

**PLASMABIOTICS®**

IN ASSOCIATION WITH **PENTAX MEDICAL**

Technical Manual for User  
**PlasmaTYPHOON+**

Technical Manual for User



**Advanced plasma unit for fast drying and active storage of endoscopes**

**PENTAX**  
MEDICAL

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## 1. INTRODUCTION

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

It is highly recommended to read this manual carefully before installing, uninstalling and/or using the PlasmaTYPHOON+ for the first time. This manual is intended to be used by technical staff in charge of the equipment in the health institution (biomedical engineer, technician...).

Besides general description and characteristics of the device, this manual includes installation and peripherals configuration instructions, ENDO database modification procedure, administrator mode descriptions, as well as the instructions how to connect the PlasmaTYPHOON+ device to internal network.

## 2. INDICATION

### 2.1. INTENDED USE AND PERFORMANCE

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

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

### 2.2. INTENDED USERS AND OPERATING LOCATION

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

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

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

### 2.3. INTENDED USE AND BENEFIT

The intended use of the PlasmaTYPHOON+ is as follows:

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

### 2.4. CONTRA-INDICATION



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



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



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

### 3. GENERAL CHARACTERISTICS

#### 3.1. ELECTRICAL AND MECHANICAL CHARACTERISTICS

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

#### 3.2. MATERIALS AND SUBSTANCES

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

## 4. INSTALLATION



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

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

1) Facility:

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

2) Provided by PENTAX Medical or local distributor:

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



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

### 4.1. OPERATING AND STORAGE CONDITION OF THE DEVICE

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

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

Operation altitude: max 2000 m

### 4.2. ELECTRICAL CONNECTION

For the installation of the PlasmaTYPHOON+ system, 2 electrical sockets are mandatory: one for PlasmaTYPHOON+ device and one for the printer. The power cables must be plugged into electrical sockets with 3 terminals (live, neutral and earth).

Barcode scanner is powered via the USB cable connected to the PlasmaTYPHOON+. RFID scanner is battery powered and can be charged when needed using its power charger.

### 4.3. MEDICAL AIR SUPPLY

The PlasmaTYPHOON+ has a **medical air inlet** at the rear. This inlet must be connected to an external source of medical air (ex. medical air pipeline system). An air compressor for medical applications may also be used: oil-free, with filters, desiccation system and antimicrobial coating for the tank. A pressure regulator shall be used to set the medical air inlet pressure between 3 bar (43.51 psi) and 4 bar (58.02 psi) in static mode, in order to ensure the pressure of 3 bar (43.51 psi) in dynamic mode. The minimal gas flowrate of the supply system (gas pipeline system + pressure regulator) must be 60 l/min.

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

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



**Warning:** The medical air supplying the PlasmaTYPHOON+ must be free from contamination and must be of a purity class according to the local regulation. The vapor water concentration must be less than 67 ml/m<sup>3</sup>.

- ✓ The PlasmaTYPHOON+ must not be operated, if the water vapor concentration is above 67 ml/m<sup>3</sup>.
- ✓ The presence of liquid water in the medical air represents a risk of damaging the PlasmaTYPHOON+ equipment. The manufacturer is not liable for any damages in the event of water ingress via the medical air inlet.



Figure 2. Rear of the PlasmaTYPHOON+

#### 4.4. PERIPHERAL DEVICES AND NETWORK CONNECTION

Peripheral devices, i.e. printer, barcode scanner and RFID scanner, shall be connected to the PlasmaTYPHOON+ as a part of its traceability system. All peripheral devices need to be configured/paired in order to function with PlasmaTYPHOON+ (see Section 5).

##### 4.4.1. Printer connection

Printer needs to be connected to the PlasmaTYPHOON+ 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 PlasmaTYPHOON+ (see Fig. 3). Once connected and powered, the printer shall be configured with the PlasmaTYPHOON+ (see Section 5).



Figure 3. Connecting the printer to PlasmaTYPHOON+

#### 4.4.2. Barcode scanner connection

Barcode scanner or barcode scanner's base (in case of wireless barcode scanner) needs to be connected to the PlasmaTYPHOON+ via the provided connection cable that shall connect the corresponding RJ45 port on the scanner or scanner's base to the USB port named "SCAN" at the rear of the PlasmaTYPHOON+ (see Fig. 4). Once connected and charged, barcode scanner shall be configured (see Section 5).

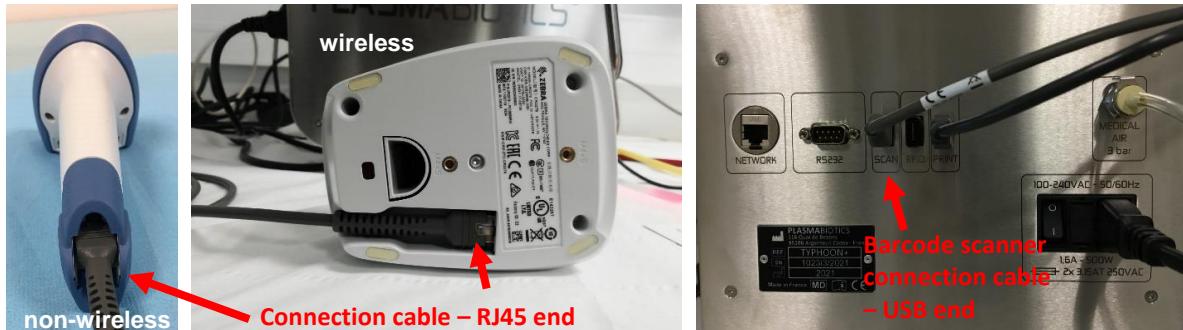


Figure 4. Connecting the non-wireless and wireless barcode scanner to PlasmaTYPHOON+

#### 4.4.3. RFID scanner connection

RFID scanner is connected to the PlasmaTYPHOON+ via a Bluetooth dongle installed on the USB port named "RFID" (see Fig. 5). Once the RFID scanner is charged (via its power charger), it shall be paired with PlasmaTYPHOON+ (see Section 5).



Figure 5. Bluetooth dongle connection and power charger of the RFID scanner

#### 4.4.4. Network connection

PlasmaTYPHOON+ can be connected to the local network and/or internet via the Ethernet (RJ45) port at the rear of the device (see Fig. 2). This connection enables access to the recorded traceability data i.e. history of all performed cycles, temporarily stored on the PlasmaTYPHOON+ 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.

### 4.5. GAS/PLASMA OUTLETS

PlasmaTYPHOON+ has 4 **gas/plasma outlets** on the front (see Fig. 6):

- Suction/operating channel – red color
- Air/water channel – blue color
- Water jet channel – yellow color
- Storage – green color

