PLASMABIOTICS®

IN ASSOCIATION WITH PENTAX MEDICAL

Instructions for use

AquaTYPHOON™

Instructions for use

Advanced unit for fast and effective cleaning of endoscopes

CONTENTS

1. INTRODUCTION

Flexible endoscopes are highly complex semi-critical or critical medical devices. During a procedure, endoscope can become highly contaminated with blood, proteins, other debris and microorganisms. From this reason, endoscope must be reprocessed before being used on a subsequent patient. Cleaning of the endoscope is one of the most important steps in the endoscope reprocessing procedure aiming to remove organic and inorganic residuals from endoscope channels, as well as from external endoscope surface.

AquaTYPHOON™ is an automated device designed for fast and effective brushless cleaning of endoscopes, intended to be implemented in the endoscope reprocessing cycle after the bedside (point of care) cleaning and before the automated endoscope washing and disinfection in an automated endoscope reprocessor (AER) or the manual washing and disinfection. This device is an alternative solution to manual cleaning of endoscopes (with brushes and detergent), offering higher performance, improved comfort of use, increased security, full traceability and more sustainability.

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 AquaTYPHOON™ operation. It is strongly requested that you read this manual carefully before using the AquaTYPHOON™ system for the first time.

2. INDICATION

2.1 INTENDED USE AND PERFORMANCE

AquaTYPHOON™ is used for endoscope cleaning within endoscope reprocessing procedure in order to remove residuals from endoscope channels, as well as from external surface of the endoscope. Implemented in the endoscope reprocessing cycle, cleaning with AquaTYPHOON™ addresses the cleaning step following the bedside (point of care) cleaning, and preceding endoscope washing and disinfection in an AER or the manual washing and disinfection. AquaTYPHOON™ has two main functionalities: an automated leak test and a cleaning cycle.

The AquaTYPHOON™ cleaning cycle consists of automated brushless cleaning of all endoscope channels and manual cleaning of external endoscope surface using AquaJET. Automated endoscope channels cleaning cycle lasts between 2 and 10 minutes, depending on the endoscope type. A specifically designed process combining only water and air in a highly turbulent two-phase fluid flow at a specific frequency and pressure, creates a strong shear stress on endoscope channel walls and allows for effective removal of organic residuals from endoscope channels.

The endoscope cleaning procedure using AquaTYPHOON™ has been validated by PlasmaBiotics according to the ISO 15883 standards. Validation test reports are available upon request.

AquaTYPHOON™ 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 treatment cycle. History database that contains all performed cycles, is archived on the AquaTYPHOON™ 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: personnel which is competent, knowledgeable and well-educated in endoscope reprocessing (e.g. endoscopy nurses, decontamination staff). A biomedical technician or biomedical engineer can operate the device for maintenance purposes only.

AquaTYPHOON™ is intended for operation in hospitals as an active cleaning system for flexible endoscopes. The intended operating location is the dirty area of an endoscope reprocessing unit or Central Sterilization (Service) Department (CS(S)D).

Specific training on the use of the AquaTYPHOON™ is mandatory for the intended users.

2.3 INTENDED USE AND BENEFIT

The intended use of the AquaTYPHOON™ is as follows:
- to test the integrity of the endoscope via the leak test, and / or
- to clean the endoscope by removing residuals from all endoscope channels, as well as from the external surface of the endoscope.

2.4 CONTRA-INDICATION

Warning: PlasmaBiotics does not warrant the correct functioning of the AquaTYPHOON™ without the use of validated connection sets and water filter. PlasmaBiotics assumes no warranty or liability for any damages on AquaTYPHOON™, an endoscope, or any other damages, each resulting out of the use of an endoscope that has not been cleaned with validated connection sets, including but not limited to damages suffered by patients treated with such an endoscope.

3. GENERAL CHARACTERISTICS

3.1 ELECTRICAL AND MECHANICAL CHARACTERISTICS

CHARACTERISTIC / PARAMETER	Sym	VALUE	
Model	#	AquaTYPHOON™	
Reference	REF	**AquaTYPHOON™**	
Medical device	MD	**Class I**	
UDI ID	UDI	03701354420113	03701354420106
Power supply / electrical network		100-130 VAC	200-240 VAC
Fuse		T 2*5A	T 2*2A
Maximal power		100 W	
Frequency		50 Hz / 60 Hz	
Overvoltage		Category II	
Power supply cable		H05VV-F 3G 1mm²	
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 (50.76 psi)	
Minimal gas flowrate		70 l/min	
Minimal water inlet pressure		3 bar (43.51 psi)	
Maximal water inlet pressure		4 bar (50.76 psi)	
Medical air & water 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	IPX2	

3.2 MATERIALS AND SUBSTANCES

COMPONENT	Abr	MATERIALS / SUBSTANCES
Box	SS	Stainless Steel
Connection set		Silicone and Stainless Steel
Air & water supply tube	PU	Polyurethane

4. INSTALLATION

Warning: The following instructions are intended to ensure that the AquaTYPHOON™ and its peripheral devices are operated appropriately. Non-compliance with these instructions may influence the efficacy of the cleaning 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 AquaTYPHOON™ system (Figure 1):
1) Facility:

- Power supply / electrical network
- Medical air grade supply with minimal pressure: 3 bar (43.51 psi), minimal flowrate: 70 l/min.
- Tap water quality supply with minimal pressure: 3 bar (43.51 psi)
- Sink unit

2) Provided by PENTAX Medical or local distributor:

- Air pressure regulator, delivery pressure: 0 to 5 bar (72.52 psi), minimal flowrate: 70 l/min
- Peripheral devices (e.g. printer, bar-code scanner, RFID tag scanner…)
- PlasmaBiotics connection sets for AquaTYPHOON™ corresponding to different endoscope brands and models.

Figure 1. AquaTYPHOON™ with its peripheral devices (barcode scanner, RFID scanner and 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 power socket with 3 terminals (live, neutral and earth).

Warning: AquaTYPHOON™'s power cable must be plugged directly into the wall power socket. Do NOT use a multi-socket adapter.

4.3 MEDICAL AIR INLET

AquaTYPHOON™ has a **medical air inlet** at the rear (see Figure 2). 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 4 bar (58.02 psi) in static mode. The minimal gas flowrate of the supply system (gas pipeline system + pressure regulator) must be 70 l/min.

Medical air inlet must be connected to an external source of medical air via an air supply tube (Figure 3A), a polyurethane tube of internal diameter 4 mm (0.16 in) and external diameter 6 mm (0.24 in), equipped with corresponding CPC connectors.

In the event that an external source of medical air is not connected to the AquaTYPHOON™ 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.

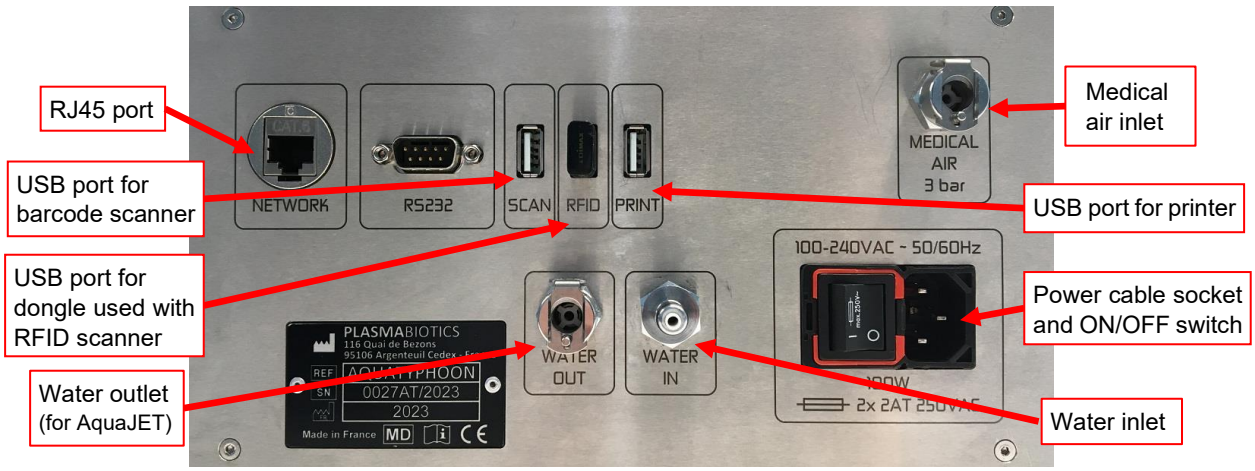


Figure 2. Rear of AquaTYPHOON™ device

Warning: The medical air supplying the AquaTYPHOON™ must be free from contamination and must be of a purity class according to local regulation. The presence of liquid water in the medical air represents a risk of damaging the AquaTYPHOON™ equipment. The manufacturer is not liable for any damages in the event of water ingress via the medical air inlet.

4.4 WATER INLET AND OUTLET

AquaTYPHOON™ has a **water inlet** at the rear (see Figure 2). This inlet must be connected to an external source of water (ex. tap water system) via a water supply tube (Figure 3B), a polyurethane tube of internal diameter 4 mm (0.16 in) and external diameter 6 mm (0.24 in), equipped with corresponding CPC connectors. The water pressure range has to be between 3 bar (43.51psi) and 4 bar (58.02 psi).

Depending on the diameter of the water tap, a corresponding CPC adapter shall be mounted in order to install the water filter. This filter is valid for 2 months and needs to be replaced before the expiry date. The other side of the filter shall be connected to the water supply tube. The use of the water filter is highly recommended.

In the event that an external source of water is not connected to the AquaTYPHOON™ or that the water pressure is too low, an error message will appear on the screen and it will not be possible to perform the cycle.

AquaTYPHOON™ has also a **water outlet** at the rear of the device. This outlet must be connected to the AquaJET, 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 AquaJET to the AquaTYPHOON™, plug-in the CPC connector to the water outlet connector at the rear of the AquaTYPHOON™. To disconnect the AquaJET, unplug the CPC connector while pressing the button above.

4.5 AIR AND WATER SUPPLY TUBES

AquaTYPHOON™ device is provided with air and water supply tubes, equipped with corresponding CPC connectors. Different types of CPC connectors were used for air inlet (female CPC) and water inlet (male CPC) in order to avoid inappropriate connection of water supply to the medical air inlet. The provided air and water supply tubes shall be connected to the respective air and water sources and shall be plugged into the air and water inlets at the rear of the AquaTYPHOON™ device (see Figure 2). To disconnect the air and water supply tubes, first stop the medical air and water flow and then unplug the CPC connectors while pressing the buttons above.

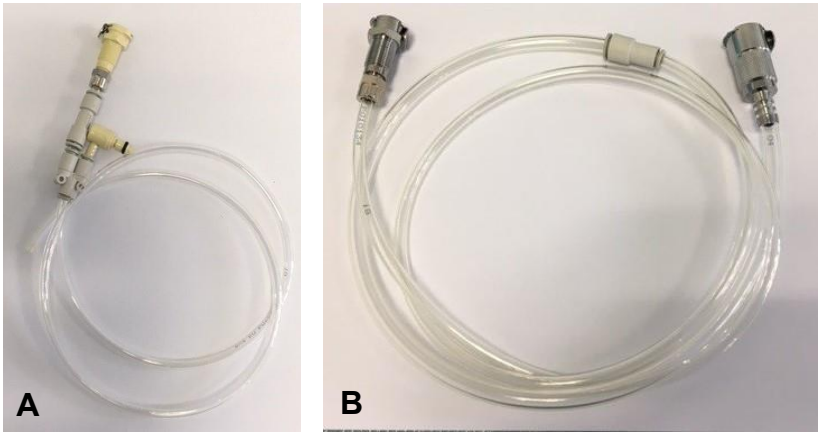


Figure 3. Air supply tube (A) and water supply tube (B).

For a regular use of the AquaTYPHOON™ device, the air and water supply tubes shall be connected as shown in Figure 4. This connection needs to be modified in order to carry out the purge cycle (see Section 7.2).

