PLASMABIOTICS®

IN ASSOCIATION WITH **PENTAX MEDICAL**

Technical Manual for User

AquaTYPHOON™

Technical Manual for User

Advanced unit for fast and effective cleaning of endoscopes

PENTAX MEDICAL

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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 pre-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 pre-cleaning of endoscopes (with brushes and detergent), offering higher performance, improved comfort of use, increased security, full traceability and more sustainability.

This manual includes various technical instructions related to AquaTYPHOON™ system. It is intended for biomedical engineers and technicians of the healthcare institution, as well as for distributor's field technicians and application specialists. This manual provides installation instructions (including configuration of peripherals), describes settings options, access to the ENDO database, access to the recorded traceability data and instructions for connection to the hospital network. In addition, maintenance instructions and recommendations are also provided. It is highly recommended to read this manual carefully before any technical intervention on the AquaTYPHOON™ system.

2. INDICATION

2.1. INTENDED USE AND PERFORMANCE

AquaTYPHOON™ is used for endoscope pre-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 pre-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 7 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 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. The history database containing all completed 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 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 AquaTYPHOON™ is intended for operation in hospitals as an active cleaning system. 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 healthcare operators.

2.3. INTENDED USE AND BENEFIT

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

2.4. CONTRA-INDICATION

Warning: PlasmaBiotics does not warrant the correct functioning of the AquaTYPHOON™ without the validated connection sets. 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™**	
UDI ID	UDI	03701354420113	03701354420106
Medical device	MD	**Class I**	
Power supply / electrical network		100-130 V	200-240 V
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 (58.02 psi)	
Minimal gas flowrate		70 l/min	
Minimal water inlet pressure		3 bar (43.51 psi)	
Maximal water inlet pressure		4 bar (58.02 psi)	
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	IPX2	

3.2. MATERIALS AND SUBSTANCES

COMPONENT	Abr	MATERIALS / SUBSTANCES
Box	SS	Stainless Steel
Connection set		Silicone and Stainless Steel
Air 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 efficiency 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 electrical 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.

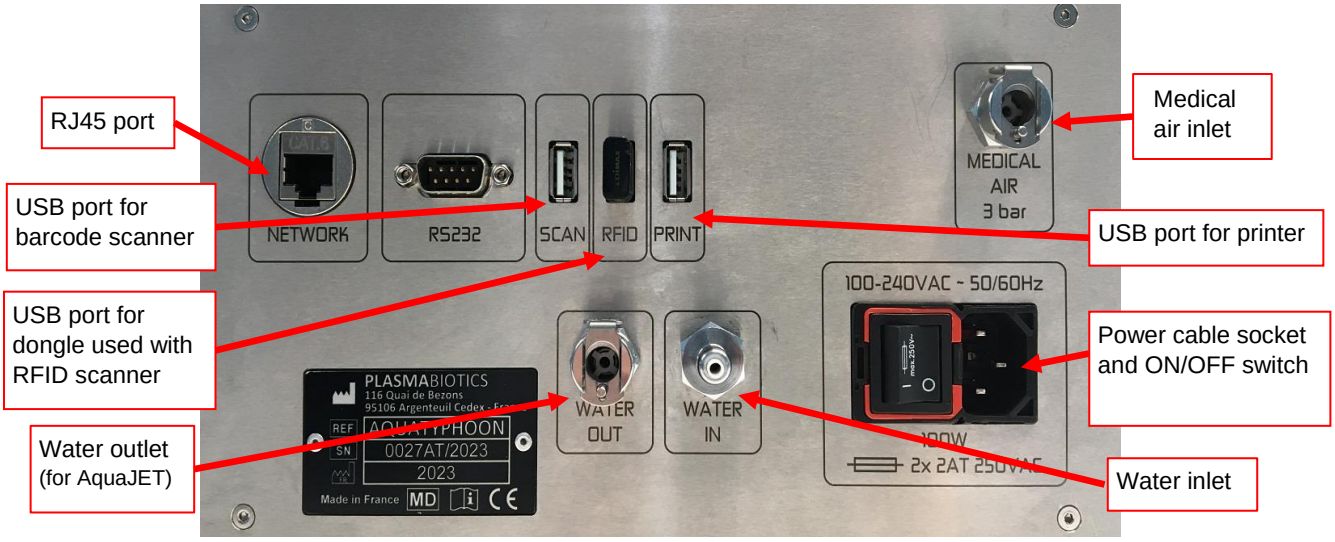


Figure 2. Rear of AquaTYPHOON™ device

Warning:

The medical air supplying the AquaTYPHOON™ must be free from contamination and must be of a purity class according to local regulation. The vapour water concentration must be less than 67 ml/m3.
1. The AquaTYPHOON™ must not be operated, if the water vapour concentration is above 67 ml/m3.
2. 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 & 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 (58.01 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.

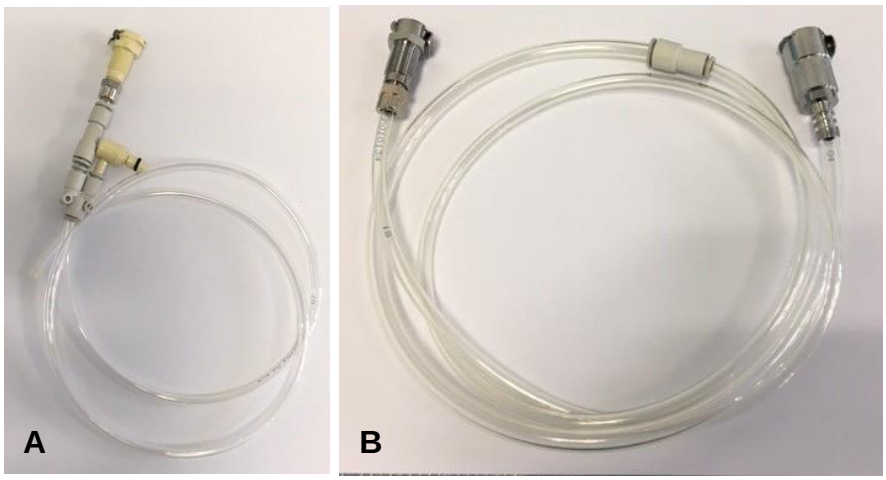


Figure 3. Air supply tube (A) and water supply tube (B).

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 10.4).

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 4). 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 Ethernet port at the rear of the device.

4.6.1. Printer connection

Printer needs to be connected to the AquaTYPHOON™ via the provided USB cable that shall connect the corresponding UBS port at the rear of the printer to the USB port named “PRINT” at the rear of the AquaTYPHOON™ (see Figure 5). Once connected and powered, the printer shall be configured with the AquaTYPHOON™ (see Section 5).

Figure 5 Connecting the printer to AquaTYPHOON

4.6.2. Barcode scanner connection

Barcode scanner or barcode scanner’s base (in case of wireless barcode scanner) needs to be connected to the AquaTYPHOON™ via the provided connection cable that shall connect the corresponding USB port on the scanner or scanner’s base to the USB port named “SCAN” at the rear of the AquaTYPHOON™ (see Figure 6). Once connected and charged, barcode scanner shall be configured (see Section 5).

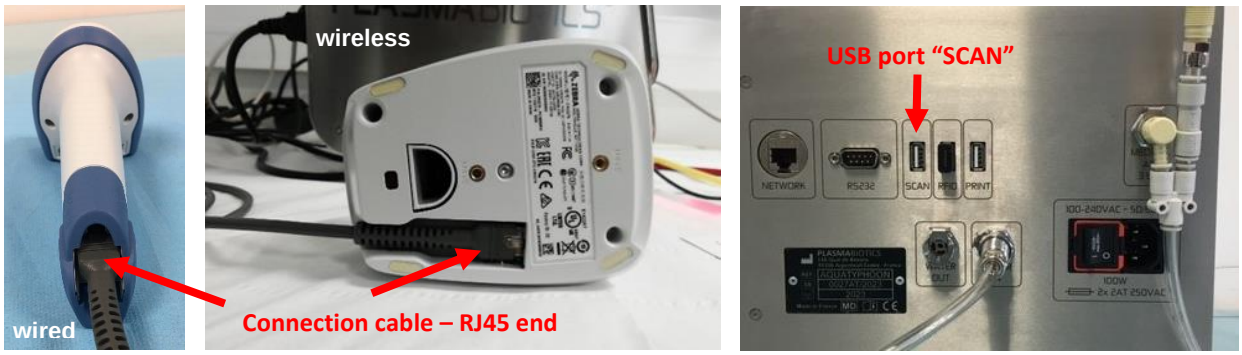


Figure 6 Connecting wired and wireless barcode scanner to AquaTYPHOON™

4.6.3. RFID scanner connection

RFID scanner is connected to the AquaTYPHOON™ via a Bluetooth dongle installed on the USB port named “RFID” (see Figure 7). Once the RFID scanner is charged (via its power charger), it shall be paired with AquaTYPHOON™ (see Section 5).

Figure 7 Bluetooth dongle connection and power charger of the RFID scanner

4.6.4. Network connection

AquaTYPHOON™ can be connected to the local network and/or internet via the Ethernet (RJ45) port at the rear of the device (see Figure 2). This connection enables access to the recorded traceability data i.e. history of all performed cycles, temporarily stored on the AquaTYPHOON™ hard drive - in the file named “REPORT” in the folder named “History”.

Note: This recording is not an archive. It is hospital’s / clinic’s responsibility to store and archive these data in their own data storage system.

4.7. AIR/WATER OUTLETS AT THE FRONT

AquaTYPHOON™ has three air/water outlets and one air outlet at the front (see Figure 8) identified by colour code. Red, blue and white outlet 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.

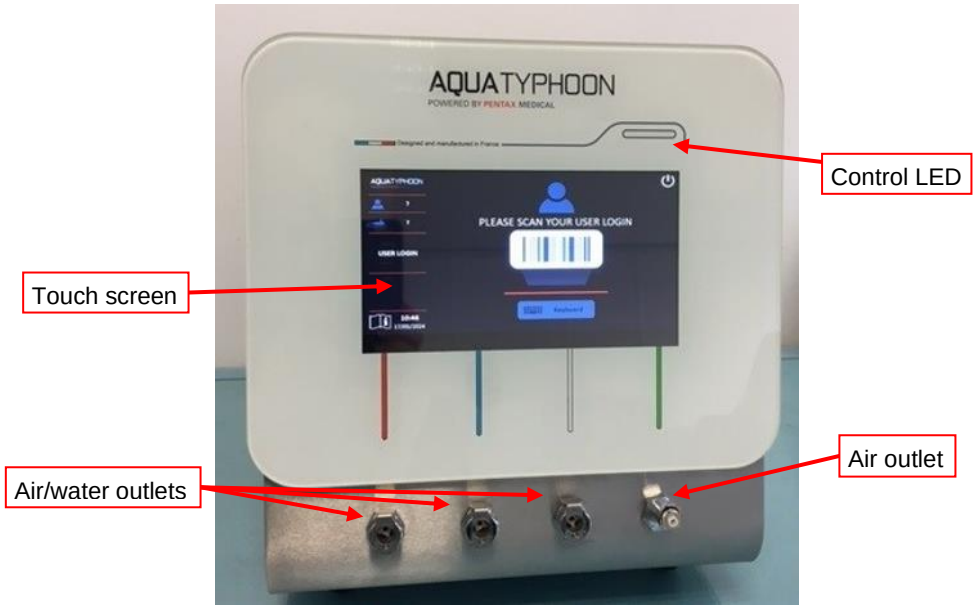


Figure 8. Front of AquaTYPHOON™ device

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 8).

