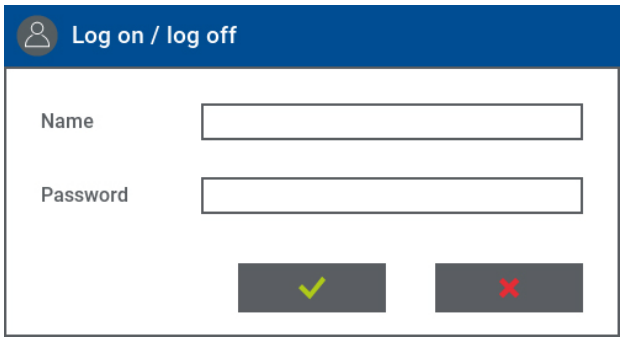


Fig. 28

- When you touch the »User« field, the alphanumeric keypad is displayed.
- Fill in the user name.
- Confirm your entry by clicking on ↵.
- Do the same in the »Password« field. Enter your password and confirm with (✓).

After a successful login, the corresponding username will be displayed in the header.

The user can now perform actions for which he/she has permissions.

User logout

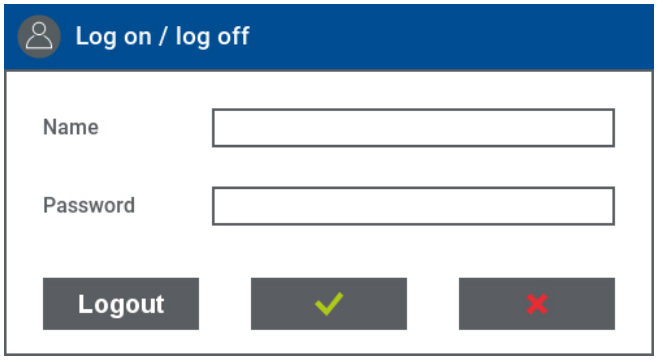


Fig. 29

Click on the »Logout« button.

The user »NOBODY« is displayed in the user bar.

By logging out, you can prevent the device from being misused by an unauthorised person.

Automatic logout can occur after a defined period of inactivity. The length of this interval can be set individually for each user in the user management.

5.4 Endoscope drying process – single-door version

This procedure describes the steps following washing and disinfection in the Uniclean PLE3 washer manufactured by MMM.

5.4.1 Preparation

- Before machine drying, conduct the endoscope pre-drying, see 5.1.
- Carry the basket with the endoscope and adapter kit to the EDScab®.

5.4.2 Login

➢ Perform RFID login using your personal ID card (or login via the menu). See 5.3.1, 5.3.2.



Fig. 30

➢ Activate the button



.

The device door is then unlocked.

➢ Open the door, read the type of endoscope using its ID card (RFID) or select it in the relevant menu.

5.4.3 Endoscope reading

5.4.3.1 Reading the endoscope via RFID

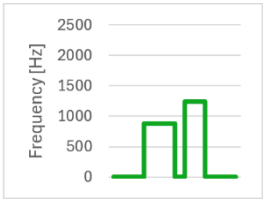
➢ Put the tag located on the basket closer to the RFID reader, see Fig. 31.



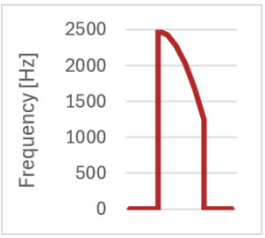
Fig. 31

Endoscope reading via RFID is indicated acoustically and visually.

Successful login: green flashing lights + 2 × beeps (low and medium tone)



Unsuccessful login: yellow flashing lights + 1 × beep (high tone)



5.4.3.2 Endoscope selection via the Menu

- Activate the endoscope selection button



Fig. 32

- Select the appropriate endoscope.
- Confirm with .

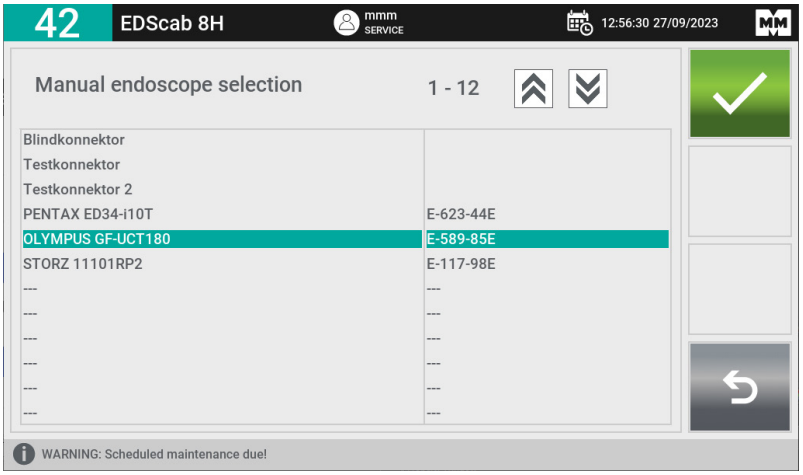


Fig. 33

TLP:GREEN

➢ The Endoscope Information Label is displayed:

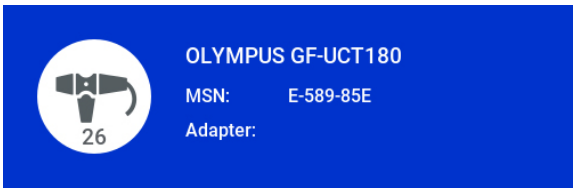


Fig. 34

The connection of the 10-pin connector plug of the adapter set to the socket on the respective shelf must be completed within 30 seconds. The remaining time is displayed on the endoscope label (Fig. 34).

5.4.3.3 Unspecified endoscope

Alternatively, the endoscope may first be connected to the shelf and identified only subsequently. In this case, it is marked as »UNASSIGNED« (see Fig. 35). The corresponding shelf is illuminated in purple.

Selection of one of the registered endoscopes may be performed only after the endoscope has been connected. However, if the doors are closed after connecting the endoscope, the assignment of the endoscope identity must be completed within 30 seconds from door closure. The remaining time is displayed on the lower bar of the control panel (Fig. 35).

The drying cycle will be performed even if the endoscope type has not been assigned at all. In this case, the endoscope is displayed in red in the list and a warning is shown (»Unassigned device in the chamber!«).

If more than one unassigned endoscope is connected to the device, the identity can be assigned only to the endoscope that was inserted last.

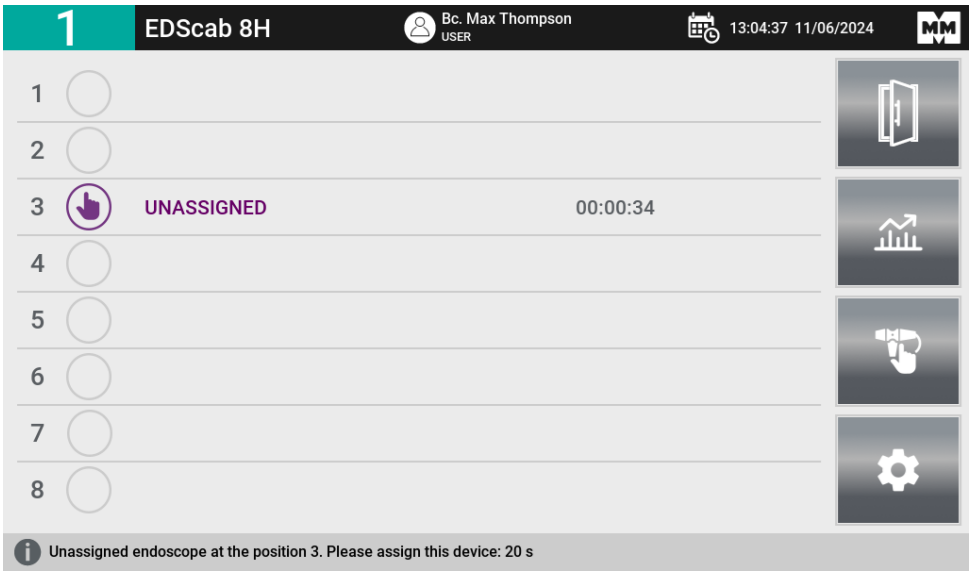


Fig. 35

5.4.4 Connection of the adapter set on the shelf:

- Pull out the respective shelf. Place the basket with the connected adapter set onto the shelf.
- Verify that the red locking latch of the 10-pin connector of the adapter set is in the »OPEN« position.



Fig. 36

- Connect the 10-pin connector plug of the adapter set to the socket on the shelf and secure the red locking latch (»LOCK«). See Fig. 37.



Fig. 37

- The endoscope connection is automatically detected.

Verify that the correct type of endoscope has been loaded on the appropriate shelf.

If no loading has occurred, check the connection of the 10-way connector.

TLP:GREEN

Ensure that air is flowing into the connected endoscope:

- Air, together with a small amount of water (spraying droplets), emerges from the distal end of the endoscope.
- A stream of air emerges from any unsealed openings on the adapter plug (if present)

- Push the extended shelf all the way in with a smooth motion.
- Close the door and press lightly. Activate the button to close the door , the door will be locked.