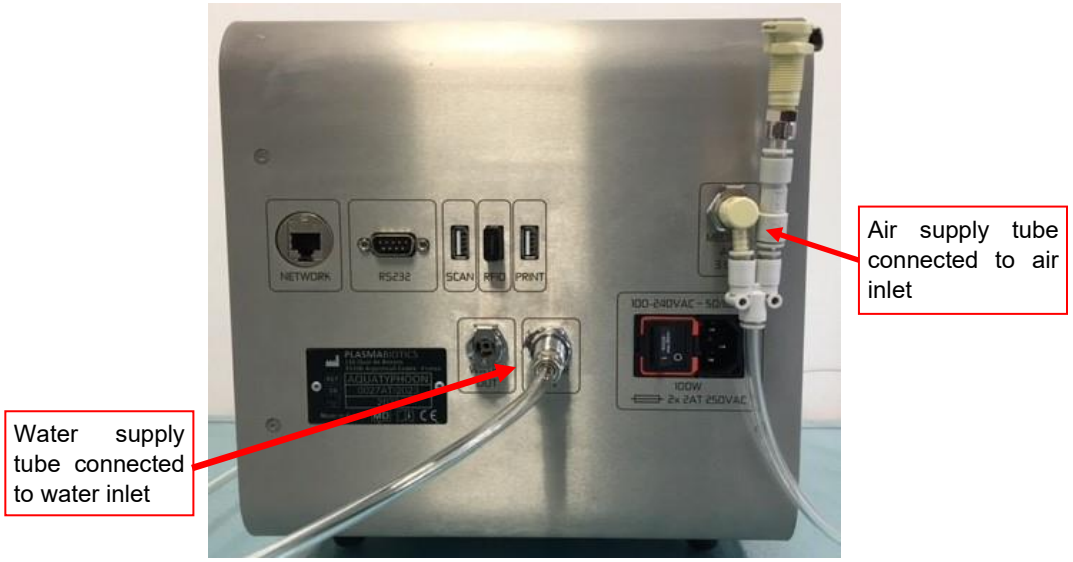


Figure 4. Connection of air and water supply tubes at the rear of AquaTYPHOON™ device for a regular use

4.6 PERIPHERAL DEVICES AND NETWORK CONNECTION

Peripheral devices barcode scanner and printer shall be connected to the AquaTYPHOON™ via the corresponding USB ports, named “SCAN” and “PRINT”, at the rear of the device (see Figure 2). RFID scanner is connected to the AquaTYPHOON™ via a dongle installed on the USB port named “RFID”. All peripheral devices need to be configured in order to function with AquaTYPHOON™.

AquaTYPHOON™ can be connected to the local network and/or internet via the RJ45 port at the rear of the device.

4.7 AIR/WATER OUTLETS AT THE FRONT

AquaTYPHOON™ has three air/water outlets and one air outlet at the front (see Figure 5) identified by colour code. The red, blue and white outlets enable the mixture of medical air and water to be injected into the endoscope channels and the green outlet enables the medical air to be insufflated into the endoscope sleeve via corresponding PlasmaBiotics connection sets. Red, blue and white outlet are equipped with female CPC connector, while the green outlet is equipped with male CPC connector, in order to avoid inappropriate connection of the connection sets.

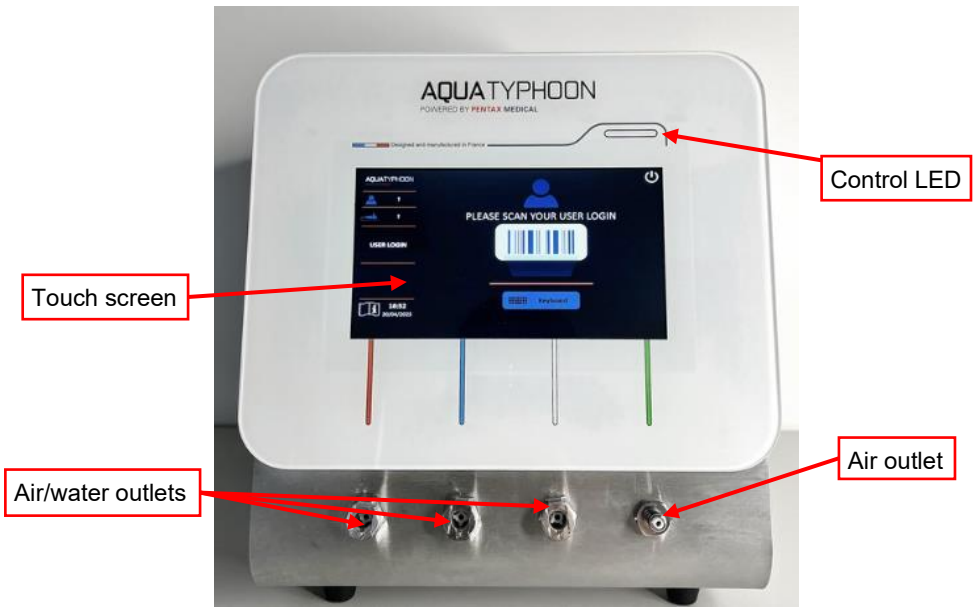


Figure 5. Front of AquaTYPHOON™ device

Depending on the endoscope type, different outlets shall be connected to corresponding endoscope channels, as shown in the table below:

Colour code	GI/EUS	EBUS	Broncho/ Cysto/Uretero
RED	**Suction**	**/**	**/**
BLUE	**Air/water & Auxiliary**	**Suction & Biopsy**	**Suction & Biopsy**
WHITE	**Biopsy**	**Auxiliary**	**/**
GREEN	**Leak test**	**Leak test**	**Leak test**

4.8 SWITCHING ON

In order to switch ON the AquaTYPHOON™, use the “ON/OFF” switch located at the rear of the device (see Figure 2). AquaTYPHOON™ software runs automatically after switching ON the device. The AquaTYPHOON™ is in a Standby mode upon start-up: the touchscreen display is ON and the user (operator) identification can be entered (see Figure 7).

4.9 DEVICE QUALIFICATION

Installation of AquaTYPHOON™ 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.

5. OPERATING INSTRUCTIONS

5.1 STANDBY MODE

The AquaTYPHOON™ is in Standby mode upon start-up. By pressing the AquaTYPHOON™ logo in the upper left corner of the screen, one can access the AquaTYPHOON™ homepage where manufacturer and distributor details are displayed. In addition, this page contains language settings (see Figure 6).

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 AquaTYPHOON™ 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.

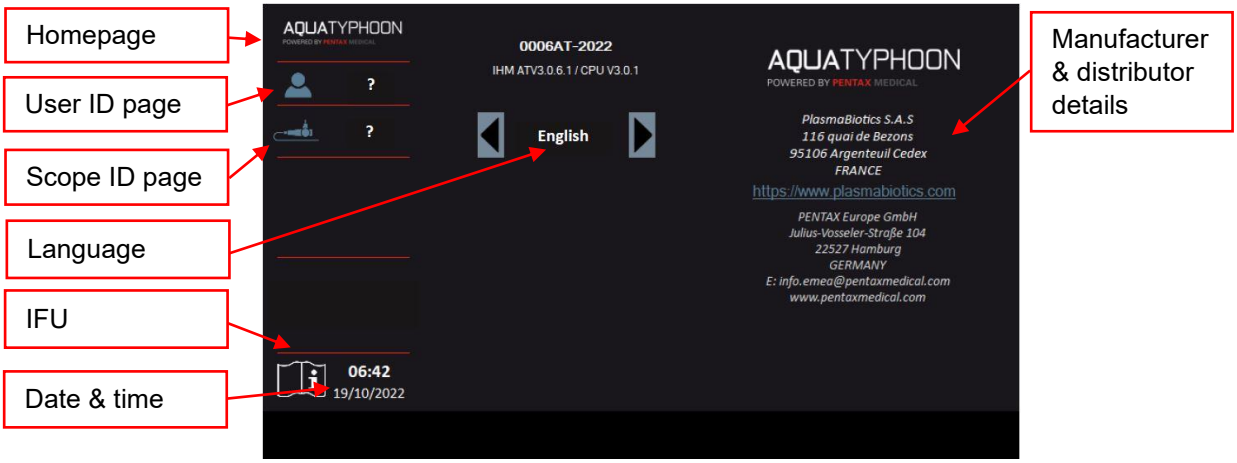


Figure 6. Homepage screen

5.2 USER IDENTIFICATION AND USERS DATABASE

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 Figure 7). 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.

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 (see Figure 8).

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" in Figure 10), and the device will proceed to the next step of the process.

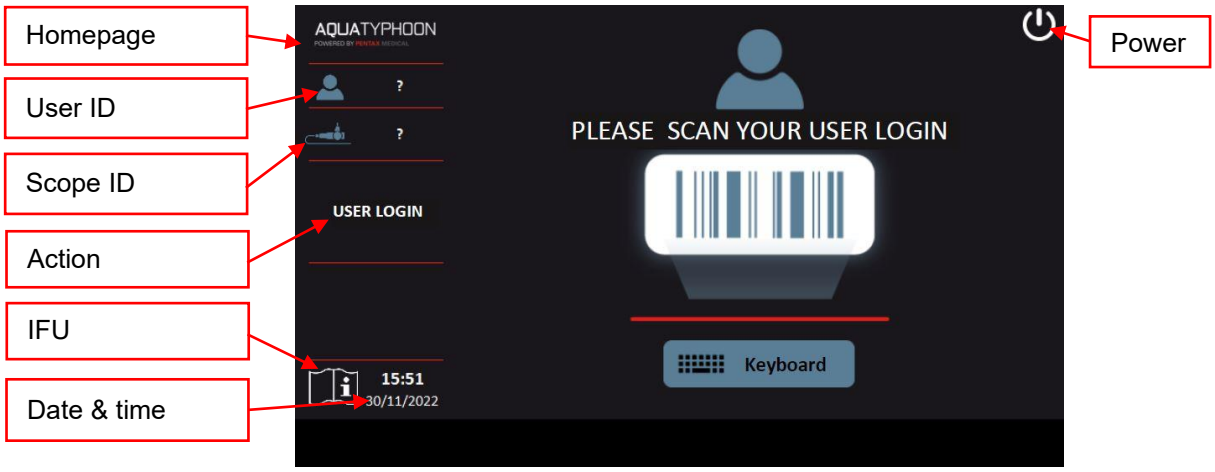


Figure 7. User ID page

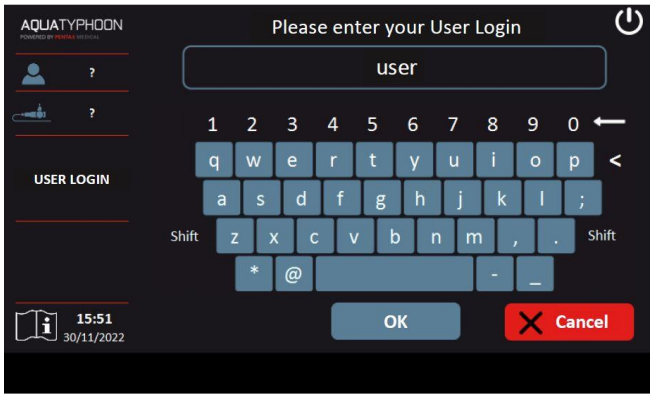


Figure 8. User login via the alphanumerical keyboard

An integrated Users Database, if activated, will enable access only to registered users. For optimal operation of this feature, users database, named **"USERS"**, must be set up during the AquaTYPHOON™ installation procedure. The database is a CSV file containing a list of all registered users, previously trained and authorized to use the AquaTYPHOON™ device. USERS database can be accessed via AquaTYPHOON™ software (see Figure 9). The list of registered users can be completed or amended by the person in charge of the unit.

The users database "USERS" includes:

- ✓ User's ID number (barcode, RFID, or an attributed ID number)
- ✓ User's last name
- ✓ User's first name

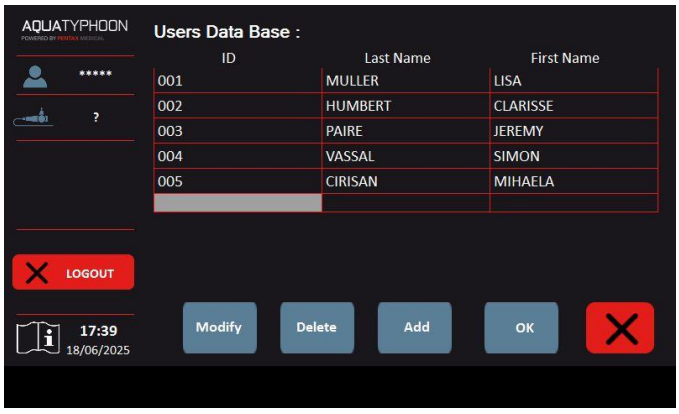


Figure 9. USERS database example

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 Figure 10). 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.

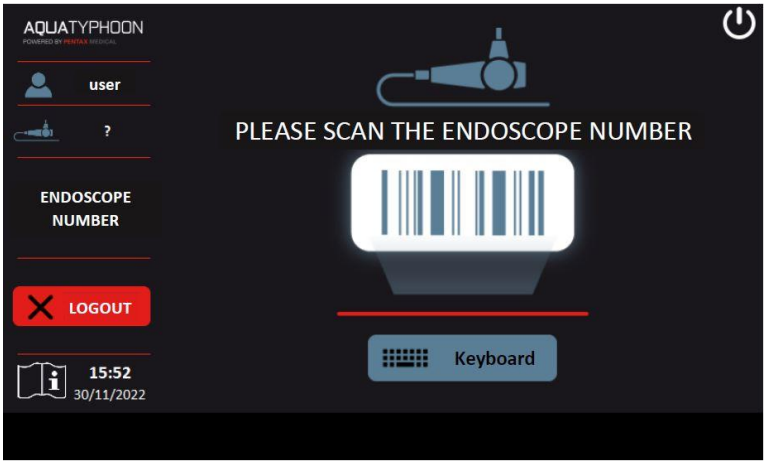


Figure 10. Endoscope ID page

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 (see Figure 11)
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 11 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" in Figure 12). 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: leak test cycle, cleaning cycle or a succession of both leak test and cleaning cycle (see Figure 12).