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

#### 4.6. SWITCHING ON

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

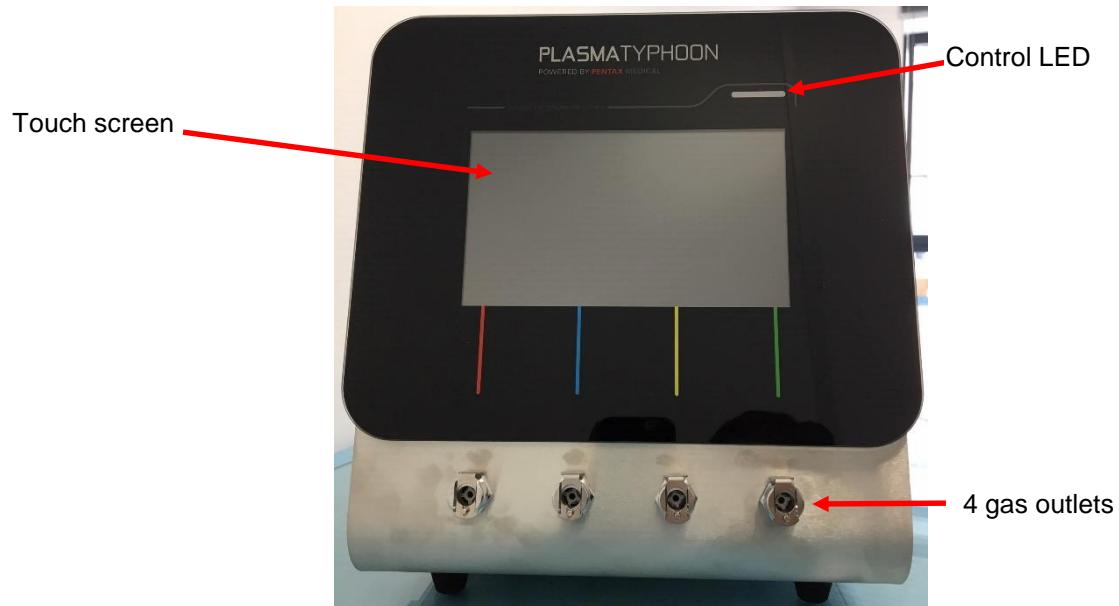


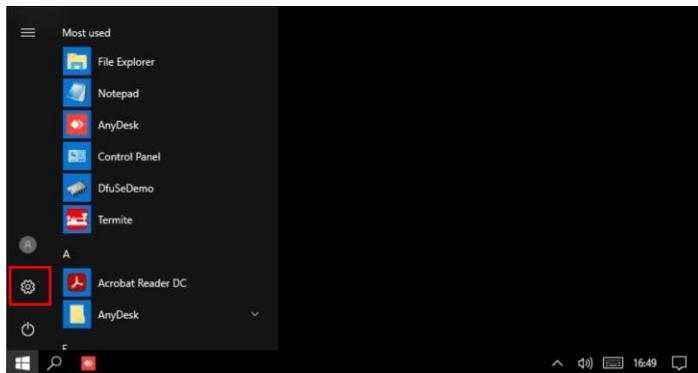
Figure 6. Front of the PlasmaTYPHOON+

## 5. CONFIGURATION OF PERIPHERAL DEVICES

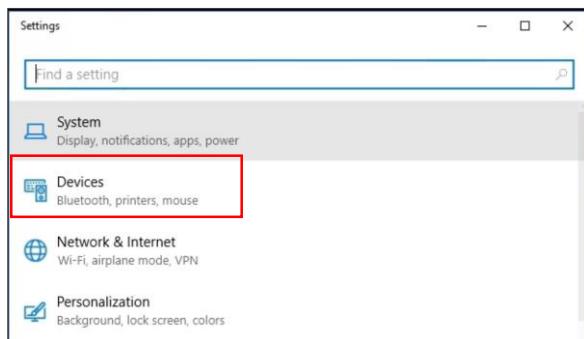
Peripheral devices i.e. printer, barcode scanner and RFID scanner, need to be configured and/or paired with PlasmaTYPHOON+. Once that all peripheral devices are charged and connected to the corresponding USB ports at the rear of the PlasmaTYPHOON+ (see Fig. 3), one can start the configuration/pairing procedure.

### 5.1. PRINTER CONFIGURATION

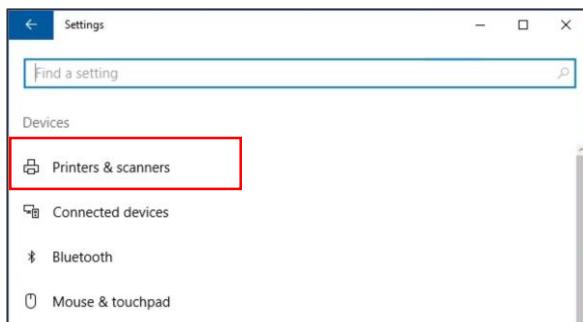
1. Switch ON the printer
2. Switch ON the PlasmaTYPHOON+
3. Click on USER symbol to access the User Login page
4. Login as: \*ESCAPE\* (to exit PT+ software)
5. Click on Windows logo , and then on Settings 



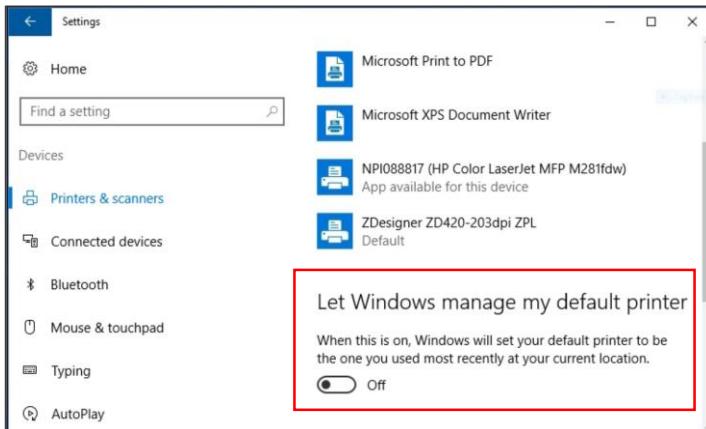
6. Click on “Devices”



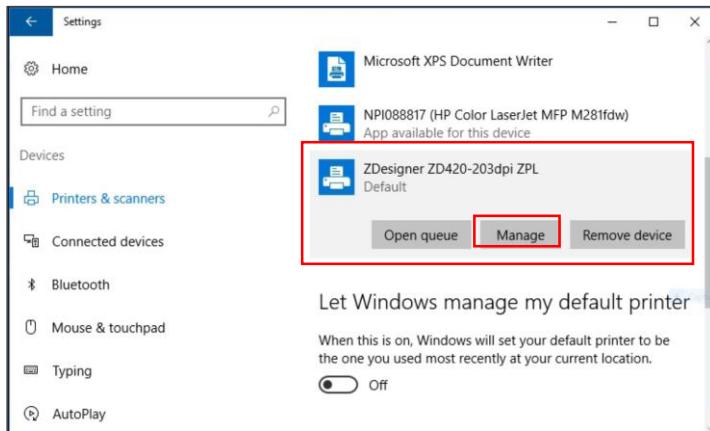
7. Click on “Printers and scanners”



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



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

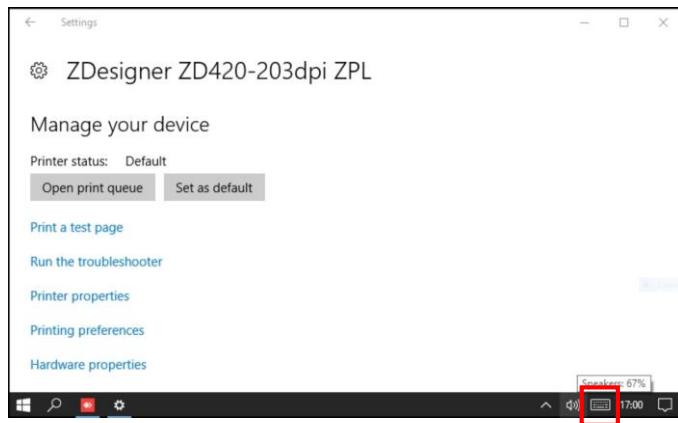


10. Set it as default printer by clicking “Set as default”

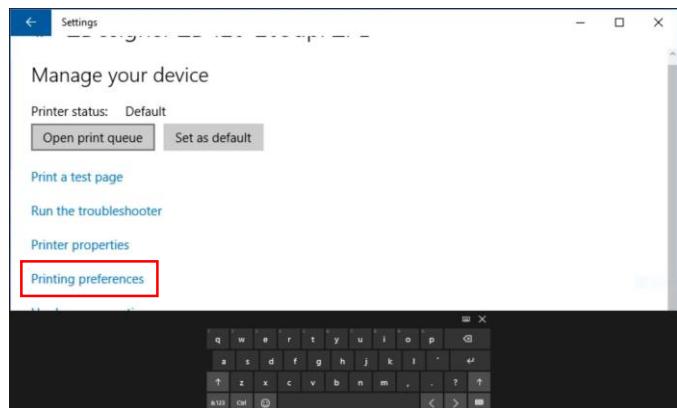


11. Click on “Print a test page” and check if the printer printed out a test page.

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”.

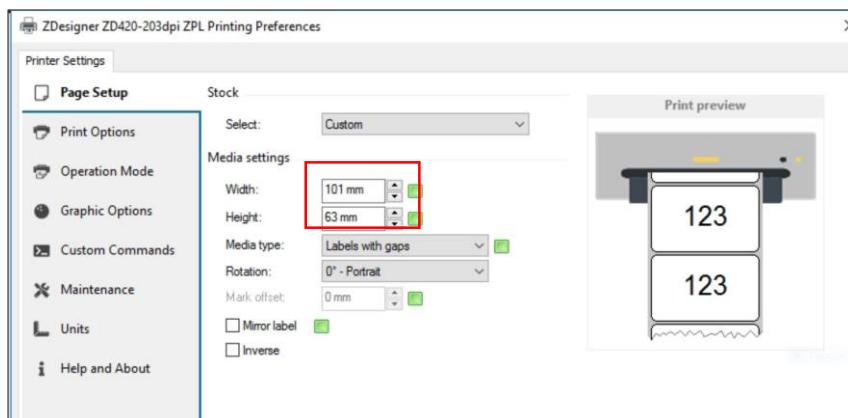
### Case 1

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.

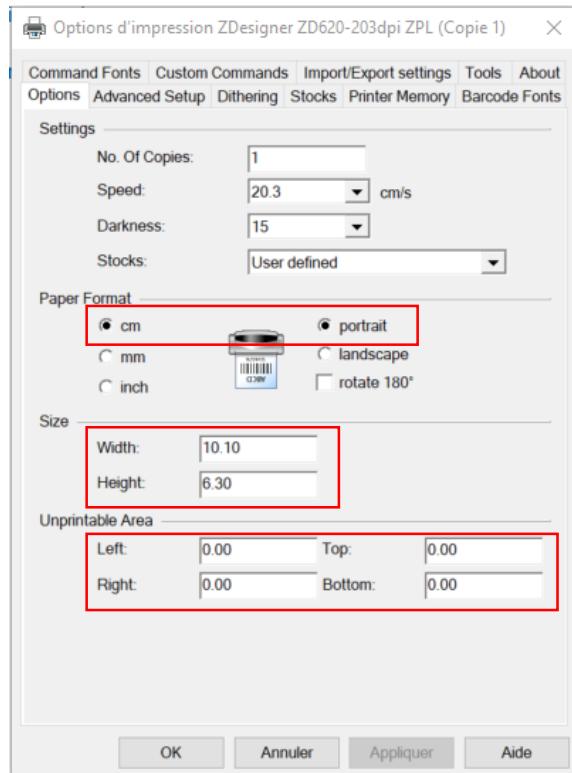


### Case 2

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.