5.4.5 Drying and storage phase

- After the endoscope is inserted into the device, the drying phase is automatically started. Drying is carried out without operator intervention until the endoscope is completely dry, af-ter which the storage phase is initiated.

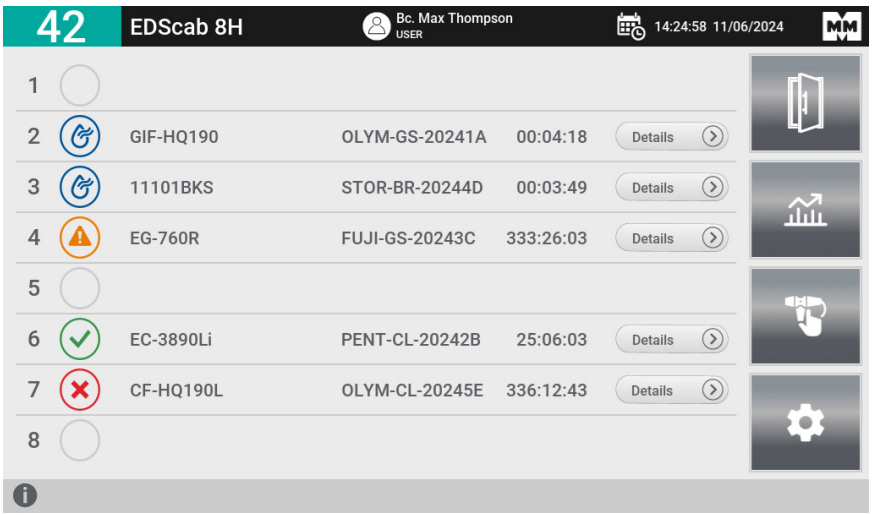


Fig. 38

- The drying phase is indicated by the coloured LED lighting of the respective shelf.

Colour	Drying stage
Blue	Drying in progress.
Green	Drying successfully completed.
Yellow	The notice that the maximum permitted stor-age time will be reached soon.
Red	Fault
White	Lights up when the door is opened.
Purple	Unassigned endoscope.

- The drying phase is followed by the storage phase.

The endoscope storage duration is adjustable. Adjustment requires intervention by an authorized service technician.

Factory setting: 14 days

5.4.6 Removing the endoscope:

- When the drying process is completed, perform a user login.
- Activate the button to open the door .
- Open the door, slide out the shelf, disconnect the adapter, remove the endoscope basket.
- Push the extended shelf all the way in with a smooth motion.
- Close the door, press and activate the door close button .

When closing the door, make sure that there are no obstacles in the way!

Once the endoscope has been inserted into the EDScab®, it is not possible to open the door of the device for more than 30 minutes (i.e. the sum of the individual opening times) during the next 3 hours. Exceeding this time will result in the declaration the drying process to be incorrect.

5.5 Two-door design

5.5.1 Inserting the endoscope

- Pre-dry the endoscope, see 5.1.
- Transport the endoscope basket attached to the appropriate adapter to the loading side of the EDScab®.
- Log in using the personal ID card (or menu) on the loading side of the device.
- Activate the button to open the door .
- The door on the loading side will be unlocked and the door will be slightly ajar.
- Read the type of endoscope using its ID card (RFID) or select it in the relevant menu (see 5.4). It is also possible to first connect the adapter set with the endoscope and assign its identity only afterwards (see 5.4.3.3).
- Pull out the appropriate shelf. Place the basket with the adapter attached on a shelf.
- Verify that the locking latch of the 10-way connector of the adapter set is in the »OPEN« position, see Fig. 36.
- Connect the 10-pin connector plug of the adapter set to the socket on the shelf and secure it with the red locking latch (»LOCK«), see Fig. 37.
- The connection of the adapter is automatically detected.

The doors are blocked and cannot be opened simultaneously.

Verify that the correct type of endoscope has been loaded on the appropriate shelf.

If loading has not occurred, check whether the 10-way connector is connected properly.

TLP:GREEN

It is forbidden to put any objects through the device from the unloading side to the loading side!

- Push the extended shelf in with a smooth motion and stop it in the middle position.
- Close the door on the loading side, press lightly and activate the door close button . After that they will be blocked.
- When the endoscope is inserted into the device, the drying phase is automatically started. Drying is carried out without operator intervention until the endoscope is completely dry, after which the storage phase is initiated.
- The drying phase is indicated by the coloured LED lighting of the respective shelf:

Colour	Drying stage
Blue	Drying in progress.
Green	Drying successfully completed.
Yellow	Notice that the maximum permitted storage time will be reached soon.
Red	Fault
White	Lights up when the door is opened.
Purple	Unassigned endoscope.

5.5.2 Taking the endoscope out

- To remove the endoscope, perform a user login on the unloading side.
- Press the door release button  to unlock the door.
- The door on the unloading side is unlocked and can be freely manipulated. Open the door.
- Choose the endoscope that you want to remove.
- Pull out the shelf, disconnect the adapter, remove the endoscope basket.
- Check out the endoscope using the appropriate RFID card.
- Push the extended shelf in with a smooth motion and stop it in the middle position.
- Close the door, press and activate the door close button .

When closing the door, check that nothing prevents the door from closing!

5.6 Door handling

5.6.1 Door blocking

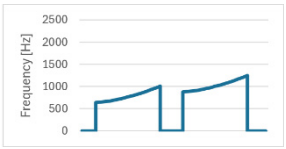
During drying (storage), unintended opening of the doors is prevented by a locking mechanism, the position of which is controlled by compressed air.

If the automatic door locking function is enabled on the device, the doors will automatically lock 2 seconds after being closed (pressed shut).

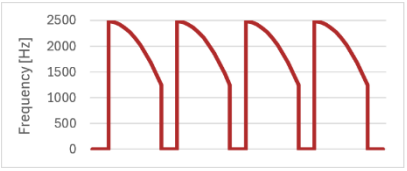
When handling the doors, take care to avoid trapping any part of the body, clothing, or other objects in the device doors.

The actions of door locking and unlocking are indicated acoustically and visually. The indication settings can be adjusted in the device service menu. Adjustment requires intervention by an authorized service technician.

Door locking successful → confirmation sound:



Door locking unsuccessful → warning sound:



5.6.1.1 Door opening

Touching the button  releases the door lock and allows the door to open partially.

5.6.1.1.1 Open door indication

If the device contains endoscopes and the doors remain open for more than 2 minutes, this condition is indicated both visually and acoustically. The warning »Open-Door« is displayed. Timers for the opendoor warning can be adjusted in the device service menu. Adjustment requires intervention by an authorized service technician.

Opening time [min]	Signalling
2	Flashing (orange) and beeping (buzzer on the control panel).
3	External acoustic indication activated (optional accessory, see 3.5.6.18).
4	Alarm triggered. Flashing color changed from orange to red. Flashing and beeping frequency reduced.

5.6.1.2 Automatic door unlocking

The doors automatically unlock (and partially open) when the user logs in via RFID. This function can be configured in the device service menu. Adjustment requires intervention by an authorized service technician.

If the user logs in at the device control panel, the doors will not unlock.

5.7 Drying process

An example of the drying process in the EDScab® device is shown in Fig. 39. The above procedure is only illustrative, the specific workflow depends on the type of endoscope being processed.

Drying is initiated by introducing the pressurized air into the endoscope and starting the circulating fan. The required air pressure and flow are maintained for the time duration necessary to dry the endoscope. During the drying process, the air can be introduced into the endoscope in different modes (depending on the specific endoscope type).

The circulation fan runs at high speed throughout the drying process. In storage mode, the speed of the circulation fan is reduced.

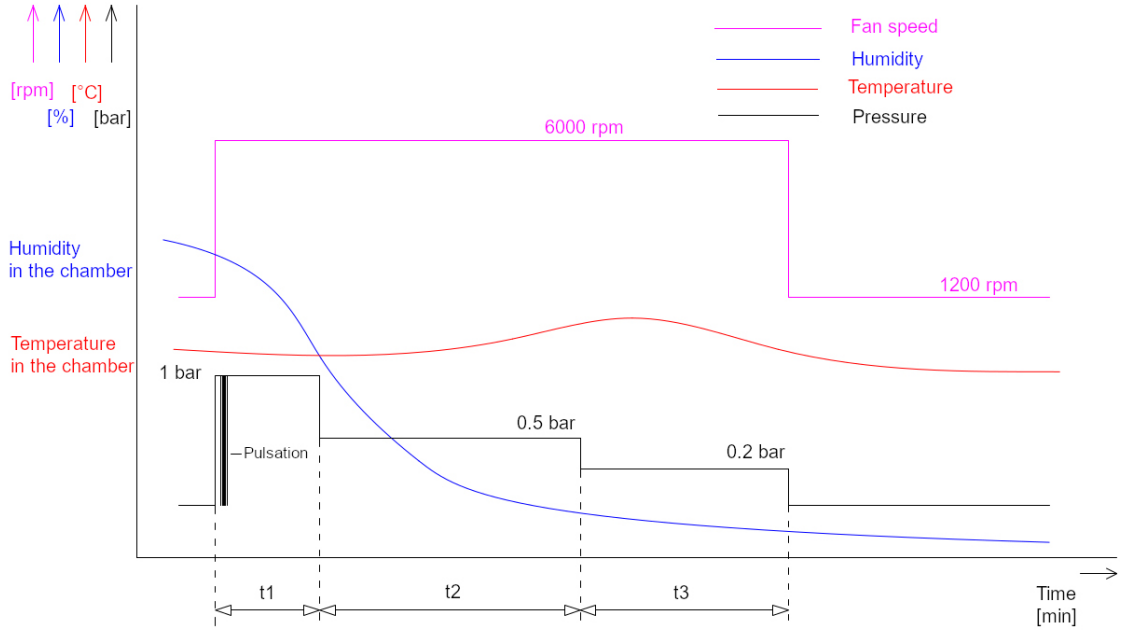


Fig. 39

Pulsation:

Pulsation = drying mode with intermittent air supply to the endoscope, which increases drying efficiency.