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

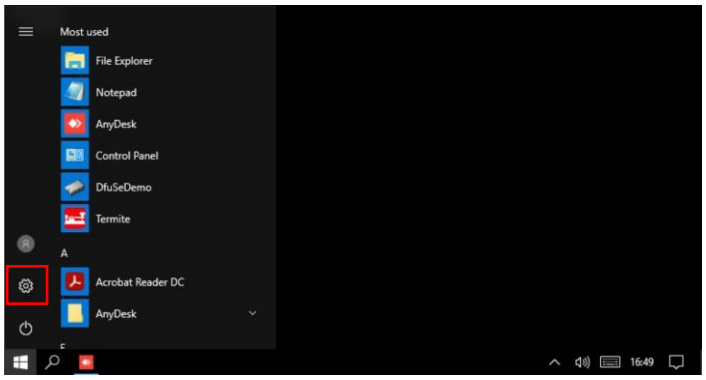
Please refer to the relevant regulations or guidelines in your country.

5. CONFIGURATION OF PERIPHERAL DEVICES

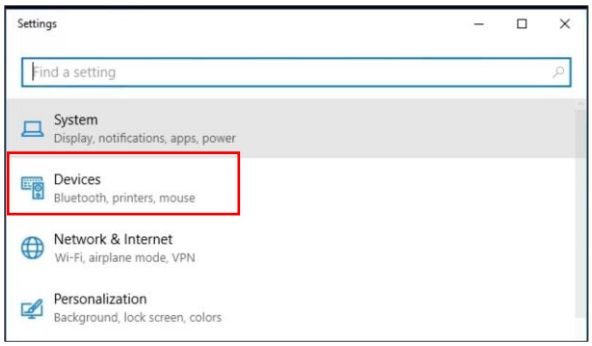
Peripheral devices i.e. printer, barcode scanner and RFID scanner, need to be configured and/or paired with AquaTYPHOON™. Once that all peripheral devices are charged and connected to the corresponding USB ports at the rear of the AquaTYPHOON™ (see Figure 2), one can start the configuration/pairing procedure.

5.1. PRINTER CONFIGURATION

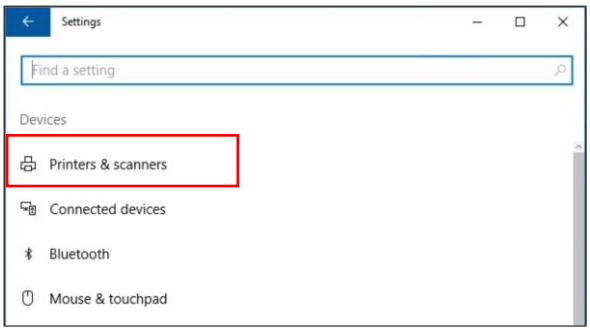
1. Switch ON the printer
2. Switch ON the AquaTYPHOON™
3. Click on USER symbol to access the User Login page
4. Login as: *ESCAPE* (to exit the software)
5. Click on Windows logo  , and then on Settings 



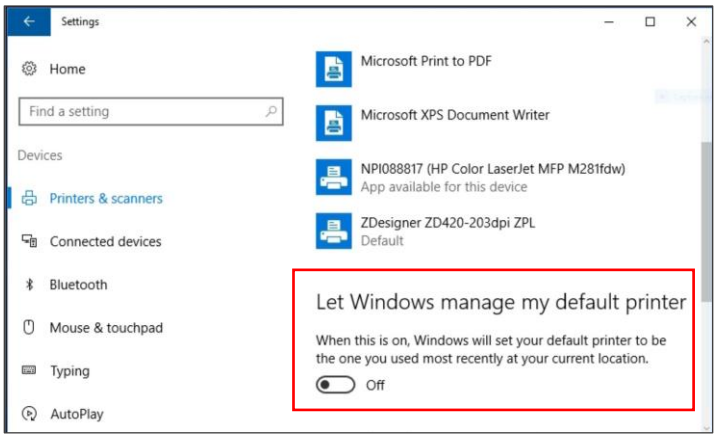
6. Click on “Devices”



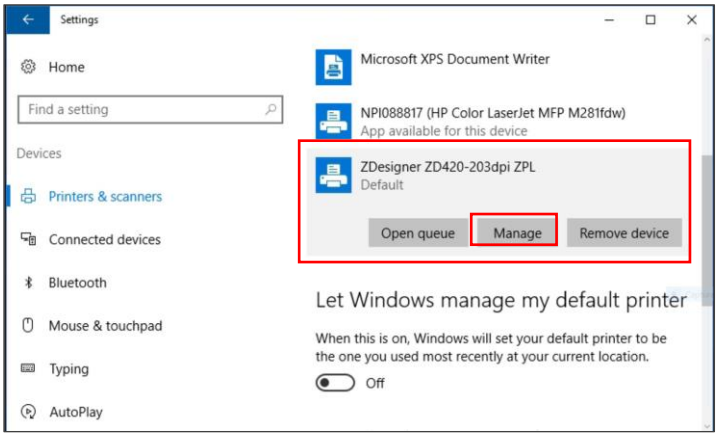
7. Click on “Printers and scanners”



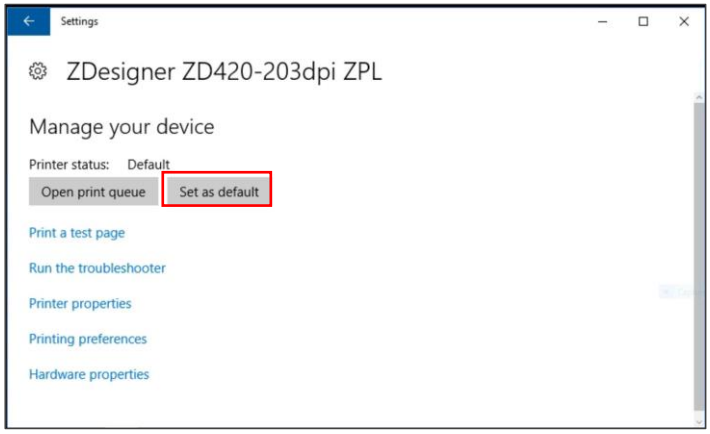
8. Deactivate the option « Let Windows manage my default printer”



9. Click on the printer « ZDesigner ZD420-203dpi ZPL », and then on “Manage”

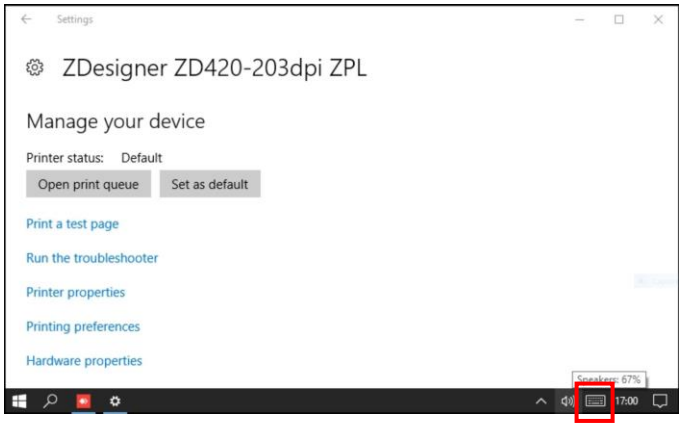


10. Set it as default printer by clicking “Set as default”

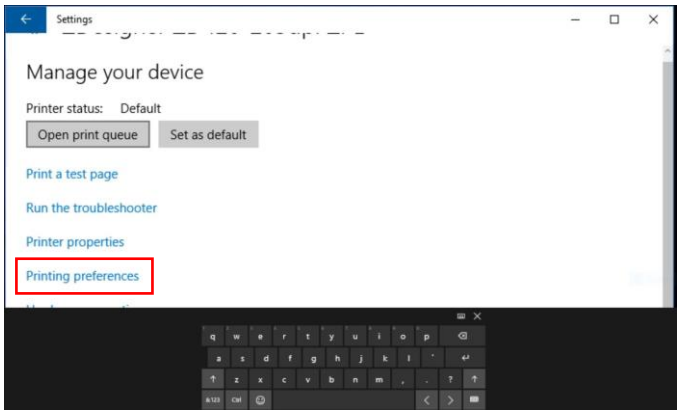


11. Click on “Print a test page” and check if the printer printed out a test page.

12. Open the computer keyboard here



13. Click on “Printing preferences”



14. Depending on the driver version installed in the printer, one may obtain different pop-up window display/interface when clicking on “Printing preferences”.

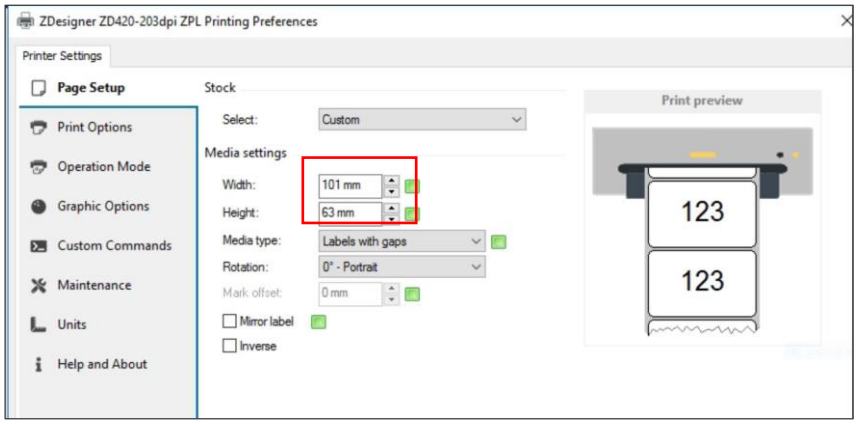
Case 1

If the “Printing preferences” pop-up window display corresponds to the image below, follow these instructions:

Enter the following **Media settings** in **mm** using the keyboard:

- **Width : 101 mm**
- **Height : 63 mm**

Then press “Enter” on the keyboard.

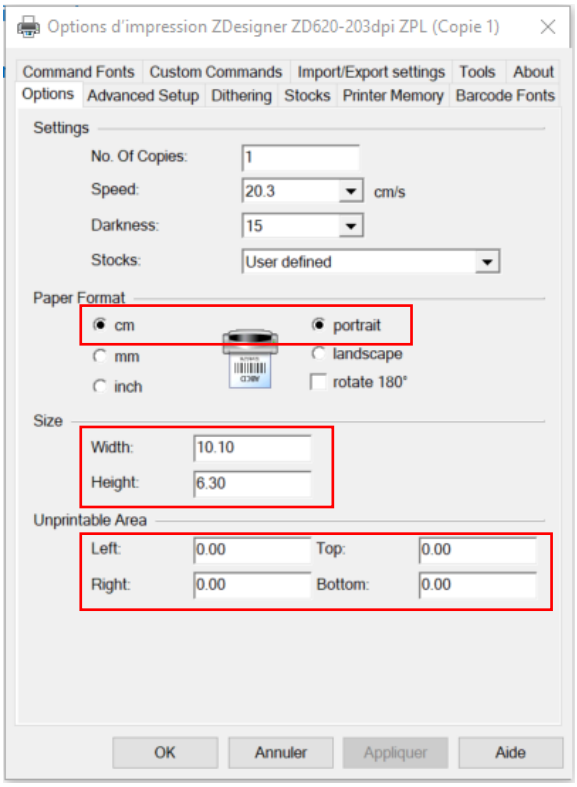


Case 2

If the “Printing preferences” pop-up window display corresponds to the image below, follow these instructions:

1. Make sure “**cm**” units and “**portrait**” are selected in the **Paper format** section
2. Enter the following paper **Size** settings in **cm** using the keyboard:
   - **Width: 10.10 cm**
   - **Height: 6.30 cm**
3. Make sure that all settings of **Unprintable Area** are set to **0.00**

Then click OK or press “Enter” on the keyboard.



