

PLASMABIOTICS®

IN ASSOCIATION WITH **PENTAX MEDICAL**

Instructions for use
PlasmaTYPHOON+

Instructions for use



Advanced plasma unit for fast drying and active storage of endoscopes

PENTAX
MEDICAL

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1. INTRODUCTION

Drying and storage of endoscope are very important steps in the endoscope reprocessing procedure aiming to stop the proliferation of microorganisms within this device. **PlasmaTYPHOON+** is a device designed for this purpose having two functionalities: fast drying of endoscope channels and storage of endoscope in a single-use bag under controlled atmosphere in order to preserve its disinfected state. **PlasmaTYPHOON+** is a new, more advanced version of PlasmaTYPHOON, offering new features, higher performance, improved comfort of use and increased security.

It is requested that you read this manual carefully before using the PlasmaTYPHOON+ for the first time. These instructions for use include installation and operating instructions, maintenance recommendations, safety instructions, as well as a list of possible error messages that may appear during PlasmaTYPHOON+ operation.

2. INDICATION

2.1 INTENDED USE AND PERFORMANCE

PlasmaTYPHOON+ is used within the endoscope reprocessing procedure in order to dry the endoscope channels following a cleaning and disinfection operation, performed either manually or in an automated endoscope reprocessor (AER). The PlasmaTYPHOON+ endoscope drying cycle lasts between 1 and 3 minutes, depending on the endoscope type. Once dried, the endoscope can be placed in a single-use PlasmaBAG, which is specifically designed for endoscope storage. Insufflating plasma, containing ozone molecules, into the bag for 5 seconds ensures the endoscope's disinfected state is maintained for up to 744 hours (31 days). National regulations may impose a more restrictive storage time for the endoscope (see Chapter 5.8).

The endoscope drying and storage procedure using PlasmaTYPHOON+ has been validated by PlasmaBiotics according to the EN 16442:2015 standard. Validation test reports are available upon request.

PlasmaTYPHOON+ is equipped with a traceability system, including a barcode scanner, RFID tag scanner and a printer. The barcode or the RFID scanner are used for operator and endoscope identification. The printer delivers a traceability label at the end of the drying and/or storage cycle. The history of all completed cycles is archived on the PlasmaTYPHOON+ hard drive and can be accessed via the Ethernet network.

2.2 INTENDED USERS AND OPERATING LOCATION

The intended users are medical and paramedical staff involved in endoscope reprocessing operations, such as a trained nurse or decontamination staff. A biomedical technician or biomedical engineer can operate the device for maintenance purposes.

The PlasmaTYPHOON+ is intended for operation in hospitals as an active drying and clean storage system. The intended operating location is the clean area of an endoscope reprocessing unit or Central Sterilization (Service) Department (CS(S)D).

Specific training on the use of the PlasmaTYPHOON+ is mandatory for healthcare operators.

2.3 INTENDED USE AND BENEFIT

The intended use of the PlasmaTYPHOON+ is as follows:

- to dry endoscope channels following a cleaning and disinfection operation, and / or
- to provide active storage for the endoscope in a single-use PlasmaBAG in order to maintain its disinfected state.

2.4 CONTRA-INDICATION



Warning: PlasmaBiotics does not warrant the correct functioning of the PlasmaTYPHOON+ without the validated connection sets and PlasmaBAG (when storage option is used). PlasmaBiotics assumes no warranty or liability for any damages on a PlasmaTYPHOON+, an endoscope, or any other damages, each resulting out of the use of an endoscope that has not been dried with validated connection sets and stored in the validated PlasmaBAG, including but not limited to damages suffered by patients treated with such an endoscope.



Warning: The PlasmaBAG is not destined for sterilisation. The PlasmaBAG is not a sterile barrier.



Warning: An endoscope shall not be stored in a PlasmaBAG if the endoscope was not previously appropriately dried with the PlasmaTYPHOON+.

3. GENERAL CHARACTERISTICS

3.1 ELECTRICAL AND MECHANICAL CHARACTERISTICS

CHARACTERISTIC / PARAMETER	Sym	VALUE
Model	#	PlasmaTYPHOON+
Reference	REF	TYPHOON+
UDI ID	UDI	03701354408104
Medical device	MD	Class I
Power supply / electrical network		100-240 V
Fuse		T3.15AT 250VAC
Maximal power		500 W
Frequency		50 Hz / 60 Hz
Oversupply		Category II
Power supply cable		H05VV-F 3G 1mm ²
Pollution degree		Degree 2
Pressure regulator – delivery pressure		0 to 5 bar (75.52 psi)
Dimension (length / width / height)		300 / 280 / 260 mm (11.8 / 11.0 / 10.2 in)
Minimal air inlet pressure		3 bar (43.51 psi)
Maximal air inlet pressure		4 bar (58.02 psi)
Minimal gas flowrate		60 l/min
Medical air supply tube dimensions		Internal diameter: 4 mm (0.16 in) External diameter: 6 mm (0.24 in)
Weight		10.7 kg (16.53 lb)
Ingress protection rating	IP	IP20

3.2 MATERIALS AND SUBSTANCES

COMPONENT	Abr	MATERIALS / SUBSTANCES
Box		Stainless Steel
Discharge chamber		Macor and Tungsten (W)
PlasmaBAG	LDPE	Low Density Polyethylene
Connection set		Silicone and Stainless Steel
Air supply tube	PU	Polyurethane
Plasma delivered during storage cycle	O ₃	Ozone

4. INSTALLATION



Warning: The following instructions are intended to ensure that the PlasmaTYPHOON+ and its peripheral devices are operated appropriately. Non-compliance with these instructions may influence the efficiency of the drying cycle and may cause damages that are not covered by the manufacturer warranty (as mentioned in 2.4).

The following must be ensured for appropriate installation of the PlasmaTYPHOON+:

1) Facility:

- Power supply / electrical network.
- Medical air grade supply with minimal pressure: 3 bar (43.51 psi), minimal flowrate: 60 l/min.

2) Provided by PENTAX Medical or local distributor:

- Air pressure regulator, delivery pressure: 0 to 5 bar (72.52 psi), minimal flowrate: 60 l/min
- Peripheral devices (e.g. printer, bar-code scanner, RFID tag scanner...)
- PlasmaBiotics connection sets corresponding to different endoscope brands and models.



Figure 1. PlasmaTYPHOON+ with its peripheral devices (a barcode scanner and a printer)

4.1 OPERATING AND STORAGE CONDITION OF THE DEVICE

Store at ambient temperature: 15 – 40 °C (59 - 104 °F) and 30 – 85 % RH.

Operate at ambient temperature: 15 – 40 °C (59 – 104 °F) and 30 – 85 % RH.

Operation altitude: max 2000 m

4.2 ELECTRICAL CONNECTION

The power cable must be plugged into the electrical socket with 3 terminals (live, neutral and earth).

4.3 MEDICAL AIR INLET

PlasmaTYPHOON+ has a **medical air inlet** at the rear. This inlet must be connected to an external source of medical air (ex. medical air pipeline system). An air compressor for medical applications may also be used: oil-free, with filters, desiccation system and antimicrobial coating for the tank. A pressure regulator shall be used to set the medical air inlet pressure between 3 bar (43.51 psi) and 3.5 bar (50.76 psi) in static mode, in order to ensure the pressure of 3 bar (43.51 psi) in dynamic mode. The minimal gas flowrate of the supply system (gas pipeline system + pressure regulator) must be 60 l/min.

In the event that an external source of medical air is not connected to the PlasmaTYPHOON+ or that the gas pressure or flowrate is too low, an error message will appear on the screen and it will not be possible to perform the cycle.

The medical air inlet must be connected to an external source of medical air via a polyurethane tube of internal diameter: 4 mm (0.16 in) and external diameter: 6 mm (0.24 in) equipped with a CPC type connector. To connect the medical air supply tube to the PlasmaTYPHOON+, plug the CPC connector to the medical air inlet connector at the rear of the PlasmaTYPHOON+. To disconnect the tube, first disconnect the pressure regulator and then unplug the CPC connector while pressing the button (see Fig. 2).



Figure 2. Connection and disconnection of the medical air supply tube



Warning: The medical air supplying the PlasmaTYPHOON+ must be free from contamination and must be of a purity class according to local regulation. The vapor water concentration must be less than 67 ml/m³.

1. The PlasmaTYPHOON+ must not be operated, if the water vapor concentration is above 67 ml/m³.
2. The presence of liquid water in the medical air represents a risk of damaging the PlasmaTYPHOON+ equipment. The manufacturer is not liable for any damages in the event of water ingress via the medical air inlet.

4.4 PERIPHERAL DEVICES AND NETWORK CONNECTION

Peripheral devices barcode scanner and printer shall be connected to the PlasmaTYPHOON+ via the corresponding USB ports, named "SCAN" and "PRINT", at the rear of the device (see Fig. 4). RFID scanner is connected to the PlasmaTYPHOON+ via a dongle installed on the USB port named "RFID". All peripheral devices need to be configured in order to function with PlasmaTYPHOON+.

PlasmaTYPHOON+ can be connected to the local network and/or internet via the Ethernet port at the rear of the device.

4.5 GAS/PLASMA OUTLETS

PlasmaTYPHOON+ has **4 gas/plasma outlets** on the front (see Fig. 3):

1. Suction/operating channel – red colour
2. Air/water channel – blue colour
3. Water jet channel – yellow colour
4. Storage – green colour

These gas/plasma outlets enable the medical air to be insufflated into the endoscope channels and the plasma to be insufflated into the PlasmaBAG via corresponding PlasmaBiotics connection sets. PlasmaBiotics connection sets are available for different endoscope types and brands.

4.6 SWITCHING ON

In order to switch ON the PlasmaTYPHOON+, use the “ON/OFF” switch located at the rear of the device (see Fig. 4). PlasmaTYPHOON+ software runs automatically after switching ON the device. The PlasmaTYPHOON+ is in a Standby mode upon start-up: the display is ON and the user (operator) identification can be entered.

4.7 DEVICE QUALIFICATION

Installation of PlasmaTYPHOON+ equipment shall be followed by:

1. Installation qualification (performed by local service representative)
2. Operational qualification (performed by local service representative)
3. Performance qualification

Please refer to the relevant regulations or guidelines in your country.