Pulsation begins 1 minute after the doors are closed.

Pulsation parameters are adjustable. Adjustment requires intervention by an authorized service technician.

5.7.1 Incorrect drying process

In the event of an abnormal drying process, a red status bar with an error message is displayed at the bottom of the screen. If the error concerns a specific endoscope, the corresponding shelf is illuminated in red (or all shelves in the device are illuminated in red). See also Chapter 9. The operator must take the necessary measures to resolve the issue.



If a defect has occurred during drying an endoscope, the endoscope in question must be treated in the same way as an endoscope that has not undergone the machine washing and disinfection process.

The endoscope must pass the machine washing and disinfection process again.

5.7.2 Correct drying process

The operation of the EDScab® from drying to storage is controlled by the control unit. The control unit ensures the correct sequence and duration of the individual process stages, continuously monitors the process data (temperature, relative humidity, pressure) and checks that they are within the permitted limits. The control unit compares the detected operating data with the set values. If the values of the mon-itored parameters are within the permitted limits throughout the process, the process is considered to be correct.

Visual inspection of process efficiency

After removing the endoscope to be processed from the chamber, a visual check of the process efficiency must be performed.



Check that no changes have been made to the inserted endoscope.

In particular, check the connection of the adapter set.

Check the drying result.

TLP:GREEN

6 Settings menu





Some of the settings described below require the device to be restarted. If a prompt to restart is displayed after changing the corresponding parameter (Fig. 40), turn the device off and on using the main power switch (see 4.1.1).

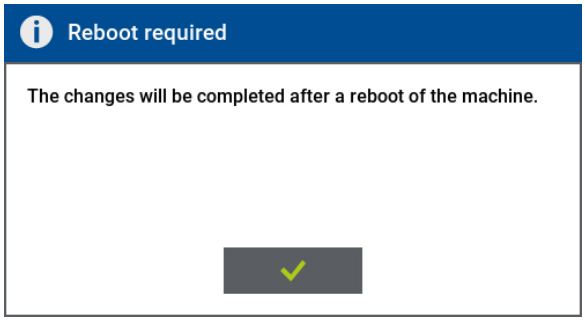
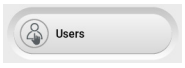
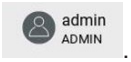


Fig. 40

6.1 Creating, modifying and deleting users

 → 

To create a new operator, you must enter the operator‘s name and password. Different operators can be assigned different levels of permissions to control the device.

➢ Log in as ADMIN or MMM user 

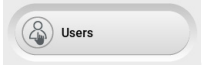
.

Preset login credentials:	
Name:	Admin
Password:	Admin



After the first login, change your login details. This prevents unauthorised persons from accessing the device.

➢ Enter the settings menu .

➢ Select 

.



The menu below (Fig. 40) can also be used to edit the login data of an existing user. Select a user and instead of creating a new user, just change the existing data.

➢ To create a new operator, select »New« (see „1.“, Fig. 41). The operator will be automatically assigned a new position in the list.

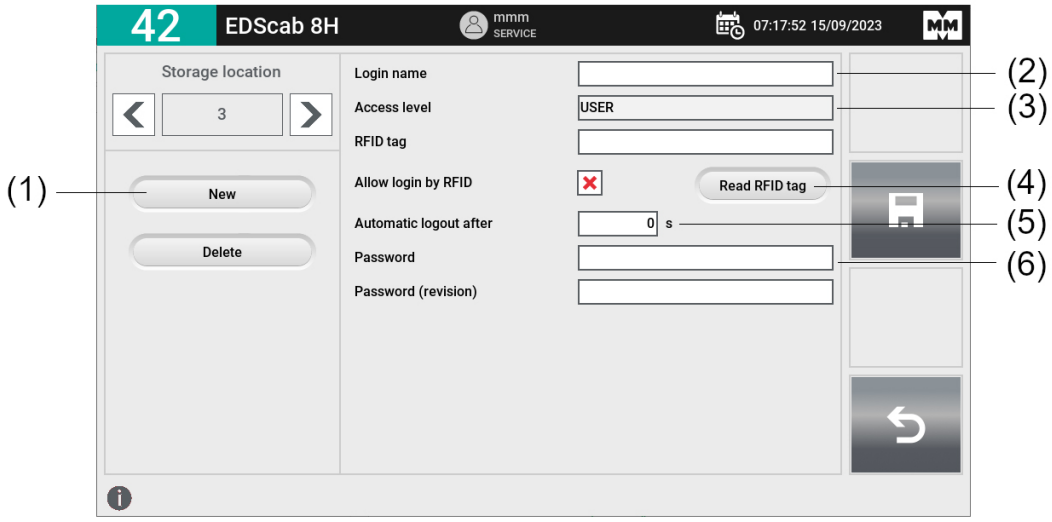


Fig. 41

(1) Create a new user

(2) Login name

(3) Permission level

(4) Reading the RFID tag of a new user

(5) The time after which an automatic logout occurs if no activity has been detected on the panel.

(6) Password and password retry.

➢  Save the entered data.

6.1.1 Permission Levels

Level	Username	User	Permission:
1	USER	Authori-sed user	A personal account with an individual login name and individual password. Permission: ➢ He can load and unload endoscopes.
2	SUPERVISOR	Person respon-sible for the device	A personal account with an individual login name and individual password. Permission: ➢ Confirmation of alarms ➢ Adding/changing an endoscope

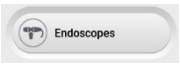
TLP:GREEN

Level	Username	User	Permission:
3	ADMIN	Person responsible for the device (IT)	A personal account with an individual login name and individual password. Permission: ➢ Access to LAN settings. ➢ Date and time settings ➢ User rights settings. ➢ Display settings
4	MMM	Expert, MMM Group Customer Service	➢ Single account ➢ Login name: MMM (invariable) ➢ Password validity: 1 month ➢ Possibility of individual password for MMM Group customer service.

The ADMIN user has the following factory preset credentials:	
Name:	**admin**
Password:	**admin**

To increase the security and prevent any unwanted access, the user is automatically logged out of the system after a set period of inactivity (see »5«, Fig. 41)

6.2 Add, change and delete an endoscope

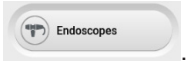
 → 

The menu for setting the endoscope parameters described in this chapter is common for the EDScab® and the Uniclean PLE 3 endoscope washer, manufactured by MMM. Many of the parameters listed below are related to the endoscope machine washing process in the indicated washer and are not relevant for the drying and storage process!

The description of these parameters is given in the Uniclean PLE 3 endoscope washer instructions of use.

➢ Log in as SUPERVISOR.

➢ Enter the settings menu .

➢ Select menu »Endoscopes« 

.

The »Copy« button can be used to create a new item. The data are copied and can then be changed.

The menu below (Fig. 41) can also be used to edit data from an existing endoscope. Select the appropriate item (see »Storage location«, Fig. 41) and change the existing data.

The »Delete« button can be used to remove already created endoscopes from the list.

Basic data:

See also the instructions for use of the Uniclean PLE 3 endoscope washer, manufacturer MMM.

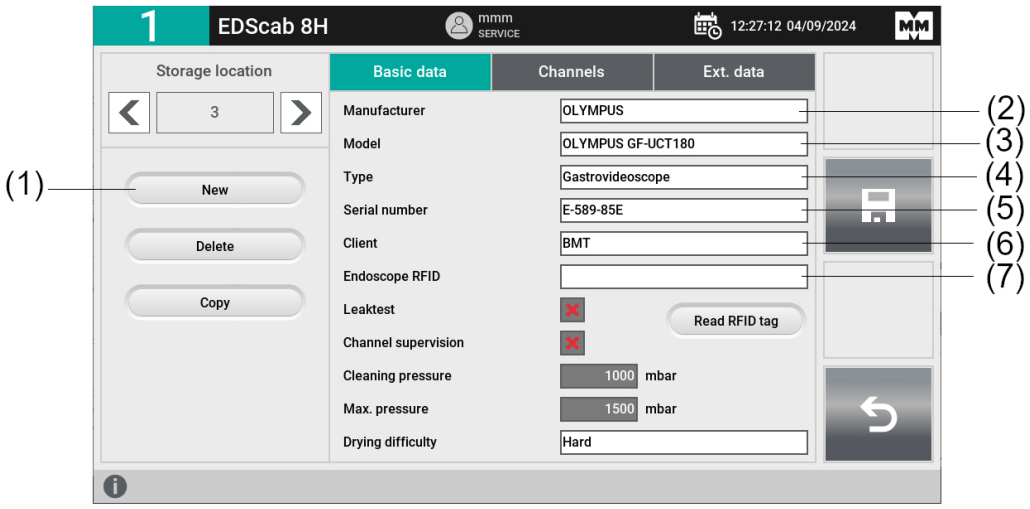


Fig. 42

(1) Creating a new endoscope

(2) Manufacturer, will be shown in the log.