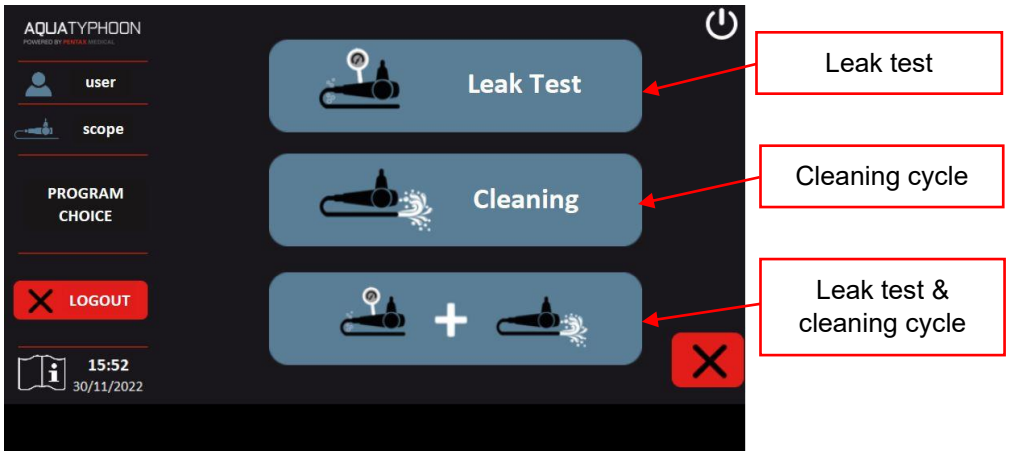


Figure 12. Treatment cycle selection page

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 (Figure 13). Once entered and validated, the endoscope ID number is displayed next to the endoscope symbol in the left-side menu (see Figure 12).

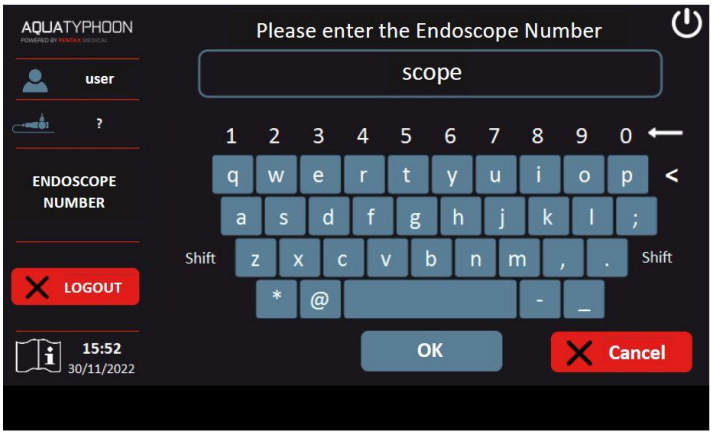


Figure 13. Endoscope identification via alphanumerical keyboard

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 Figure 14).

Finally, the user must select the treatment cycle that he/she wishes to perform: leak test cycle, cleaning cycle or both cycles (see Figure 12). CARE button is related to device maintenance features. For more information see Section 7.

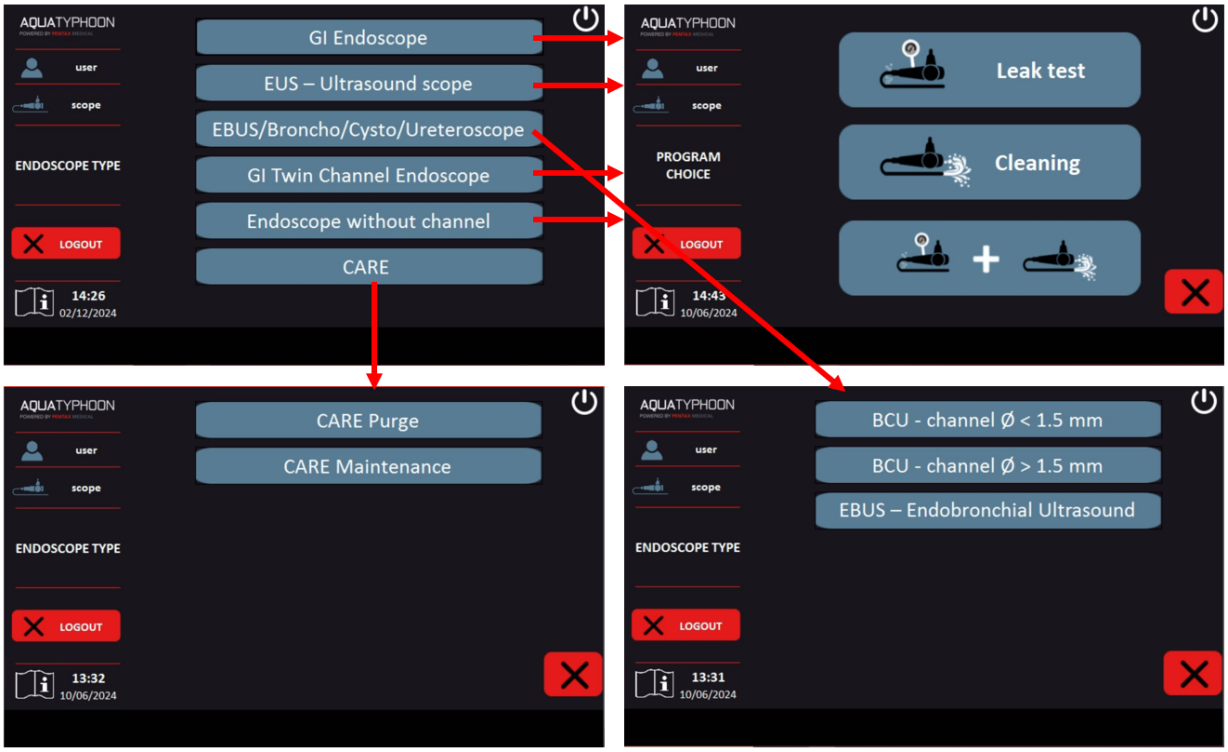


Figure 14. Endoscope type selection pages

5.4 AUTOMATIC ENDOSCOPE TYPE SELECTION AND ENDO DATABASE

Automatic endoscope type selection is a feature that enables automatic selection of the corresponding cleaning cycle depending on the endoscope type. For optimal operation of this feature, an **endoscope database**, named **"ENDO"**, must be set up during the AquaTYPHOON™ installation procedure. The database is a CSV file containing a list of all endoscopes meant to be treated with AquaTYPHOON™. ENDO database can be accessed via AquaTYPHOON™ software (see Figure 15). 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 / cycle code (see the table below)
- ✓ endoscope brand
- ✓ endoscope model
- ✓ endoscope serial number
- ✓ endoscope inventory number (optional)

Endoscope types

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

Cycle code	Description	Specification
GI	Gastrointestinal (GI) endoscope	with and without auxiliary channel
EUS	Ultrasound gastrointestinal endoscope (EUS)	with and without auxiliary channel
BCU-TC	Bronchoscope, naso-laryngoscope, cystoscope and ureteroscope	with operating channel Ø < 1.5mm, no unconnected suction connector or valve port (see connection card)
BCU-BCU	Bronchoscope, naso-laryngoscope, cystoscope and ureteroscope	with operating channel Ø > 1.5mm, or unconnected suction connector or valve port (see connection card)
BCU-EBUS	Ultrasound bronchoscope (EBUS)	
DOC	Twin channel GI endoscope	with and without auxiliary channel
NCH	Endoscope without channels	

Endoscope brands and models compatible with AquaTYPHOON™ are listed in the AquaTYPHOON™ compatibility table, that can be provided by the distributor or local service representative. This table indicates the corresponding connection set reference and cycle code to be used with each compatible endoscope model.

An example of an ENDO database is presented in the Figure 15

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 Figure 14) will appear immediately after endoscope identification.

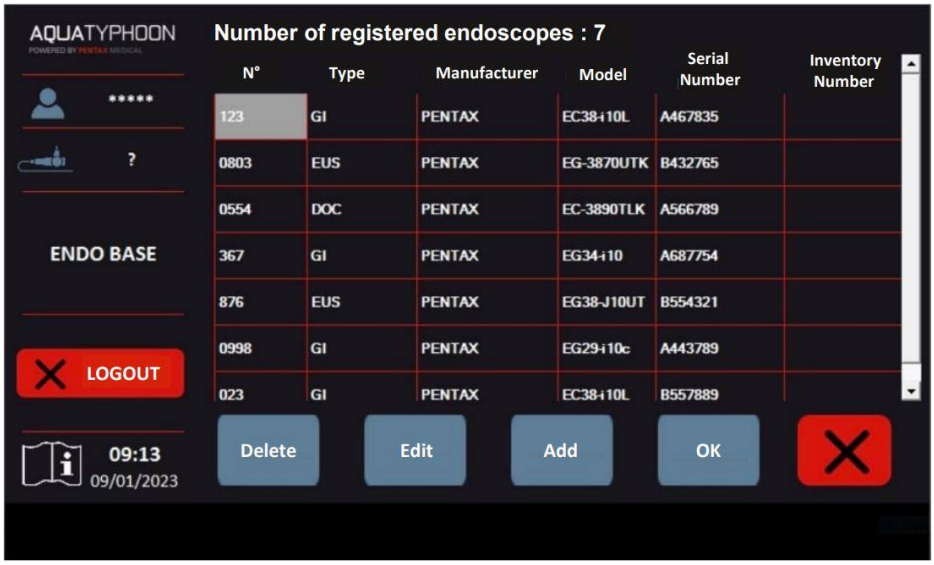


Figure 15. ENDO database example

5.5 LEAK TEST

Once the user has selected to perform a **leak test** cycle by pressing “Leak test” button (see Figure 12), a new page appears requesting the user to prepare the endoscope for the leak test (see Figure 16).

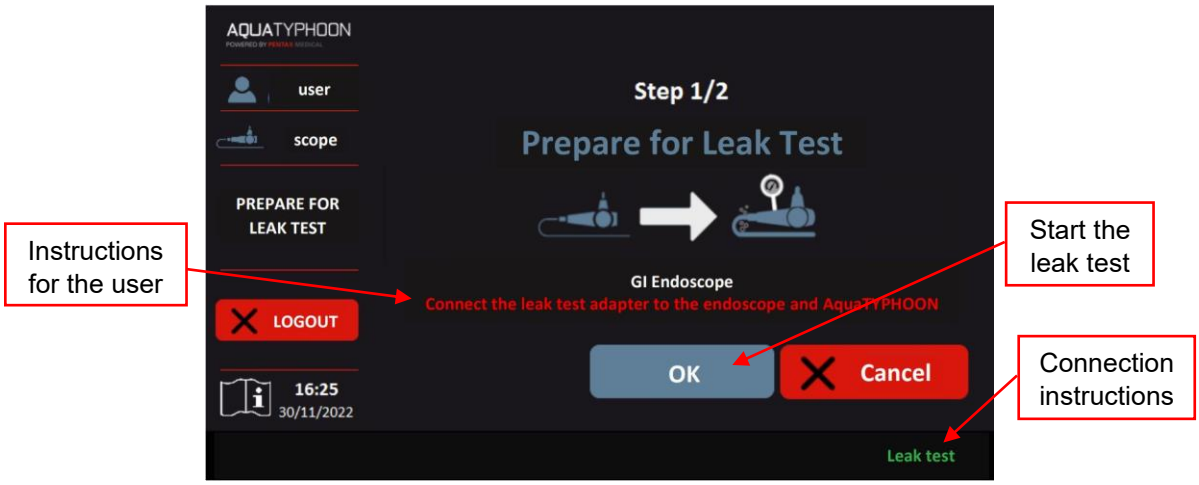


Figure 16. Prepare for Leak test page

The user shall then use the corresponding green connection set for leak test to connect the endoscope to the AquaTYPHOON™ (see Figure 17). The leak test connection sets are available for different endoscope types and brands and can be found in the PlasmaBiotics Product Overview which can be provided by the distributor or local service representative. The user shall make sure that the leak test adapters both on the endoscope and on the connection set are clean and dry before connecting them. Once connected, the leak test may be initiated by pressing OK button on the screen.