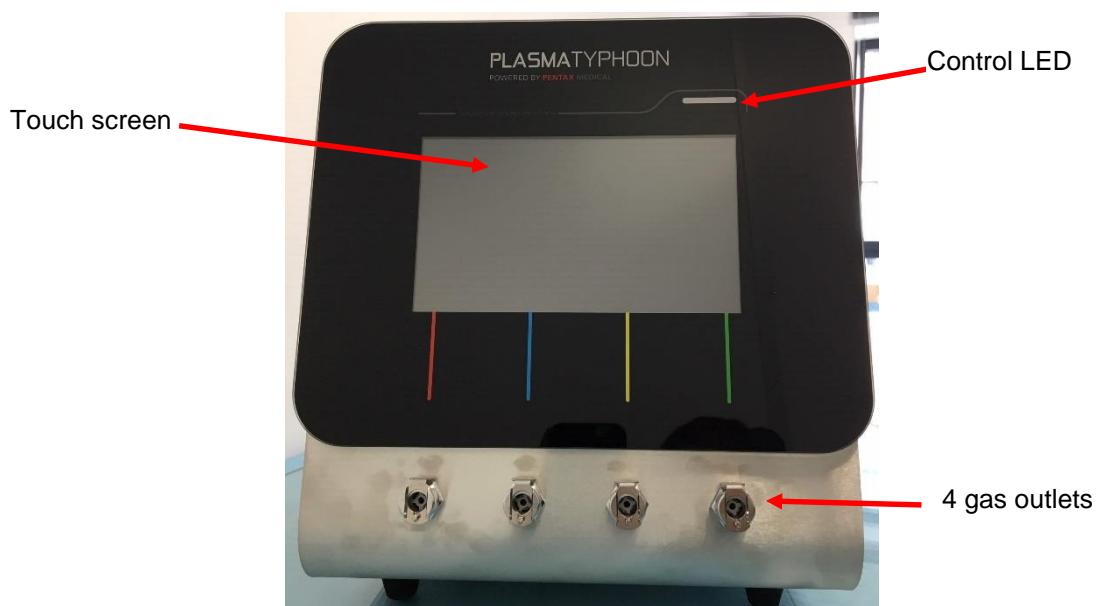


Figure 3. Front of the PlasmaTYPHOON+



Figure 4. Rear of the PlasmaTYPHOON+

5. OPERATING INSTRUCTIONS

5.1 STANDBY MODE

The PlasmaTYPHOON+ is in Standby mode upon start-up. By pressing the PlasmaTYPHOON+ logo in the upper left corner of the screen, one can access the PlasmaTYPHOON+ homepage where manufacturer and distributor details are displayed. In addition, this page contains language settings.

The left-side menu, that is permanently displayed on the screen, provides a direct access to the User ID and Endoscope ID page, by pressing the user and endoscope symbol, respectively. Once identified, the user and endoscope ID will be displayed next to the corresponding symbol. IFU of the PlasmaTYPHOON+ can be displayed on the screen by pressing the IFU symbol in the lower left corner of the screen. In addition, date and time are also displayed in the lower left corner of the screen.

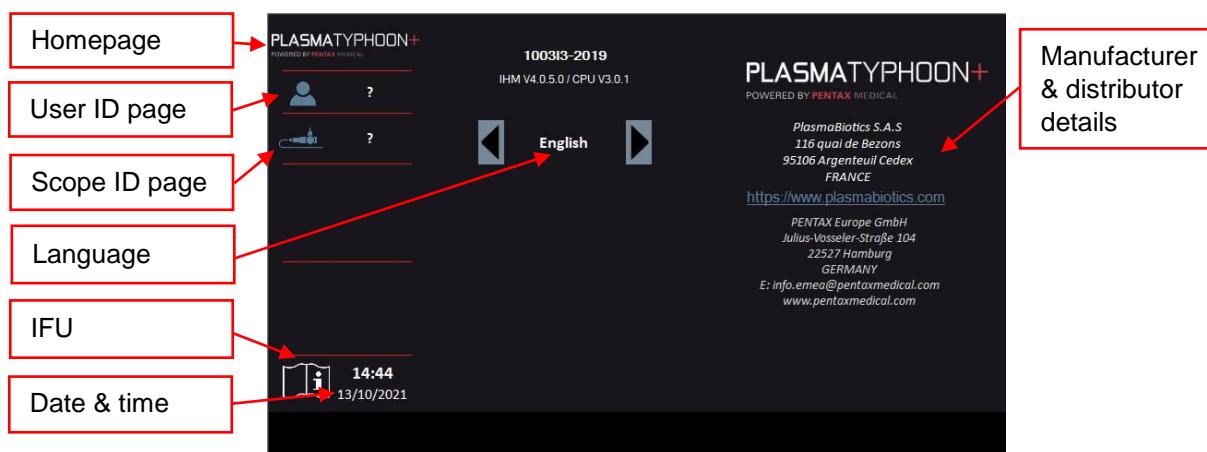


Figure 5. Homepage screen

5.2 USER IDENTIFICATION

User identification page can be accessed by pressing the user symbol in the left-side menu. A question mark displayed next to the user symbol indicates that the user has not been identified (see Fig. 6). If the user's action is requested, the instruction is clearly indicated in the centre of the screen. In addition, a short recall of the requested action is also displayed in the central part of the left-side menu.

User (operator) identification can be performed:

1. Using **the barcode scanner**: The user scans the barcode on his/her badge or ID card
2. Using **the RFID tag scanner**: The user scans his/her personal RFID tag
3. By entering a **User ID**: A user can enter his/her name or a personal user login (attributed to each user by the person in charge of the unit) via an alphanumerical keyboard that will appear on the screen when pressing the "Keyboard" button.

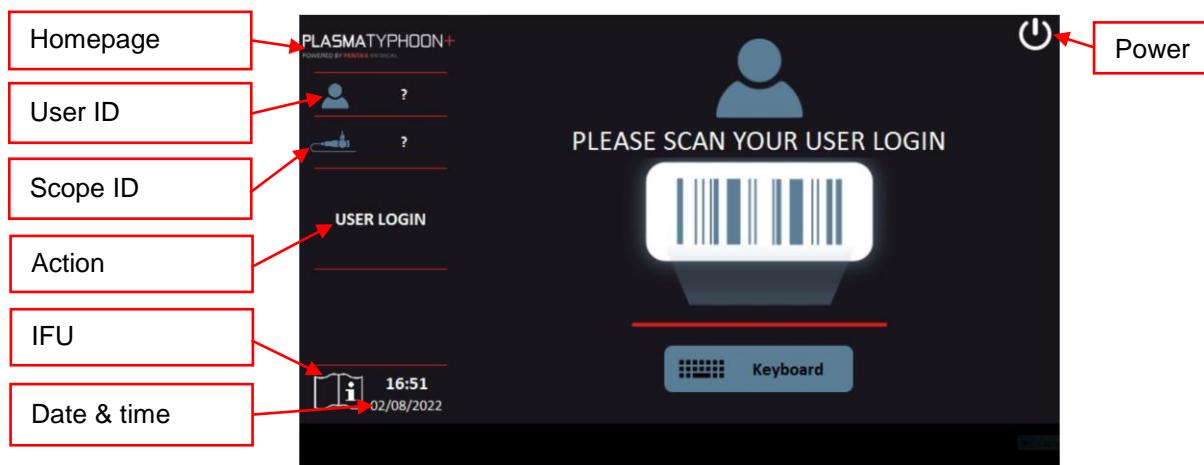


Figure 6. User ID page

When the alphanumerical keyboard is displayed, the user should type his/her name or login number. The typed name/number is displayed in the upper box. The user can use the backspace button “←” to erase, as well as the “Cancel” button to return to the previous page.

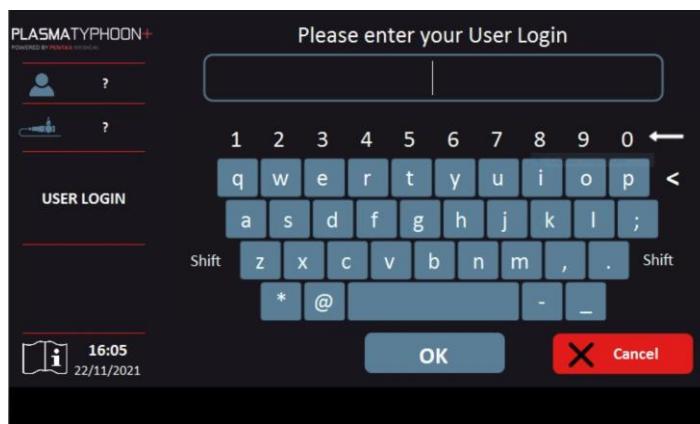


Figure 7. User login via the alphanumerical keyboard

Once the user is identified, his/her login ID (name or number) will appear next to the user symbol in the left-side menu (e.g. “user test” in Fig. 8), and the device will proceed to the next step of the process.

5.3 ENDOSCOPE IDENTIFICATION AND CYCLE SELECTION

Endoscope identification page can be accessed by pressing the endoscope symbol in the left-side menu. A question mark displayed next to the endoscope symbol indicates that the endoscope has not been identified (see Fig. 8). If the user's action is requested, the instruction is clearly indicated in the centre of the screen. In addition, a short recall of the requested action is also displayed in the central part of the left-side menu.