15. Reopen “Printing preferences” to check if the introduced parameters have been saved
16. Start the AquaTYPHOON™ software (by clicking the icon on the desktop or the application in C:\AquaTYPHOON™\AquaTYPHOON™.exe)
17. Run a leak test cycle and check if all data on the printed traceability label are correct

5.2. BARCODE SCANNER CONFIGURATION

In case of wireless barcode scanner, the scanner’s base shall be connected to the AquaTYPHOON™ via a corresponding USB cable. In case of non-wireless barcode scanner, the scanner shall be directly connected to the AquaTYPHOON™ via a corresponding USB cable.

1. Switch ON the AquaTYPHOON™
2. Place the (wireless) barcode scanner on its base and let it charge for a while
3. Use the barcode scanner to scan the ***Set Defaults*** barcode in the Quick Start Guide provided with the barcode scanner:

Return to Factory Defaults

4. Place the (wireless) barcode scanner on its base and let it validate the configuration
5. Use the barcode scanner to scan the ***Add An Enter Key*** barcode in the Quick Start Guide provided with the barcode scanner:

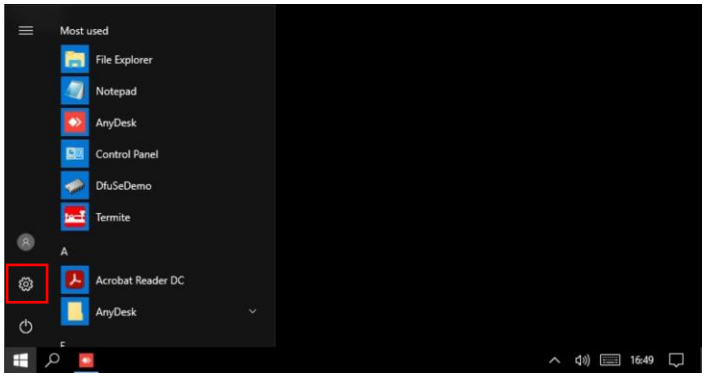
Add Enter Key (Carriage Return/Line Feed)

6. Place the (wireless) barcode scanner on its base and let it validate the configuration
7. Start the AquaTYPHOON™ software (by clicking the icon on the desktop or the application in C:\AquaTYPHOON™\AquaTYPHOON™.exe)
8. Click on USER symbol to access the User Login page
9. Scan a random user's barcode and check if the user's name or number is displayed on the screen next to the USER symbol
   Note: This test can also be done by accessing the Endoscope identification page and scanning a random endoscope barcode

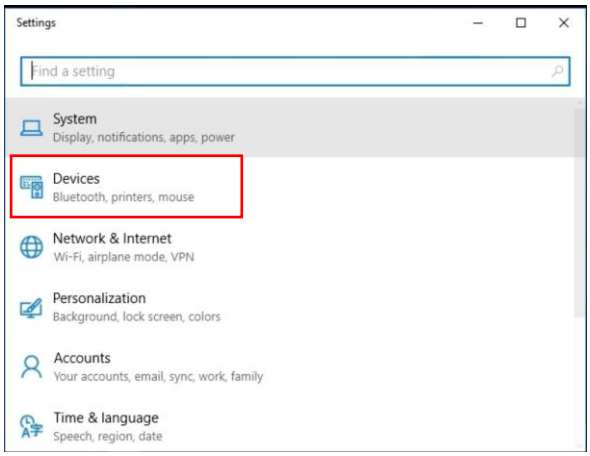
5.3. RFID SCANNER PAIRING

Before starting the pairing procedure of the RFID scanner with AquaTYPHOON™, the RFID scanner needs to be charged. Check if the battery is already placed inside the RFID scanner. If not, please, do it. Then use the provided charger to charge the RFID scanner. Bluetooth dongle is already connected to the USB port named "RFID" at the rear of the AquaTYPHOON™ and configured. Once the RFID scanner is charged:

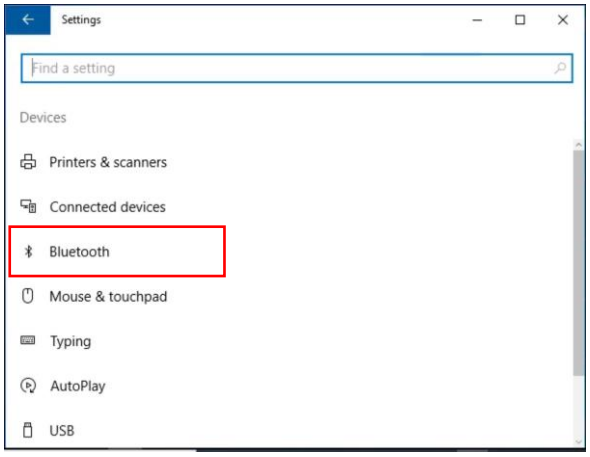
1. Switch ON the AquaTYPHOON™
2. Click on USER symbol to access the User Login page
3. Login as: *ESCAPE* (to exit the software)
4. Click on Windows logo  , and then on Settings 



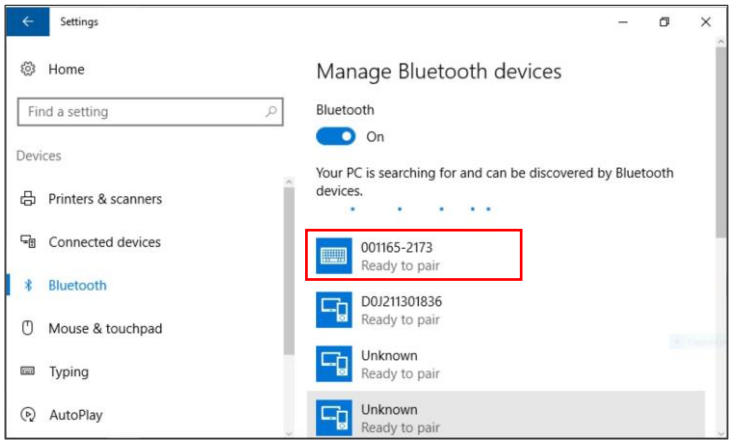
5. Click on "Devices"



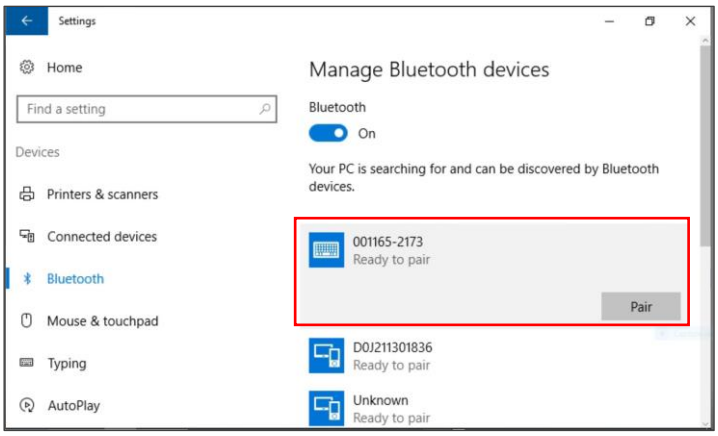
6. Click on “Bluetooth”



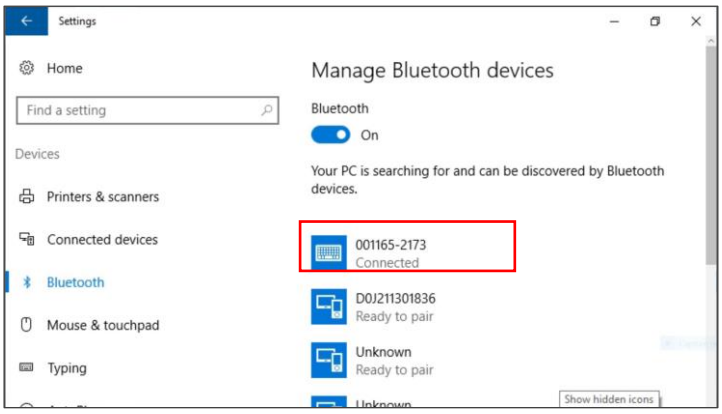
7. Place the RFID scanner close to the AquaTYPHOON™ and wait until it gets detected by the AquaTYPHOON™. Serial number of the RFID scanner will be displayed on the screen, followed by indication “Ready to pair”:



8. Click on the serial number of the RFID scanner. Button “Pair” will appear. Now click on “Pair” button and wait until the pairing of the two devices is done.



9. Once the pairing is done, “Connected” will be displayed below the serial number of the RFID scanner:



10. Start the AquaTYPHOON™ software (by clicking the icon on the desktop or the application in C:\AquaTYPHOON™\AquaTYPHOON™.exe)
11. Click on USER symbol to access the User Login page
12. Scan a random user’s RFID tag and check if the user’s name or number is displayed on the screen next to the USER symbol
    Note: This test can also be done by accessing the Endoscope identification page and scanning a random endoscope RFID tag

6. ENDOSCOPES DATABASE

ENDO database is a CSV file containing a list of all customer's endoscopes. It contains endoscope data that are relevant for traceability, as well as for proper functioning of AquaTYPHOON™ (i.e. automatic selection of the cleaning cycle depending on the endoscope type and specification). This database is installed on the customer's AquaTYPHOON™ device in scope of the installation procedure.

Endoscopes database ENDO includes the following data:

- ✓ Endoscope ID number (barcode or RFID number)
- ✓ Endoscope type (cycle code)
- ✓ Endoscope brand
- ✓ Endoscope model
- ✓ Endoscope serial number
- ✓ Endoscope inventory number (optional)

ENDO database can be accessed via AquaTYPHOON™ software in order to be modified. The access to the ENDO database is limited to the technical personnel only, via the Administrator mode.

6.1. ACCESS TO ENDO DATABASE

Once the customer's ENDO database has been integrated to AquaTYPHOON™ (in scope of the installation procedure), it can be displayed on the screen of the device. In order to acces the ENDO database via the AquaTYPHOON™ software, enter User Login : ***ADMIN**, press AquaTYPHOON™ **logo** to access the Homepage, and then press the **Access ENDO Database** button (see Figure 9).

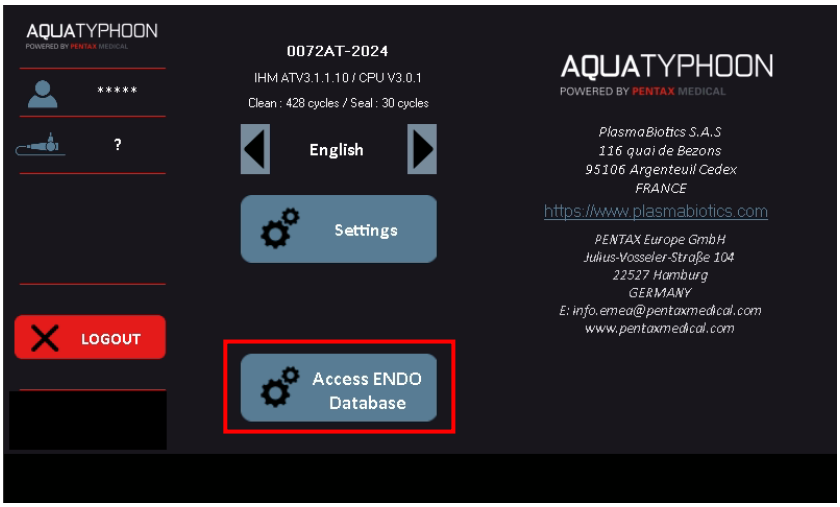


Figure 9. Accessing the ENDO database via AquaTYPHOON™ software

An example of ENDO database displayed in AquaTYPHOON™ software is given in Figure 10. Each line represents one endoscope. All modifications of the ENDO database can be performed directly via the touchscreen of the AquaTYPHOON™. One can add an endoscope by pressing the **Add** button. A new window appears enabling the user to enter the endoscope data. **"…"** button provides the access to an alphanumerical keyboard. In case of endoscope Type selection, there is a scrolling menu proposing all available endoscope types / cycle codes (see Figure 11). Table 1 provides necessary instructions in order to select the corresponding cycle code depending on the endoscope type and specification. AquaTYPHOON™ compatibility table may help to easier identify the corresponding cycle code for each endoscope model.