15. Reopen “Printing preferences” to check if the introduced parameters have been saved
16. Start the PlasmaTYPHOON+ software (by clicking the icon on the desktop or the application in C:\PlasmaTYPHOON-I3\PlasmaTYPHOON-I3.exe)
17. Connect a storage connector, run a storage cycle and check if all data on the printed traceability label is correct

## 5.2. BARCODE SCANNER CONFIGURATION

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

1. Switch ON the PlasmaTYPHOON+
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:

## Set Defaults



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 An Enter Key (Carriage Return/Line Feed)

*To add an Enter key after scanned data, scan the bar code below.*



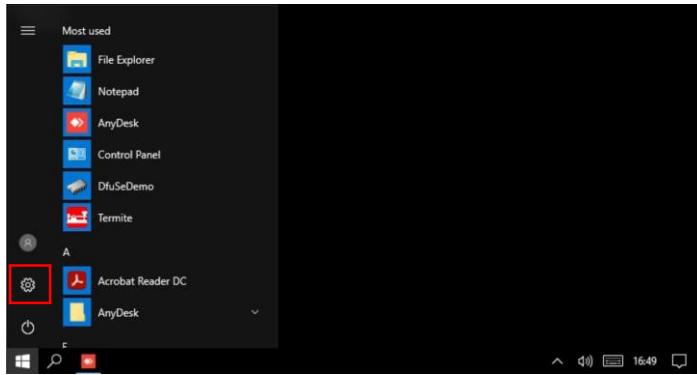
ADD AN ENTER KEY (CARRIAGE RETURN/LINE FEED)

6. Place the (wireless) barcode scanner on its base and let it validate the configuration
  7. Start the PlasmaTYPHOON+ software (by clicking the icon on the desktop or the application in C:\PlasmaTYPHOON-I3\PlasmaTYPHOON-I3.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

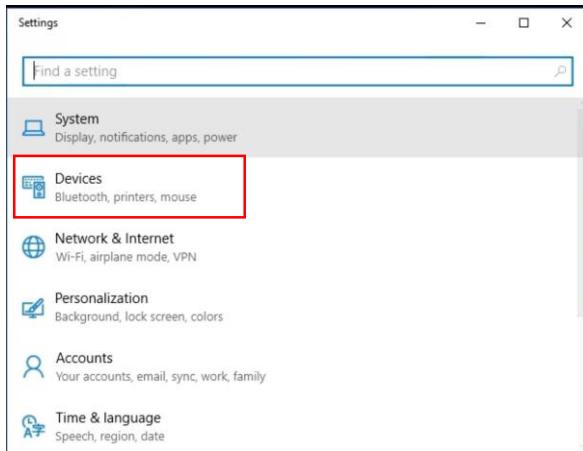
### 5.3. RFID SCANNER PAIRING

Before starting the pairing procedure of the RFID scanner with PlasmaTYPHOON+, 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 PlasmaTYPHOON+ and configured. Once the RFID scanner is charged:

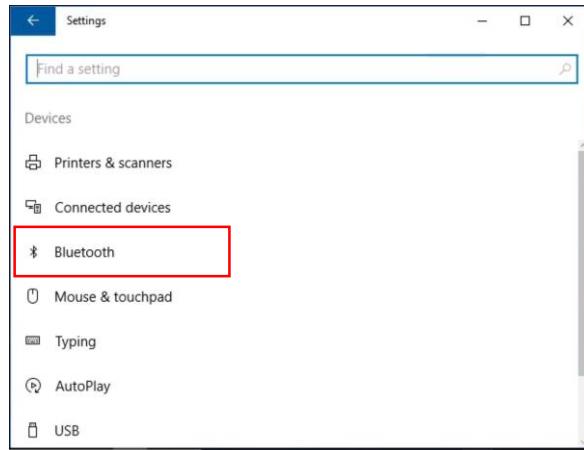
1. Switch ON the PlasmaTYPHOON+
2. Click on USER symbol to access the User Login page
3. Login as: \*ESCAPE\* (to exit PT+ software)
4. Click on Windows logo and then on Settings



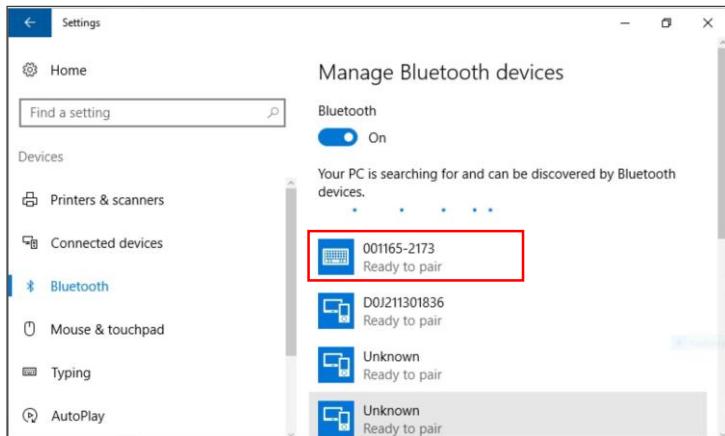
5. Click on “Devices”



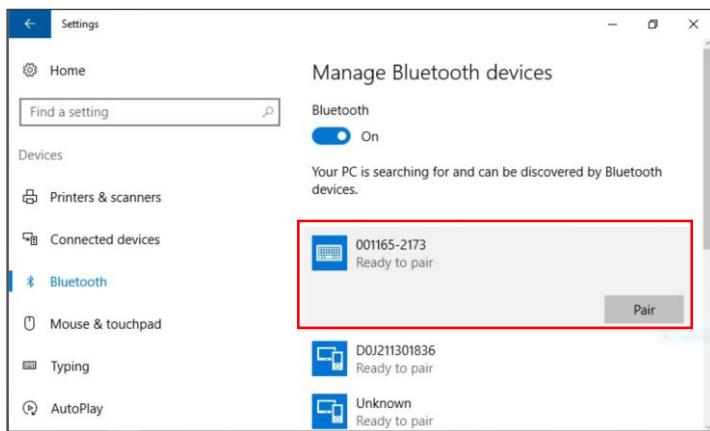
6. Click on “Bluetooth”



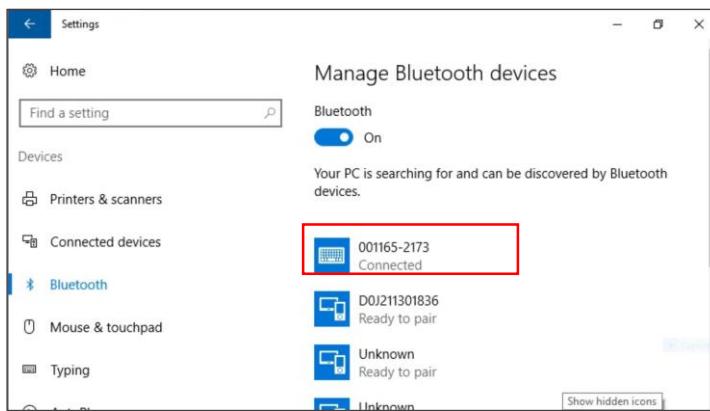
7. Place the RFID scanner close to the PlasmaTYPHOON+ and wait until it gets detected by the PlasmaTYPHOON+. Serial number of the RFID scanner will be displayed on the screen, followed by indication “Ready to pair”:



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 PlasmaTYPHOON+ software (by clicking the icon on the desktop or the application in C:\PlasmaTYPHOON-I3\PlasmaTYPHOON-I3.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 PlasmaTYPHOON+ (i.e. automatic selection of the drying cycle depending on the endoscope type and specification). This database is installed on the customer's PlasmaTYPHOON+ device in scope of the installation procedure.

Endoscopes database ENDO includes the following data:

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

ENDO database can be accessed via PlasmaTYPHOON+ 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 PlasmaTYPHOON+ (in scope of the installation procedure), it can be displayed on the screen of the device. In order to access the ENDO database via the PlasmaTYPHOON+ software, enter User Login : \*ADMIN, press PlasmaTYPHOON+ logo to access the Homepage, and then press the **Access ENDO Database** button (see Fig. 7).