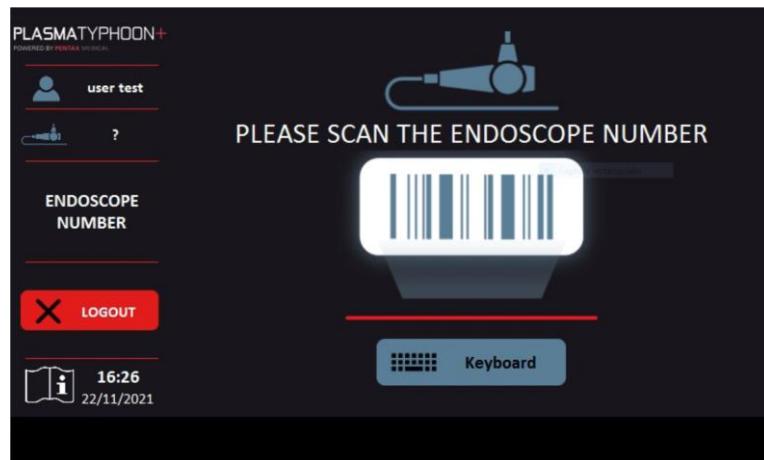


Figure 8. Endoscope ID page

At this point, the user must identify the endoscope and select the corresponding treatment cycle. Endoscope identification can be performed:

1. Using **the barcode scanner**: The user scans the endoscope barcode
2. Using **the RFID tag reader**: The user scans the endoscope RFID tag
3. By entering **an endoscope ID number**: An endoscope ID number is attributed to each endoscope by the person in charge of the unit or by the biomedical engineer



Figure 9. Endoscope identification via the barcode scanner

If the endoscope identification is performed using the barcode or RFID scanner, the endoscope ID number automatically appears next to the endoscope symbol in the menu on the left side of the screen (e.g. “scope test” in Fig. 10). If the automatic selection of the endoscope type is activated (see section 5.4), the endoscope type selection is done automatically as soon as the endoscope is identified. In this case, the user only needs to select the treatment cycle that he/she wishes to perform: drying cycle, storage cycle or a succession of both drying and storage cycle (see Fig. 10). In case of endoscope without channel only storage cycle will be proposed.

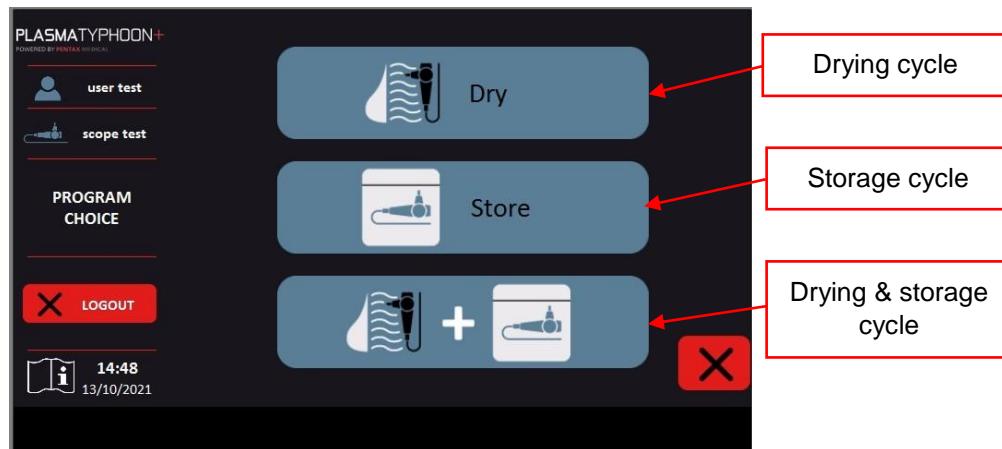


Figure 10. Treatment cycle selection page

If endoscope identification is performed by manually entering the endoscope ID number, the user must first press the “Keyboard” button in order to access the alphanumerical keyboard. Once entered and validated, the endoscope ID number is displayed next to the endoscope symbol in the left-side menu (see Fig. 12).

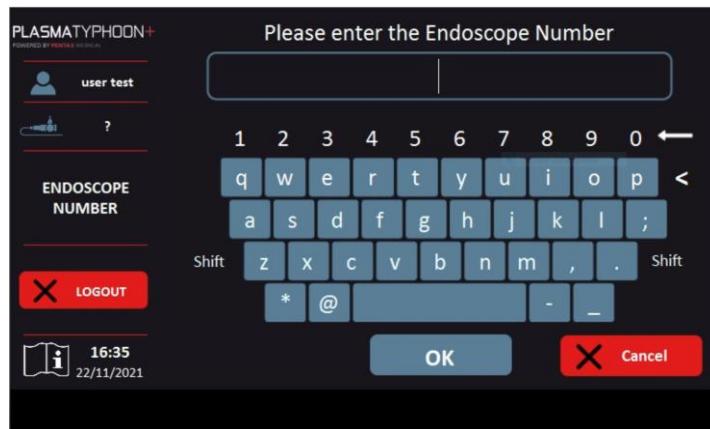


Figure 11. Endoscope identification via alphanumerical keyboard

In case of the absence of automatic selection of the endoscope type (see section 5.4), the user must select the corresponding endoscope type himself/herself. Following pages will appear in order to enable the user to select the corresponding endoscope type (see Fig. 12).

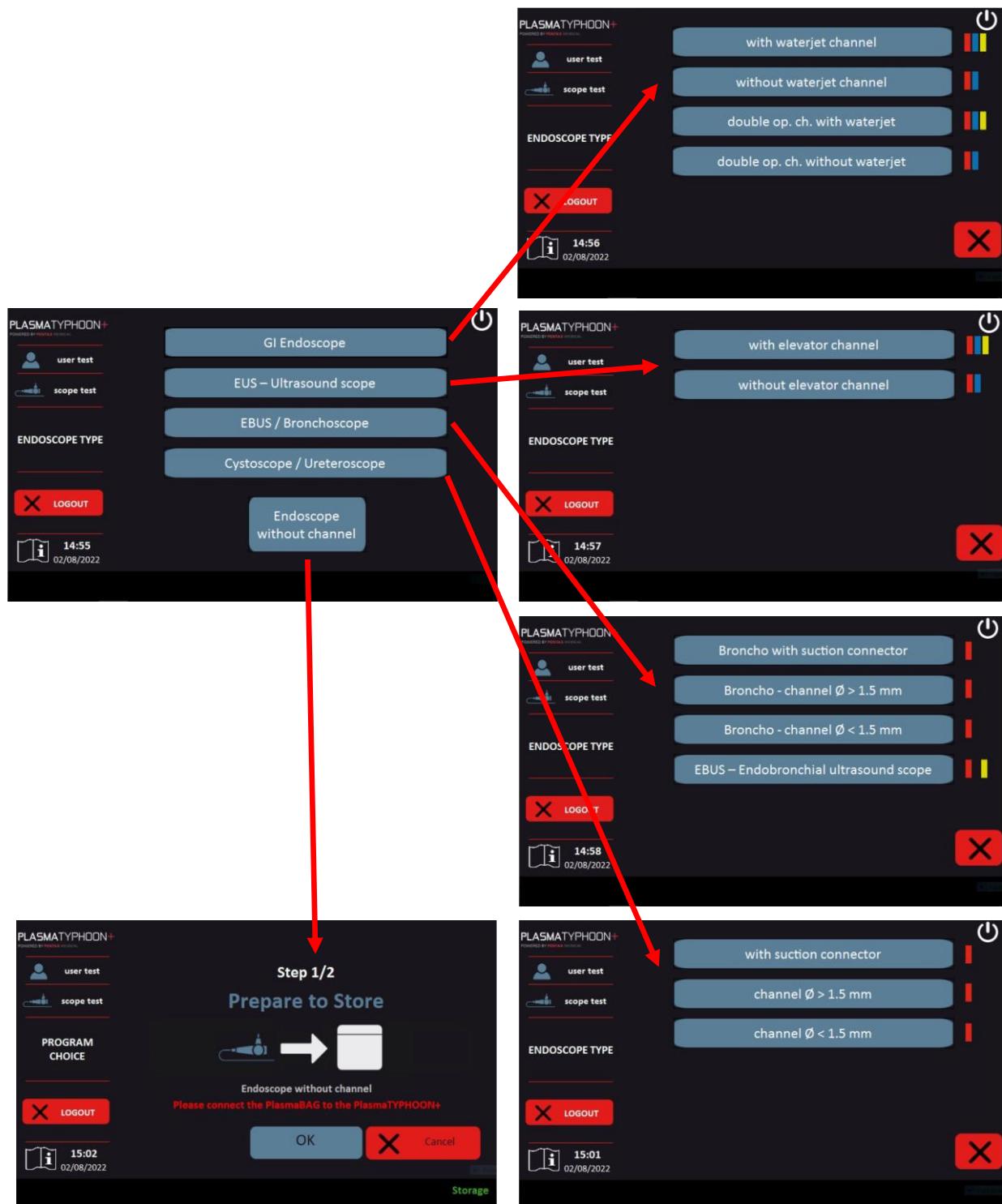


Figure 12 Endoscope type selection pages

Finally, the user must select the treatment cycle that he/she wishes to perform: drying cycle, storage cycle or a succession of both drying and storage cycle (see Fig. 10). In case of endoscope without channel only storage cycle will be proposed (see Fig. 12).

5.4 AUTOMATIC ENDOSCOPE TYPE SELECTION & ENDO DATABASE

Automatic endoscope type selection is a feature that enables automatic selection of the corresponding drying cycle depending on the endoscope type. For optimal operation of this feature, an **endoscope database**, named “**ENDO**”, must be set up during the PlasmaTYPHOON+ installation procedure. The database is a CSV file (see an example below, Fig. 13) containing a list of all endoscopes meant to be treated with PlasmaTYPHOON+. This list can be completed or amended when new endoscopes are purchased.

The endoscope database “ENDO” includes:

- ✓ endoscope ID number (barcode, RFID, or an attributed ID number)
- ✓ endoscope type (see the table below)
- ✓ endoscope brand
- ✓ endoscope model
- ✓ endoscope serial number
- ✓ endoscope inventory number (optional)

Endoscope types

One shall use the following codes to indicate the endoscope type in the 2nd column of the ENDO database:

Code	Description	Specification
GI-WJ	Gastrointestinal (GI) endoscope	with waterjet channel
GI-NWJ	Gastrointestinal (GI) endoscope	without waterjet channel
GI-DOCWJ	Gastrointestinal (GI) endoscope	with double operating channel and waterjet channel
GI-DOCNWJ	Gastrointestinal (GI) endoscope	with double operating channel and without waterjet channel
EUS-EC	Ultrasound endoscope (EUS)	with elevator channel
EUS-NEC	Ultrasound endoscope (EUS)	without elevator channel
BR-SC	Bronchoscope, naso-laryngoscope	with suction connector
BR-LC	Bronchoscope, naso-laryngoscope	without suction connector, channel diameter > 1.5 mm
BR-TC	Bronchoscope, naso-laryngoscope	without suction connector, channel diameter < 1.5 mm
BR-EBUS	Ultrasound bronchoscope (EBUS)	
CU-SC	Cystoscope, ureteroscope	with suction connector
CU-LC	Cystoscope, ureteroscope	without suction connector, channel diameter > 1.5 mm
CU-TC	Cystoscope, ureteroscope	without suction connector, channel diameter < 1.5 mm
NCH	Endoscope without channel	

An example of an ENDO database is presented in the Figure 13.