(3) Model, e.g. OLYMPUS GF-UCT180.

(4) The type, e.g. bronchoscope, will be shown in the documentation of the respective cycle.

(5) The serial number will be displayed when the endoscope is selected via the menu.

(6) The client, e.g. the name of the doctor or department, will be displayed in the cycle log.

(7) Reading the RFID tag for the respective endoscope.

TLP:GREEN

Channels:

See instructions for use of the Uniclean PLE 3 endoscope washer, manufacturer MMM.

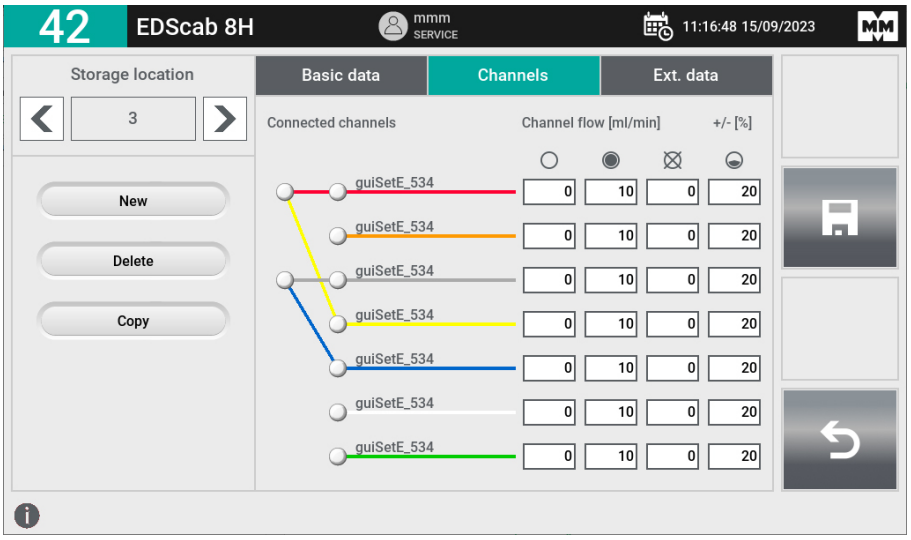


Fig. 43

Extended data:

See also the instructions for use of the Uniclean PLE 3 endoscope washer, manufacturer MMM.

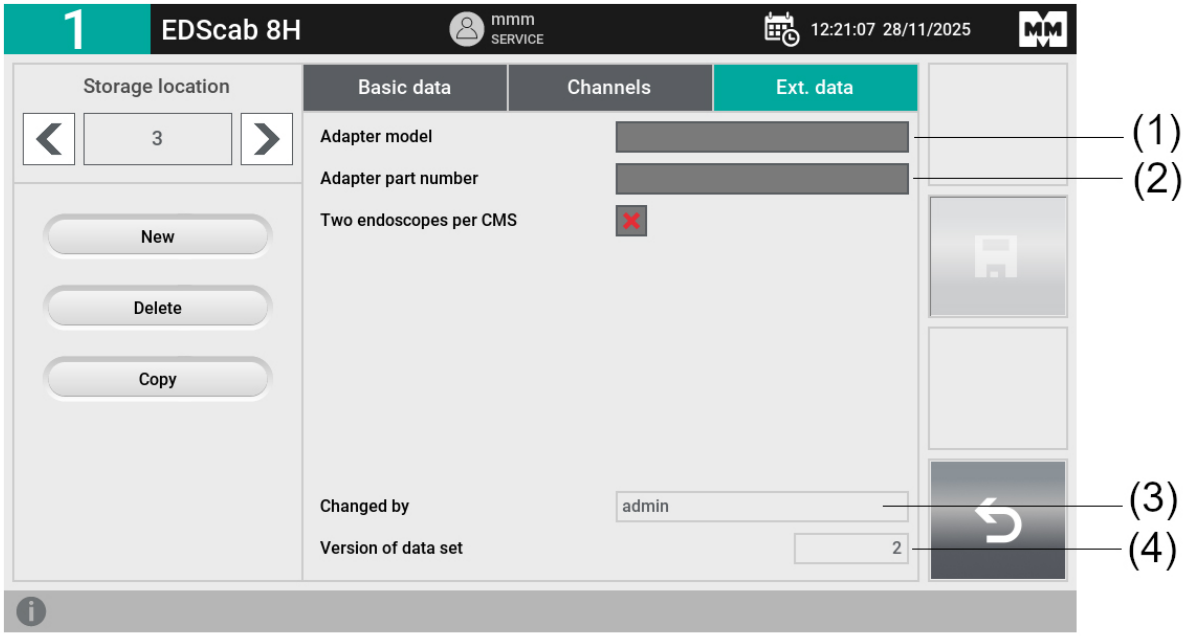


Fig. 44

(1) Adapter kit model

(2) Material number of the adapter set

(3) Author of the last parameter change

(4) Endoscope parameter versions

- *The version is incremented every time the parameters are changed.*
- *The version is handled by the EndoAdmin application.*

➢ Save the data.

6.3 Date and time

→ Date / time

Setting the time zone and the current date and time.

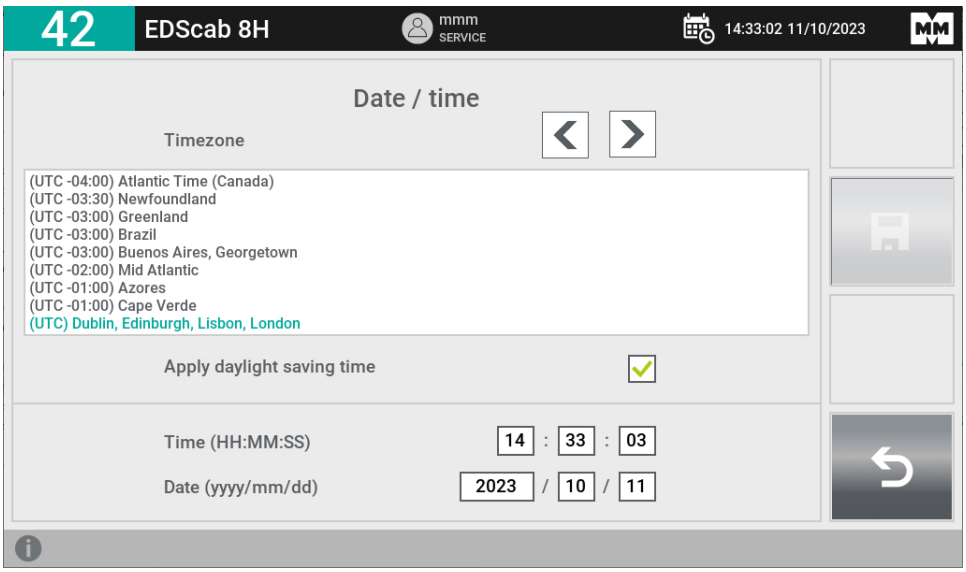


Fig. 45

Factory settings:

(UTC+01:00) Amsterdam, Berlin, Bern, Rome, Stockholm, Vienna

TLP:GREEN

6.4 Display and touch screen



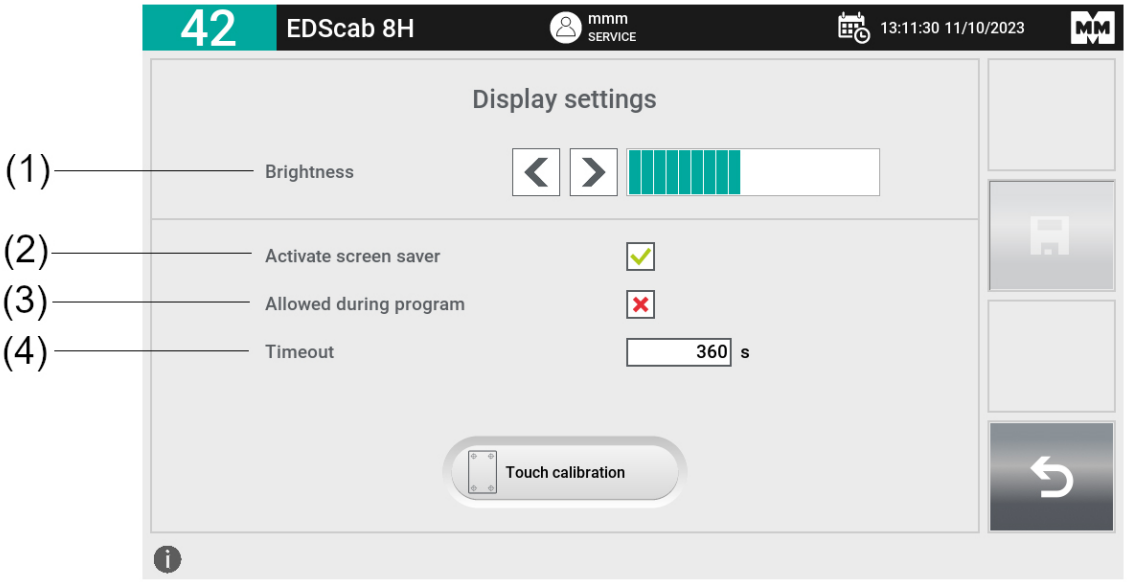


Fig. 46

(1) Brightness

(2) Activating the saver

(3) Enable activation of the saver during drying.