Figure 7. Accessing the ENDO database via PlasmaTYPHOON+ software

An example of ENDO database displayed in PlasmaTYPHOON+ software is given in Fig. 8. Each line represents one endoscope. All modifications of the ENDO database can be performed directly via the touch screen of the PlasmaTYPHOON+. 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 type codes. Table 1 provides necessary instructions in order to select the corresponding endoscope type code depending on the endoscope type and specification.

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.

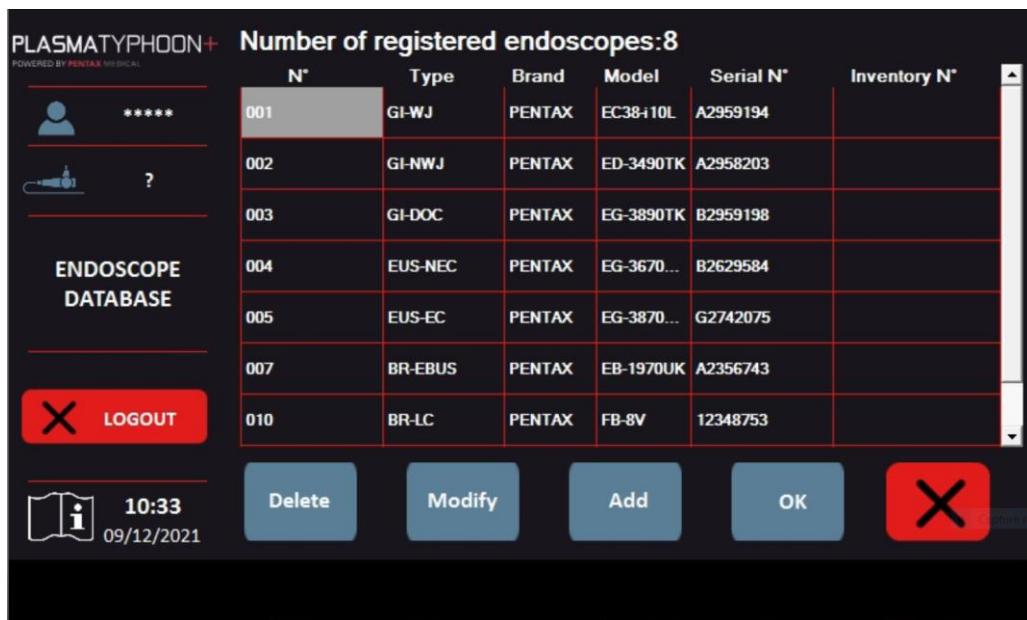


Figure 8. Example of ENDO database displayed in PlasmaTYPHOON+ software

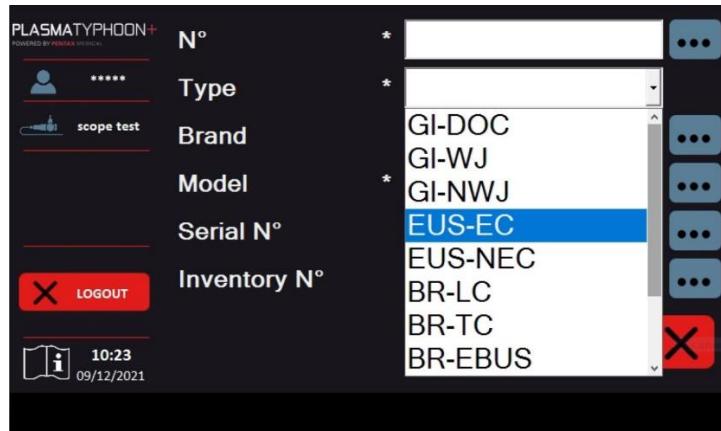


Figure 9. Adding new endoscope data via PlasmaTYPHOON+ software

Table 1. Endoscope type codes for PlasmaTYPHOON+

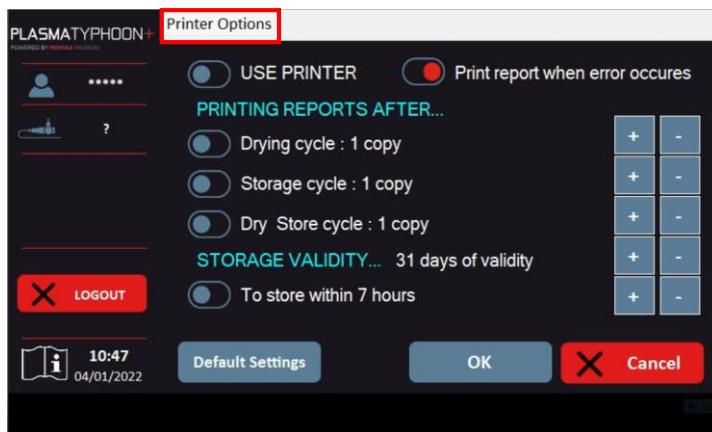
| Code           | Description                     | Specification                                  |
|----------------|---------------------------------|--|
| <b>GI-WJ</b>   | Gastrointestinal (GI) endoscope | with waterjet channel                          |
| <b>GI-NWJ</b>  | Gastrointestinal (GI)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

## 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 PlasmaTYPHOON+ 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 drying cycle
- Print report after storage cycle
- Print report after drying & storage 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.

Maximal storage duration validated by PlasmaBiotics is 31 days, but in some countries maximal endoscope storage time may be subjected to national regulations. Due to this, one has the possibility to adjust:

- Maximal storage validity time (up to 31 days)
- Maximal delay time between drying and storage procedure according to the national regulations in his/her country.

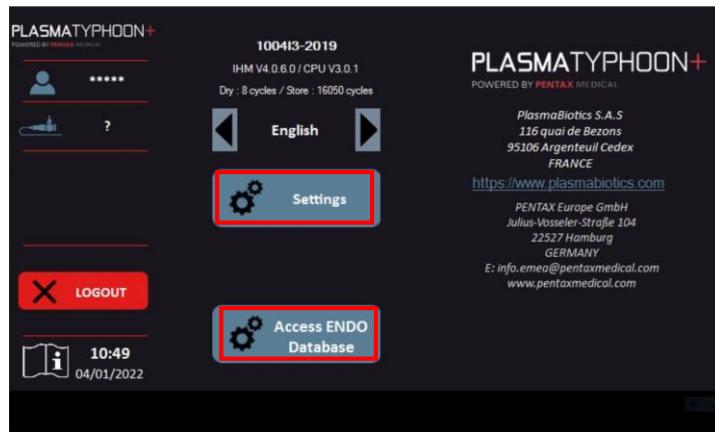
Finally, click "OK" to validate the settings.

## 8. ADMINISTRATOR MODE

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

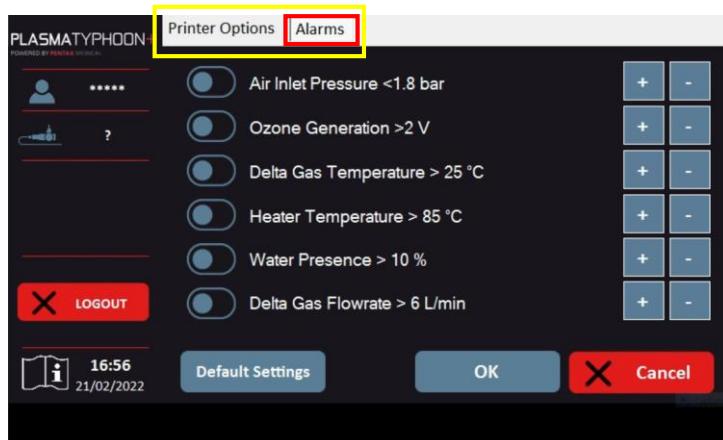
- ENDO database (see section 6)
- PlasmaTYPHOON+ settings – including printer options and alarms

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



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

- Printer Options window (the same as in section 7)
- Alarms (security systems) window



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:

- Input Pressure – Minimal air inlet pressure alarm
- Plasma, Ozone – Plasma/ozone generation alarm
- Delta Temperature – Maximal gas temperature deviation alarm
- Heater Temperature – Maximal heater temperature alarm
- Humidity Level – Water presence alarm
- Alarm Flow Regulation Error by Delta – Maximal gas flowrate deviation alarm

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 PENTAX or local distributor's technician.

## 9. HISTORY DATABASE

PlasmaTYPHOON+ has an electronic traceability system, i.e. the history of all treatment cycles performed by PlasmaTYPHOON+ is saved in a database named REPORT. This CSV file is located in "History" folder on PlasmaTYPHOON+ 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 code
- ✓ Endoscope ID (barcode or RFID tag) number
- ✓ Endoscope model
- ✓ Endoscope serial number
- ✓ User (operator) name or number
- ✓ Completed cycle (drying, storage or both) and cycle conformity (DONE)

An example of REPORT database (displayed in Excel) is presented in Fig.10.