One can also **Delete** or **Modify** a specific line containing endoscope data, after selecting it in the table. All operations shall be validated by pressing the **OK** button.

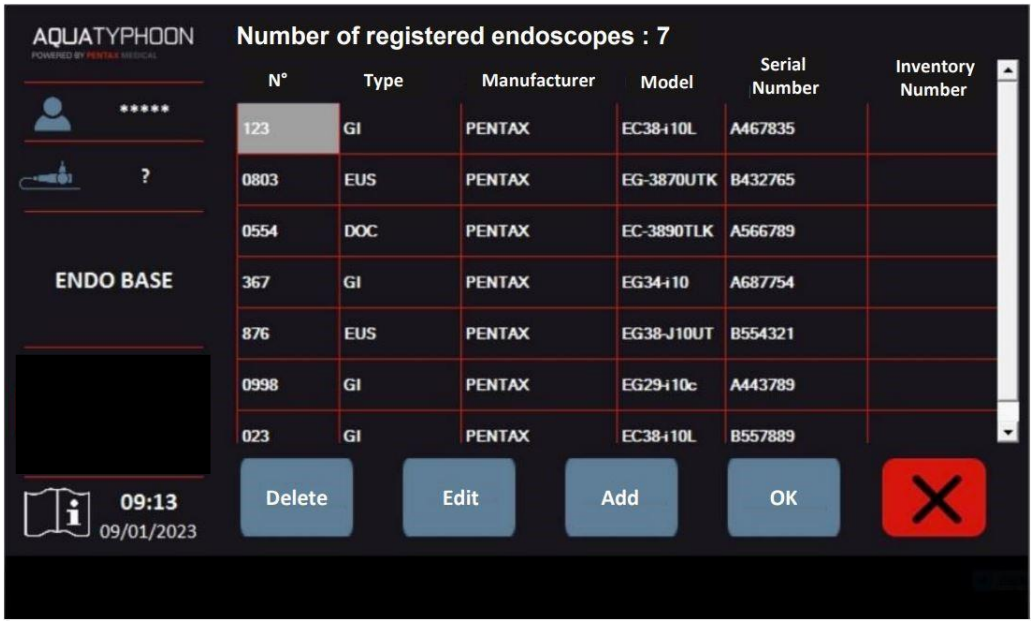


Figure 10. Example of ENDO database displayed in AquaTYPHOON™ software

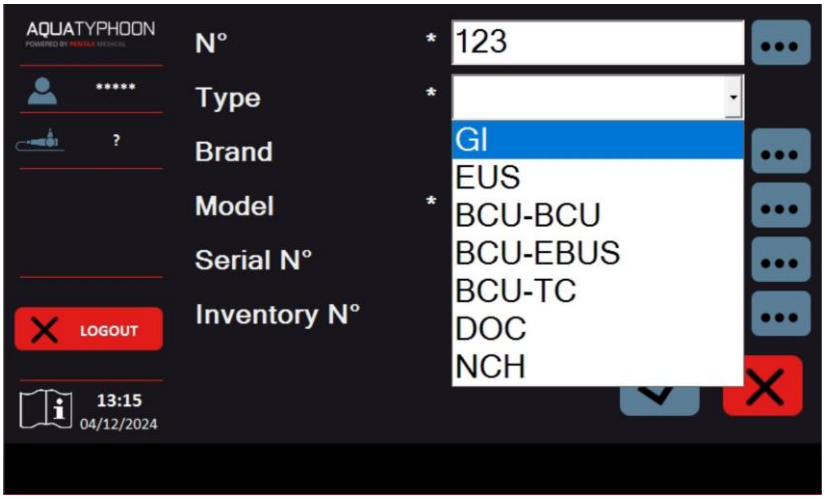


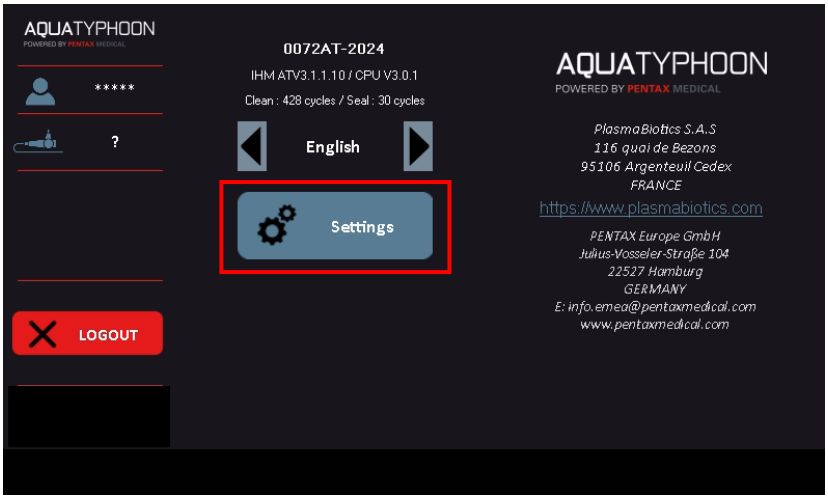
Figure 11. Adding new endoscope into ENDO database via AquaTYPHOON™ software

Table 1. Cycle codes for AquaTYPHOON™

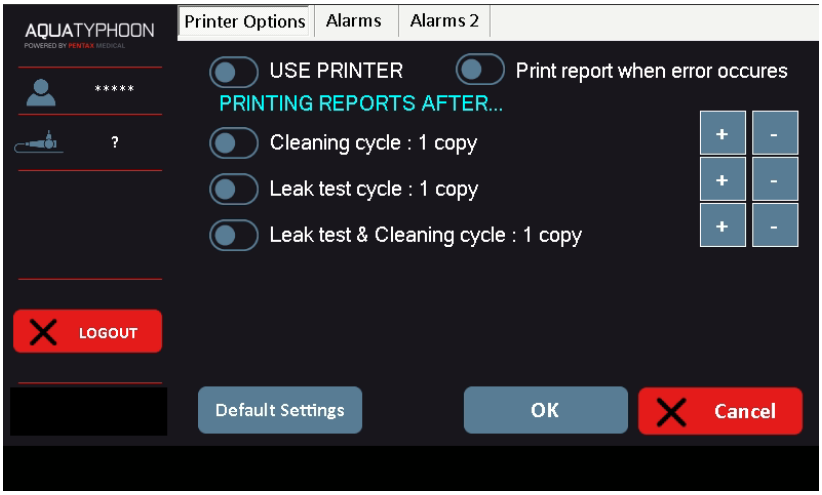
Code	Description	Specification
GI	Gastrointestinal (GI) endoscope	with and without auxiliary channel
EUS	Ultrasound gastrointestinal endoscope (EUS)	with and without auxiliary channel
BCU-TC	Bronchoscope, naso-laryngoscope, cystoscope and ureteroscope	with operating channel Ø < 1.5mm, no unconnected 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	

7. PRINTER MODE

Printer mode enables the person in charge to access printer settings. In order to access the Printer mode, enter User Login: ***1234**, and then press AquaTYPHOON™ **logo** to access the Homepage. A button **Settings** appears in this mode.



Click on **Settings** button. Printer Options window appears on the screen.



In order to activate or deactivate an option use the BLUE (activation) / RED (deactivation) button on left-hand side of each option description:

- Use printer
- Print report when error occurs

- Print report after Cleaning cycle
- Print report after Leak Test cycle
- Print report after Leak Test & Cleaning cycle

One can also choose the quantity of identical printed traceability labels, for each of above cited cycles, using **+** and **–** buttons on the right-hand side.

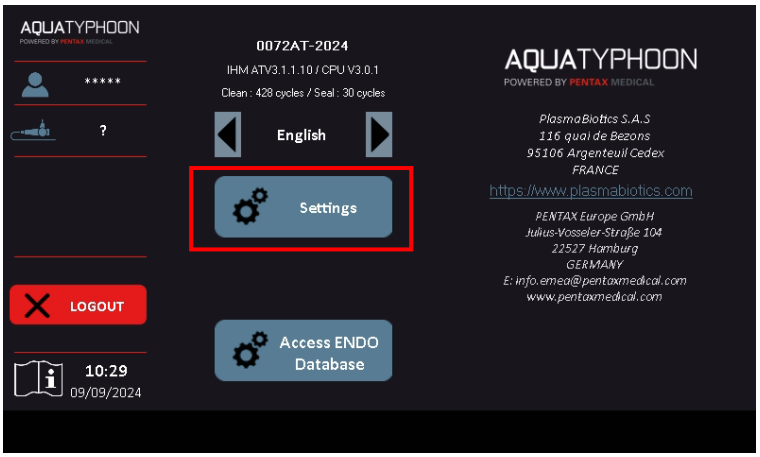
Finally, click “OK” to validate the settings.

8. ADMINISTRATOR MODE

Administrator mode enables the person in charge (i.e. biomedical engineer or technician) to access:

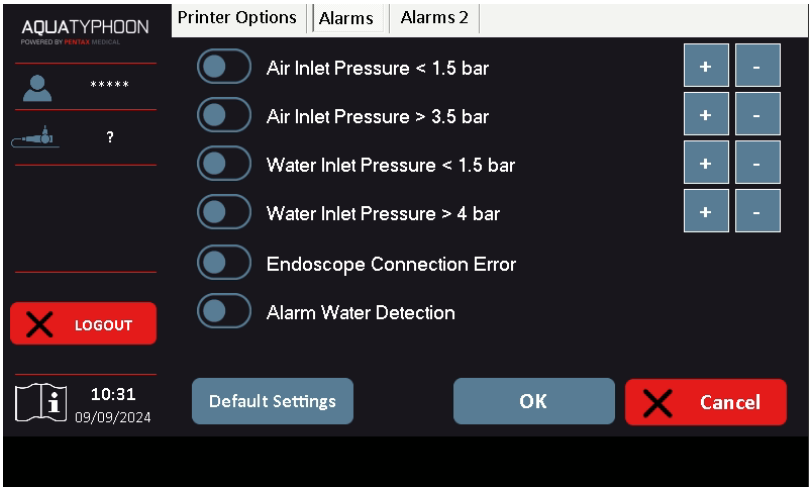
- ENDO database (see Section 6)
- AquaTYPHOON™ settings – including printer options and alarms

In order to access the Administrator mode, enter User Login: ***ADMIN**, and then press AquaTYPHOON™ **logo** to access the Homepage. Buttons **Settings** and **Access ENDO Database** appear in this mode.