(4) Idle time for activating the saver

6.4.1 Touch panel calibration



Calibrating the touch panel can help when the controls on the display do not respond correctly.

Four aiming points will gradually appear in the corners of the screen.

Use the stylus pen to touch the aiming points as accurately as possible.

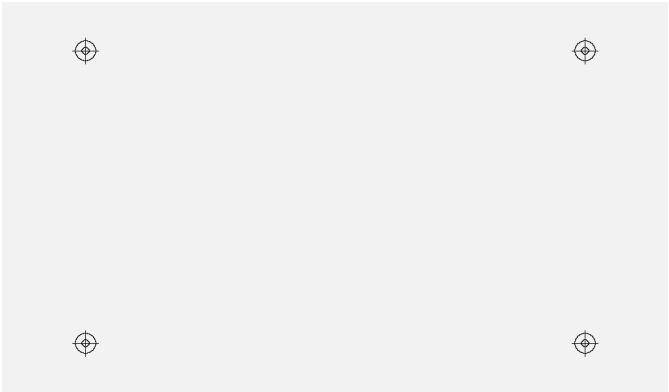


Fig. 47

6.5 LAN settings



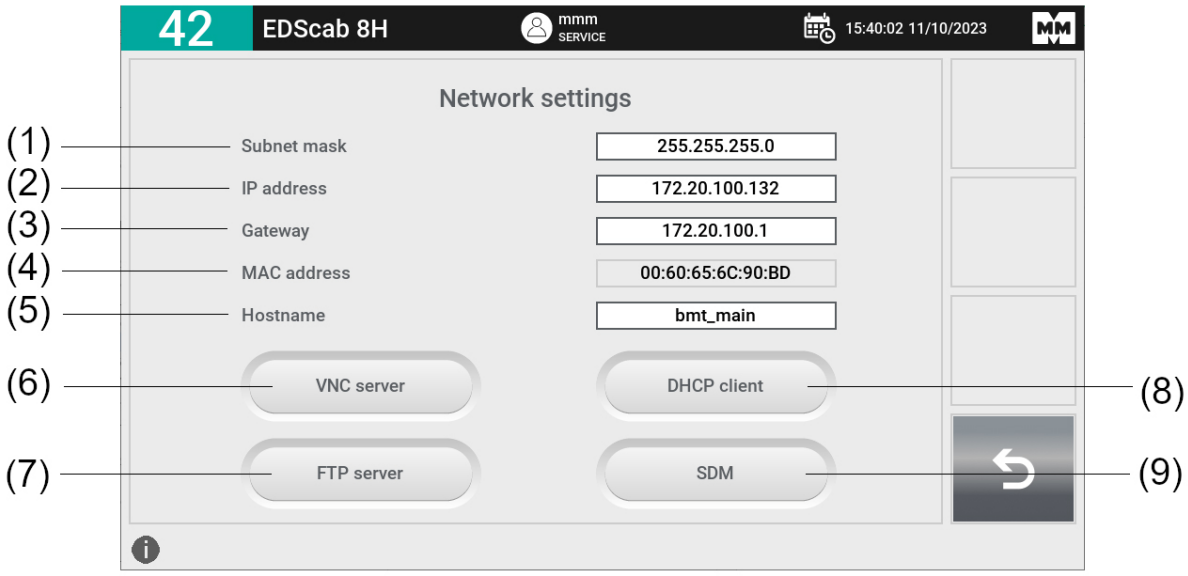


Fig. 48

(1) The mask of the network to which the device is connected.

(2) IP address of the device

(3) Gateway

(4) MAC address of the device

(5) Device identifier in the network

(6) VNC server
Allows access from a remote PC (VNC client) to the graphic user interface (client-server architecture).

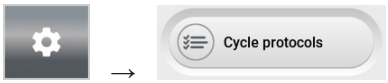
(7) FTP server
Allowsto transfer files between the server (EDScab®) and client (e.g. remote PC).

(8) DHCP client
The DHCP protocol allows to configure automatically the computers connected to the computer network. Using the DHCP protocol, the server (e.g. remote PC) assigns an IP address, netmask, default gateway and DNS server address to the client (EDScab®).

(9) SDM
System Diagnostics Manager is a software tool of the company B&R for diagnostics of programmable automatic machines B&R. SDM can be used for a remote (within an intranet or the Internet) diagnosis of B&R programmable automatic machines using a standard web browser and TCP/IP connection.

TLP:GREEN

6.6 Cycle protocols



The cycle protocol contains information on the course of the drying and storage of the endoscope in the EDScab® device.

After completion of drying (and, where applicable, storage) and after disconnection of the endoscope, the protocol is sent to the RUMED application, which ensures its accessibility to personnel and its archiving.

Via the »Cycle protocols« menu, the protocols can be resent in cases where their successful delivery did not occur.

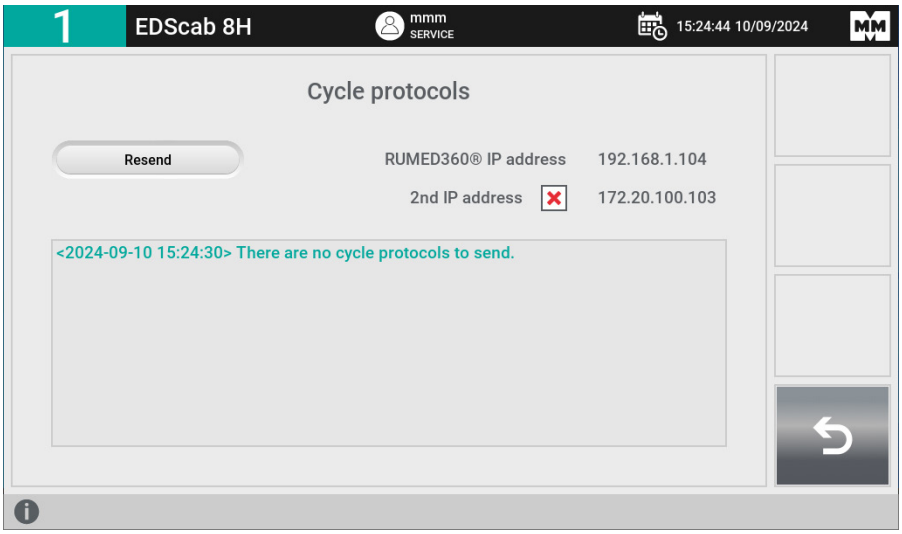


Fig. 49

After each removal of an endoscope from the device, it is necessary to check the course and the result of the drying process as recorded in the corresponding cycle protocol.

Access to the protocols is available via the RUMED application; alternatively, access via FTP (File Transfer Protocol) is possible.

6.6.1 Access via FTP

(1) A prerequisite for access via FTP is that the FTP server is enabled in the network settings menu; see 6.5.

(2) Access to the cycle protocols is carried out via an FTP client (e.g. FileZilla).

(3) The protocols are stored in XML format.

FTP client settings:

Parameter	Setting	Note
Port	21	
Password		Contact authorized MMM service.
IP address	= device IP address	
Username		Contact authorized MMM service.

FTP client example:

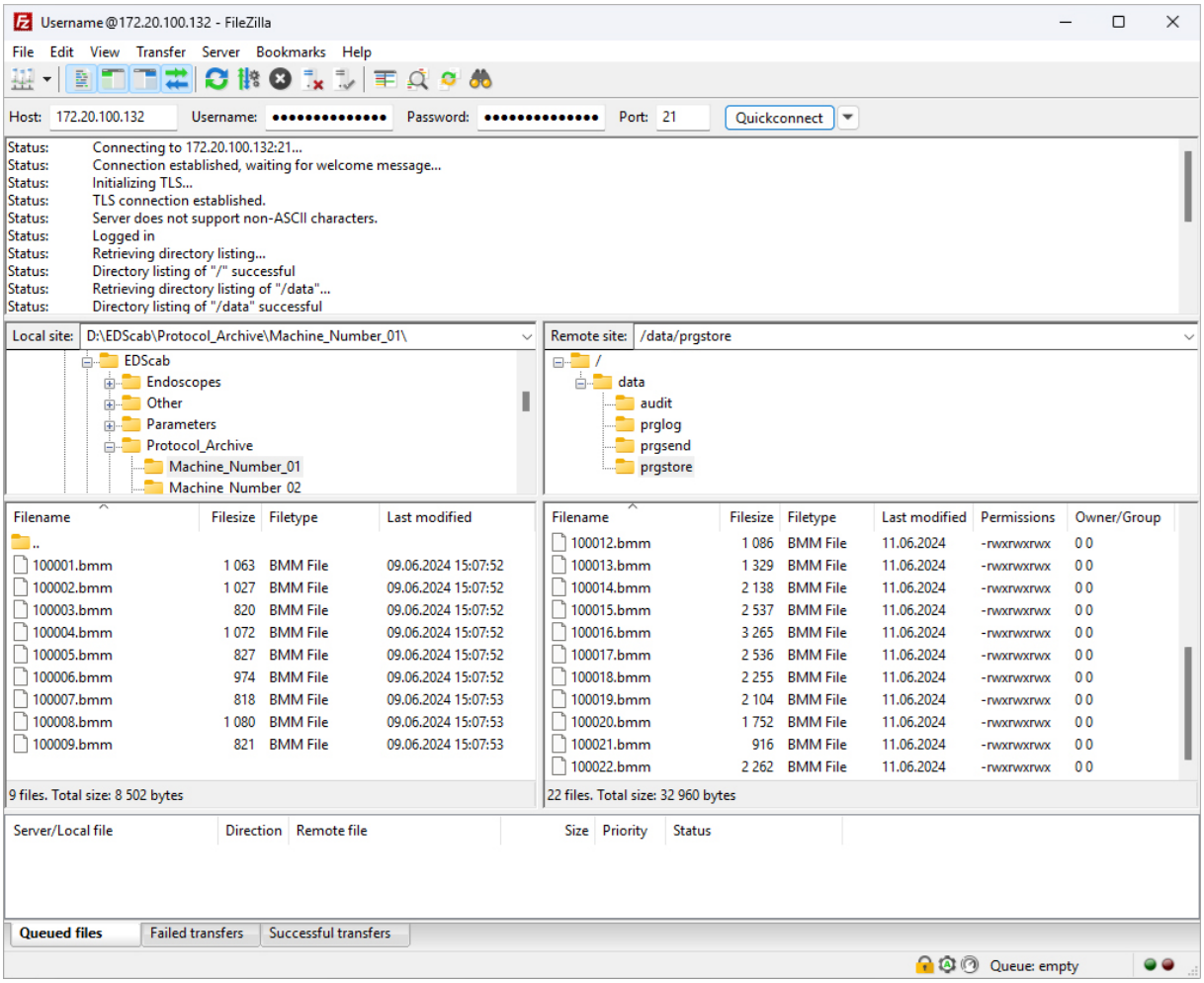


Fig. 50

The cycle protocols are stored in the »prgstore« directory, see Fig. 50. Cycle protocols originating from the EDScab® device can be identified by the “bmm” file extension. These are XML files compressed in GZ format. The files are stored in the “prgstore” directory in a tree structure organized by the year and month of file creation. Up to 10,000 protocols can be archived.

During regular service inspections, it is recommended to archive the protocols on reliable storage media and to delete the contents of the “prgstore” directory.

6.7 Language



Setting the national environment.

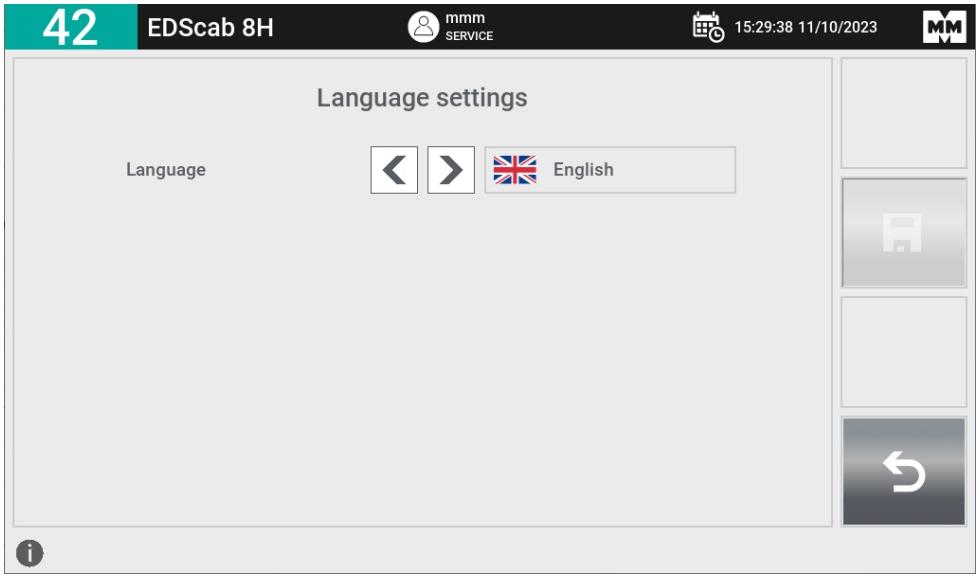


Fig. 51

7 Charts



Graphic representation of the time course of the monitored or regulated variables:

- Temperature
- Humidity
- Pressure

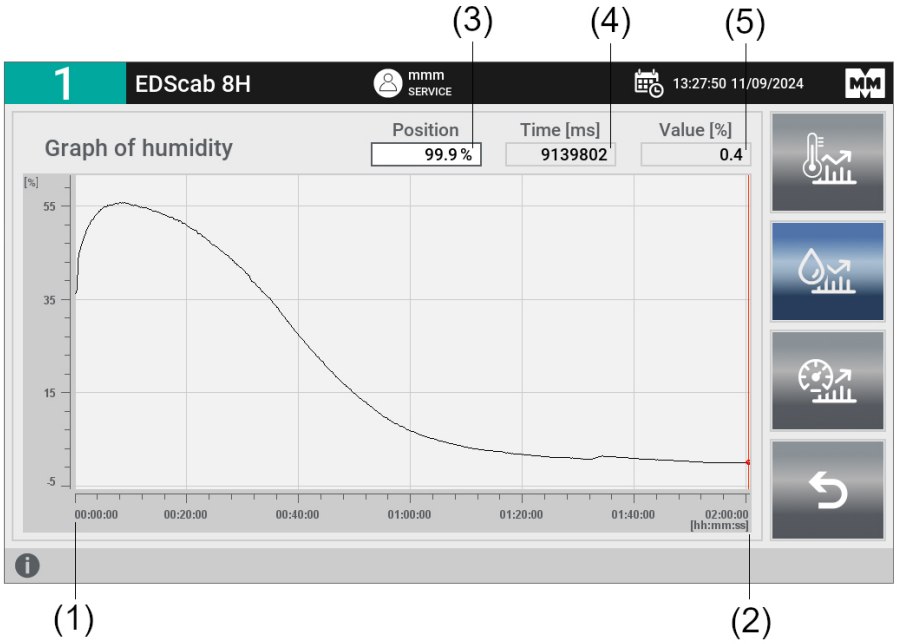


Fig. 52

(1) Timeline - start of record

(2) Timeline - present

(3) Entering a point on the timeline [%]

- *0 %...* *start of record*
- *100 %...* *present*

(4) Time [ms] corresponding to the selected point

(5) Value of the variable at the selected point

TLP:GREEN

8 System information



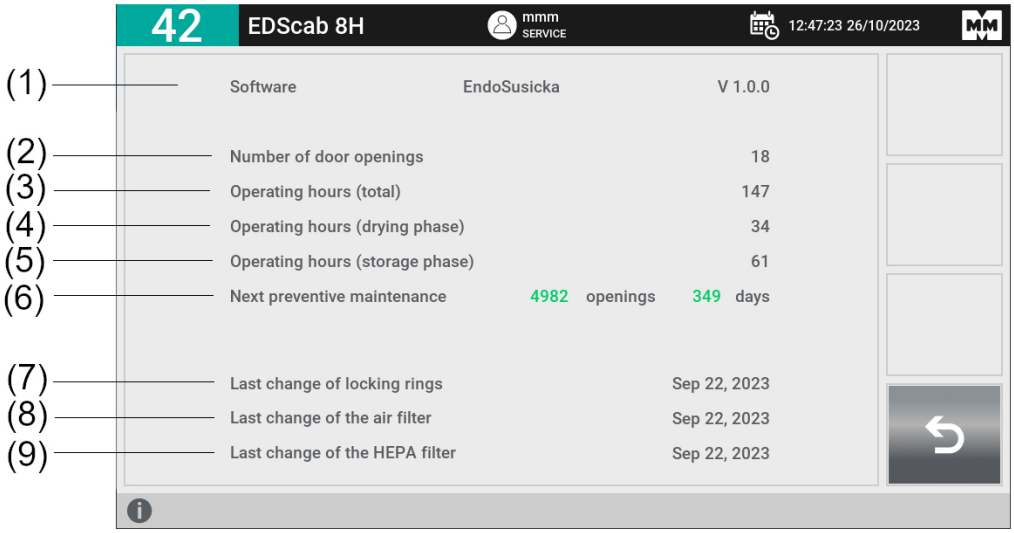


Fig. 53

(1) Software version
(2) Number of drying and storage cycles
(3) Number of door openings
(4) Total time of the device switched on
(5) Total drying time
(6) Total storage time
(7) Time (or number of door openings) remaining until next scheduled maintenance
(8) Date of last door locking mechanism replacement
(9) Date of last chamber filter change
(10) Date of last HEPA filter change

9 Faults

In the event of a fault, the device is in a safe state or is put into a safe state.