Figure 17. Connecting endoscope to AquaTYPHOON™ for the leak test

The leak test has to be done on a flat surface, preferably inside an empty sink. It allows users to detect major leakages. The leak test duration is 1 minute. While the leak test is running the user **must slowly turn the left/right, up/down knobs** performing the angulation of the distal end, in order to detect major leakages.

Note: In case that *Leak test and Cleaning cycle* option is selected (see Figure 12), after this initial dry leak test, the leak test will continue running during the entire cleaning cycle, thus enabling the detection of minor leakages. From this reason, the green leak test connection set shall remain connected to the endoscope until the very end on the Cleaning cycle.

5.6 CLEANING CYCLE

The cleaning cycle consists of three steps:

1. Initial external cleaning using AquaJET (section 5.6.2)
2. Automated cleaning of all endoscope channels (section 5.6.4)
3. Final external cleaning using AquaJET (section 5.6.5)

Clear step-by-step instructions on the touch screen guide the user through the entire process. After every completed step, device will wait for the user to proceed to the next step.

Warning: When individual cleaning cycle is selected only, no leak test will be performed during the cleaning cycle. Depending on the endoscope manufacturer's instructions, the user may eventually use separate leak test tool/device for this purpose.

5.6.1 Preparation for the cleaning cycle

Once the user has selected to perform a **cleaning cycle** by pressing "Cleaning" button (see Figure 12), a new page appears requesting the user to prepare for the cleaning cycle.

The user must select the corresponding connection set and connect it to the AquaTYPHOON™ outlets. Blinking text at the bottom of the screen indicates the colour code of the connection tubes to be connected to the outlets (see Figure 18). 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 the distributor or local service representative.

Figure 18. Prepare to Clean page

Warning: At this step, the user **must not yet connect** the connection set to the endoscope. The channel inlets shall be cleaned using the AquaJET, before connecting the connection set to the endoscope. The user can also choose to connect the connection set to both AquaTYPHOON™ and endoscope just before initiating the Automated cleaning of endoscope channels (see Section 5.6.3).

5.6.2 Initial external cleaning with AquaJET

Once the user launched the cleaning cycle, he/she shall proceed to the initial cleaning of the external endoscope surface, performed manually using the AquaJET (see Figure 19).

External cleaning using the AquaJET consists of:

1. Cleaning the endoscope channel inlets (Figure 19A, duration: minimum 20s)
2. Cleaning the endoscope body until it's visually clean (Figure 19B, duration: minimum 20s)
3. Cleaning the endoscope distal end (Figure 19C, duration: minimum 20s)

Instructions reminding the user of each step of the external cleaning are clearly indicated on the screen during the process (see Figure 19).

Detailed protocol on the cleaning of endoscope surface using the AquaJET is given in Annex III. In case that there is a remaining visible soil on the endoscope, the cleaning using the AquaJET shall be prolonged as much as necessary, until all visible soil is removed.

Note: During the initial external cleaning of endoscope, user shall pay particular attention to properly clean the channel inlets: suction port, air/water port, biopsy channel inlet and auxiliary channel inlet; since the connection set shall be connected to these ports afterwards in order to carry out the automated cleaning of endoscope channels.

WARNING: AquaJET cleaning of the endoscope surface, being a manual process, is under a full responsibility of the user. Hence, user shall pay particular attention to properly carry out the entire process, following the protocol provided in Annex III.

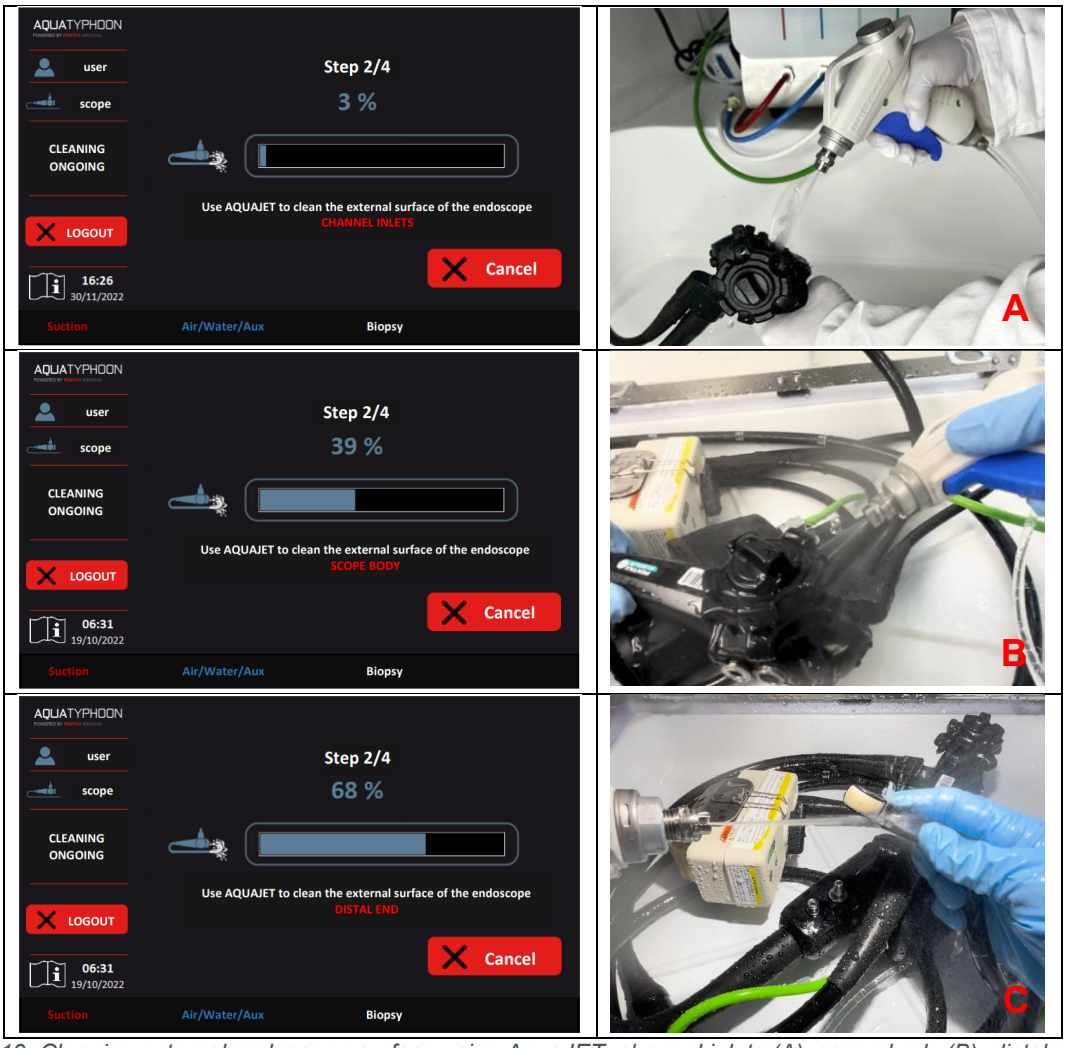


Figure 19. Cleaning external endoscope surface using AquaJET: channel inlets (A), scope body (B), distal end (C).

Note: In order to avoid excessive splashing during the external endoscope cleaning using AquaJET, the endoscope can be submerged in water, or a specially designed AquaTYPHOON™ shield or TyphoonBOX can be used. TyphoonBOX is a thermoformed box designed to provide protection to the user and surrounding environment from the splashing and spattering with contaminated water during the cleaning process. TyphoonBOX shall be placed on top of the sink, and the endoscope placed inside can be entirely cleaned, externally and internally, using the AquaTYPHOON™ system without excessive splashing.

Once the external cleaning step is completed, the device is waiting for the user to connect the connection set to the endoscope and proceed to the next step – automated cleaning of endoscope channels (see Figure 20).

5.6.3 Endoscope connection

At this step (see Figure 20) the user shall connect the connection set, previously plugged-in to the AquaTYPHOON™ outlets, to the endoscope (see Figure 21). 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 the distributor or local service representative. AquaTYPHOON™

compatibility table provides corresponding connection set reference for each compatible endoscope model.

Figure 20. Prepare for Automated Cleaning page

Warning: Incorrect connection of the endoscope to the AquaTYPHOON™, via inappropriately installed connection set, may lead to air or water leakage causing a potential risk of ineffective cleaning of endoscope channels.

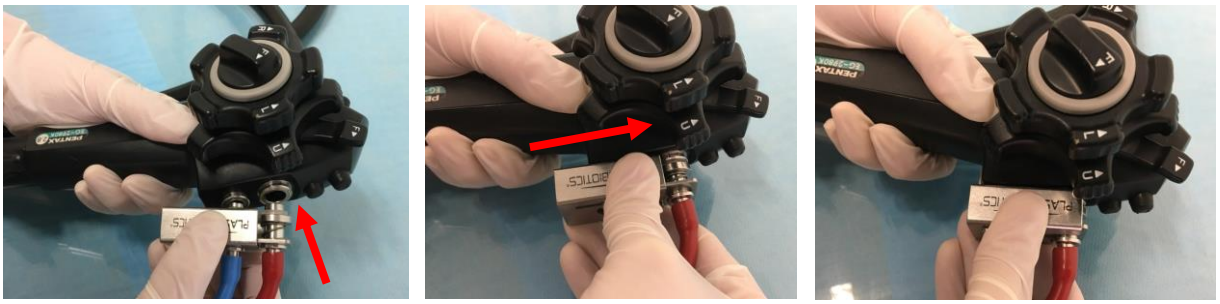


Figure 21. Connecting the connection set to the endoscope

Warning: The endoscope must be connected to the AquaTYPHOON™ using the provided connection sets only and following the recommendations of PlasmaBiotics. If the connection sets are modified, we cannot guarantee efficient and complete cleaning of the endoscope channels.
Note: In case when TyphoonBOX is used, the connecting of the connection set is performed directly inside the box.

Warning: If the endoscope does not have an auxiliary channel (waterjet or elevator channel), the Y-shaped part of the blue tubing intended to be connected to the auxiliary channel shall be disconnected (see Figure 22). Not following this instruction where applicable, may lead to ineffective cleaning of endoscope channels.

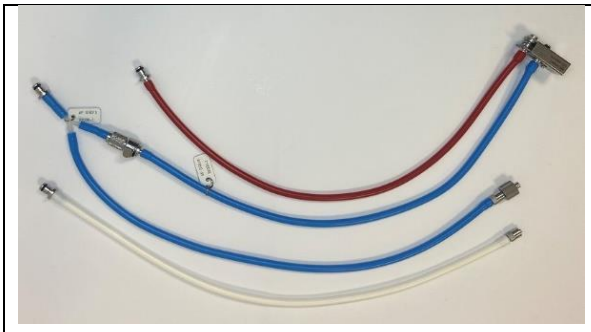
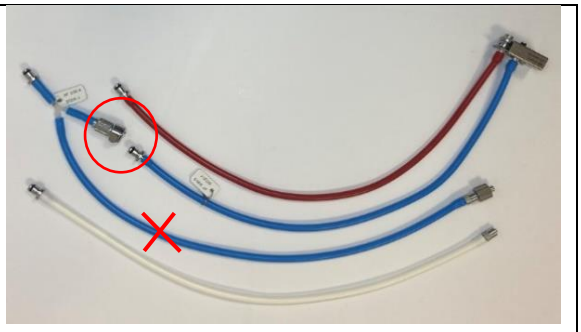
	
Connecting endoscope with auxiliary channel: Y-shaped blue tube shall be used	Connecting endoscope without auxiliary channel: Y-shaped blue tube shall be removed

Figure 22. Connection set adjustment for GI or EUS endoscopes with or without auxiliary channel

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, before starting the automated cleaning of endoscope channels. The air/water channel bridge is not provided with the connection set, but it is provided with the endoscope itself (as part of the manual disinfection kit).

Note: In case of duodenoscopes or linear ultrasound (EUS) endoscopes, the user must place the elevator in the lower (open) position before starting the automated cleaning of endoscope channels.

5.6.4 Automated cleaning of endoscope channels

Once all endoscope channels are connected to the AquaTYPHOON™ via the corresponding connection set, the user can start the automated cleaning of endoscope channels by pressing “OK” button (see Figure 20).

The progress status of the cleaning cycle is displayed in the central part of the screen (see Figure 23). Selected endoscope type determining the corresponding cleaning cycle is indicated below the progress bar. The cleaning cycle can be stopped at any moment by pressing the “Cancel” button.

Warning: Do not attempt to disconnect the endoscope from the AquaTYPHOON™ during the automated cleaning cycle. Do not use AquaJET during the automated cleaning cycle.

Warning: In case of uncompleted cleaning cycle or accidental disconnection of the connection set during the automated cleaning cycle, run a new cleaning 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 air/water in order to guarantee effective cleaning of endoscope channels.