Click on **Settings** button. Now, three windows are available:

- Printer Options window (the same as in 7 Printer Mode)
- Two Alarms (security systems) windows



In order to activate or deactivate an alarm one can use the BLUE (activation) / RED (deactivation) button on left-hand side of each alarm description:

- « Air Inlet Pressure < » – Minimal air inlet pressure alarm
- « Air Inlet Pressure > » – Maximal air inlet pressure alarm
- « Water Inlet Pressure < » – Minimal water inlet pressure alarm
- « Water Inlet Pressure > » – Maximal water inlet pressure alarm
- « Endoscope Connection Error » – Detection of incorrect connection of connection set to AquaTYPHOON™ front outlets

One can also adjust the corresponding alarm thresholds, using **+** and **–** buttons on the right-hand side.

Warning: No alarm deactivation or threshold modification shall be self-initiated. It shall be performed ONLY under guidance of the manufacturer (PlasmaBiotics) or local distributor's technician.

9. HISTORY DATABASE

AquaTYPHOON™ has an electronic traceability system, i.e. the history of all treatment cycles performed by AquaTYPHOON™ is saved in a database named REPORT. This CSV file is located in “History” folder on AquaTYPHOON™ hard drive. Each line in the REPORT database corresponds to a single treatment cycle.

The columns of REPORT database indicate the following data:

- ✓ Date of the treatment
- ✓ Time of the treatment
- ✓ Endoscope type (cycle code)
- ✓ Endoscope ID (barcode or RFID tag) number
- ✓ Endoscope model
- ✓ Endoscope serial number
- ✓ User (operator) name or number
- ✓ Completed cycle (CLEANING, LEAK TEST or both) and cycle conformity (DONE or FAIL)
- ✓ If cycle is FAIL, the cycle time (seconds) of the failure

An example of REPORT database (displayed in Excel) is presented in Table 2.

Table 2. REPORT Database - treatment cycles history database

	A	B	C	D	E	F	G	H
1	Date	Time	Type Endo	Number	Model	Serial Number	Operator	Cycle Report
2	29/12/2022	08:04	EUS	603	EG-3870UTK	7923453	CIRISAN Mihaela	LEAK TEST + CLEAN DONE
3	29/12/2022	08:16	GI	604	ED34-i10T	2912824	CIRISAN Mihaela	LEAK TEST + CLEAN DONE
4	29/12/2022	08:22	GI	401	EG34-i10	2730534	CIRISAN Mihaela	LEAK TEST + CLEAN DONE
5	29/12/2022	08:30	EUS	081	EG-3670URK	2510115	CASTILLA Marion	LEAK TEST + CLEAN DONE
6	29/12/2022	08:36	GI	400	EC38-i10c	2731626	CASTILLA Marion	LEAK TEST + CLEAN DONE
7								

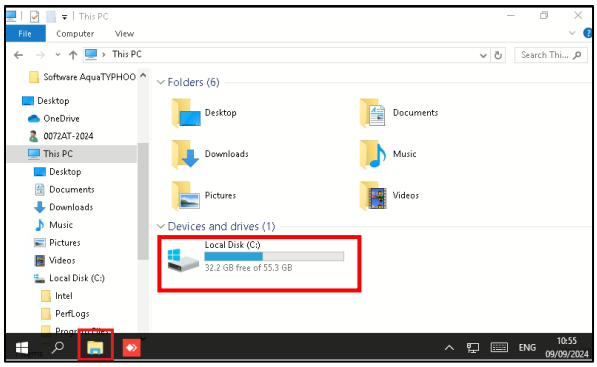
Warning: This recording is not an archive. It is hospital’s/clinic’s responsibility to store and archive these data in their own data storage system.

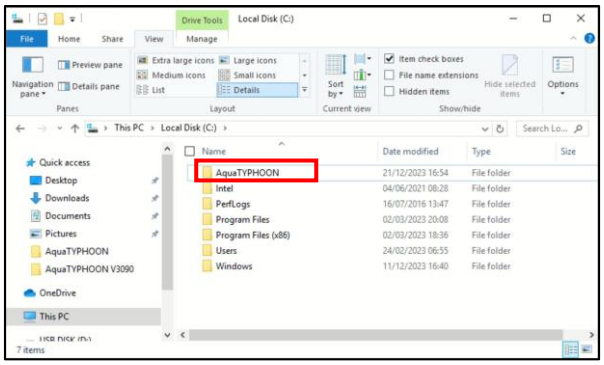
Being located on AquaTYPHOON™ hard drive, REPORT database can be accessed via Windows File Explorer (see the instructions below).

9.1. ACCESS TO REPORT DATABASE

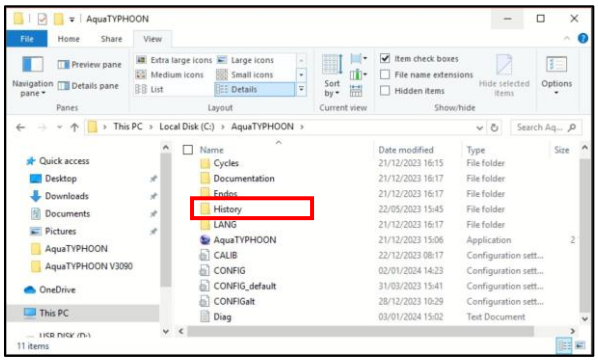
- Switch ON the AquaTYPHOON™
- Connect a mouse and a USB stick to a USB port at the rear the AquaTYPHOON™
- Click on User Login symbol
- Enter User Login: *ESCAPE* in order to exit AquaTYPHOON™ software and access Windows

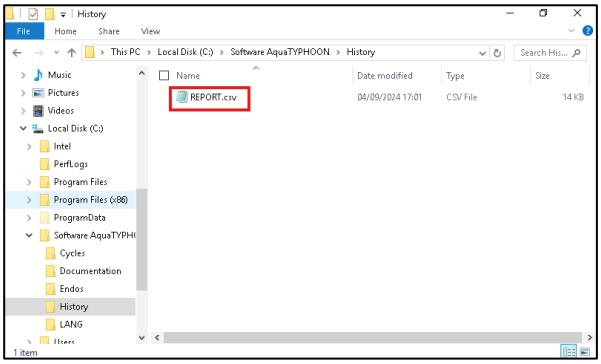
REPORT database is located on the hard drive of AquaTYPHOON™, in the folder AquaTYPHOON™ and subfolder History: C:\AquaTYPHOON™\History





Click on **AquaTYPHOON™** and then on **History**





REPORT database, being a CSV file, if it is open on the AquaTYPHOON™ PC, it will be displayed in a Notepad.

One can copy/paste the REPORT file to his USB stick, in order to store it elsewhere.

10. MAINTENANCE

10.1. 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 clean the device.

10.2. 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 12). 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 AquaBOX, and select and run the CARE Purge cycle (see Figure 13).

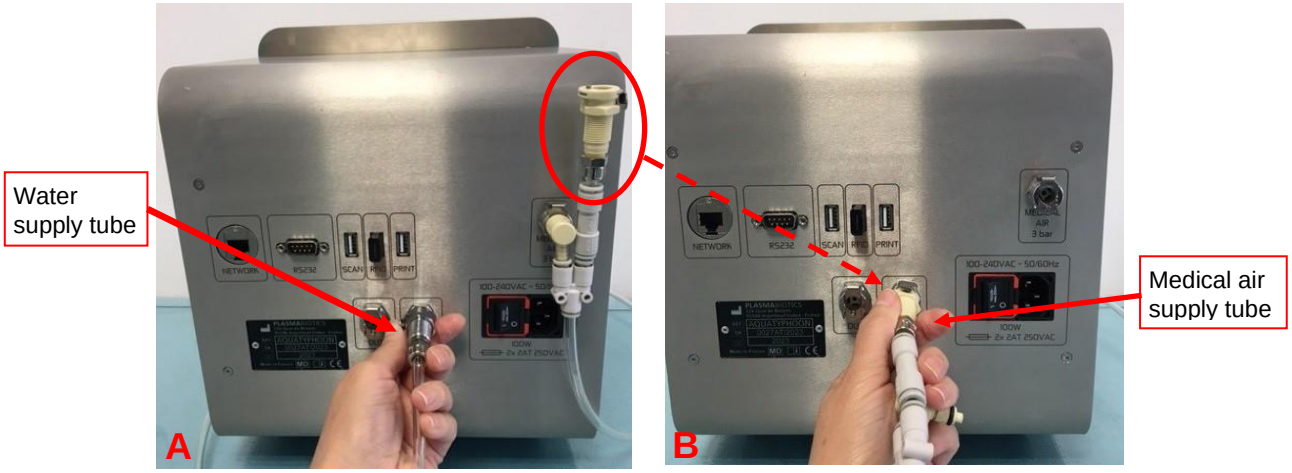


Figure 12. Disconnecting water supply tube (A) and connecting air supply tube (B) to the water inlet

Figure 13. Prepare for purge page

10.3. 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.

10.4. 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 (see Figure 14). 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. The instructions for use of the AquaTYPHOON™ maintenance kit and performing the maintenance cycle are provided below.

Figure 14. 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.

1. 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 15).
2. Connect any three-colored connection set to the RED, BLUE and WHITE front outlets of the AquaTYPHOON™ device (see Figure 16).

Figure 15. Disconnecting air and water supply tubes

Figure 16. Three-colored connection set connected

3. Via the touch screen, select CARE Maintenance button to go to “Prepare for Maintenance” page (see Figure 17).

Figure 17. Prepare for maintenance page

4. Dilute the content of the bag (citric acid-based cleaner in powder) provided in the AquaTYPHOON™ Maintenance kit (see Figure 14) into 0.5 liters of lukewarm water. Stir for a few seconds for faster dilution.
5. Fill the syringe with 50 ml of the prepared solution.
6. Start AquaTYPHOON™ Maintenance cycle by pressing OK button on the touch screen (Figure 18)
7. 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 18). The solution shall be coming out of the tubings connected to the front outlets of the device. If needed, repeat the solution irrigation process.
8. Cycle counts down the contact time (around 15 min)
9. When indicated on the screen (Figure 19) reconnect air and water supply tubes to the backside of AquaTYPHOON™ device (Figure 20)
10. Open air and water supply and click OK button on the touch screen to proceed (Figure 19)

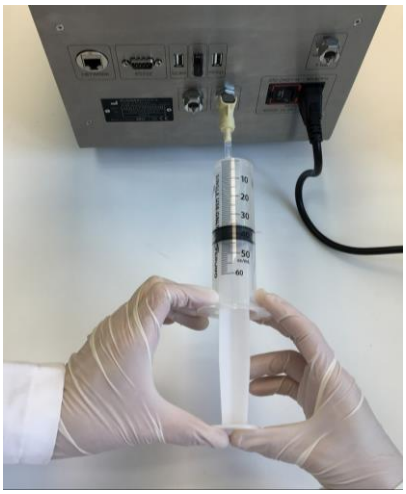


Figure 18. Irrigation of prepared solution into AquaTYPHOON™ device

Figure 19. Pause for reconnection of air and water supply

Figure 20. Reconnecting air and water supply tubes

11. GLOBAL TRACEABILITY

AquaTYPHOON™ contains an embedded PC, a PICO-APL1 minicomputer from the Pico-ITX family.

Here are the main features of this embedded PC:

- Processor: Celeron® N3350.
- Memory: It is equipped with a 4GB DDR3L, with a maximum frequency of 1600MHz.
- Storage: It is equipped with a 64GB mSATA.
- Connectivity: The integrated PC has USB 3.2 Gen 1 and USB 2.0 ports, as well as an Intel® Gigabit Ethernet LAN port, making it easy to connect to networks and other peripherals, depending on installation requirements.
- Security and network configuration: These devices run on Windows 10 IoT Enterprise LTSB 2016 and incorporate native cybersecurity features, Windows Defender.
- Automatic updates are disabled by default.