The occurrence of a fault is indicated by an alarm, see 9.1.

Equipment malfunction can cause incorrect drying of endoscopes that are in the equipment during the malfunction!

The manufacturer of the equipment is not liable for any personal injury or material damage caused by the use of endoscopes whose drying or storage has been interrupted by a malfunction!

The operator of the equipment is fully responsible for the use of endoscopes that have malfunctioned during drying or storage.

WARNING **Follow the instructions in the chapter 2.**

If the fault is of such a nature that it is not possible to have it repaired by a trained person, contact MMM Group Customer Service or a person or company authorised by MMM Group.

9.1 Alarms

If a fault occurs during operation of the device, the corresponding error message (alarm) is displayed on the lower status bar, the fault is also indicated audibly.

There are 3 levels of alarms in EDScab:

Severity	Icon	Description
Info		Status information
Warning		A warning is issued when a non-critical fault occurs, or it may be a warning of a potentially dangerous phenomenon.
Error		It is declared when a critical fault occurs.

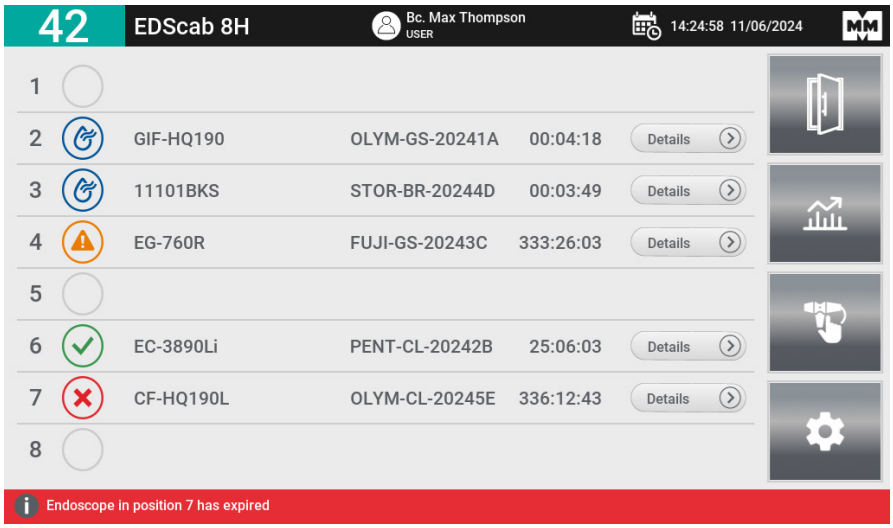


Fig. 54

TLP:GREEN

9.2 Behaviour during the fault

Procedure in the event of a fault:

(1) Analyse the fault and remove it (if possible).

(2) Report the fault to the person responsible for the device without interfering with the device in any way.

(3) Analyse the fault and have the cause removed by a specialist.

(4) Depending on the type of fault, inform MMM Group Customer Service, stating the text displayed on the screen and the fault number.

(5) If the malfunction has affected the endoscopes in the device, these endoscopes must be washed again.

9.2.1 Alarm cancellation

WARNING	**Alarms can only be cancelled after the cause of the alarm has been removed.**

If the user is not logged in or does not have permission to cancel the alarm, the user login (logout) window is displayed.

Click on the alarm bar on the display (on the loading side of the two-door version). See Fig. 54.

A list of active alarms is displayed (Fig. 55).

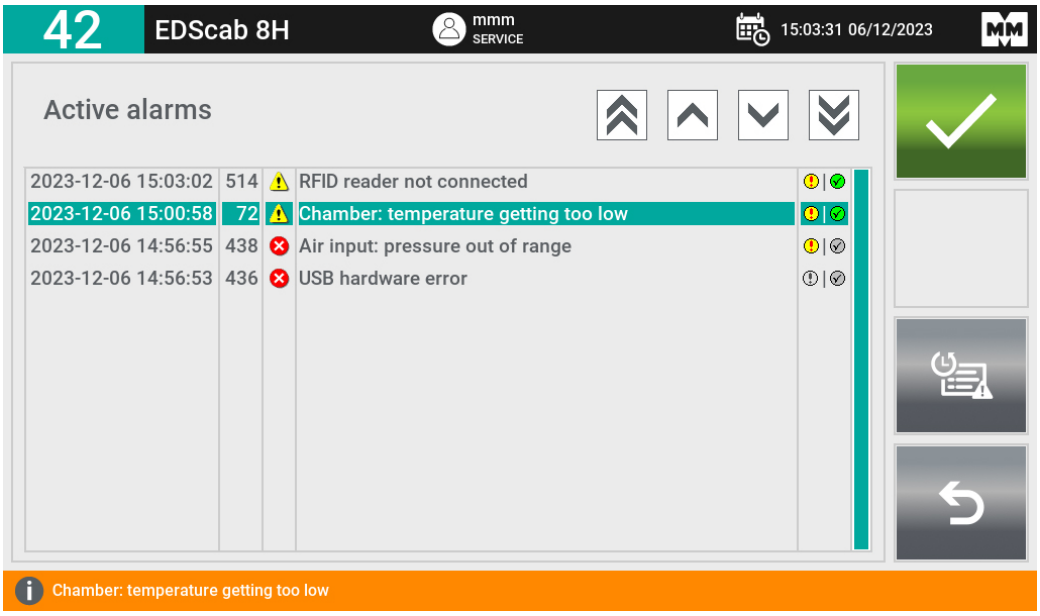


Fig. 55

Active alarms – the legend	
	The alarm is active and will not need to be acknowledged (if deactivated, it will disappear from this menu). The cause of the alarm persists. If removed, the alarm will not need to be acknowledged.
	Alarm inactive and waiting for confirmation. The cause of the alarm has been remedied (or has passed), the alarm is waiting for confirmation.
	Active and unacknowledged alarms (active alarms cannot be acknowledged until they go into an inactive state). The cause of the alarm persists. In order for an alarm to be acknowledged, the cause of the alarm must first be remedied.

To cancel an alarm, the cause of its activation must first be eliminated. Subsequently, the alarm can be acknowledged by pressing the button  Alarms whose cause has been eliminated and which have been acknowledged by the authorized operator are removed from the list of active alarms and transferred to the alarm history.

If all alarms are acknowledged, the device is ready for operation.

The  button displays the alarm history:

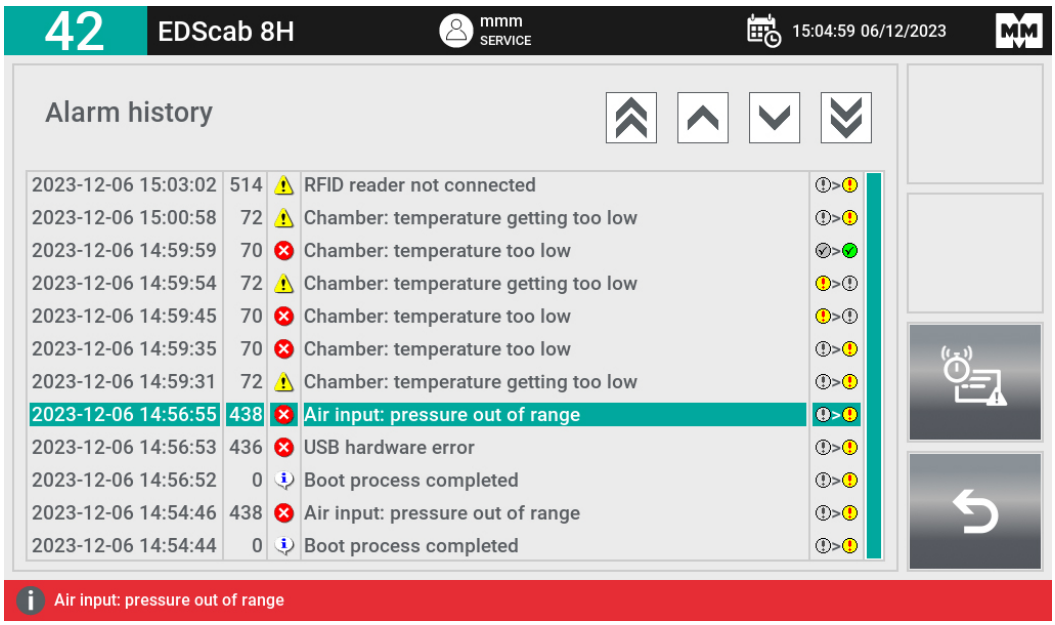


Fig. 56

Alarm history – the legend	
	The alarm has gone from inactive to active state (i.e. the alarm is triggered). The condition for an alarm has been met.
	The alarm has gone from active to inactive state (i.e. the alarm is off). The cause of the alarm has been remedied (or has passed).
	The alarm has gone from an unconfirmed state to a confirmed state. The alarm has been acknowledged in the list of active alarms with the button .

TLP:GREEN

9.3 Action in case of special faults

9.3.1 Power failure

If the process does not run during a power failure, no intervention is required. The media valves are closed when the device is idle. Items to be processed remain in the chamber until the power is restored. When the power is restored, the device will attempt to resume the activity that started before the power failure.