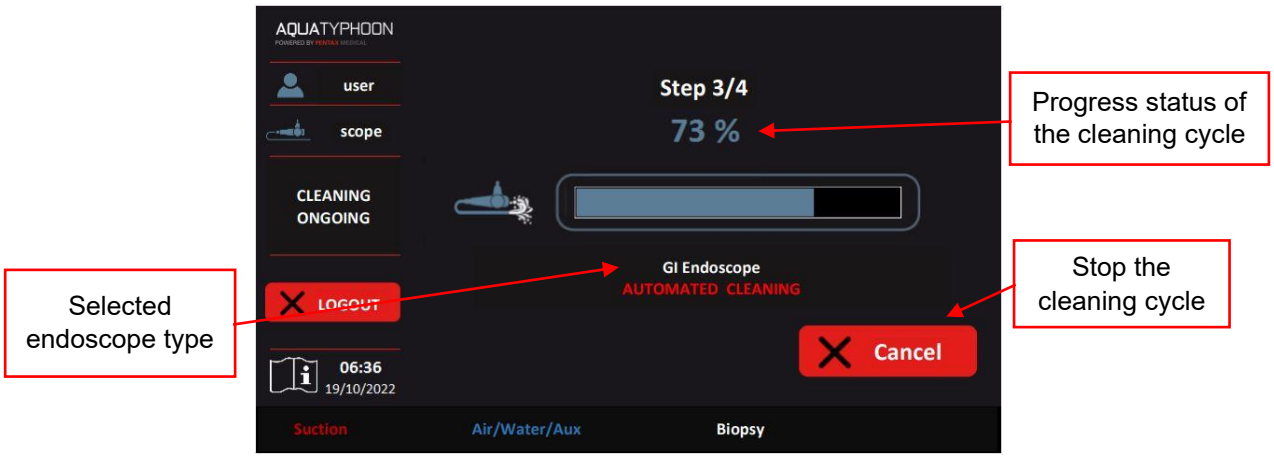


Figure 23. Cleaning cycle in progress

The duration of automated cleaning of endoscope channels depends on the endoscope type (see the table below):

Endoscope type	Automated cleaning time
Bronchoscope, naso-laryngoscope, cystoscope, ureteroscope, ultrasound bronchoscope (EBUS)	**2 min**
GI endoscopes (gastroscope, duodenoscope, enteroscope, colonoscope)	**5 min**
GI ultrasound endoscope (EUS)	**7 min**
Twin channel GI endoscope	**10 min**

5.6.5 Final external cleaning with AquaJET

At the end of the automated cleaning of endoscope channels, the user shall disconnect the connection set from the endoscope and repeat the external cleaning using AquaJET.

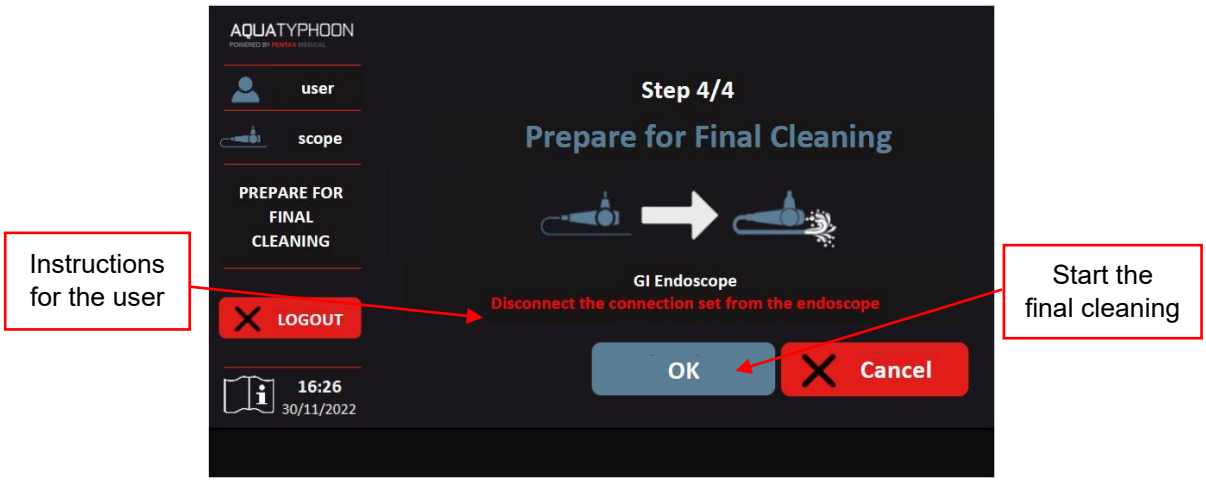


Figure 24. Prepare for Final Cleaning page

External cleaning using the AquaJET consists of:

1. Cleaning the endoscope channel inlets (Figure 19A, duration: minimum 20s)
2. Cleaning the endoscope body until it's visually clean (Figure 19B, duration: minimum 20s)
3. Cleaning the endoscope distal end (Figure 19C, duration: minimum 20s)

Instructions reminding the user of each step of the external cleaning are clearly indicated on the screen during the process (see Figure 19).

WARNING: This step is particularly important for the endoscopes having an elevator at the distal end (duodenoscopes and linear EUS scopes). The user must place the elevator in both lower (open) and upper (closed) position in order to thoroughly clean it.

Detailed protocol on the cleaning of endoscope surface using the AquaJET is given in Annex III. In case that there is a remaining visible soil on the endoscope, the cleaning using the AquaJET shall be prolonged as much as necessary, until all visible soil is removed.

Note: The AquaJET shall be used for external cleaning of the endoscope. It is user's responsibility to use the AquaJET before and after the automated cleaning of endoscope channels until the soil has visually disappeared. The entire outer surface of the endoscope, including channel inlets, outlets, on and in between the steering wheels, **must be completely clean**. Cleaning should be ensured by a visual inspection.

WARNING: AquaJET was validated for external cleaning of endoscope during 1 minute before and 1 minute after the automated cleaning of endoscope channels. Hence, the customer that decides to reduce the duration of this step or completely eliminate this step, engages his own responsibility in terms of the outcome of the cleaning process.

When the final external cleaning with AquaJET is completed, five beeps indicate that the treatment has been completed successfully and a message "**Cleaning completed**" appears on the screen (Figure 25). The AquaTYPHOON™ is in a standby mode and the user shall take the endoscope out of the sink or TyphoonBOX and place it into the AER to continue the reprocessing cycle. The user has a possibility to end the treatment by pressing the "OK" button or reprint a traceability label by pressing the "Reprint" button. In case that the user completed the use of AquaTYPHOON™, he/she can logout by pressing the "LOGOUT" button.

Figure 25. Cleaning cycle completed

Once the cleaning cycle is completed, the user shall clean/disinfect the used connection sets, as well as the sink or TyphoonBOX (if this is requested by local guidelines). Instructions on cleaning and disinfection of the connection sets are provided in the section 9.3. Instructions on cleaning and disinfection of the TyphoonBOX are provided in the section 13.3.

5.7. LEAK TEST AND CLEANING CYCLE

Leak test and Cleaning cycle option enables the user to successively run leak test and cleaning cycle on the same endoscope without having to repeat endoscope identification step. Once the user has selected the button “Leak test + Cleaning cycle” (see Figure 12), a new page appears requesting the user to prepare the endoscope for the leak test (see Figure 16). The user shall follow the instructions as described in sections 5.5 and 5.6.

 **Warning:** When *Leak test and Cleaning cycle* option is selected (see Figure 12), the leak test is continuously running till the end of the cleaning cycle. From this reason, the user must not disconnect the leak test connection set as soon as the leak test is completed. The leak test connection set shall remain connected till the end of the cleaning cycle. Continuing leak test during the cleaning cycle allows for detection of micro-leakages.

5.8 TRACEABILITY

The AquaTYPHOON™ is equipped with a printer, which prints a traceability label at the end of the leak test and cleaning cycle. The traceability label (see Figure 26) includes the following information:

In the header:

- ✓ Serial number (SN) of the concerned AquaTYPHOON device,
- ✓ Version of the AquaTYPHOON software
- ✓ Unique cycle number (UN)

In the central part:

- ✓ Endoscope barcode
- ✓ Endoscope ID (barcode or RFID tag) number
- ✓ Endoscope serial number (if indicated in the ENDO database)
- ✓ Date and time of the treatment
- ✓ User (operator) name or number
- ✓ Validation of treatment parameters values and cycle code of performed cycle (in brackets)
- ✓ Completed cycle (leak test, cleaning or both) and cycle conformity (OK)
- ✓ QR code containing all traceability data present on the label

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

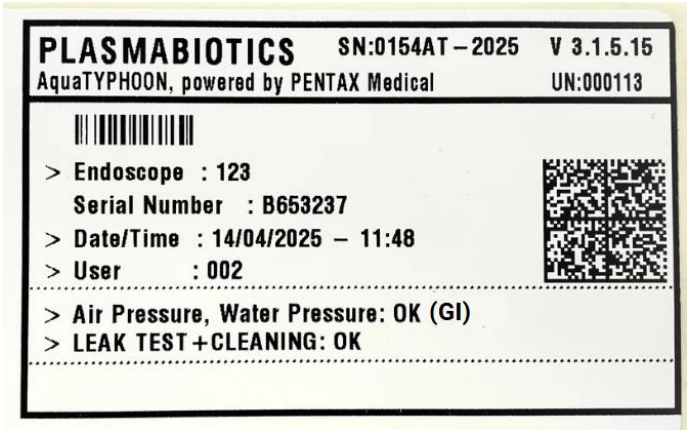


Figure 26. Traceability label

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

AquaTYPHOON™ provides the history of all treatment cycles performed by the device. This **history database** is saved as a CSV file named “REPORT” and located in “History” folder on AquaTYPHOON™ 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:

- ✓ Unique Cycle Number
- ✓ Date of the treatment
- ✓ Time of the treatment
- ✓ Endoscope type (cycle code from ENDO database)
- ✓ Endoscope ID (barcode or RFID tag) number
- ✓ Endoscope model
- ✓ Endoscope serial number
- ✓ User (operator) name or ID number
- ✓ Software version
- ✓ Cycle performed (cycle code of performed cycle)
- ✓ Cycle report: Treatment performed and its conformity (DONE/FAILED)
- ✓ Time delay when error appeared (if applicable)
- ✓ PICO number

Example of the “REPORT” database is presented in Figure 27.

	A	B	C	D	E	F	G	H	I	J	K	L	M	N
1	Unique Cycle Number	Date	Time	Type Endo	Number	Model	Serial Numbe	Operator	Sofware ver	Cycle perform	Cycle Report	Time Error	PICO Number	
2	0027AT-2023-000007	05/06/2025	12:15:49	EUS	603	EG-3870UTK	7923453	001	3.1.6.2	EUS	LEAK TEST + CLEANING DONE		PICO-APL105062025121549	
3	0027AT-2023-000008	12/06/2025	09:58:57	GI	604	ED34-i10T	2912824	002	3.1.6.2	GI	CLEANING DONE		PICO-APL112062025095857	
4	0027AT-2023-000009	12/06/2025	10:01:32	GI	401	EG34-i10	2730534	002	3.1.6.2	GI	LEAK TEST FAILED	10s	PICO-APL112062025100132	
5	0027AT-2023-000010	12/06/2025	15:08:12	EUS	081	EG-3670URK	2510115	005	3.1.6.2	EUS	LEAK TEST DONE		PICO-APL112062025150812	
6	0027AT-2023-000011	12/06/2025	15:36:55	GI	400	EC38-i10c	2731626	005	3.1.6.2	GI	CLEANING DONE		PICO-APL112062025153655	
7	0027AT-2023-000012	12/06/2025	15:54:32	EUS	603	EG-3870UTK	7923453	003	3.1.6.2	EUS	LEAK TEST + CLEANING DONE		PICO-APL112062025155432	
8	0027AT-2023-000013	12/06/2025	16:10:03	GI	604	ED34-i10T	2912824	004	3.1.6.2	GI	LEAK TEST + CLEANING DONE		PICO-APL112062025161003	
9	0027AT-2023-000014	12/06/2025	16:15:47	GI	401	EG34-i10	2730534	001	3.1.6.2	GI	LEAK TEST FAILED	20s	PICO-APL112062025161547	
10	0027AT-2023-000015	12/06/2025	16:18:29	EUS	081	EG-3670URK	2510115	001	3.1.6.2	EUS	LEAK TEST DONE		PICO-APL112062025161829	
11	0027AT-2023-000016	12/06/2025	16:19:35	GI	400	EC38-i10c	2731626	001	3.1.6.2	GI	CLEANING DONE		PICO-APL112062025161935	
12														

Figure 27. “REPORT” – treatment cycles history database

5.9 SWITCHING OFF

AquaTYPHOON™ 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/slide the finger on the screen.
AquaTYPHOON™ may be switched OFF in case of prolonged unuse (on weekends, holidays). In order to switch OFF the AquaTYPHOON™, use the “Power” button in the upper right corner of the screen (see Figure 7) 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 AquaTYPHOON™ 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. Error message displayed on the screen is also printed out on a traceability label and recorded in the history database named "REPORT".