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

Figure 10. REPORT database – treatment cycles history table

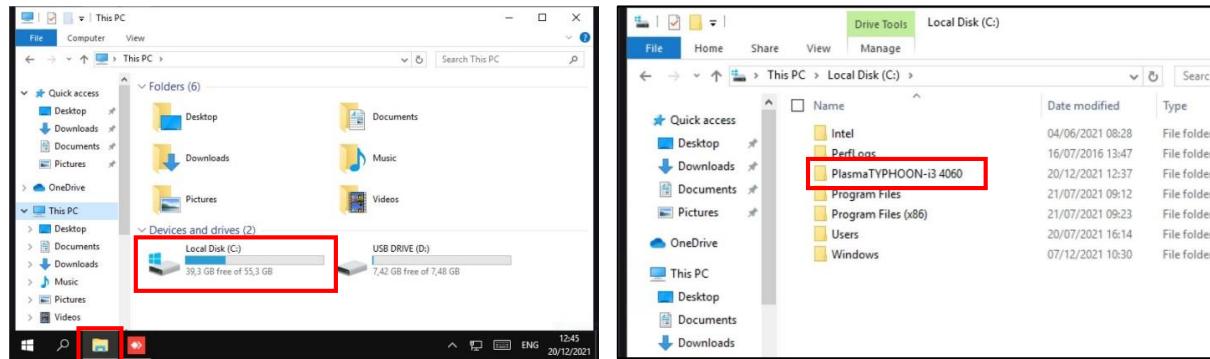
 **Warning:** This recording is not an archive. It is hospital's/clinic's responsibility to store and archive these data in their own data storage system.

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

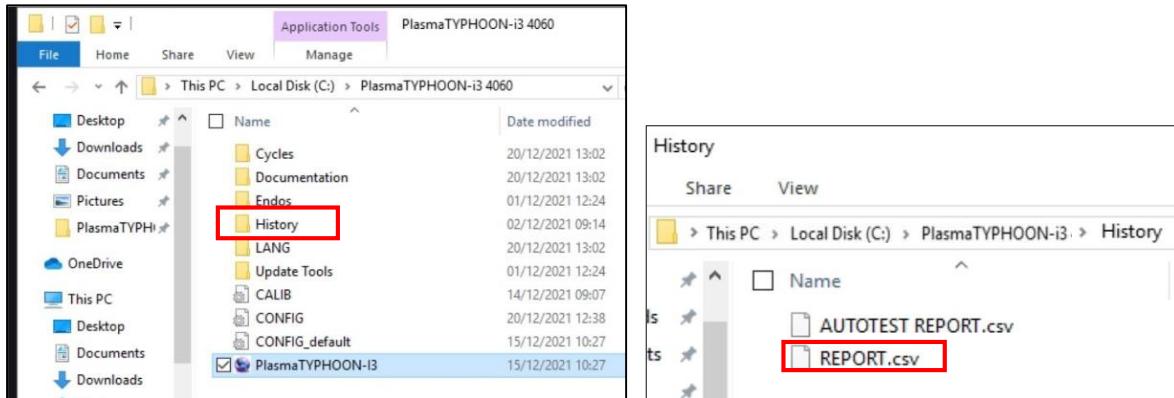
### 9.1. ACCESS TO REPORT DATABASE

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

History folder is located on the hard drive **Local Disk (C:)** in a folder named **PlasmaTYPHOON-i3**.



- Click on **PlasmaTYPHOON-i3** and then on **History**



REPORT database, being a CSV file, if it is open on the PlasmaTYPHOON+ PC, it will be displayed in a Notepad (see Fig. 11)

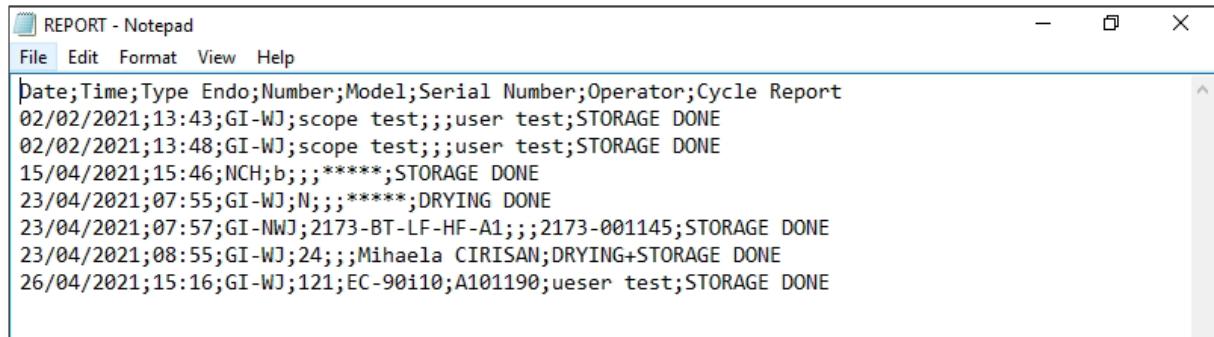


Figure 11. REPORT database displayed in a Notepad.

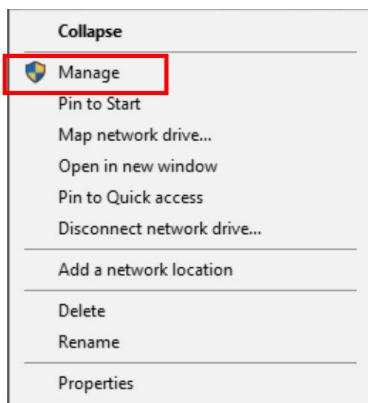
One can copy/paste the REPORT file to his USB stick, in order to store it elsewhere.

## 10. GLOBAL TRACEABILITY

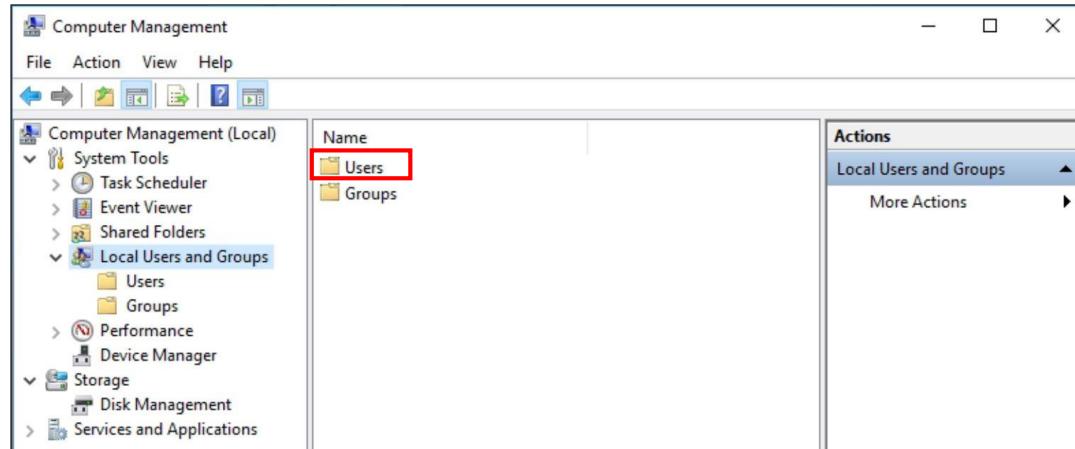
Thanks to its integrated PC board, PlasmaTYPHOON+ device can be connected to the healthcare facility network. In order to do so, Ethernet (RJ45) port of the PlasmaTYPHOON+ device shall be connected to the local network. The instructions on how to connect and access electronic traceability data (REPORT file), located in the History folder on the local disk C, are given below.

### 10.1. CREATE A NEW USER

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

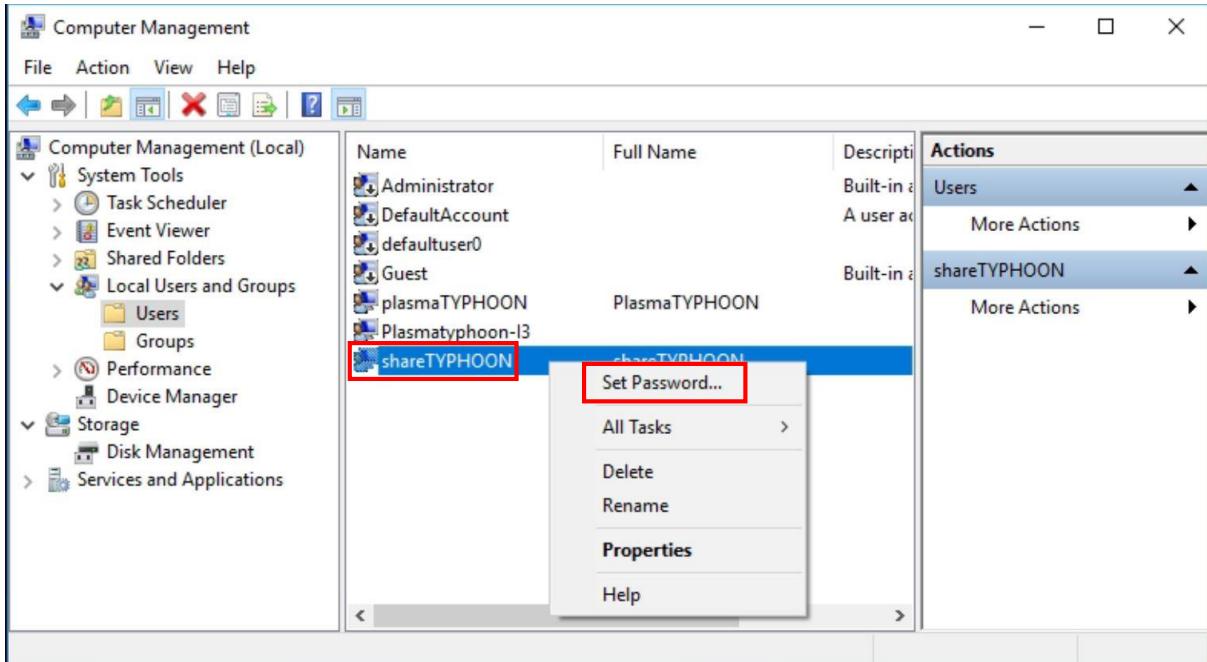


- In the left-side menu click on “Local Users and Groups”
- Then click on “Users”