If a failure occurs during the process (drying or storage), process data will be lost. Once power is restored, the endoscopes must be reprocessed.

If an error message is displayed after the power is restored, the cause of the fault must be remedied and the error message acknowledged, see 9.2.1. In the event of an extended power outage, all endoscopes must be washed and disinfected again.

9.3.2 Emergency door opening

In the event of a failure of the opening mechanism, power failure or failure of the pressure air supply, the door closure can be released using a special tool, see the figure below. The tool must be inserted into the opening that is accessible from the top of the unit near the edge on the side of the door handle. Then turn the tool 360° clockwise 4 times to connect the key and the opening mechanism. Then force the tool upwards until the door is released. Locking the door is done in the same way, but the door locking tool must be pushed downwards.

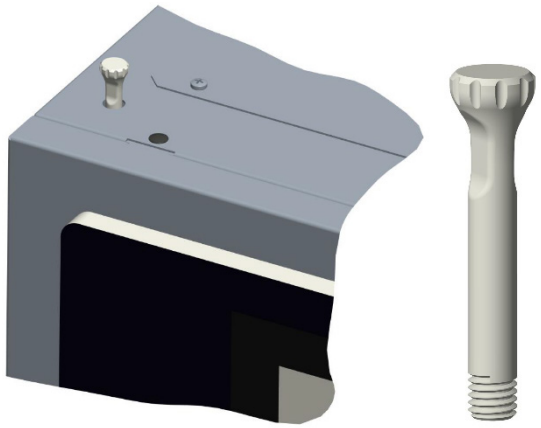


Fig. 57

9.4 Unsatisfactory drying result

If the drying result is not satisfactory, check the following points:

- Was the preparation of the endoscope before drying done correctly?
- Was the correct adapter used for the endoscope? Does the adapter meet the manufacturer‘s recommendations? Was the adapter properly connected and secured?
- Are all pins of the adapter fully passable? Is the air allowed to pass freely?



Strictly follow the safety instructions and warnings in the accessory‘s instructions for use!

Drying efficiency can only be guaranteed if the appropriate adapter is used for the endoscope to be dried and the endoscope and adapter are correctly connected.

If not so, the drying efficiency may be reduced. Check the drying result.

If the drying result is unsatisfactory, it must be repeated.

TLP:GREEN

10 Maintenance

WARNING | **Follow the safety instructions in chapter 2.5!**

10.1 Regular maintenance

Regular maintenance and inspection must be performed at least once a year (regular maintenance and inspection). However, this inspection alone is not sufficient to ensure adequate safety and longterm reproducibility of device operation. The manufacturer therefore recommends supplementing the regular inspections of the device with additional preventive inspections.

After 12 months or after a specified fixed number of door openings (whichever occurs first), preventive inspection and maintenance must be performed. For this purpose, the device is equipped with a door opening counter. The counter displays the number of door openings remaining until the next preventive inspection. The counter is decremented with each door opening. When the counter reaches zero, the following warning is displayed: “Preventive maintenance required”. This warning is also recorded in the protocols of all affected cycles. The current counter status can be viewed in the “Information” menu (see 8).

10.2 Maintenance agreement

We recommend you to conclude a maintenance agreement.

The routine tasks described below are also checked during the maintenance. If a device fault is detected which cannot be remedied immediately, a fault report is drawn up.

Corrective measures are not part of the maintenance agreement. If necessary, these measures are initi-ated only after consultation with the operator.

10.3 Cleaning the controls

10.3.1 Touch screen

WARNING

Clean at regular intervals.

Clean the device with a cloth dampened with water and screen cleaner. If necessary, disinfect with an alcohol-based product (ethanol, propanol).

Spray the cleaner on the fabric first, do not spray it directly on the screen!

Do not use aggressive solvents, chemicals, abrasives, compressed air or steam!

The touch screen can only be cleaned in screen cleaning mode (Fig. 58).

✓ 

You can then swipe the touch screen for 30 seconds without unwanted button activation.



Fig. 58

10.3.2 Main switch

If the device is switched off, the main switch button (see 2.6.2) can only be wiped briefly, a longer touch will switch the device on.

10.4 Cleaning the outer surfaces and chamber of the device

WARNING	Check the cleanliness of the device and disinfect it at regular intervals. For disinfection, use products intended for disinfection of medical devices and surfaces, follow the package leaflet for their application.
WARNING	If the device is shut down for more than 24 hours, we recommend to disinfect the device.

TLP:GREEN

10.5 Maintenance of the adapter set



Leaks in the adapter set can cause errors in the measurement of process variables!

Lubricate the O-rings regularly to prevent premature degradation!

- Before each use of the adapter kit, check the 10-way connector and the integrity of the adapter tubing.
- Replace damaged or worn O-rings. Replacement requires the intervention of an authorized service technician!
- Lubricate the O-rings regularly (but at least once a week).

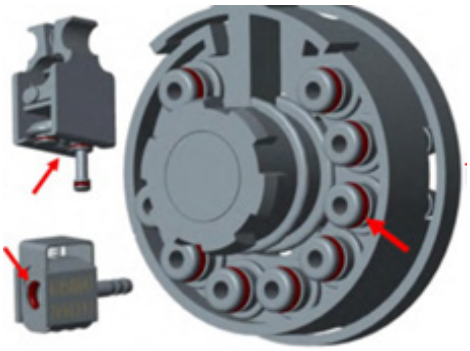
10.6 Regular maintenance

10.6.1 Daily

WARNING The following measures must be carried out by a person trained by a specialist.

What	How	Note
Adapter kit	1. Check the 10-way connector to be intact 2. Check the paint tubing for damage and flexibility.	Visual inspection
Endo basket	1. Check the integrity of the basket wires 2. Check the attachment and presence of the RFID card	Visual inspection
Door seals	1. Check the integrity and fit of the seal around the perimeter of the door	Visual inspection

10.6.2 As needed

What	How	Note
Cleaning and disinfection of the outer surface of the device	Outer surfaces ➢ Wipe the front lining with a lint-free cloth. ➢ Disinfect and clean stainless steel surfaces with a suitable disinfectant or surface treatment. Follow the manufacturer‘s instructions! **Colour touchscreen** See chapter 10.3.1 ➢ Disinfect and clean the colour touchscreen with a suitable cleaner or a common surface disinfectant. Follow the manufacturer‘s instructions!	
Adapter set	Lubricate all circular seals on the 10-way connector and on the connection adapters with a small amount of special lubricant with the number 010631255. **Use only the approved lubricant!** **Do not use silicone sprays! These contain additives that can damage the adapter kit!**  **Fig. 59**	If the plug of the 10-way connector is difficult to insert into the socket on the shelf, but at least once a week.
	Replace worn or damaged O-rings. **The O-rings must be replaced by an authorized service technician!**	In case of leaks between the socket and the plug of the 10-way connector or leaks between the connecting adapter and the endoscope.

TLP:GREEN

10.6.3 Quarterly

WARNING The following measures must be carried out by a person trained by a specialist.

Carry out with the unit switched off and empty.

In the case of a two-door design, make sure that the loading and unloading sides are not directly connected. Ensure that at least one door is always closed when cleaning.

What	How	Note
Cleaning the seals and the inner surface of the door	1. If the seal is dirty, wipe it with a lint-free cloth and a suitable cleaning and disinfecting agent for silicone seal. 2. Wipe the inner surface of the door with a lint-free cloth and a suitable cleaning and disinfectant.	
Cleaning the inner plates of the chamber	Wipe the surfaces with a lint-free cloth and a suitable cleaning and disinfecting agent.	
Cleaning the shelves and 10-way connector	In case of light soiling, wipe the surfaces with a lint-free cloth and a suitable cleaning and disinfecting agent. In case of heavy soiling, the shelves including the connector can be removed and machine washed in a suitable dishwasher (e.g. instrument dishwasher) using a neutral or slightly alkaline product up to 50 °C. Do not use the thermal disinfection programme! After washing, the shelves must be dried before reas-sembly. **Before machine washing, it is necessary to screw the protective sealing plugs (accessories supplied with the device) onto the inductive sensors! See Fig. 60.**	

	 **Fig.** 60 **Do not use the thermal disinfection programme!í!** **The temperature of the cleaning agent used to clean the shelves and the 10-way connector must not exceed 50 °C!** **Only an authorised service engineer can dismantle and assemble the shelves.**	
Cleaning and checking the air supply hose to the shelf	1. Very carefully wipe the surface of the tubing with a lint-free cloth and a manufacturer-approved cleaner. 2. Check that the hose is intact, attached and properly tensioned, including the supply elbows.	

TLP:GREEN

10.6.4 Annually

What	How	Note
Chamber HEPA filter (FIL1)	Replace the filter at least once per year	 **May be performed only by an authorized service technician.**
Inlet filter (FILA)	Replace the filter at least once per year	 **May be performed only by an authorized service technician.**
Sliding rollers in the door locking system	Replace the sliding rollers once per year	 **May be performed only by an authorized service technician.**
Cycle protocols	Archive the protocols from completed cycles on secure storage. Subsequent-ly, delete the contents from the “prgstore” directory.	 **May be performed only by an authorized service technician.**