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 AquaTYPHOON™, 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 4 bar (58.02 psi) in static mode.

Figure 28. 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 4 bar (58.02 psi) in static mode.

- **ERROR: Water inlet pressure too low**

This error may occur when starting the cleaning cycle or even during the cleaning cycle if no or insufficient water pressure is detected at the water inlet. In this case, check the tube connection to the water inlet at the rear of the AquaTYPHOON™, as well as the tube connection to the external water supply. Make sure the water tap is open (if applicable) and that there is no water leakage. Check the water inlet pressure: it shall be between 3 bar (43.51 psi) and 4 bar (58.02 psi) in static mode.

- **ERROR: Water inlet pressure too high**

This error may occur when starting the cleaning cycle or even during the cleaning cycle if the water pressure at the water inlet is too high. In this case, check the water inlet pressure at the external regulator: it shall be between 3 bar (43.51 psi) and 4 bar (58.02 psi) in static mode.

- **ERROR: Leak test error**

This error may occur during the leak test cycle or even during the cleaning cycle (if *Leak test & Cleaning cycle* option was selected). In this case, user shall check that the leak test connection set is properly connected to the endoscope and to the AquaTYPHOON™. If the error message appears again, it may indicate that the endoscope is damaged and shall be repaired. One may use an alternative leak test method to check the integrity of the endoscope sleeve.

- **ERROR: Connection error**

This error may occur when connection tube is not properly connected to the AquaTYPHOON™. In this case, the user shall verify the connection of the connection set to AquaTYPHOON™ and restart the cycle. Additionally, this error message may also indicate that one of the endoscope channels is obstructed. In this case, the user shall use an alternative method to verify if endoscope channel is obstructed.

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.

6.4 ELECTRICAL SHUTDOWN

In the event that an electrical shutdown of the mains occurs during a cycle:
- Check that the electricity is still operational
- Start the device and run a new cycle

7. MAINTENANCE

7.1 CLEANING

At the end of the day, the device shall be cleaned using a surface-disinfectant. If contamination of the device is noticed, it shall be directly removed, cleaned and disinfected using a surface-disinfectant. Always refer to the disinfectant manufacturer's instructions regarding the contact time.

Warning: AquaTYPHOON™ 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 wipe the device.

7.2 PURGE CYCLE

At the end of the day, or at least before the weekend or an extended period of non-use, the user shall carry out the purge cycle in order to purge the water from the internal water circuit of the device. Before starting the cycle, the **water flow shall be stopped** (by closing or disconnecting the water supply), the water supply tube shall be disconnected from the water inlet and the air supply tube shall be connected to it instead (see Figure 29). Then, the user shall connect any red, blue and white tubing connection set to the outlets at the frontside of AquaTYPHOON™, cover the sink or close the TyphoonBOX, and select and run the CARE Purge cycle (see Figure 30).

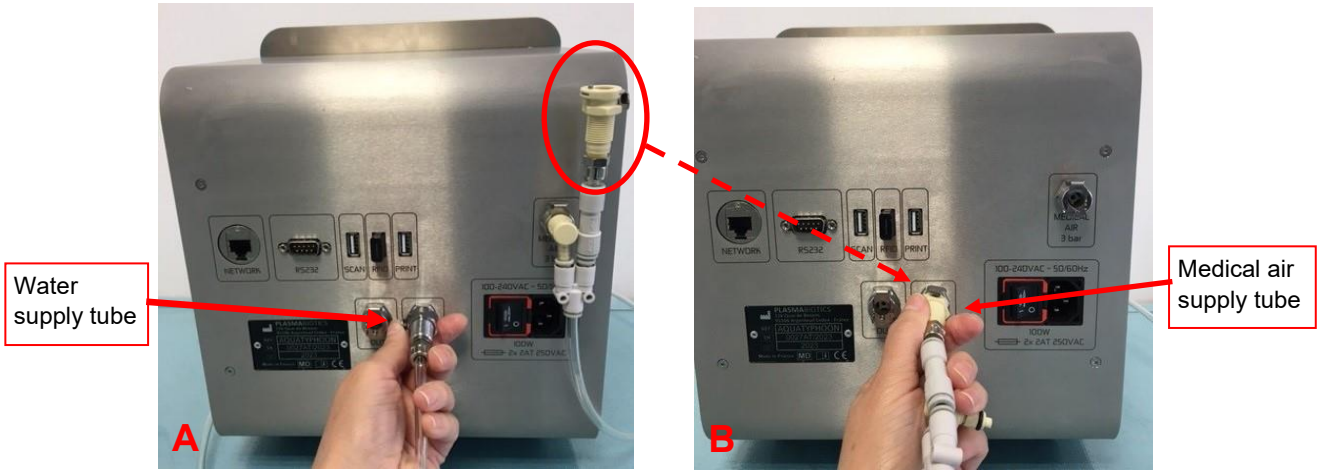


Figure 29. Disconnecting water supply tube (A) and connecting air supply tube (B) to the water inlet

Figure 30. Prepare for purge page

7.3 TECHNICAL MAINTENANCE

In order to maintain correct operation and efficacy of the AquaTYPHOON™, technical maintenance must be carried out once a year or every 15000 cycles. Once 15000 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 AquaTYPHOON™ includes: device inspection, dust-cleaning, replacement of certain components/spare parts (if needed), internal cleaning of the device, verification/recalibration of integrated sensors, software update, verification of device parameters) and security systems. A technical maintenance contract is offered by the distributor of AquaTYPHOON™. In order to comply with the general safety and performance requirement, the maintenance of the AquaTYPHOON™ shall be performed only by authorized medical service centre.

7.4 MAINTENANCE CYCLE

In scope of the annual maintenance of AquaTYPHOON™, a maintenance cycle shall be carried out in order to clean the internal water circuit of the device. For this purpose, AquaTYPHOON™ maintenance kit shall be used (Figure 31). A citric acid-based cleaner is irrigated into the water circuit of AquaTYPHOON™ and rinsed after the corresponding contact time duration. This process shall be carried out at least once a year, as part of the annual maintenance of the device. In addition, it is also recommended to carry out a maintenance cycle if the device has not been used for more than a month. The instructions for use of the AquaTYPHOON™ maintenance kit and performing the maintenance cycle are given in Annex IV.

Figure 31. AquaTYPHOON™ maintenance kit

8. WARRANTY, LIFETIME AND ELIMINATION

8.1 WARRANTY OF THE AQUATYPHOON™

PlasmaBiotics provides a one-year warranty on AquaTYPHOON™ starting on the date of installation.

8.2 LIFETIME OF THE AQUATYPHOON™

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

8.3 ELIMINATION

AquaTYPHOON™ shall be discarded as electronic waste.

9. CONNECTION SETS

9.1 LEAK TEST CONNECTION SETS

The leak test connection sets are used to connect the endoscope sleeve to the AquaTYPHOON™ in order to perform the leak test cycle. The corresponding 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 endoscope must be connected to the AquaTYPHOON™ using the provided connection set and according to the recommendations of PlasmaBiotics. Modification of the connection set is prohibited and voids warranty.

9.2 ENDOSCOPE CONNECTION SETS

Endoscope connection sets are used to connect endoscopes to the AquaTYPHOON™ in order to perform the cleaning of endoscope channels. The corresponding 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 AquaTYPHOON™ using the provided connection sets and according to the recommendations of PlasmaBiotics. Modification of the connection sets is prohibited and voids warranty.

9.3 MAINTENANCE OF CONNECTION SETS

All parts of the outer surface of the connection sets must be cleaned and disinfected after each cycle using a surface-disinfectant. Use a lint-free cloth or gauze slightly moistened with surface-disinfectant or a ready to use disinfectant wipes to clean and disinfect the AquaTYPHOON™ connection sets. Please, refer to the disinfectant 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.

If possible, at the end of the day, perform a full cleaning and disinfection of the connection sets or a sterilization in an autoclave (see Annex I), following the internal hospital's requirements and procedures. After this step, the connection sets must be stored under clean, dust-free and dry conditions. PlasmaBiotics products PlasmaTYPHOON or PlasmaTYPHOON+, and PlasmaBAG can be used for this purpose.

It is recommended to sterilize the connection sets at least once a month. Disinfection and sterilization shall always be performed after the annual maintenance and/or after replacing the O-rings or other parts of the connection sets.

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.

Warning: Before every connection, always inspect the connection set on damages or deviations. Connection sets with damages or deviations shall never be used, as this may lead to inefficient cleaning of the endoscope.

In the event of intensive use of the connection set, or if required due to a hard connection to the AquaTYPHOON™, 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 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. SAFETY INSTRUCTIONS: RISKS AND PRECAUTIONS

10.1 RISK OF ELECTRIC SHOCK AND ELECTROMAGNETIC FIELD

AquaTYPHOON™ is connected to the electrical power supply (electrical network). When running/operating, all the electrical components are at a certain voltage, representing a high risk of electric shock.

 **Warning:** AquaTYPHOON™ should be completely closed when running/operating. Do not open the device without prior authorization from PlasmaBiotics.

 **Warning:** AquaTYPHOON™ emits electromagnetic waves and may interfere with other electronic 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.

10.2 IN THE EVENT OF A SERIOUS INCIDENT

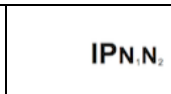
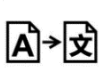
 **Warning**: Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the EU member state in which the user and/or patient is based.

11. GENERAL INFORMATION

11.1 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

11.2 REGULATIONS & STANDARDS

Comply with the following regulations and standards:
Regulation (EU) 2017/745 on medical devices
IEC 61010-1: 2017
IEC 61326-1:2021
EN ISO 15883-4 :2018
EN ISO 15883-5 :2021
EN ISO 15223-1:2021

CE

12. ANNEX I – MAINTENANCE OF CONNECTION SETS

12.1 INTRODUCTION

AquaTYPHOON™ connection sets are manipulated all day long and successively connected to different endoscopes. Due to the fact that they are used on contaminated endoscopes, it is highly recommended to take precautions in order to avoid any potential cross-contamination, following the procedures described in this manual.
As stated in section 9.3, the surface of the connection sets shall be cleaned and disinfected after each cycle using a surface-disinfectant.
In addition, it is highly recommended to perform a complete disinfection or sterilization of the connection sets at the end of the day, as well as after the annual maintenance or after replacing the O-rings or other spare parts on the connection sets.

12.2 CLEANING AND DISINFECTION PROCEDURE

AquaTYPHOON™ connection sets can be cleaned and disinfected manually following the procedure indicated below. Alternatively, cleaning and disinfection of the connection sets can also be carried out in an AER, if the process has been previously validated.

Manual cleaning and disinfection of the connection sets shall be done in a clean disinfected tray or sink. The procedure consists in cleaning and disinfecting the connection set using a detergent and disinfectant solution (low level disinfection).

- ✓ For detergent and disinfectant concentration, contact time and temperature, please, follow the detergent/disinfectant manufacturer's instructions.
- ✓ Staff shall use personal protective equipment when performing cleaning and disinfection of the connection sets.

Step-by-step cleaning procedure:

1. Prepare the detergent solution in a clean disinfected tray or sink
2. Immerse the connection set(s) in the detergent solution
3. Use a new clean single use syringe to irrigate the tubes with a detergent 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 detergent solution
6. Use a syringe with air to purge detergent solution from the tubes, 100 ml/tube
7. Drain the tray or sink
8. Rinse the tray or sink of detergent solution and fill it with clean filtered (microbiologically controlled, at least drink water quality) water
9. Immerse the connection set in the clean rinse water
10. Use the syringe from step 6 to irrigate the tubes with 100 ml of clean water in order to rinse each tube
11. Purge all water from the tubes

Step-by-step disinfection procedure:

1. Prepare the disinfectant solution in a clean disinfected tray or sink
2. Immerse the connection set(s) in the disinfectant solution
3. Use a new clean single use syringe 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 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, at least drink water quality) water

9. Immerse the connection set in the clean rinse water
10. Use the syringe from step 6 to irrigate the tubes with 100 ml of clean water in order to rinse each tube
11. Purge all water from the tubes
12. Use a lint-free gauze to wipe the external surfaces to remove any remaining disinfectant solution

Note: In case that a detergent-disinfectant solution in used, cleaning and disinfection are completed in one procedure instead of two. Please, follow all steps as described above, with the use of a detergent-disinfectant solution.

12.3 DRYING OF THE CONNECTION SETS

After disinfection, connection sets must be dried. PlasmaTYPHOON or PlasmaTYPHOON+ can be used for this purpose. The procedure is indicated below.