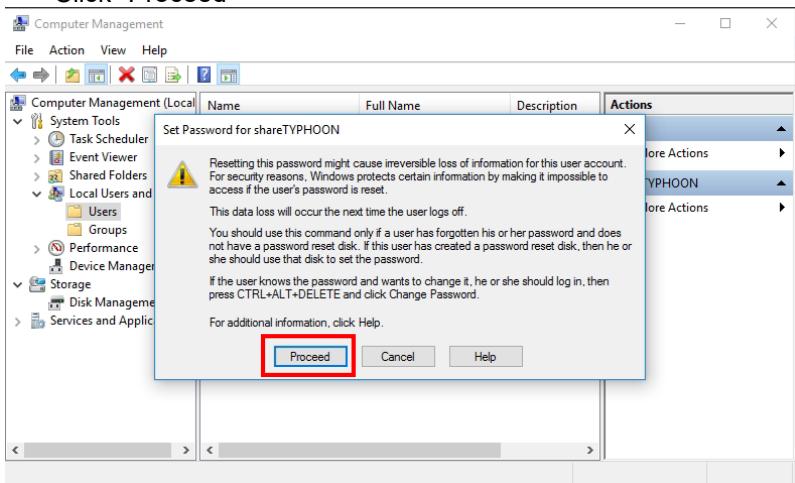


- Right click on “shareTYPHOON”
- Then click on “Set password...”

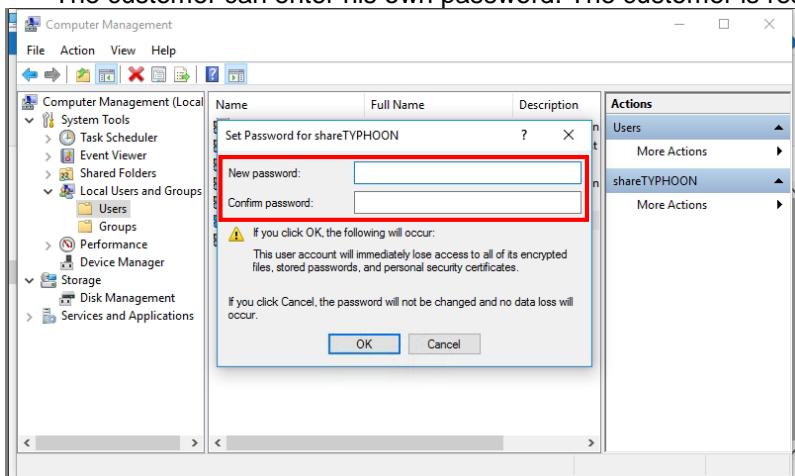
## PlasmaTYPHOON+ Technical Manual for User



- Click "Proceed"

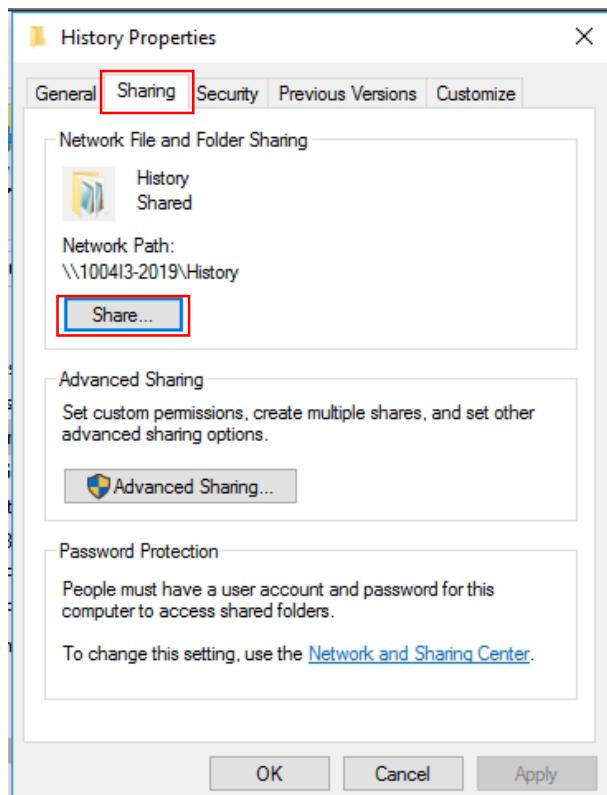


- The customer can enter his own password. The customer is responsible for his password.

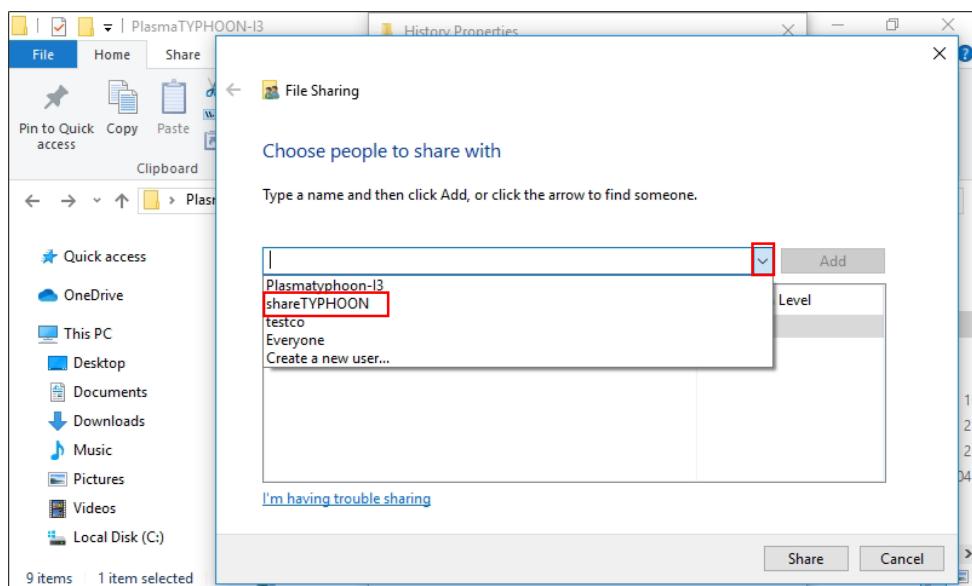


## 10.2. SHARE THE HISTORY FOLDER

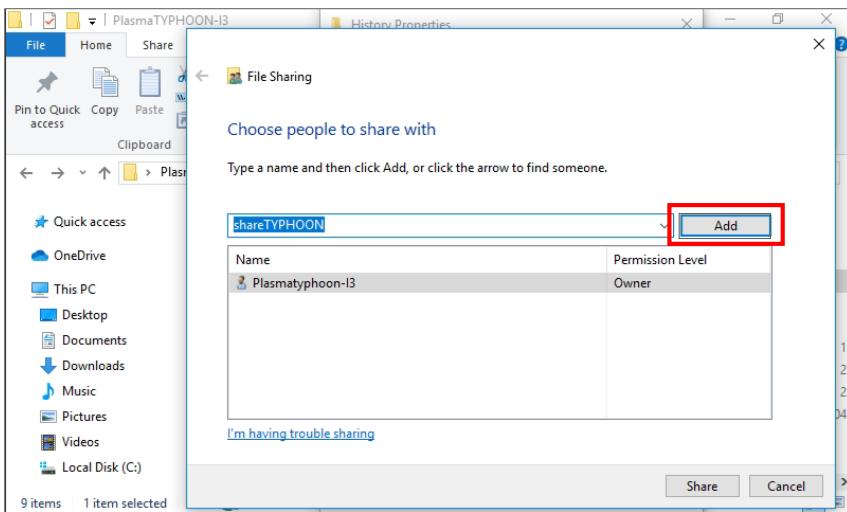
- Click on Local Disk (C:)
- Click on PlasmaTYPHOON-I3 folder
- Right click on “History” folder
- Click on “Properties”
- In the pop-up window “History Properties” click on the Tab “Sharing”
- Then click on the button “Share”