Note: In case that the ENDO database is not correctly completed, or that there are some missing data (e.g. endoscope ID number, endoscope type, etc.), automatic endoscope type selection feature will not function. In that case, endoscope type selection pages (see Fig. 12) will appear immediately after endoscope identification.



Figure 13. Endoscope "ENDO" database example

5.5 ENDOSCOPE CONNECTION

Once the user has selected to perform a **drying cycle** by pressing “Dry” or “Dry & Store” button (see Fig. 10), a new page appears requesting the user to prepare the endoscope for the drying process (see Fig. 14).

Before connecting the endoscope to the PlasmaTYPHOON+, all channel ports (eg. suction, working/biopsy/operating, air/water channel, waterjet channel) **must be completely dried** by using a single-use lint free cloth and/or an airgun. Dryness should be ensured by a visual inspection before connecting the corresponding adapter of the connection set.

The user must connect all endoscope channels to the PlasmaTYPHOON+ gas outlets via the corresponding connection set. The connection sets are available for different endoscope types and brands, and can be found in the PlasmaBiotics Product Overview which can be provided by your distributor or local service representative. Connection cards providing instructions on the correct connection of PlasmaBiotics connection sets to the endoscopes are available for all connection set references and can be provided by your distributor or local service representative.

Blinking text at the bottom of the screen indicates the endoscope channels that need to be connected to the corresponding gas outlets following the colour code of the connection tubes (see Fig. 14 and the table below).



Figure 14 Drying cycle preparation page

Before starting the drying cycle by pressing “Dry” button, all endoscope channels must be connected to the PlasmaTYPHOON+ gas outlets using the corresponding PlasmaBiotics connection set (see Fig. 15). The user shall verify that the connection set is correctly connected to the endoscope and to the PlasmaTYPHOON+ before starting the drying cycle.



Warning: Incorrect connection of the endoscope to the PlasmaTYPHOON+, via inappropriately installed connection set, may lead to gas leakage causing a potential risk of ineffective drying of endoscope channels.



Figure 15 Connecting the connection set to the endoscope



Warning: The endoscope must be connected to the PlasmaTYPHOON+ using the provided connection sets only and following the recommendations of PlasmaBiotics. If the connection sets are modified, we cannot guarantee efficient and complete drying of the endoscope channels.

Note: For FUJIFILM gastrointestinal (GI) endoscopes series **500** and **600**, the air/water channel bridge must be set at the proximal end of the endoscope, where applicable (not needed for 700 series).

Note: When drying **duodenoscopes** or **linear ultrasound (EUS)** endoscopes, the user must place the elevator in the lower (open) position.

The following table provides instructions for connecting different endoscope types:

Colour code	RED	BLUE	YELLOW
Endoscope type	Suction/operating channel	Air/water channel	Water jet/elevator channel
Gastroscope, duodenoscope, enteroscope, ultrasound scope (EUS) without water jet or elevator channel	To be used	To be used	/
Colonoscope, gastroscope, duodenoscope, ultrasound scope (EUS) with water jet or elevator channel	To be used	To be used	To be used
Bronchoscope, naso-laryngoscope, ureteroscope, cystoscope	To be used	/	/
Ultrasound bronchoscope (EBUS)	To be used	/	To be used

The drying cycle for gastrointestinal **ultrasound endoscopes (EUS)** is performed in three steps. The procedure is different depending on the endoscope brand. Please, follow the instructions indicated in the table below:

Brand	FUJIFILM	OLYMPUS	PENTAX
Prep	Install the air/water bridge (A)		
Step 1	Connect the ultrasound endoscope (EUS) to the PlasmaTYPHOON+ using the corresponding connection set and run the corresponding drying cycle		
Message: "Install the closure valves on suction and air/water connector, then click OK"			
Step 2	Install the closure valve on the suction connector (B)		
	Keep the air/water bridge (A) in place	Install the air/water bridge (A)	
	Install the closure valve on the air insufflation connector (C)		
Step 3	Click OK to continue the drying cycle		

Below one can find examples of different ways of installing closure valves and air/water bridges depending on the ultrasound endoscope brand (see Fig. 16).

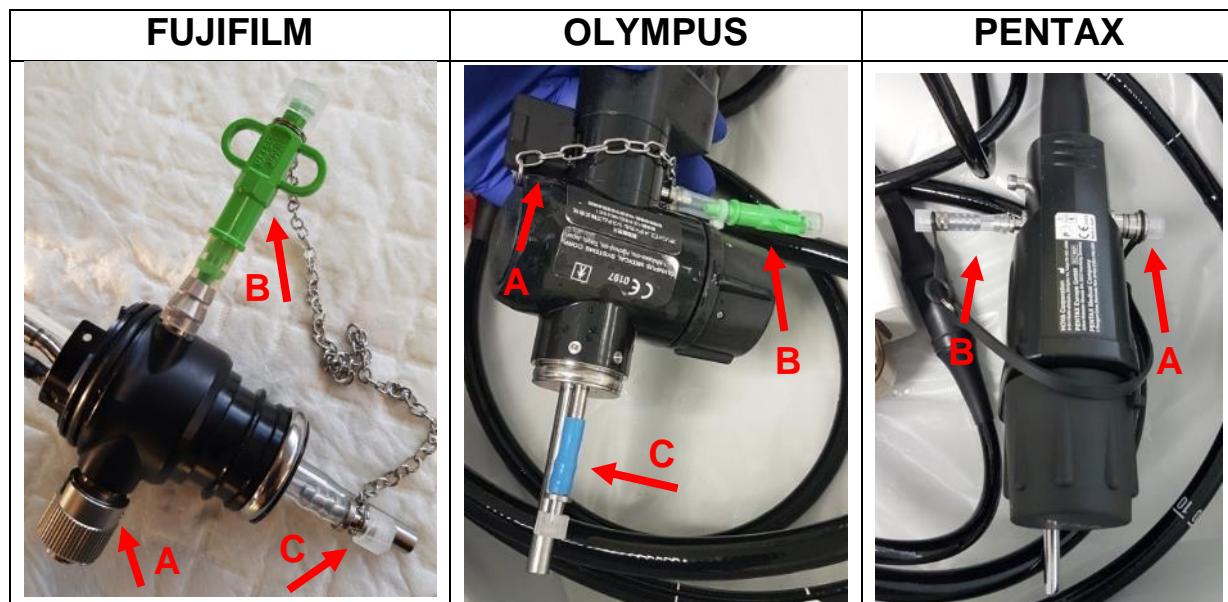


Figure 16. Installing the closure valves and air/water bridge on EUS endoscopes

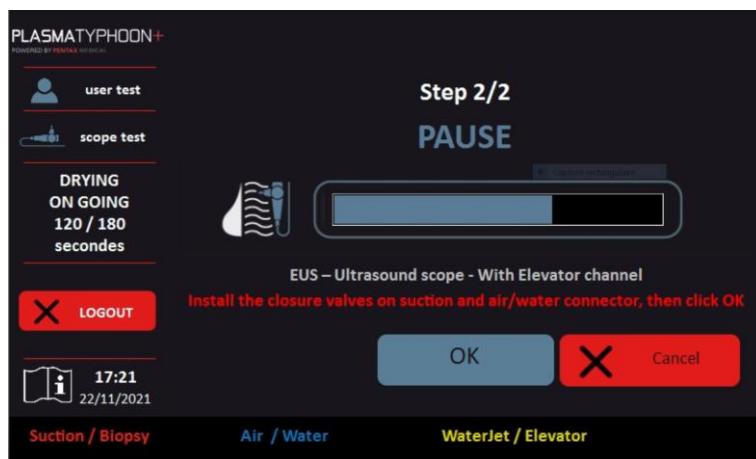


Figure 17. Screenshot of EUS drying cycle pause

5.6 DRYING CYCLE

Once all endoscope channels are connected to the PlasmaTYPHOON+ via the corresponding connection set, the user can start the drying cycle by pressing “Dry” button (see Fig. 14).

The progress status of the drying cycle is displayed in the central part of the screen (see Fig. 18). The selected endoscope type determining the corresponding drying cycle is indicated below the progress bar. The drying cycle can be stopped at any moment by pressing the “Cancel” button.



Warning: Do not attempt to disconnect the endoscope from the PlasmaTYPHOON+ during the drying cycle.



Warning: In case of uncompleted drying cycle or accidental disconnection of the connection set during the drying cycle, run a new drying cycle.



Warning: Pay attention not to obstruct endoscope channels outlets by placing the endoscope in an inappropriate manner. Nothing shall obstruct the flow of the medical air in order to guarantee effective drying of endoscope channels.



Figure 18. Drying cycle in progress

The drying time depends on the endoscope type:

Endoscope type	Drying time
Cystoscope, ureteroscope	1 min
Bronchoscope, ultrasound bronchoscope (EBUS), naso-laryngoscope	1 min 30 s
Gastroscope, duodenoscope, enteroscope, colonoscope	2 min 30 s
Gastrointestinal ultrasound endoscope (EUS), GI endoscope with double operating channel	3 min

Note: The entire outer surface of the endoscope, including on and in between the steering wheels, **must be completely dried** by using a single-use lint free cloth and/or an airgun. Dryness should be ensured by a visual inspection. See Annex I for more details.

At the end of the drying cycle, five beeps indicate to the user that the treatment has been completed successfully and a message “Drying completed” appears on the screen. The PlasmaTYPHOON+ is in a standby mode and the user may disconnect the endoscope. The user has a possibility to proceed to the storage cycle by pressing the “Store” button, end the treatment by pressing the “OK” button or reprint a traceability label by pressing the “Reprint” button. In case that the user terminated the use of PlasmaTYPHOON+, he/she can logout by pressing the “LOGOUT” button.



Figure 19. Drying cycle completed

5.7 ENDOSCOPE STORAGE

Once the endoscope dried, the user may proceed to the storage of the endoscope in a single-use PlasmaBAG, which is specifically designed for endoscope storage. In order to do so, the user can press the “Store” button (see Fig. 10 and Fig. 19). A new page appears requesting the user to prepare the endoscope for the storage process (see Fig. 20).