Step-by-step procedure:

1. Depending on the number of tubes of each connection set 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
4. Use the airgun and/or new clean lint-free cloth or gauze 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

12.4 STERILIZATION

As stated in section 9.3, AquaTYPHOON™ connection sets can be sterilized using an autoclave. Sterilization parameters are indicated in the table below. However, please, follow the requirements of your health center to ensure adherence to local guidelines and regulations.

Sterilization	**Treatment**	Pre-vacuum
	Temperature	132–134°C (270–274°F)
	Exposure time	5 minutes (refer to national guidelines)

13. ANNEX II – TYPHOONBOX

TyphoonBOX is specially designed box to provide protection to the user and surrounding environment from splashing and spattering with contaminated water during the endoscope cleaning process. TyphoonBOX shall be placed on top of the sink, and the endoscope placed inside can be entirely cleaned, externally and internally, using the AquaTYPHOON™ system without excessive splashing.

13.1 INSTALLATION OF TYPHOONBOX

TyphoonBOX shall be installed as a part of AquaTYPHOON™ system during the installation process. TyphoonBOX is provided with:

- Color-coded tubings (red, blue, white) intended to connect TyphoonBOX to AquaTYPHOON™ (green and transparent tubings are connected directly to AquaTYPHOON™ device)
- Adjustable feet
- Draining tube

TyphoonBOX shall be placed on top of the sink and its feet shall be adjusted to the width of the sink. AquaTYPHOON™ unit and peripheral devices (printer, barcode or RFID scanner) shall be placed next to the respective sink (on left-hand or right-hand side). TyphoonBOX shall be then connected to AquaTYPHOON™ via the color-coded tubings. Finally, draining tube connected to the bottom of the TyphoonBOX is intended to drain the contaminated water from the TyphoonBOX into the sink.

See the document “PB-QUG_C16-002_v01_EN_TyphoonBOX_Installation instructions” for detailed instructions on TyphoonBOX installation.

13.2 INSTRUCTIONS FOR USE

When TyphoonBOX is used in combination with AquaTYPHOON™ system, the entire process including leak test and cleaning of the endoscope shall be performed inside the box. Step-by-step procedure is indicated below.

1. Before starting the procedure, the user shall make sure that the internal surface of TyphoonBOX and the connection set to be used are clean (see Section 13.3).
2. User connects the selected connection set to the TyphoonBOX. If preferred, the user has the possibility to carry out this task in the step 8.
3. User places the endoscope in the TyphoonBOX, turning its control body closer to the AquaTYPHOON™ (see Figure 32)

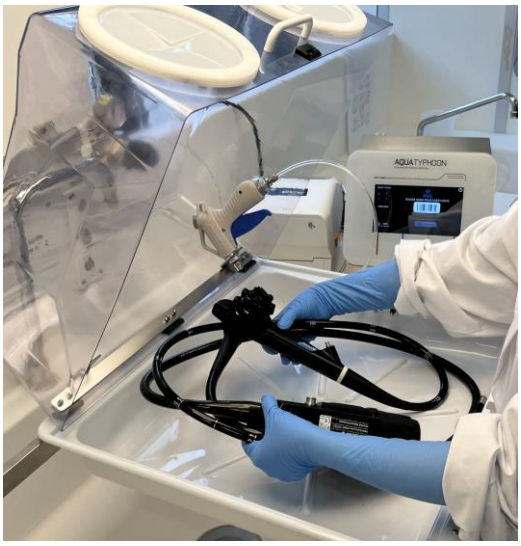


Figure 32. Placing the endoscope in the TyphoonBOX

4. User identifies himself and the endoscope using barcode or RFID scanner and selects the cycle to be performed (see Sections 5.2 and 5.3)
5. User connects the leak test adapter (green tubing) to the endoscope and to AquaTYPHOON™ and runs the LEAK TEST. While the leak test is running, the user must slowly turn the left/right, up/down knobs in order to detect major leakages. This step can be performed in open or closed TyphoonBOX (see Figure 33).

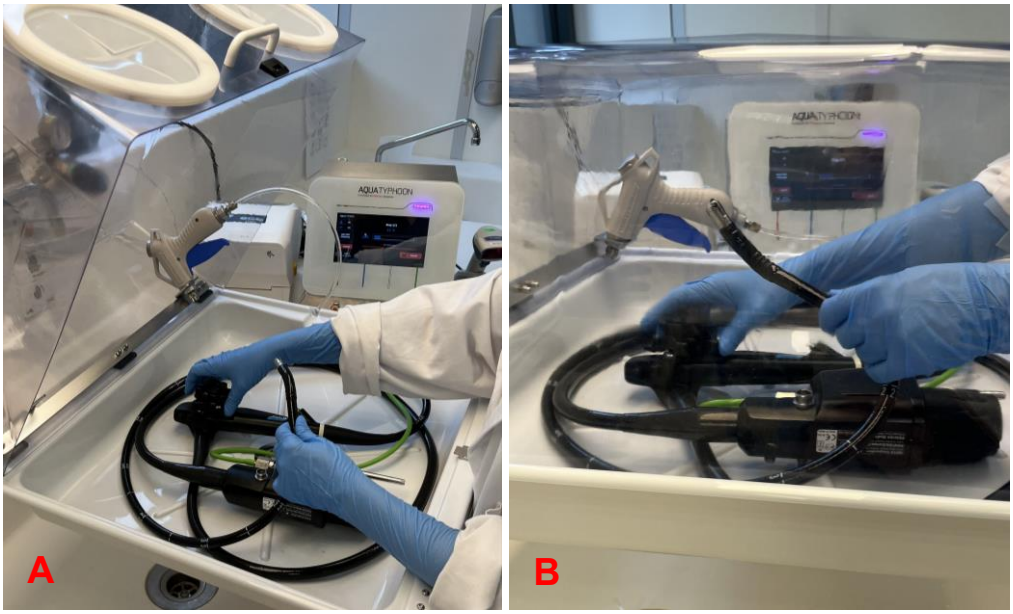


Figure 33. Performing leak test on the endoscope in the TyphoonBOX (A: open box, B: closed box)

6. Once the leak test is done, the user closes the TyphoonBOX (if it is not previously done) and starts the CLEANING CYCLE. Leak test adapter shall remain connected to the endoscope.
7. User cleans the external surface of the endoscope using the AquaJET inside the TyphoonBOX (see Figure 34), paying attention to the channel inlets, scope body and distal end.

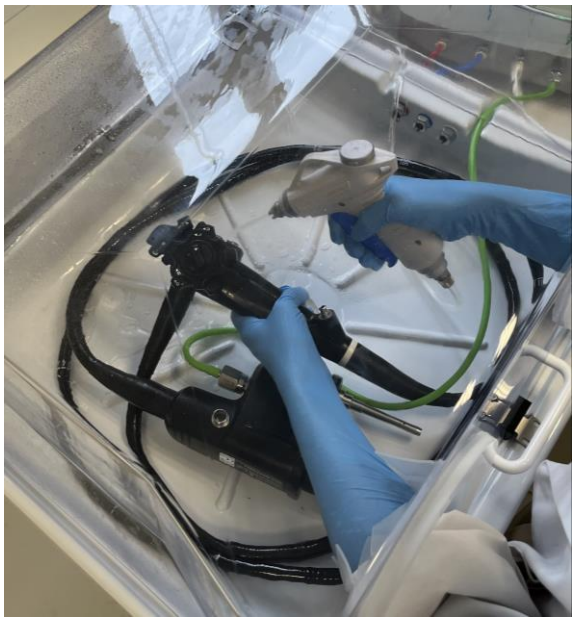


Figure 34. Cleaning the external surface of the endoscope using AquaJET

8. User connects the connection set to the endoscope inside the TyphoonBOX (see Figure 35). This step can be performed in open or closed TyphoonBOX.

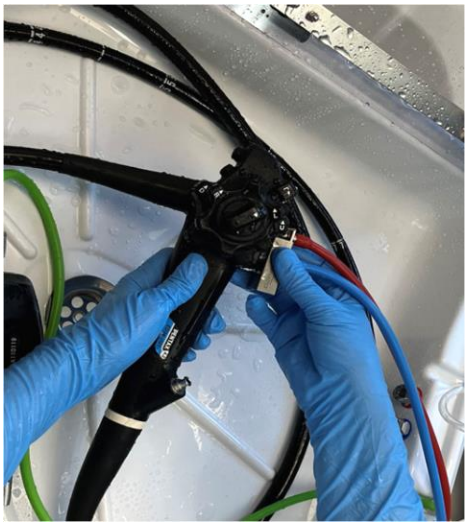


Figure 35. Connecting the connection set to the endoscope inside the TyphoonBOX

9. If possible, place the endoscope like in the picture below (Figure 36): The control body shall be placed close to the connection port side, distal end and suction port facing to the back of the box. This placement will prevent splashing towards the user.

Figure 36. Endoscope placement in the TyphoonBOX

10. User starts the automated cleaning cycle of endoscope channels (see Figure 37). While the automated cleaning cycle is running (duration: 2 to 10 minutes depending on the endoscope type), the user may take care of other tasks in the reprocessing unit.

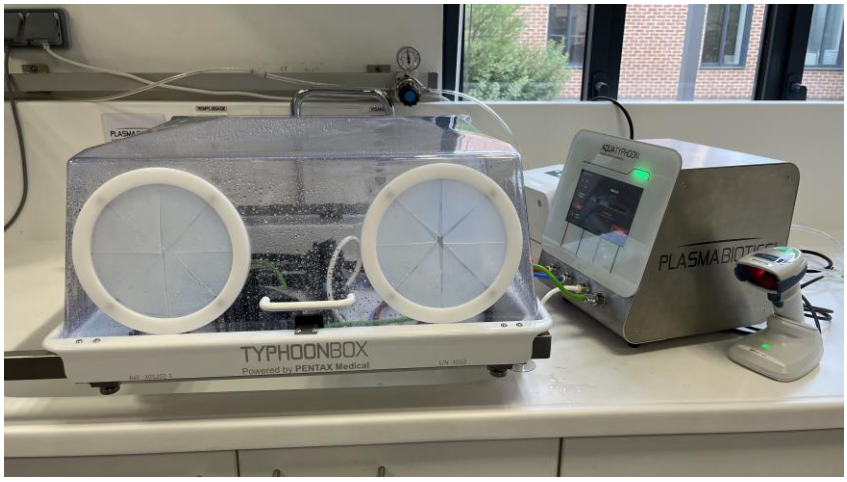


Figure 37. Automated cleaning cycle running

11. Once the automated cleaning cycle is done, the user shall disconnect the connection set from the endoscope and perform the final external surface cleaning of endoscope using the AquaJET.
12. Once the cleaning cycle is done, the user shall disconnect the leak test adapter, open the TyphoonBOX, take the endoscope out of the box and place it into the AER for the next step of the reprocessing cycle.
13. Finally, the user cleans and disinfects the used connection sets (see Section 9.3). AquaJET can be used to remove any remaining soil from the internal surface of the TyphoonBOX.

13.3 MAINTENANCE OF TYPHOONBOX

TyphoonBOX shall be cleaned and disinfected after each endoscope treatment using a lint-free cloth or gauze slightly moistened with surface-disinfectant or a ready to use disinfectant wipe, if this indication exists in the national guidelines or regulations referring to the sink in which endoscope was treated.

TyphoonBOX shall be also surface disinfected every evening. Pay attention to the internal surface in contact with the endoscopes, but also to the cover and the external surfaces. The user shall follow the instructions of the surface-disinfectant manufacturer. The TyphoonBOX shall be cleaned until all visible soil is removed. Step-by-step procedure is indicated below:

- Put some surface-disinfectant on the single-use lint free cloth or gauze
- Clean the external surface of the top cover and bottom of the TyphoonBOX
- Clean the handle
- Clean the hand ports
- Clean each connecting tube and the U-Slits
- Clean the internal surface of the top cover of the TyphoonBOX
- Clean the internal surface of the bottom of the TyphoonBOX
- Clean the CPC connectors, the U-Slits (including the O-rings if present) and the orifice blocker on the other side
- Clean the feet and the draining tube of the TyphoonBOX

Put 50ml of disinfectant into the draining tube and wait the indicated contact time before rinsing.

14. ANNEX III – AQUAJET PROTOCOL

Wearing gloves and other personal protective equipment (PPE) is mandatory when handling an endoscope, in particular a contaminated endoscope, following the instructions provided by the relevant hospital department.

Pay attention NOT to obstruct any endoscope channel inlet or outlet during the cleaning process.

Step-by-step protocol of external cleaning of endoscope using AquaJET:

1. Place the endoscope inside the TyphoonBOX or in the sink. Turn the endoscope so that its control body is placed closer to the AquaTYPHOON™ (see Figure 38). It will be easier to handle the endoscope during the cleaning process.