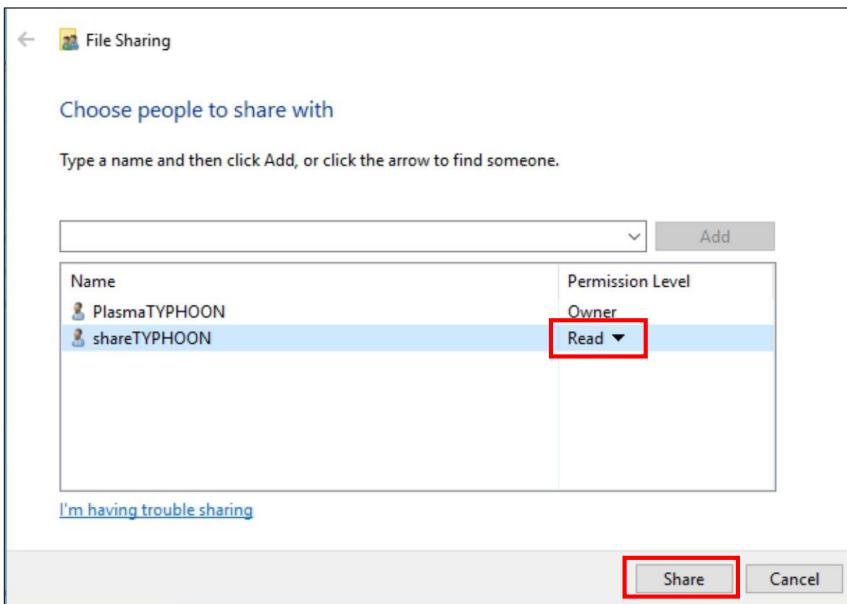
- Add “shareTYPHOON” from the scrolling menu



- Click “Add” button

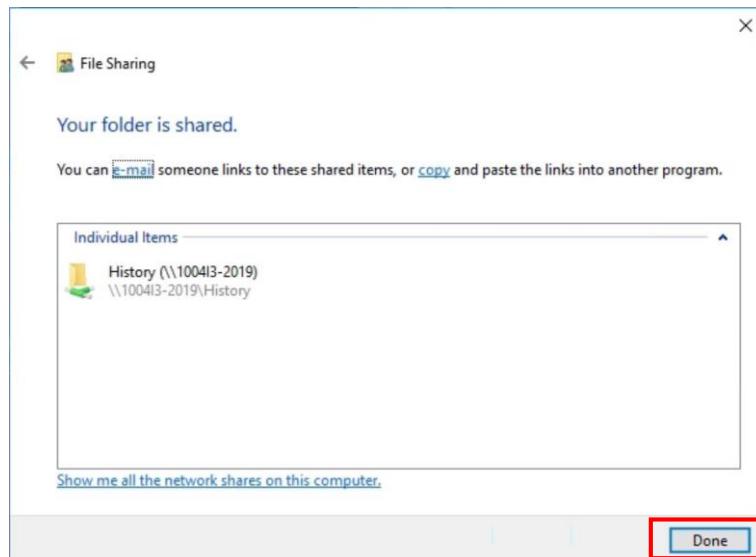


- Give “Read” permission
- Then click on “Share”

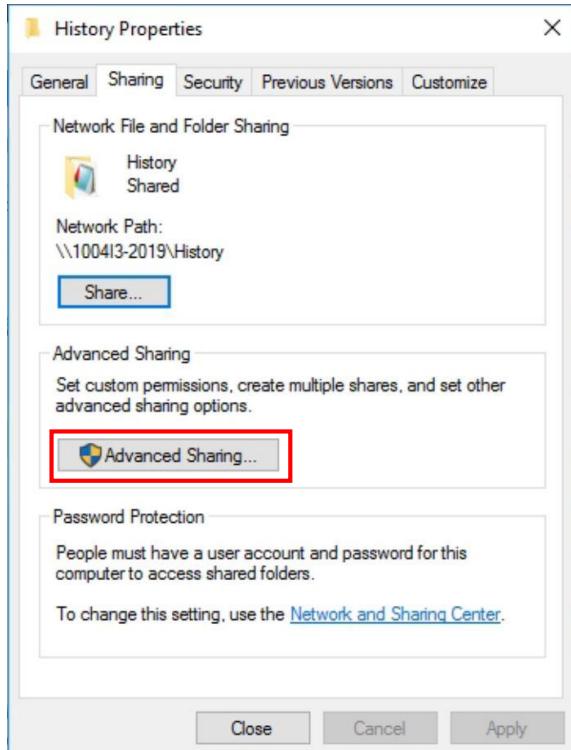


A window indicating that folder “History” is shared will appear on the screen.

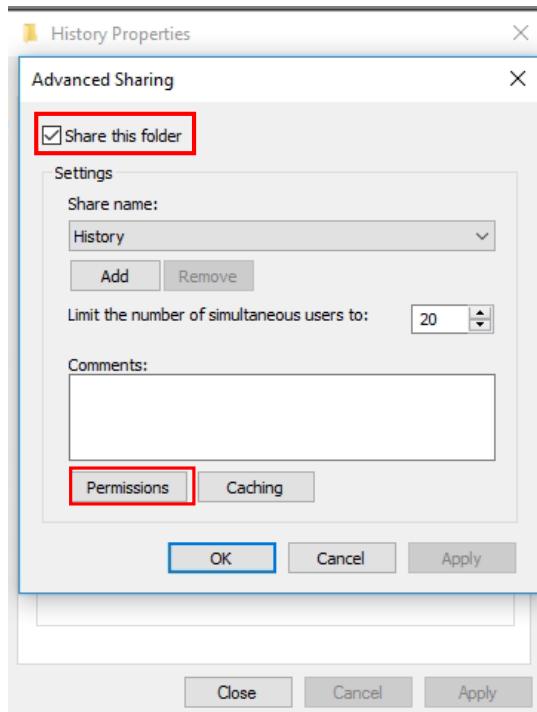
- Finally, click on “Done”



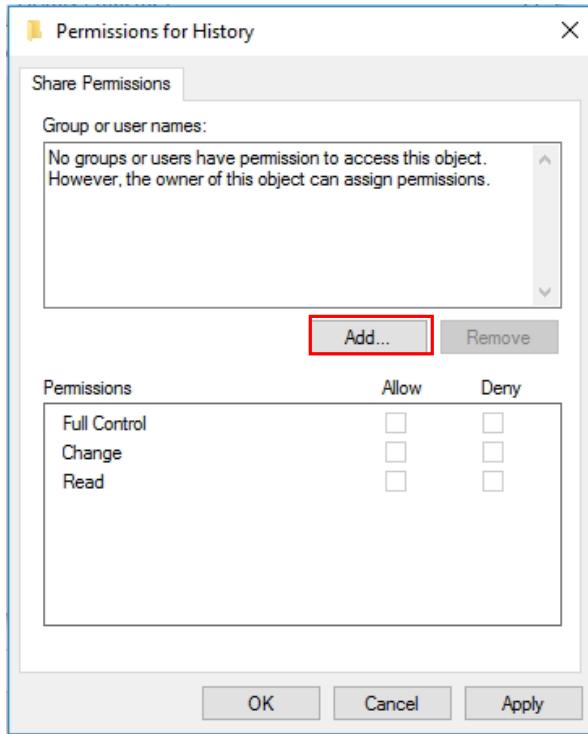
- Now, in the window “History Properties” click on “Advanced sharing”



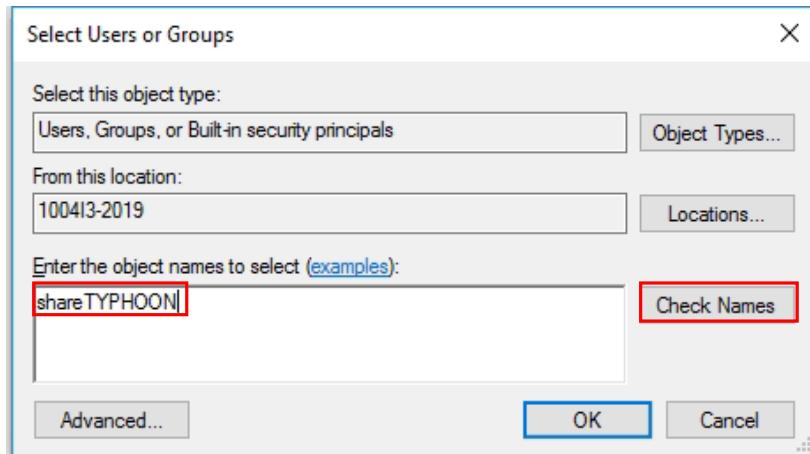
- Check “Share this folder”
- And click on “Permissions”