AquaTYPHOON™ device can be connected to the healthcare facility's network via the RJ45 port installed on the device, configured for static or DHCP IP addresses.
Nevertheless, AquaTYPHOON™ device does not require a network or internet connection for the applications/software to work. AquaTYPHOON™ HMI software is located on the C drive of the embedded PC and software updates are performed locally by trained PENTAX Medical/distributor's personnel.

In terms of security, AquaTYPHOON™ device can be managed by the healthcare facility's IT department according to the same security rules as other computer stations.
When the device is switched ON, a Windows user session/account is launched (session/account name = serial number of the device). It is possible that the IT department of the establishment manages the device as a workstation connected to the network.

The design and use of the device allows the IT department of the institution to use their EDR (Endpoint Detection and Response) when the device is connected to the network. Indeed, it does not impact the operation of AquaTYPHOON™ application. In this case, when the device is connected to the facility's network, the IT department can use their security protocols to communicate with the device. The device doesn't need to send information with components via the network for our application to work. There is no secure encryption of the information that could be communicated.

The useful information contained in the device concerns the traceability data related to its use (endoscope ID, date, time, user ID, applied cycle, etc.) and is kept in a CSV file named "REPORT". "REPORT" represents a historical database containing traceability data of all cycles performed by the device. Each line in the database corresponds to one performed cycle. REPORT.csv file is located in the "HISTORY" folder, that is located in the AquaTYPHOON™ folder, at the root of C drive (see Section 9). Regarding personal data, only the operators' identifiers are kept in the "REPORT" file.

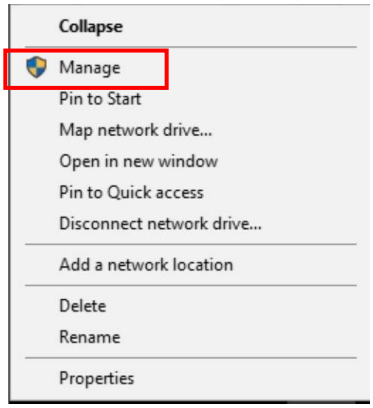
In order to centralize the traceability data, the information from the "REPORT" csv file can be retrieved by the centralized traceability system, external to the network, in a secure manner. To do so, follow the procedure described below.

It would also be possible to use a local copy of the "REPORT" file through a Windows layer before transmitting the information in a secure manner or to place this file in a directory on the server: this would require development by the provider of the centralized traceability system / IT department / competent department.

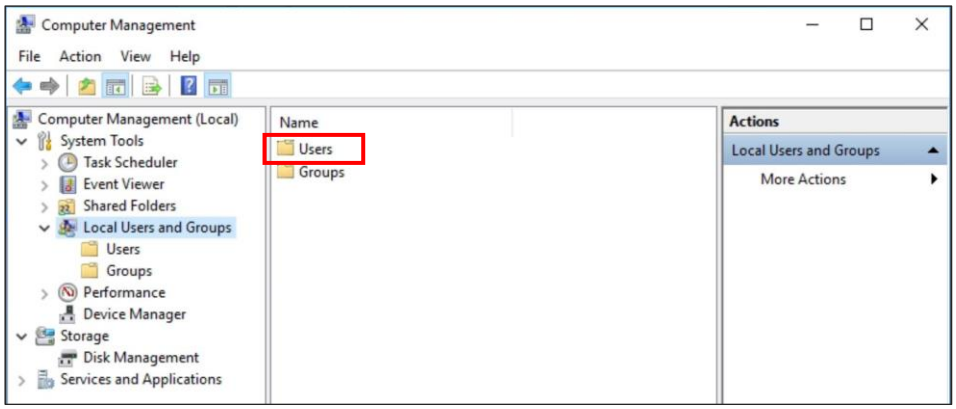
The instructions on how to connect and access digital traceability data (REPORT file), located in the History folder on the local C drive, are provided below.

11.1. CREATE A NEW USER

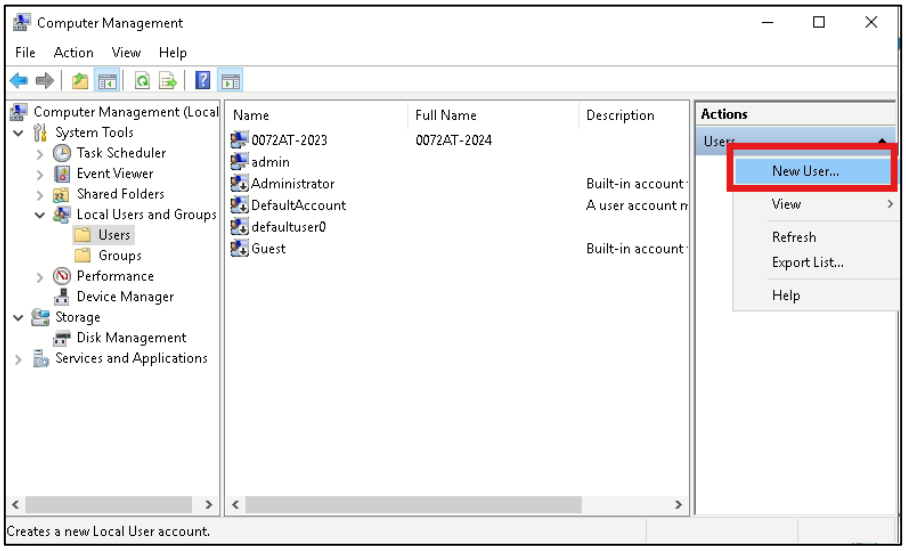
- Switch ON the AquaTYPHOON™
- Connect a mouse to a USB port at the rear the AquaTYPHOON™
- Click on User Login symbol
- Enter User Login : ***ESCAPE*** in order to exit AquaTYPHOON™ software and access Windows
- Go to Windows menu and open « File Explorer »
- Right Click on “This PC”
- Click on “Manage”



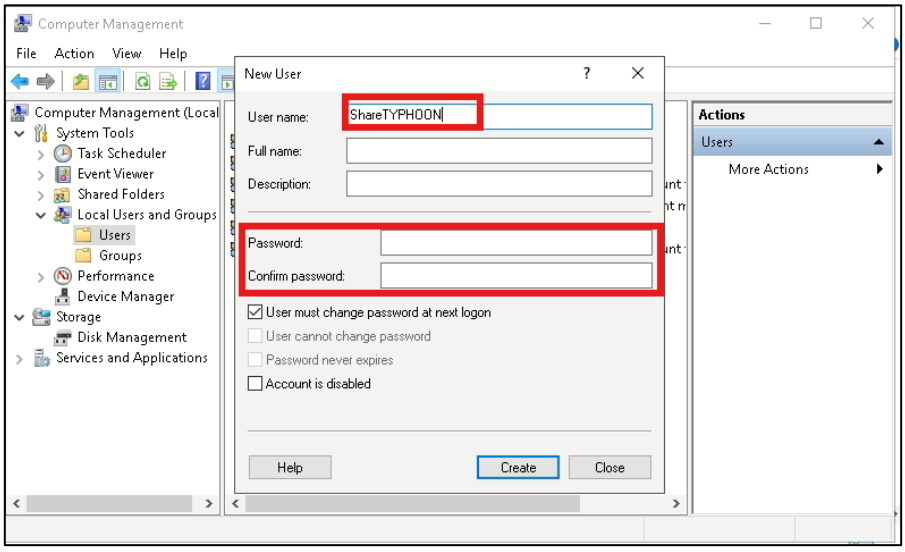
- In the left-side menu click on “Local Users and Groups”
- Then click on “Users”



- Then click on right tab and choose “new user”



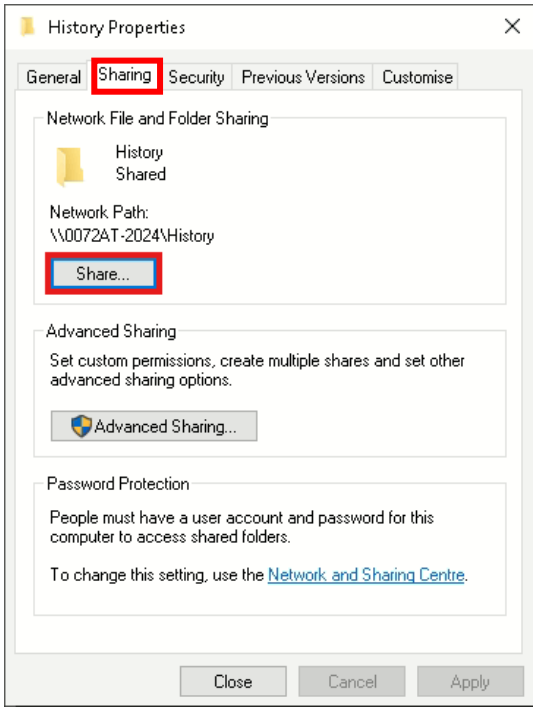
- Type the name of “ShareTYPHOON” and enter a password:



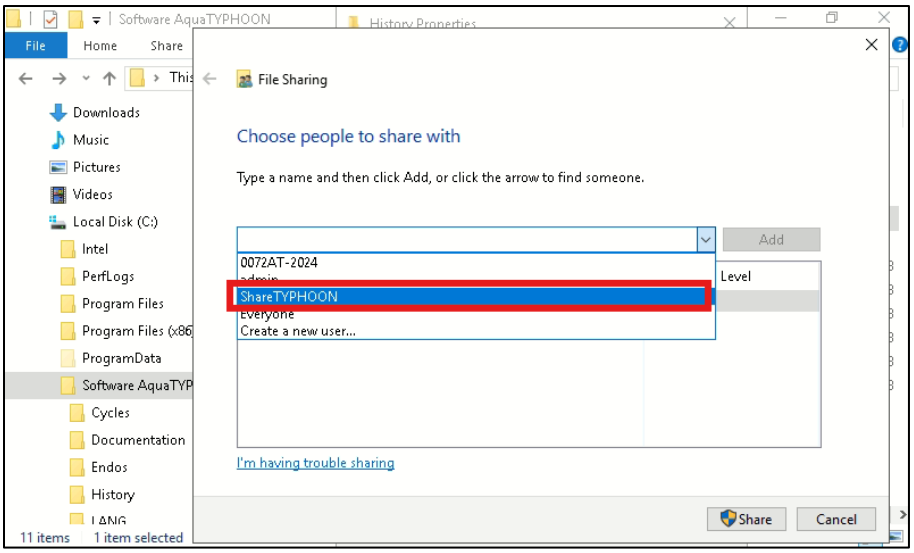
- The customer can enter his own password. The customer is responsible for his password.