Before placing the endoscope in the PlasmaBAG, the user needs to check that the entire outer surface, including all channel ports (e.g. suction, working/biopsy/operating, air/water channel, waterjet channel) and both, on and in between the steering wheels **has been completely dried** using a single-use lint free cloth and/or an airgun. Dryness should be ensured by a visual inspection.



Warning: Incomplete drying of the external surfaces of the endoscope has a negative effect on the final storage condition in PlasmaBAG. Remaining humidity on the external surfaces can enable microorganism growth during storage.

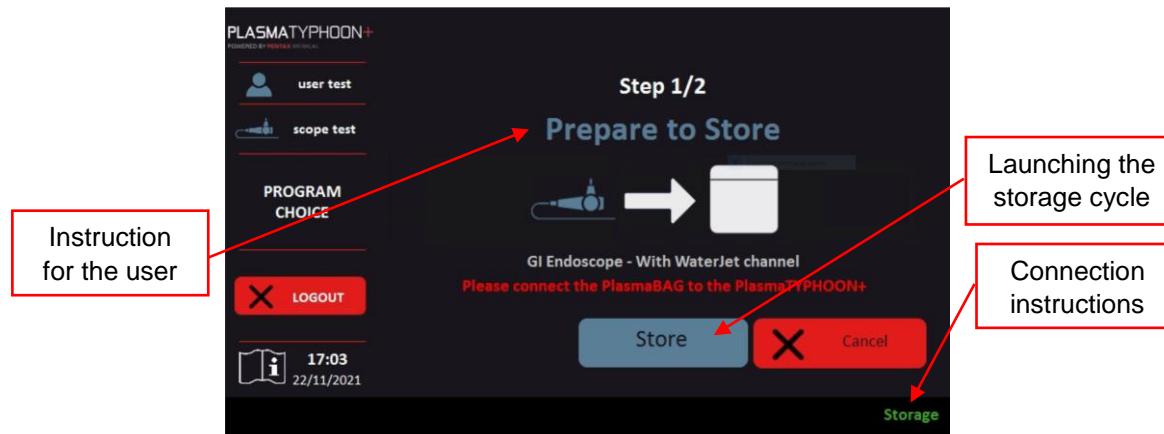


Figure 20. Storage cycle preparation page

Preparing the endoscope for the storage cycle includes (see Fig. 21):

- Placing the endoscope in a single-use PlasmaBAG
- Sealing the bag using its adhesive tape
- Connecting the PlasmaBAG to the PlasmaTYPHOON+ using the storage connection set (PBag-inj+). **Note:** Use the pointed end of the metallic cone-shaped adapter to perforate the upper side of the bag and push it in slightly so that the two lateral orifices are located inside the bag (see Section 10)

The user can start the storage cycle by pressing the “Store” button (see Fig. 20). During 5 seconds, plasma will be generated inside the PlasmaTYPHOON+ and injected inside the PlasmaBAG via the storage connector.

At the end of the storage cycle, a message “**Storage completed**” appears on the screen (see Fig. 22). The user must disconnect the PlasmaBAG from the PlasmaTYPHOON+ and seal the orifice on the PlasmaBAG with a sticker (OBag). A traceability label is printed-out by the printer. The user must stick the traceability label on the PlasmaBAG. Finally, the user has a possibility to end the treatment by pressing the “OK” button or to reprint a traceability label by pressing the “Reprint” button. In case that the user terminated the use of PlasmaTYPHOON+, he/she can logout by pressing the “LOGOUT” button.

Note: An endoscope without channels can also be stored in a PlasmaBAG under condition that it has been previously reprocessed according to manufacturer’s IFU and completely dried externally.



Figure 21. Endoscope storage in a PlasmaBAG

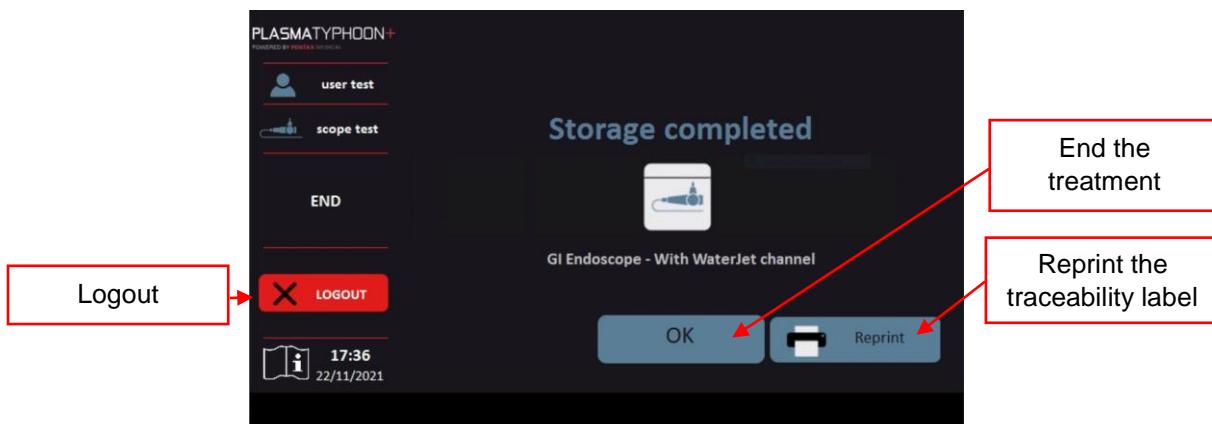


Figure 22. Storage cycle completed



Warning: Efficiency of the endoscope storage in the PlasmaBAG for up to 31 days can only be assured if the endoscope is completely dried, internally and externally.

The recommended time between the drying and storage procedure may differ between regions according to local or country-wide regulations. The user must comply with the regulations issued by the health authorities in his/her country.

5.8 STORAGE TIME

Active endoscope storage is validated for 744 hours (31 days). However, the maximal storage time of endoscopes may be subject to country regulations. For example, in France the maximal storage time is restricted to 7 days. Please refer to the relevant regulations or guidelines in your country.



Warning: Before opening the PlasmaBAG in order to use the endoscope, check the integrity of the bag. In case of a presence of up to three small holes (up to 1mm diameter) on the PlasmaBAG, the endoscope stored in the bag can still be used. If larger diameter holes are detected or if the bag is

damaged, do not use the endoscope. In this particular case, the endoscope needs to be reprocessed before being used.

5.9 TRACEABILITY

The PlasmaTYPHOON+ is equipped with a printer, which prints a traceability label at the end of the drying and/or storage cycle. The traceability label (Fig. 23) includes the following information:

1. Endoscope ID (barcode or RFID tag) number
2. Endoscope barcode
3. Endoscope serial number (if indicated in the ENDO database)
4. Date and time of the treatment
5. User (operator) name or number
6. Validation of treatment parameters values
7. Completed cycle (drying, storage or both) and cycle conformity (OK)
8. Storage validity (set-up according to national regulations) and expiry time & date
9. A QR code on the right side, containing all the previous informations

The user may choose to print a traceability label at the end of the storage cycle only or at the end of each cycle (both drying and storage). The printer may print up to 5 identical labels at the end of each cycle. These options can be modified via PlasmaTYPHOON+ Administrator mode (see Technical Manual for User).

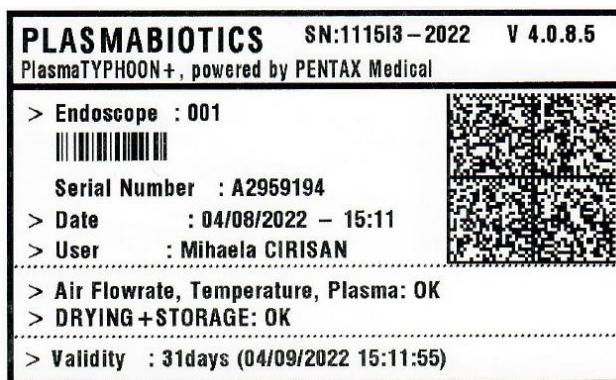


Figure 23. Traceability label

The user has the possibility to reprint the traceability label of the last completed cycle using the “Reprint” button.

The PlasmaTYPHOON+ provides the history of all treatment cycles performed by the device. This **treatment cycles history** is saved as a CSV file named “REPORT” and located in “History” folder on PlasmaTYPHOON+ hard drive. This file can be accessed via the Administrator mode (see Technical Manual for User).

Each line in the “REPORT” file corresponds to a single treatment cycle. The columns indicate:

- ✓ Date of the treatment
- ✓ Time of the treatment
- ✓ Endoscope type
- ✓ Endoscope ID (barcode or RFID tag) number
- ✓ Endoscope model
- ✓ Endoscope serial number
- ✓ User (operator) name or number
- ✓ Completed cycle (drying, storage or both) and cycle conformity (DONE)

Example of the “REPORT” database is presented in Fig. 24.

	A	B	C	D	E	F	G	H	I
1	Date	Time	Type Endo	Number	Model	Serial Number	Operator	Cycle Report	
2	29/04/2021	08:04	EUS-EC	603	EG-3870UTK	7923453	CIRISAN Mihaela	DRYING DONE	
3	29/04/2021	08:16	GI-NWJ	604	ED34-i10T	2912824	CIRISAN Mihaela	DRYING+STORAGE DONE	
4	29/04/2021	08:22	GI-WJ	401	EG34-i10	2730534	CIRISAN Mihaela	DRYING+STORAGE DONE	
5	29/04/2021	08:30	EUS-NEC	81	EG-3670URK	2510115	DUROUCHOUX Timothée	DRYING+STORAGE DONE	
6	29/04/2021	08:36	GI-WJ	400	EC38-i10c	2731626	DUROUCHOUX Timothée	DRYING+STORAGE DONE	
7									

Figure 24. “REPORT” – treatment cycles history table

5.10 SWITCHING OFF

PlasmaTYPHOON+ may remain switched ON during the weekdays. The touch screen may go into a standby mode. In order to exit the standby mode of the touch screen, one just needs to touch the screen. PlasmaTYPHOON+ may be switched OFF in case of prolonged unuse (on weekends, holidays). In order to switch OFF the PlasmaTYPHOON+, use the “Power” button in the upper right corner of the screen (see Fig. 6) to shut down the PC. Once the PC is shut down, one may switch OFF the device by using the ON/OFF switch located at the rear of the device.