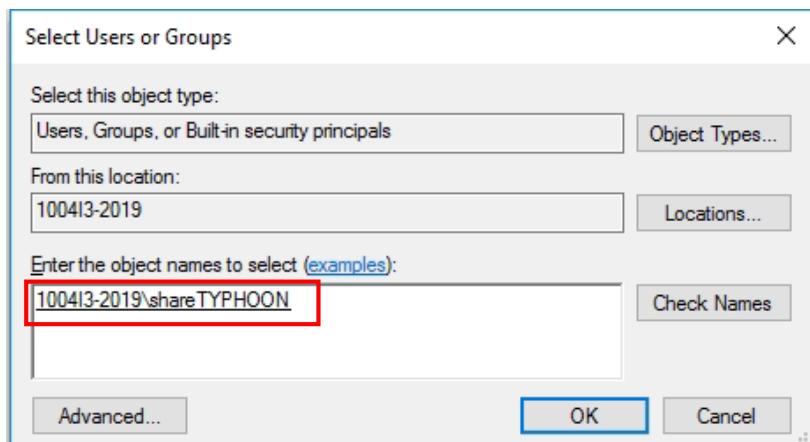
- Click on “Add” button



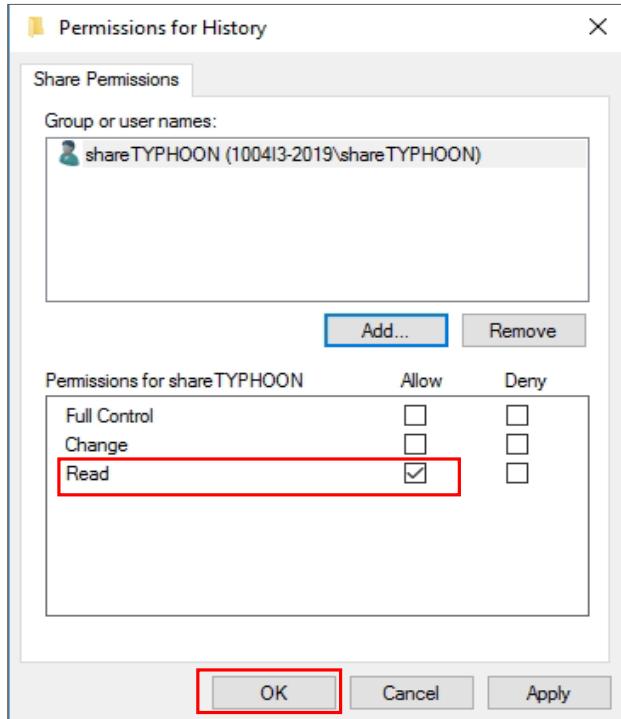
- In the pop-up window, type "shareTYPHOON" in the case "Enter the object names to select"
- And click on "Check Names"



- 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

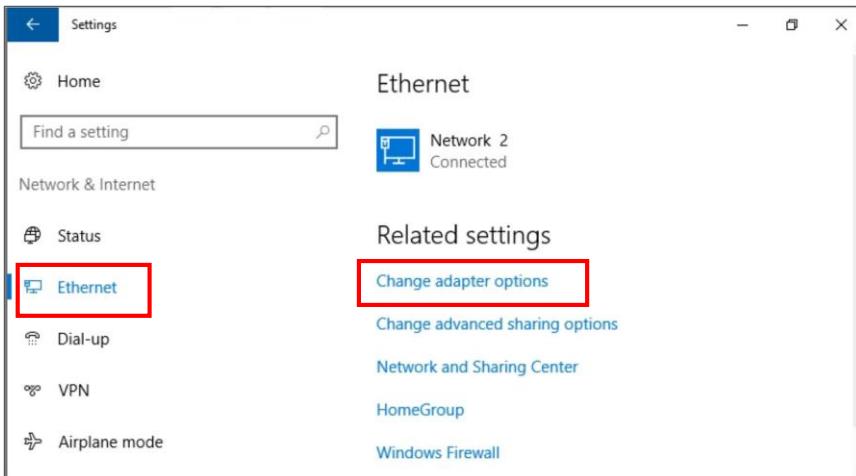


### 10.3. BLOCK THE PLASMATYPHOON+ IP ADDRESS

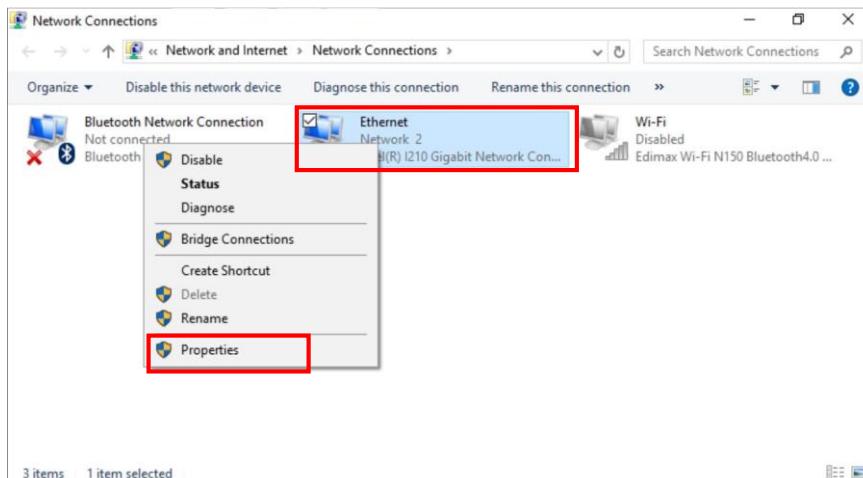
- Go to “Windows Settings”
- Click on « Network and Internet »



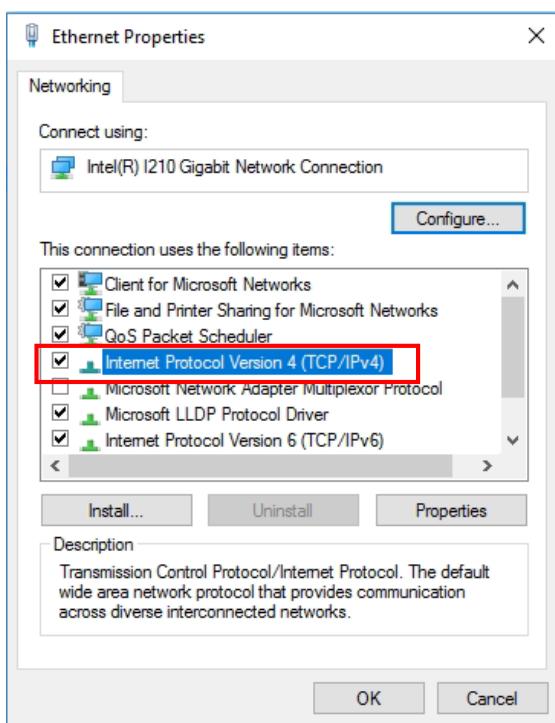
- Click on “Ethernet”
- Click on “Change adapter options”



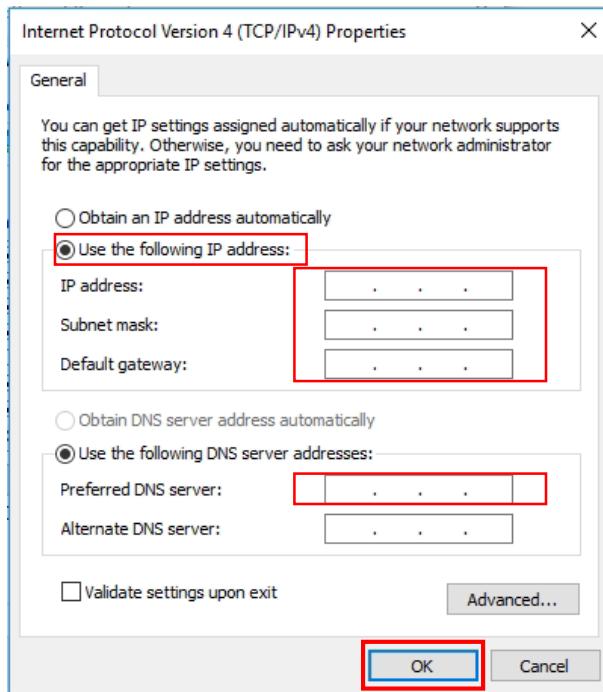
- Right click on “Ethernet”
- Click on “Properties”



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

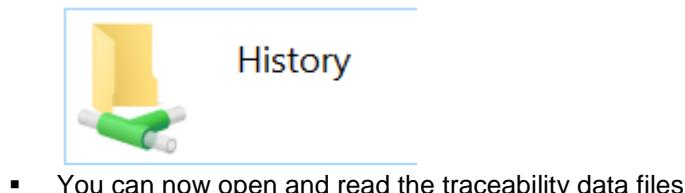


- Click on « Use the following IP address »
- The customer IT service shall choose the IP address instead of the subnet mask and default gateway
- Finally, click “OK”



#### 10.4. ACCESS TO THE HISTORY FOLDER

- Click on « Network » in the File Explorer
- Find the PlasmaTYPHOON+ 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

MANUFACTURER & SERVICE



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