11.2. SHARE THE HISTORY FOLDER

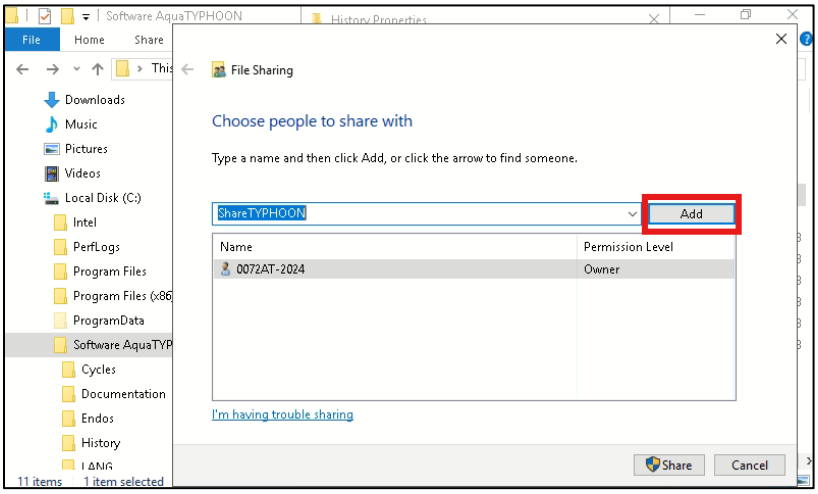
- Click on Local Disk (C:)
- Click on AquaTYPHOON™ folder
- Right click on “History” folder
- Click on “Properties”
- In the pop-up window “History Properties” click on the Tab “Sharing”
- Then click on the button “Share”



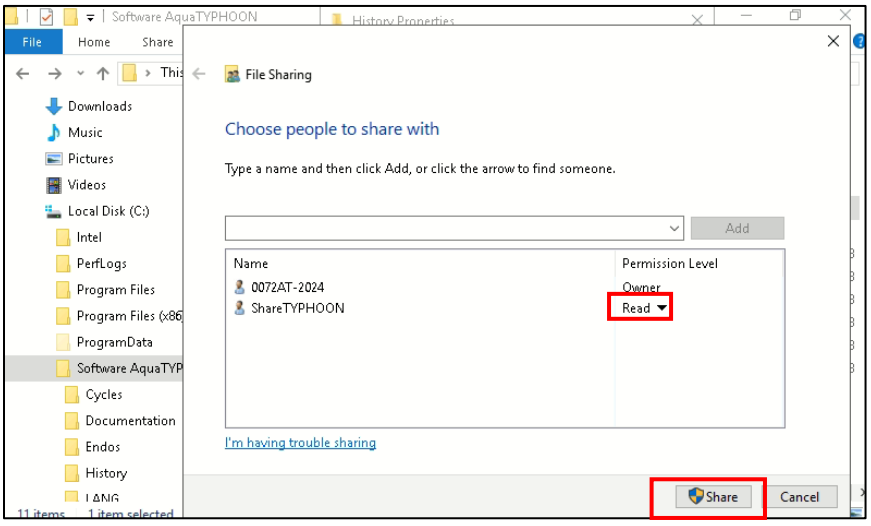
- Add “shareTYPHOON” from the scrolling menu



- Click “Add” button

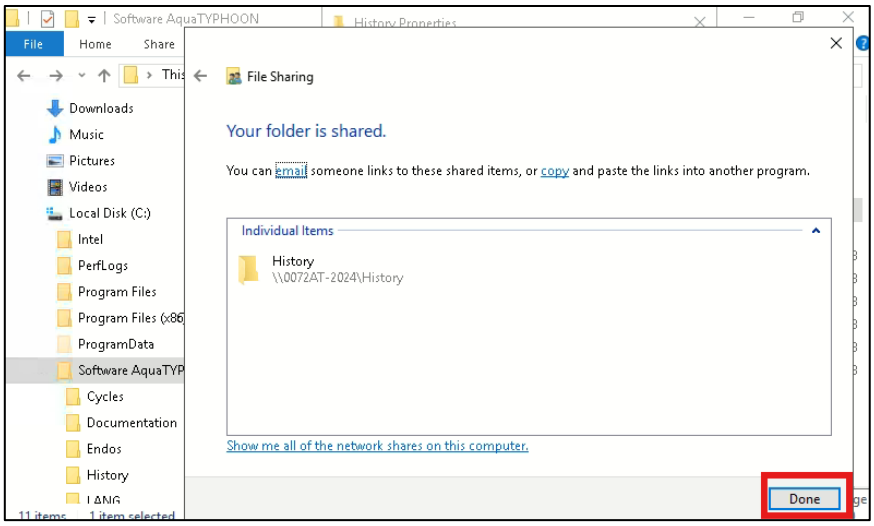


- Give “Read” permission
- Then click on “Share”

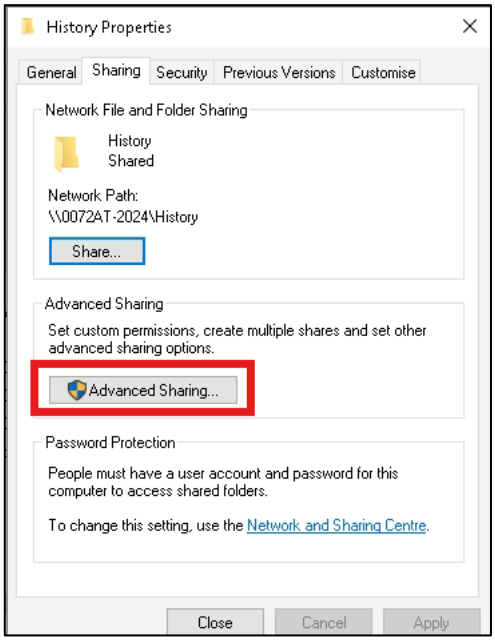


A window indicating that folder “History” is shared will appear on the screen.

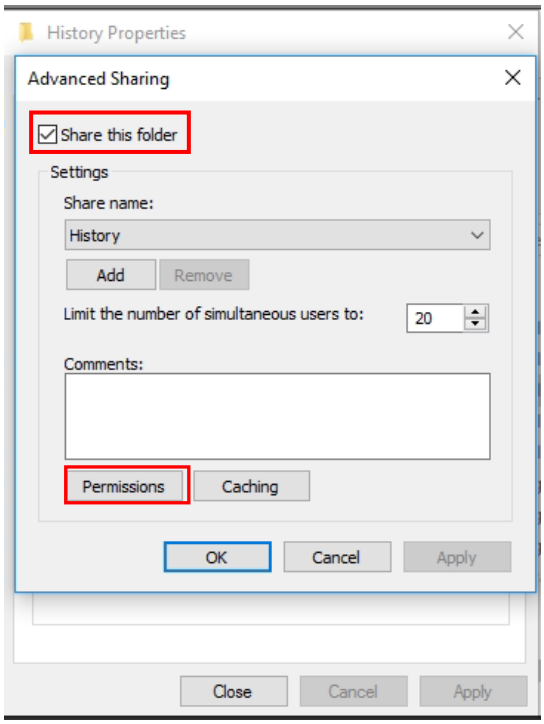
- Finally, click on “Done”



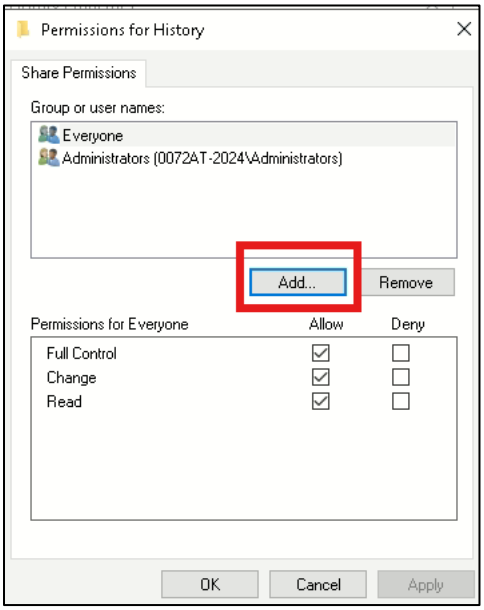
- Now, in the window “History Properties” click on “Advanced sharing”



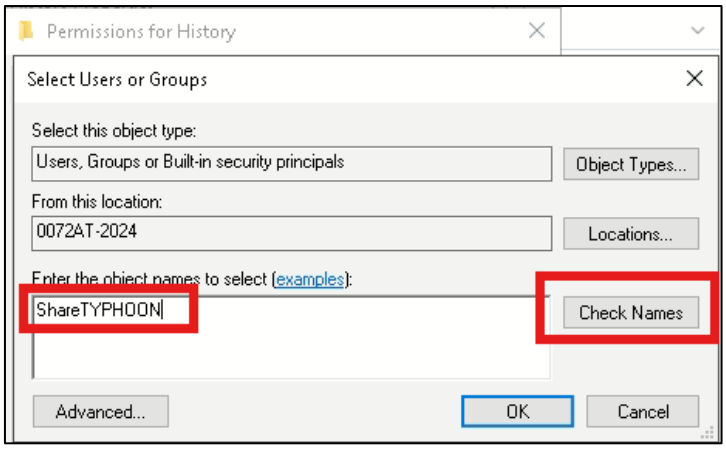
- Check “Share this folder”
- And click on “Permissions”



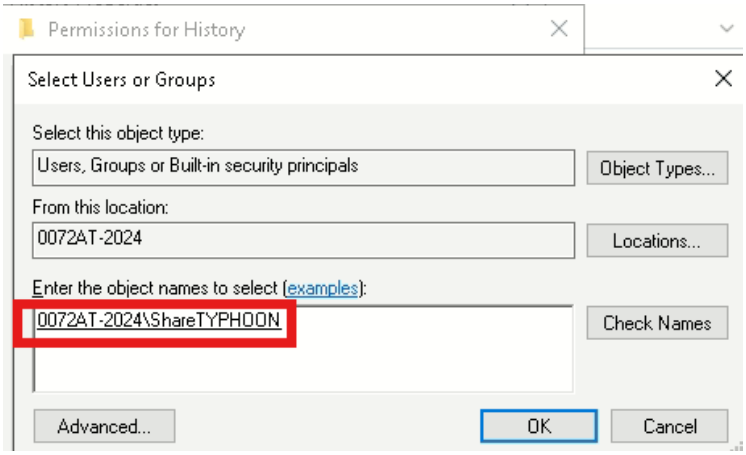
- Click on “Add” button



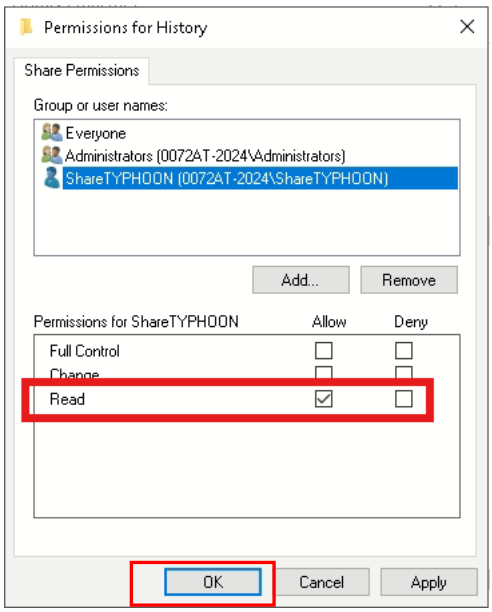
- In the pop-up window, type “shareTYPHOON” in the case “Enter the object names to select”
- And click on “Check Names”



- An object indicating “SN\shareTYPHOON” shall appear (SN – serial number of the device)
- Finally, click “OK”