6. EMERGENCY STOP AND TECHNICAL ERRORS

6.1 EMERGENCY STOP

The user can implement an emergency stop at any time by pressing the red “**Cancel**” button. The treatment cycle is stopped immediately, and the device returns to Standby mode.

6.2 POSSIBLE TECHNICAL ERRORS

Several security systems ensure that the PlasmaTYPHOON+ functions correctly. If a technical error is detected, the cycle is stopped immediately, the device returns to Standby mode and an error message is displayed in the central part of the screen. Different error messages may appear:

➤ **ERROR: Air inlet pressure too low**

This error may occur when starting the cycle or even during the cycle if no or insufficient air pressure is detected at the medical air inlet. In this case, check the tube connection to the medical air inlet at the rear of the PlasmaTYPHOON+, as well as the tube connection to the external medical air supply. Make sure there is no air leakage. Check the medical air inlet pressure: it shall be between 3 bar (43.51 psi) and 3.5 bar (50.76 psi) in static mode, in order to ensure the pressure of 3 bar (43.51 psi) in dynamic mode.



Figure 25. Example of error message: “Air Inlet Pressure too low”

➤ **ERROR: Air inlet pressure too high**

This error may occur when starting the cycle or even during the cycle if the air pressure at the medical air inlet is too high. In this case, check the medical air inlet pressure at the external pressure regulator: it shall be between 3 bar (43.51 psi) and 3.5 bar (50.76 psi) in static mode, in order to ensure the pressure of 3 bar (43.51 psi) in dynamic mode.

➤ **ERROR: Water detected in the medical air**

This error may occur if water presence is detected in the medical air. Disconnect the medical air plug and check the quality of the medical air in the pipeline system. If the error message reappears, call the after-sales service.

➤ **ERROR: Air temperature too low**

This error may occur in the event of malfunction of the heating system of the PlasmaTYPHOON+. This security system was designed to detect any insufficient gas heating. Restart the device and run the cycle again. If the error message reappears, call the after-sales service.

➤ **ERROR:** Air temperature too high

This error may occur in the event of malfunction of the heating system of the PlasmaTYPHOON+. This security system was designed to detect any gas overheating. Restart the device and run the cycle again. If the error message reappears, call the after-sales service.

➤ **ERROR:** Heater temperature too high

This error may occur if the air heater body temperature exceeds 85°C. This security system enables us to prevent any potential damage to the heating system in the event of a malfunction. Switch OFF the device and let it cool down during 10 – 15 minutes. Switch ON the device and run a drying cycle. If the message reappears, call the after-sales service.

➤ **ERROR:** Endoscope connection error

This error may occur if the connection set is not properly plugged into the PlasmaTYPHOON+ gas outlets. Check if all connection tubes of the connection set are well connected to the PlasmaTYPHOON+ and to the endoscope. Run another cycle. If the error message reappears, call the after-sales service.

➤ **ERROR:** Air flowrate regulation error

This error may occur if the gas flowrate, measured by the internal gas flowrate meter, is too low or too high. Check if all connection tubes of the connection set are well connected to the PlasmaTYPHOON+ and to the endoscope. Check the medical air inlet pressure: it shall be between 3 bar (43.51 psi) and 4 bar (58.02 psi) in static mode, in order to ensure the pressure of 3 bar (43.51 psi) in dynamic mode. Run another cycle. If the error message reappears, call the after-sales service.

➤ **ERROR:** Plasma generation error

This error may occur during the storage cycle if there is no plasma generation (no ozone detected) within 3 seconds of operation. Run another storage cycle. If the message reappears, call the after-sales service.

Note: Any serious incident that has occurred in relation to the device shall be reported to the legal manufacturer.

6.3 ERROR ACKNOWLEDGEMENT

Once a technical error has been detected, the error message is displayed on the screen. Error acknowledgment may be performed by clicking on the “OK” button or by restarting the device.

6.4 ELECTRICAL SHUTDOWN

In the event that an electrical shutdown of the mains occurs during a drying or storage cycle:

- Check that the electricity is still operational
- Start the device and run a new drying or storage cycle

7. MAINTENANCE

7.1 CLEANING

Cleaning of the device at the end of the day, or earlier if the device is contaminated, is recommended. The surface of the device can be cleaned with a surface-disinfectant. Please refer to the disinfectant manufacturer's instructions regarding the contact time.

PlasmaTYPHOON+ must be switched OFF when cleaning. **Do not spray liquid cleaning products on the device!** Use a lint-free gauze moistened with surface-disinfectant to clean the device.

7.2 TECHNICAL MAINTENANCE

In order to maintain correct operation and a good drying and storage efficacy of the PlasmaTYPHOON+, technical maintenance must be carried out once a year or every 15,000 storage cycles. Once 15,000 storage cycles have been reached, a pop-up window will start regularly appearing in order to remind the user to schedule annual maintenance of the device.

Annual technical maintenance of the PlasmaTYPHOON+ includes: device inspection, replacement of certain components/spare parts, dust-cleaning, verification of device parameters (electrical measurements, verification/recalibration of pressure sensors and gas flowrate meter, discharge verification). A technical maintenance contract is offered by the distributor of PlasmaTYPHOON+. In order to comply with the general safety and performance requirement, the maintenance of the PlasmaTYPHOON+ shall be performed only by authorized medical service centre.

8. WARRANTY, LIFETIME AND ELIMINATION

8.1 WARRANTY OF THE PLASMATYPHOON+

PlasmaBiotics provides a one-year warranty on PlasmaTYPHOON+ starting on the date of installation.

8.2 LIFETIME OF THE PLASMATYPHOON+

Lifetime of PlasmaTYPHOON+ is seven years, provided that the annual preventive maintenance is performed as recommended by the manufacturer.

8.3 ELIMINATION

PlasmaTYPHOON+ shall be discarded as electronic waste.

9. CONNECTION SETS

9.1 ENDOSCOPE CONNECTION SETS

Endoscope connection sets are used to connect endoscopes to the PlasmaTYPHOON+ in order to perform the drying of endoscope channels. The connection set reference depends on the endoscope type and brand. Please refer to PlasmaBiotics Product Overview which can be provided by your distributor.



Warning: The endoscopes must be connected to the PlasmaTYPHOON+ using the provided connection sets and according to the recommendations of PlasmaBiotics. Modification of the connection sets is prohibited and voids warranty.

9.2 STORAGE CONNECTION SET

The storage connection set **PBag-inj+** is used to connect a PlasmaBAG to the PlasmaTYPHOON+ in order to inject plasma into the PlasmaBAG during the storage cycle.



Warning: PlasmaBAG must be connected to the PlasmaTYPHOON+ using the provided connection set and according to the recommendations of PlasmaBiotics. Modification of the connection set is prohibited and voids warranty.

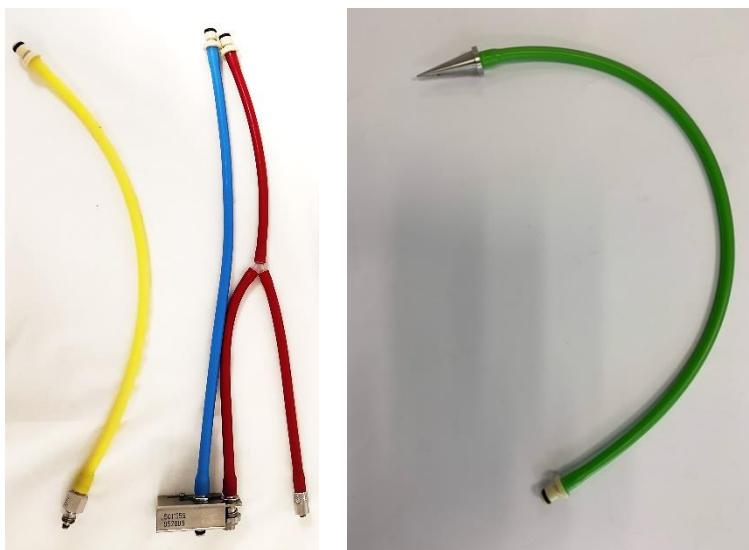


Figure 26. Example of endoscope connection set and storage connection set (PBag-inj+)

9.3 MAINTENANCE OF CONNECTION SETS

All parts of the outer surface of the connection sets must be cleaned/disinfected on a daily basis using a surface disinfectant cleaner. Use a lint-free cloth or gauze slightly moistened with surface disinfectant cleaner for cleaning/disinfecting the PlasmaTYPHOON+ connection set. Please, refer to the disinfectant cleaner manufacturer's instructions regarding the contact time. Pay particular attention to the components that are in contact with the endoscope: the plug for the suction cylinder and air/water feeding cylinder, the biopsy channel and the auxiliary channel.

At the end of the day after use and cleaning/disinfecting, the connection sets must be stored under clean and dry conditions. A single-use PlasmaBAG can be used for that purpose.

Complete manual disinfection of connection sets must be performed at least once a month, as well as during the annual maintenance procedure and/or after replacing the O-rings or other parts of the connection sets. See Annex II for instructions.

In case that a part of the connection set was damaged prior to the annual maintenance, please contact your local PENTAX Medical representative in order to replace the damaged part. Finally, complete manual disinfection of connection set must be performed following the instructions in Annex II.

In the event of intensive use of the connection set, or if required due to a hard connection to the PlasmaTYPHOON+, PlasmaBiotics recommends lubricating the O-rings of the connection sets with medical grade silicone oil.

9.4 WARRANTY OF CONNECTION SETS

PlasmaBiotics provides a one-year warranty on connection sets starting on the date of purchase.

9.5 LIFETIME OF CONNECTION SETS

Lifetime of the connection sets is 3 years in average (depending on the frequency of use). Spare parts (O-rings, CPC connectors, valve connectors, tubes etc.) are replaced in the scope of the annual maintenance procedure if they look used/damaged.

9.6 ELIMINATION

Connection sets shall be discarded as general waste following the local regulations.

10. PLASMABAG

10.1 GENERAL CHARACTERISTICS

PlasmaBAG is a single-use bag specifically designed for endoscope storage using the PlasmaTYPHOON+ system.