Figure 38 Placing the endoscope in the TyphoonBOX.

2. If the endoscope is very contaminated, i.e. if visible soil is detected on the endoscope surface, clean the endoscope by wiping the endoscope insertion tube twice using a humid wipe or lint-free cloth, paying particular attention to the dirty area.

3. Follow step-by-step the instructions for use of AquaTYPHOON™ until reaching the Initial external cleaning step using AquaJET.

4. Once the Initial external cleaning with AquaJET is initiated, follow the instructions indicated in the central area of the touchscreen. Different steps of the procedure are indicated in RED on the touchscreen, and each of these steps is illustrated in the photos (see Figure 39) and described in detail below.

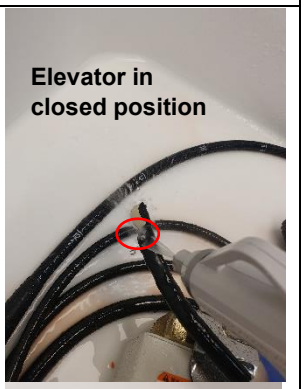
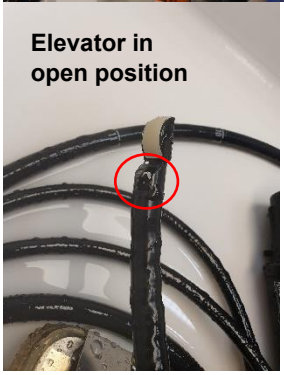
CHANNEL INLETS	SCOPE BODY	DISTAL END	ELEVATOR
			
			

Figure 39 Different steps of the cleaning procedure with AquaJET

Channel inlets and outlets cleaning

Thorough cleaning of each endoscope channel inlet and outlet listed below is mandatory during both Initial and Final external cleaning of endoscope using AquaJET, until no visible soil is detected or for a minimal duration of 5 seconds per inlet/outlet:

- Suction cylinder
- Air/water cylinder
- Biopsy channel inlet
- Auxiliary channel inlet
- Suction connector
- Air/water connector

Scope body cleaning

Clean the entire insertion tube, video box, control body, control knobs, levers, the space between the control wheels of the endoscope until no soil is visible or for a minimal duration of 20 seconds. If necessary, use the AquaJET to expel any dirt/soil between the knobs, levers and the control body.

Distal end cleaning

Hold the distal end so that it doesn't move (it can be held in one hand). Clean the distal end by slow movements of the AquaJET along the insertion tube end (Figure 40a). Then rotate the distal end by 120° and repeat the cleaning process in the same manner (Figure 40b). Finally, sweep the surface of the distal

end with the AquaJET (Figure 40c). Continue the cleaning until no soil is visible or for a minimal duration of 10 seconds.

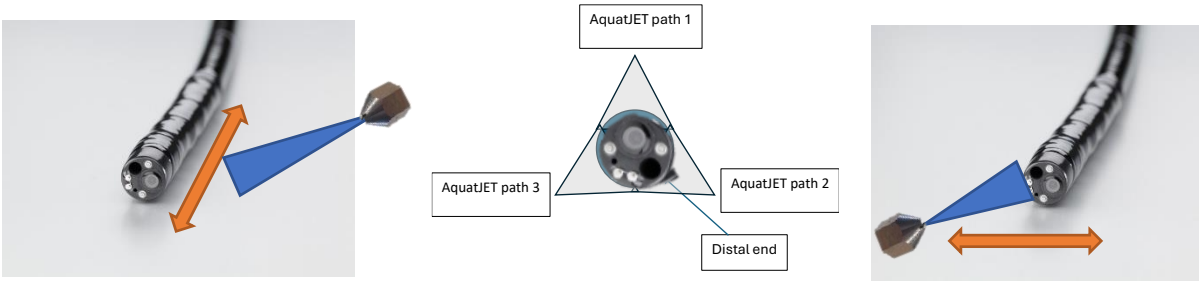


Figure 40 Distal end cleaning with AquaJET: along the insertion tube end (a), other side of the insertion tube end (b), distal end surface (c).

Elevator cleaning

In case the endoscope has an elevator, the operator shall pay particular attention to the cleaning of the elevator area, when cleaning the distal end. In addition to the steps shown in Figure 40a and Figure 40b, following procedure shall be employed:

- Place the elevator in the open position and sweep the surface with the AquaJET, extensively cleaning the elevator area (Figure 41a)
- Place the elevator in the closed position and sweep the surface with the AquaJET, extensively cleaning the elevator area (Figure 41b)
- Place the elevator again in the open position and sweep the surface with the AquaJET, extensively cleaning the elevator area (Figure 41c)
- Sweep the surface of the entire distal end area with the AquaJET (Figure 41d).

Conduct the cleaning until no soil is visible or for a minimal duration of 10 seconds.

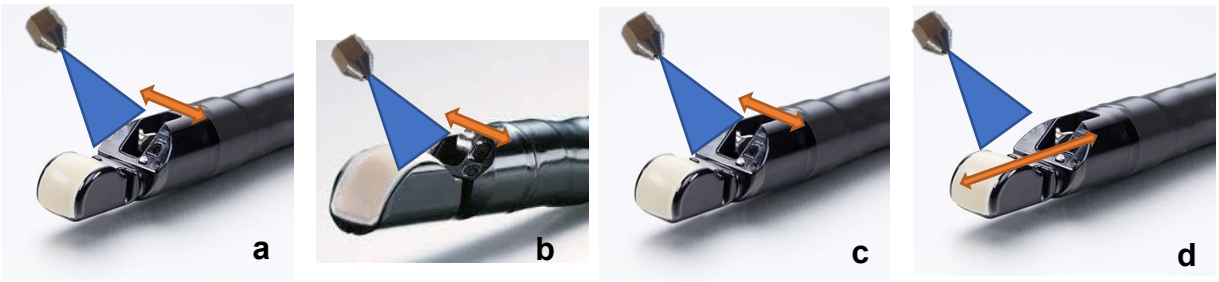


Figure 41.Elevator cleaning with AquaJET: elevator in low (open) position (a), elevator in high (closed) position (b), elevator in low (open) position (c) cleaning of the entire distal end area (d).

5. Once the cleaning steps have been completed and no trace of dirt/soil is visible, click on the "OK" button on the touchscreen to go to the next step.

6. After the Automated endoscope channels cleaning step, repeat again step 4 in scope of the Final external cleaning of the endoscope. In case the endoscope is particularly soiled, slightly lift the endoscope inside the TyphoonBOX or sink, clean the bottom of the TyphoonBOX or sink using the AquaJET and then place the endoscope back returning it to the opposite side (upside down). Then repeat again the step 4.

Note: AquaJET can also be used to clean endoscope valves. A protocol of cleaning endoscope valves using AquaJET is given below. This protocol can be applied to various valve geometries using the same principle: thorough cleaning paying particular attention to specific areas (holes, springs, joints, etc.) and rotating the valve by 360º. Valves shall be cleaned using AquaJET until no visible soil is detected.

1. Move the AquaJET up and down (from the bottom to the tip of the valve) on one side as shown in the Figure 42. Do not forget to clean inside the holes (if applicable). An average time of 5 seconds is necessary. The valve needs to be rotated by 120° twice to completely clean the valve.	 *Figure 42. Side valve cleaning*
2. Clean the tip of the valve for 5 seconds as shown in the Figure 43.	 *Figure 43. Valve tip cleaning*
3. Press the valve button and proceed as described in step 1: move the AquaJET up and down and clean the valve from the bottom to the top for 5 seconds (as shown in the Figure 44). The valve needs to be rotated by 120° twice to completely clean the valve.	 *Figure 44. Bottom valve cleaning*
4. Hold the valve by the tip and clean the valve as described in step 1 for 3 seconds (as shown in the Figure 45). The valve needs to be rotated by 120° twice to completely clean the valve.	 *Figure 45. Valve tip cleaning*
5. Clean the hole of the valve for 5 seconds as shown in the Figure 46.	 *Figure 46. Valve hole cleaning*

The cleaning times given above are indicative. The overall cleaning time depends on the length and geometry of the valves, as well as their degree of soiling.

15. ANNEX IV – AQUATYPHOON™ MAINTENANCE CYCLE

At least once a year, trained technician shall carry out the maintenance cycle of AquaTYPHOON™, in order to clean the internal water circuit of the device. This process is included in the annual maintenance procedure of the AquaTYPHOON™ device. For this purpose, the technician shall use AquaTYPHOON™ maintenance kit (Figure 47), that contains a syringe with a PTFE tube and CPC connector, as well as a bag of citric-acid based cleaner.

Figure 47. AquaTYPHOON™ maintenance kit

Wearing gloves and other personal protective equipment (PPE) is mandatory when handling AquaTYPHOON™ maintenance kit, and in particular citric acid-based cleaning solution, following the instructions provided below.

Step-by-step maintenance cycle protocol:

1. Deactivate air and water minimal pressure alarm in the Settings/Alarms (see Figure 48).

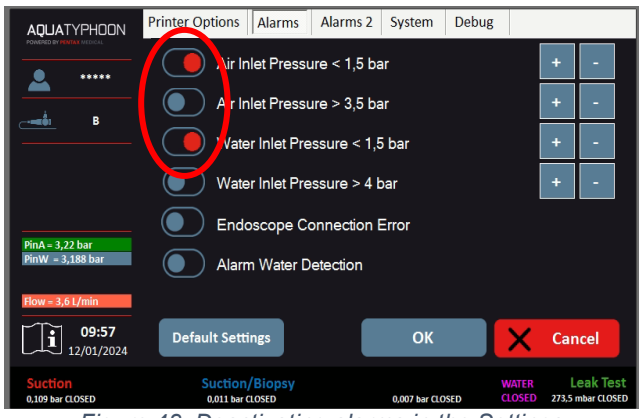


Figure 48. Deactivating alarms in the Settings

2. Via the touch screen, select CARE Maintenance button to go to “Prepare for Maintenance” page (see Figure 49).

Figure 49. Prepare for maintenance page

3. Close air and water supply (ex. close the tap) and disconnect the air and water supply tubes from air and water inlets at the back of the AquaTYPHOON™ device (see Figure 50).

Figure 50. Disconnecting air and water supply tubes

4. Connect any three-colored connection set to the RED, BLUE and WHITE front outlets of the AquaTYPHOON™ device (see Figure 51).

Figure 51. Three-colored connection set connected

5. Dilute the content of the bag (citric acid-based cleaner in powder) provided in the AquaTYPHOON™ Maintenance kit (Figure 47) into 0.5 liters of lukewarm water. Stir for a few seconds for faster dilution.
6. Fill the syringe with 50 ml of the prepared solution. Install the provided CPC connector on the syringe.
7. Start AquaTYPHOON™ Maintenance cycle by pressing OK button on the touch screen (see Figure 49)
8. Connect the CPC connector mounted on the syringe tip to the water inlet (WATER IN) at the back of the AquaTYPHOON™ device and irrigate the prepared solution into the AquaTYPHOON™ device during the first 45 seconds of the cycle (see Figure 52). The solution shall be coming out of the tubings connected to the front outlets of the device. If needed, repeat the solution irrigation process.
9. Cycle counts down the contact time (around 15 min)
10. When indicated on the screen (Figure 53) reconnect air and water supply tubes to the backside of AquaTYPHOON™ device (Figure 54)
11. Open air and water supply and click OK button on the touch screen to proceed (Figure 53)
12. At the end of the maintenance cycle, reactivate air and water minimal pressure alarm (Figure 48)

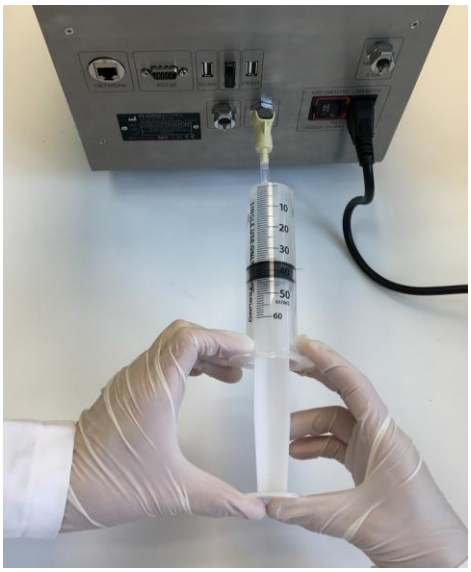


Figure 52. Irrigation of prepared solution into AquaTYPHOON™ device

Figure 53. Pause for reconnection of air and water supply

Figure 54. Reconnecting air and water supply tubes

MANUFACTURER & SERVICE


Manufacturer

PLASMABIOTICS SAS
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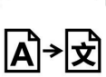
95100 Argenteuil, FRANCE
www.plasmabiotics.com

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