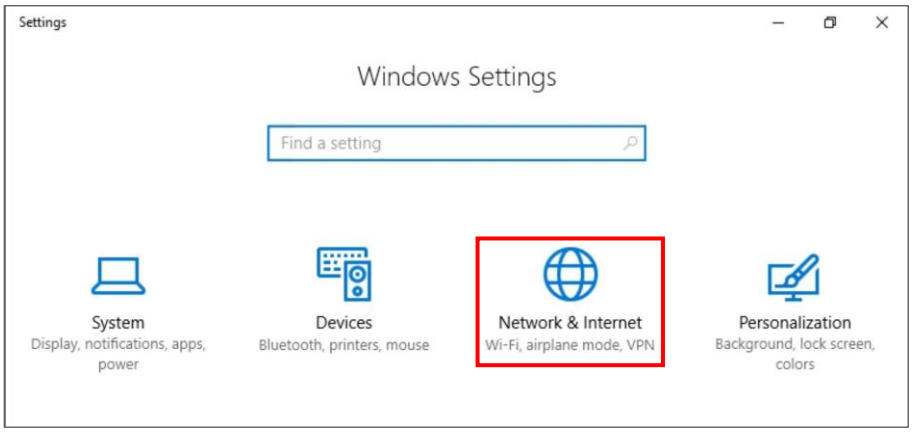


- In the lower part of the window “Permissions of History”, named “Permissions for shareTYPHOON”, allow “Read”
- Click on “OK” two times (closing two windows) and close “History Properties” window as well

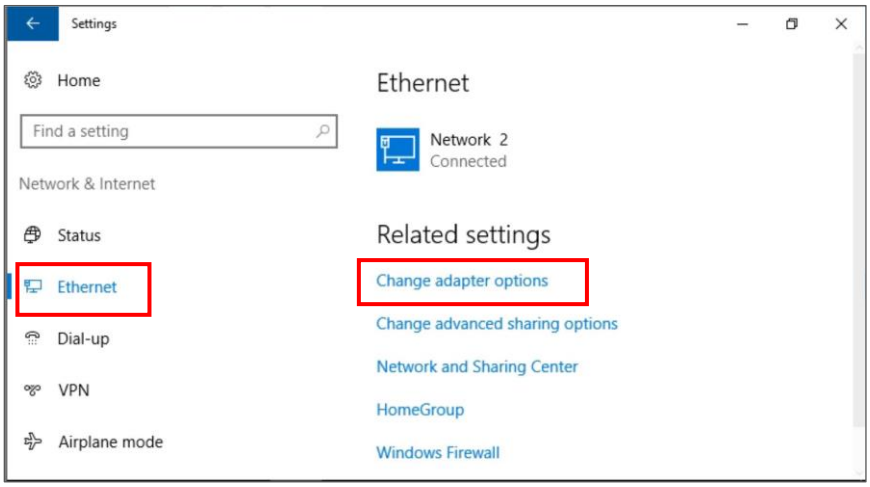


11.3. BLOCK THE AQUATYPHOON™ IP ADDRESS

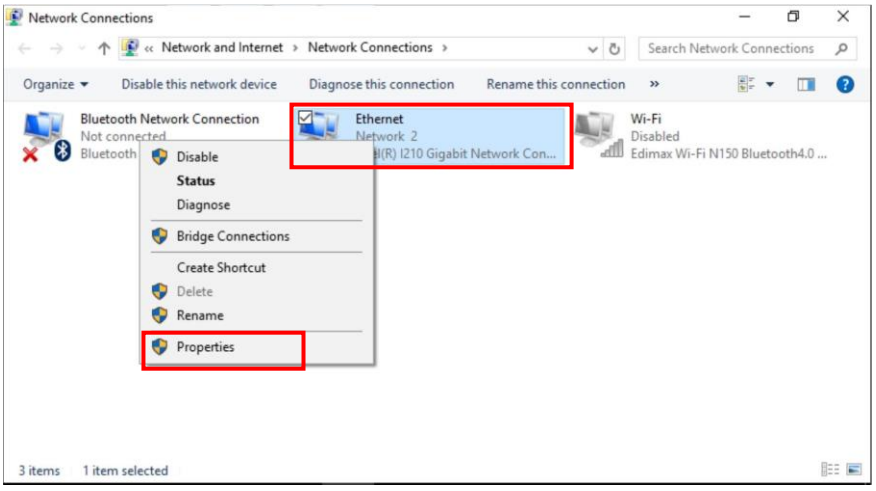
- Go to “Windows Settings”
- Click on « Network and Internet »



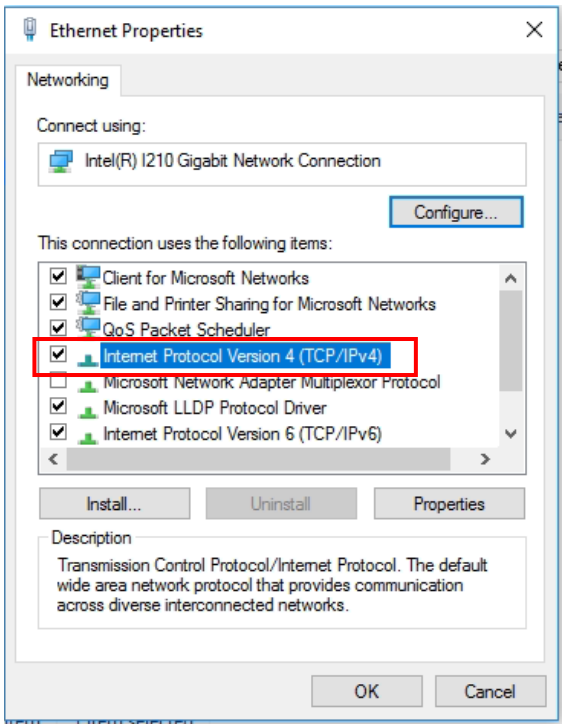
- Click on “Ethernet”
- Click on “Change adapter options”



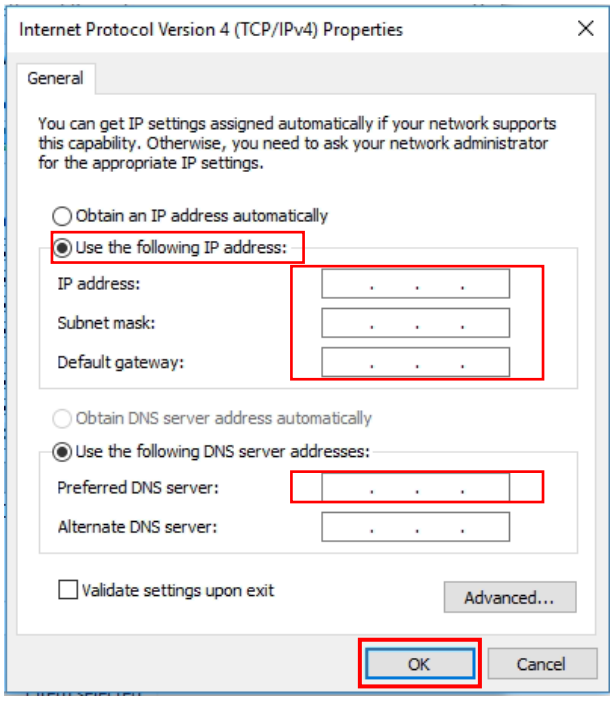
- Right click on “Ethernet”
- Click on “Properties”



- Double click on “Internet Protocol Version 4 (TCP/IPv4) »

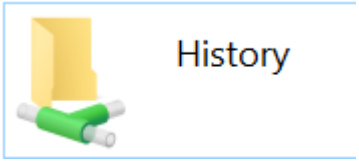


- Click on « Use the following IP address »
- The customer IT service shall choose the IP address instead of the subnet mask and default gateway
- Finally, click “OK”



11.4. ACCESS TO THE HISTORY FOLDER

- Click on « Network » in the File Explorer
- Find the AquaTYPHOON™ with the IP address you have just set
- ID : shareTYPHOON
- Password : (*defined by the customer*)
- Open the folder “History”



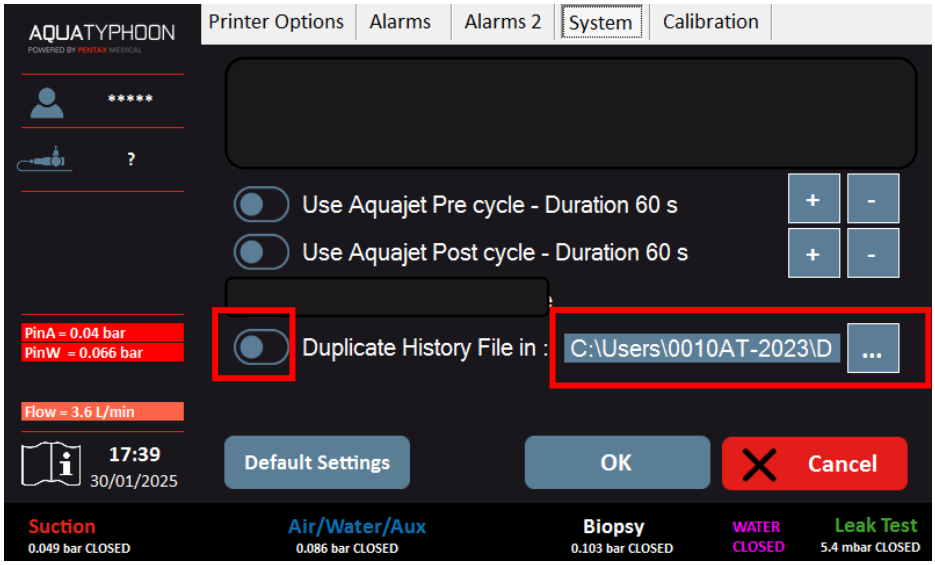
- You can now open and read the traceability data files

11.5. COPY OF THE REPORT.CSV FILE

Starting with the latest version v.3.1.5.0, AquaTYPHOON™ software has the possibility to create a copy of the REPORT.csv file at a user-specified location.

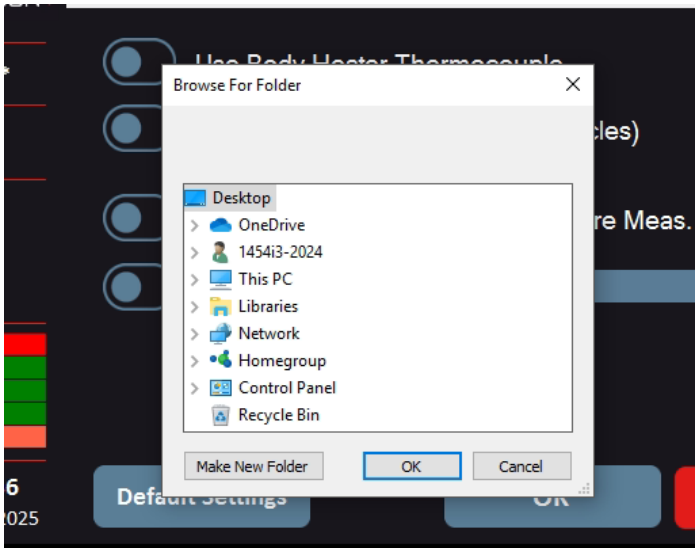
To access this option and activate it:

- Enter the *ADMIN mode
- Go to the homepage by pressing the AquaTYPHOON™ logo (left-upper corner)
- Go to the Settings by pressing Settings button
- Select the tab named System,
- Activate the option "Duplicate History File in"
- Click on the three dots “…” button to introduce the path where you wish to locate the copy of the REPORT file



Use the pop-up window to enter the destination path of the REPORT-copy file.

It is also possible to choose a destination path on the institution's network. To do this, the institution's IT department must proceed in the same way as when networking a PC.



Note that as soon as this option is activated, a REPORT-copy.csv file is created in the location specified by the user. This option does not copy all the existing traceability data from the original REPORT file, it only starts traceability recording from the moment this option was activated.

If the centralized traceability software needs to mark the read traceability lines in the REPORT.csv file, it is preferable to use this option so that the modifications are made only in the REPORT-copy file.

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