Designation	#	REF	UDI	Description / Characteristics
Standard PlasmaBAG	PlasmaBAG	PBAG	03701354403802	size: 60cm x 50cm, packaging: 400 units
XL PlasmaBAG		PBAGXL	03701354403918	size: 70cm x 64cm, packaging: 250 units
XXL PlasmaBAG		PBAGXXL	03701354403901	size: 84cm x 60cm, packaging: 300 units
PlasmaBAG Eco		PBAG ECO	03701354409606	size: 62cm x 52cm, packaging: 400 units



Warning: PlasmaBAG must be used in combination with PlasmaTYPHOON+ and storage connection set (PBAG-inj+) for plasma injection. Use only accessories provided by PlasmaBiotics. Modification of accessories is prohibited and voids warranty.

10.2 STEP-BY-STEP INSTRUCTIONS FOR USE



Warning: Check the integrity of the PlasmaBAG before each use. In the event that the PlasmaBAG is damaged or visibly contaminated (i.e. not clean after shipment), do not use it. Discard it and use a new clean PlasmaBAG.

Follow this step-by-step procedure to store a disinfected and dried endoscope into the PlasmaBAG :

1. Place the endoscope into the PlasmaBAG (see Fig. 27).

Note: Hands and wrists must be cleaned before handling the endoscope or use gloves if requested by national guidelines.



Figure 27. Placing the endoscope in the PlasmaBAG

2. To seal the bag, remove the red tape and apply pressure to the blue adhesive tape to ensure sealing (see Fig. 28).



Figure 28. Sealing the PlasmaBAG

3. Plug the storage connection set (PBAG-inj+) into the green gas outlet ("Storage") located at the front of the PlasmaTYPHOON+ (see Fig. 29).



4. Use the pointed end of the metallic cone-shaped adapter to perforate the upper side of the bag. Then insert the metallic cone-shaped adapter a bit further into the bag, so that the two lateral orifices are located inside the PlasmaBAG (the plasma is going to be insufflated into the bag via these orifices).



Figure 29. Connection of storage connector



Warning: Make sure that you do not perforate both sides of the PlasmaBAG. In the event that both sides of the PlasmaBAG are perforated, the bag cannot be inflated. Please discard it and use a new PlasmaBAG.

5. Start the storage cycle.
6. At the end of the storage cycle, remove the metallic cone-shaped adapter and seal the bag with the appropriate sticker/seal. Stick the traceability label (printed by the PlasmaTYPHOON+ printer) on the PlasmaBAG (see Fig. 30).

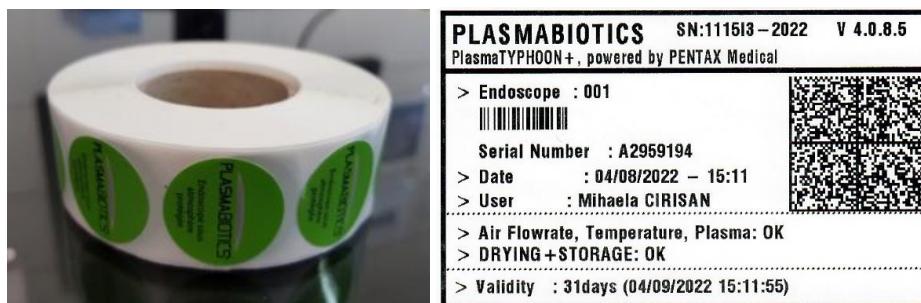


Figure 30. Sticker/seal and traceability label

7. The following step is optional. To indicate the cleanliness status of the endoscope, a double green/red label can be used on the PlasmaBAG. When the green label is visible, this indicates the endoscope stored in the PlasmaBAG is under protected atmosphere and can therefore be used.

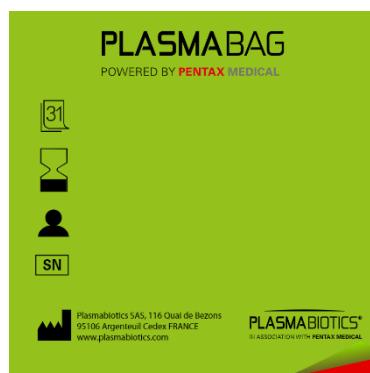


Figure 31. Green label: endoscope stored in a PlasmaBAG under protected atmosphere

8. When the endoscope is ready to be used, open the PlasmaBAG by tearing the blue adhesive tape.
9. After using the endoscope, place the contaminated endoscope inside the PlasmaBAG, refold the bag opening, and remove the green layer to reveal the red label, indicating that the endoscope is contaminated.

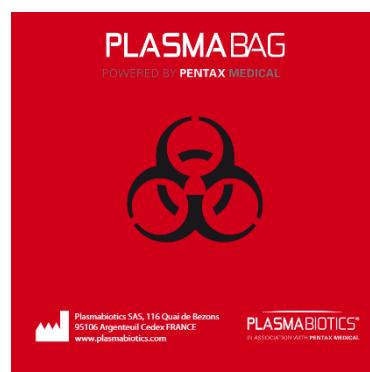


Figure 32. Red label: endoscope to be disinfected

10. After storing, transport the contaminated endoscope in the temporary refolded bag (with the red label on) to the endoscope reprocessing unit according to the procedure of your health centre for an appropriate decontamination operation.



Warning: Red label indicates that the endoscope is contaminated, and it needs to be handled with caution.

10.3 STORAGE OF ENDOSCOPE IN THE PLASMA~~BAG~~

Store the endoscope according to the procedure of your health centre. The endoscope enclosed inside the Plasma~~BAG~~ can be stored and used without any additional disinfection for up to 31 days. However, the maximal storage time of endoscopes may be subject to country regulations. **For critical endoscopes, a high-level disinfection is required before each use, regardless of the storage time.**



Warning: Do not pile up the endoscopes stored in the Plasma~~BAG~~.

10.4 STORAGE / PACKAGING OF THE PLASMA~~BAGS~~

- Do not expose to a heat source
- Do not store in an outside environment, store it in a storeroom
- Store at ambient temperature: 15 – 40 °C (59 - 104 °F) and 30 – 85 % RH.

10.5 LIFETIME OF THE PLASMA~~BAG~~



Lifetime: 2 years

The lifetime of the Plasma~~BAG~~ is 2 years from the date of the manufacture, provided that the aforementioned storage recommendations are implemented.

10.6 ELIMINATION

A Plasma~~BAG~~ used only for the storage of a clean endoscope can be recycled.



A Plasma~~BAG~~ used for the transport of a contaminated endoscope to the disinfection room has to be handled as a biohazardous waste and eliminated.

11. SAFETY INSTRUCTIONS: RISKS AND PRECAUTIONS

11.1 OZONE GENERATION

During the storage cycle, a cold plasma is generated inside the PlasmaTYPHOON+. This plasma containing active species, such as ozone molecules, is injected inside the PlasmaBAG. The concentration of ozone inside the PlasmaBAG is less than 5 ppm and decreases to roughly 0.1 ppm after 5 minutes.

During the storage cycle (5 seconds only), the operator needs to ensure that the **PlasmaBAG is well sealed** (no gas leakage) and that the **storage connector is properly connected** to the PlasmaBAG (two lateral orifices of the cone-shaped adapter are located inside the bag). An accidental plasma injection in the reprocessing room (instead of inside the PlasmaBAG) can create local ozone concentration up to 0.5 ppm, which decreases rapidly over the next 100 seconds. Note that this ozone concentration and exposure time is well below the limit that could be harmful for the user.

To prevent any possible risk of inhaling any ozone coming out of the bag, we strongly recommend to keep the PlasmaBAG closed for at least 5 minutes after the plasma injection.



Warning: Make sure that the room is equipped with controlled mechanical ventilation. If not, make sure that the room is regularly aerated/ventilated.

11.2 RISK OF ELECTRIC SHOCK AND ELECTROMAGNETIC FIELD

The PlasmaTYPHOON+ is connected to the electrical power supply (electrical network). When running/operating, all the electrical components are at a certain voltage (some are even at a few kV), representing a high risk of electric shock.



Warning: The PlasmaTYPHOON+ should be completely closed when running/operating. Do not open the device without prior authorization from PlasmaBiotics.



Warning: PlasmaTYPHOON+ emits electromagnetic waves and may interfere with other electronical devices or electro-medical equipment installed in the endoscope disinfection room. It may cause electromagnetic interference and shall not be operated at proximity with others electro-medical devices. Ensure laboratory installation in order to avoid interference with other electrical equipment.

11.3 RISK OF DAMAGE OF THE PLASMA BAG

The single-use Plasmabag could be damaged during transportation. As a result, it would be impossible to seal and inflate the PlasmaBAG for storage.



Warning: In the event that the PlasmaBAG is damaged, discard it. Use a new PlasmaBAG to store a disinfected and dried endoscope.

11.4 RISK OF CONTAMINATION BY THE PLASMA BAG DURING USE

The PlasmaBAG is a single-use device and must not be reused, unless for the transport of the used endoscope back to the reprocessing room (see section 10), where after it should then be discarded. Do not reuse the PlasmaBAG once it has been in contact with a contaminated endoscope.



Warning: In the event that a new PlasmaBAG may have come into contact with a dirty surface or contaminated endoscope, do not use this PlasmaBAG, discard it. Use a new PlasmaBAG to store a disinfected and dried endoscope.

11.5 IN THE EVENT OF A SERIOUS INCIDENT



Warning: Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the EU member state in which the user and/or patient is based.

12. GENERAL INFORMATION

12.1 LABELING DESCRIPTION

GENERAL

Manufacturer	Date of manufacture	CE mark	Catalogue number	Serial number	Batch code	Unique Device Identifier	Quantity

Consult instructions for use	Caution	Ingress Protection rating N1 Solid object N2 water	Distributor	Translation	Model number	Medical device

Temperature limits	Humidity limits	Atmospheric pressure limits

SPECIFIC PLASMABAG

Do not re-use	Non-sterile	Use-by date	Do not use if damaged	Biohazardous material

12.2 REGULATIONS & STANDARDS

Comply with the following regulations and standards:

Regulation (EU) 2017/745 on medical devices

IEC 61010-1: 2017

IEC 61326-1:2012

EN 16442: 2015

EN ISO 15223-1:2017



13. ANNEX I – EXTERNAL DRYING OF ENDOSCOPE

13.1 INTRODUCTION

Besides drying of all internal channels, external surface drying of the endoscope is an important step of the endoscope reprocessing procedure, in particular if it is followed by endoscope storage.

Endoscope drying and storage procedure using the PlasmaTYPHOON+ system requires a correct drying of the endoscope, both on the inside (the channels) and on the outside (the external surface), before placing it in the PlasmaBAG, the single use recipient for storage.

PlasmaTYPHOON+ product allows drying the internal channels of the endoscopes. For the external surface of the endoscopes **the operator must strictly follow the instructions for use provided by the endoscope manufacturer and/or the national regulation.**

This document is a recommendation from PlasmaBiotics based on the PlasmaTYPHOON users experience from France, Germany, United Kingdom and Belgium. Modification of this procedure may be required depending on the complexity of endoscope.

13.2 PROCEDURE

1. Take the endoscope out of the AER and place it on a clean, dry absorbent sheet next to PlasmaTYPHOON+.
2. Turn the endoscope control box to the PlasmaTYPHOON+.
3. Use a clean, dry wipe or a lint free cloth to dry the suction cylinder, air/water cylinder and biopsy channel inlet on the control box. Dry the inlets till no moisture is visible! Alternatively, an airgun can be used for this purpose (see Fig. 33)
4. Use the connection set to connect the PlasmaTYPHOON+ to the endoscope (Fig. 34) and start a corresponding drying cycle.

Note: When drying duodenoscopes or linear ultrasound (EUS) endoscopes, the user must place the elevator in the lower (open) position before launching the drying cycle.



Warning: Pay attention not to obstruct endoscope channels outlets by placing the endoscope in an inappropriate manner. Nothing shall obstruct the flow of the medical air in order to guarantee effective drying of endoscope channels.

5. During the automatic drying of endoscope channels performed by PlasmaTYPHOON+, dry manually the external surface of the endoscope using a clean, dry wipe or a lint free cloth.



Fig. 33 Placing the endoscope and drying endoscope channels inlets

6. Dry the control box, control wheels, the space in between the control wheels and control body of the endoscope till no moisture is visible. If necessary, use an airgun to expel all possible remaining moisture between control wheels and control body (Fig. 34).



Fig. 34 Endoscope connection, internal and external drying of endoscope

7. Dry the proximal end and the endoscope insertion tube using a clean, dry wipe or a lint free cloth (Fig. 35).

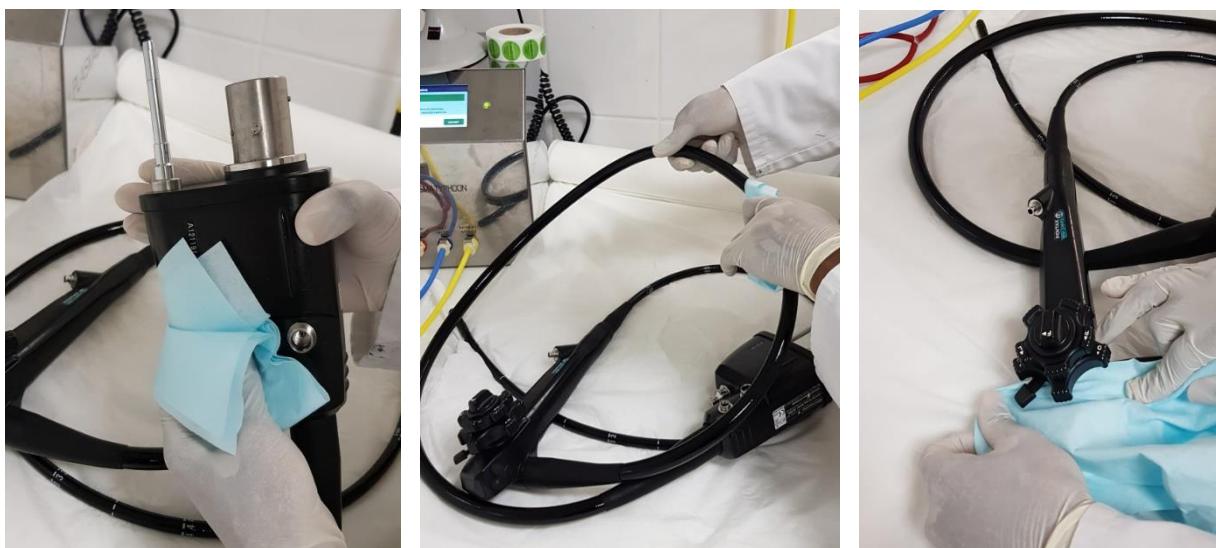


Fig. 35 Drying of the proximal end, insertion tube and control wheels

8. During the second half of the drying cycle, once that all residual water has been expelled from the channels, use the airgun to eliminate and dry all remaining water from air/water and suction connector (see Fig. 36).

Note: When drying **duodenoscopes** or **linear ultrasound (EUS)** endoscopes, pay attention to properly dry the elevator in both positions – open and closed (see Fig. 37).

9. Once the drying cycle is completed, take off the connection set and if necessary (if moisture is visible), use a clean wipe/lint free cloth to dry the endoscope channels inlets/outlets (see Fig. 38).

10. Finally, visually inspect the endoscope and make sure there is no remaining moisture visible on the endoscope, in particular at the endoscope insertion tube, at all channel inlets and outlets, as well as between the control wheels and knobs.



Fig. 36 Drying of air/water and suction connector



Fig. 37 Drying of the elevator in both positions – open and closed



Fig. 38 Drying of endoscope channels inlets/outlets

Note: Use a single use clean, dry wipe/lint free cloth for every endoscope. Change if the wipe becomes too wet to use for drying. In countries where local regulations prohibit the use of an airgun, use a clean wipe/lint free cloth for the whole procedure of external drying of the endoscope.

The duration of the manual external drying shall be at minimum equal to the PlasmaTYPHOON+ drying cycle. This depends on the endoscope complexity e.g. 1.5 min for a bronchoscope, 2.5 min for a GI scope and 3 minutes for an ultrasound (EUS) scope.

ATTENTION: When drying an **ultrasound (EUS) endoscope**, the step number 8 is slightly different:

- By the end of the first part of the drying cycle (around 100 s) once that all residual water has been expelled from the channels, use the airgun to eliminate and dry all remaining water from air/water and suction connector (Fig. 39)
- Following the instructions on the screen, place the closure valves on suction and air/water connector and continue the drying cycle (Fig. 39)
- By the end of the second part of the drying cycle, use the airgun to dry the remaining water on the distal end of the endoscope.



Fig. 39 Drying of ultrasound (EUS) endoscope

If possible, the endoscope can be placed in the following manner in order to facilitate the external drying with a clean wipe or lint free cloth (see Fig. 40). In this position, different endoscope parts do not touch each other, which reduces the risk of missing any endoscope part when drying it.



Fig. 40 Position of the endoscope facilitating external drying

14. ANNEX II – DISINFECTION OF CONNECTION SETS

14.1 INTRODUCTION

PlasmaTYPHOON+ connection sets are manipulated all day long and successively connected to different endoscopes. Even though they are used only on disinfected endoscopes, it is highly recommended to take precautions in order to avoid any potential contamination by following the procedures described in this manual.

As stated in section 9.3, the surface of the connection sets shall be cleaned/disinfected on a daily basis using a surface disinfectant cleaner.

In addition, it is highly recommended to perform a complete disinfection of the connection sets at least once a month, during the annual maintenance procedure after replacing the O-rings on the connection sets. PlasmaTYPHOON+ connection sets can be disinfected manually following the procedure indicated below.

14.2 PROCEDURE

Manual disinfection of the connection sets shall be done in a disinfected tray or sink.

The procedure consists in disinfecting the connection set using a disinfectant solution (low level disinfection).

- ✓ Disinfectant concentration: follow disinfectant manufacturer's instructions
- ✓ Contact time and temperature: follow disinfectant manufacturer's instructions

Step-by-step procedure:

1. Prepare the disinfectant solution in a disinfected tray or sink
2. Immerse the connection set(s) in the disinfectant solution
3. Use a new clean single use syringe per connection set to irrigate the tubes with a disinfectant solution, 100 ml/tube
4. Leave the connection set(s) immersed during the indicated contact time
5. Take the connection set(s) out of the disinfectant solution
6. Use a new clean single use syringe with air to purge disinfectant solution from the tubes, 100 ml/tube
7. Drain the tray or sink
8. Rinse the tray or sink of disinfectant solution and fill it with clean filtered (microbiologically controlled) water
9. Immerse the connection set in the clean rinse water
10. Use a lint-free gauze to wipe the external surfaces to remove any remaining disinfectant solution
11. Use the syringe from step 6 to irrigate the tubes with 100 ml of clean water in order to rinse each tube
12. Purge all water from the tubes

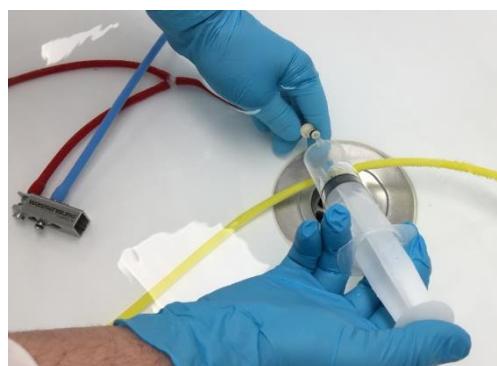


Fig. 41 Manual disinfection of connection sets

Note: In case that the connection sets is soiled, clean the connection set using a detergent solution before disinfecting it.

Drying of the connection sets:

After disinfection, connection sets must be dried with PlasmaTYPHOON+ following the procedure indicated below.

Step-by-step procedure:

1. Depending on the number of tubes to be dried, select the corresponding drying cycle following the instructions in the table below
2. Connect the disinfected connection set to PlasmaTYPHOON+ following the instructions in the table
3. Run the drying cycle (Fig. 42)
4. Use the airgun and/or lint-free cloth to dry off the external surfaces of the connection set while the drying cycle is running

Number of tubes	Drying cycle selection	RED gas outlet	BLUE gas outlet	YELLOW gas outlet
1	Cystoscope / Ureteroscope → Operating channel Ø > 1.5 mm	To be used	/	/
2	EBUS / Bronchoscope → EBUS	To be used	/	To be used
3	GI endoscope → With waterjet channel	To be used	To be used	To be used



Fig. 42 Drying of the connection set after manual disinfection

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