MD System

8072027H 2021-11-11 USERS MANUAL, ENGLISH

μ dialysis

Instructions for use MD System

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MD System

The manufacturer will be considered responsible for the device with respect to safety, reliability and function only, if:

- the device is used in conformity with these instructions for use.
- the installation, the extensions, the re-adjustments, the modifications and the repairs have been carried out by the manufacturer or authorized representatives.
- M Dialysis AB is only responsible for replacement of defective parts, not wear of parts.
- M Dialysis AB is not responsible for any personal injury or any damage resulting from incorrect use of the MD System.

Note! At the time of printing this manual correctly describes the device and its functions. However, as modifications may have been carried out since the production of this manual, the system package may contain one or more amendments to this manual. This manual including any amendments must be thoroughly read before using the device.

Contents

1. Safety-related information

Prior to using the MD System, attentively read the entire instructions for use and become familiar with the operation of the device.

Due to the lack of a limit value monitoring function, the MD System may not be used in standalone mode for intensive medical patient monitoring.

A therapy decision may not be made based solely on the information provided by MD System but must be accompanied by another method, e.g. the ICP measurement, pbtiO2 and other.

In order to ensure safety, reliability and performance of the system, the following notes shall have to be observed carefully:

- The MD System must be operated by qualified staff only. (See intended user 2.1.1)
- Prior to using the MD System, you must be completely familiar with the operation of the system.
- If two or more devices with separate main power connections are used on the same patient, the device leakage current adds up which may cause a potential hazard. In this case, use shall be permitted only, if it has been secured that patient and operator are safe, and that the requirements of standard IEC 60601-1-1 are fulfilled.
- Prior to using the MD System, the correct condition of the device and any accessories shall have to be checked. Check the plausibility of the readings before using the device for monitoring. The device and the accessories must not be damaged or soiled; otherwise the device must not be used.
- Do not use the device if it reveals obvious signs of a mal function; in this case forward the unit to the after-sales service of the manufacturer.
- For service-related questions, contact the manufacturer directly. If required, the manufacturer will direct you to a local authorized service partner.
- The MD System should be positioned and/or fastened in a manner by which the device is secure and cannot be damaged or cause hazards. Care must be taken to prevent cables attached to the MD System from tipping or moving the system.
- After use, clean, disinfect and/or sterilize the accessories according to the instructions for use. If the accessory has been provided with separate instructions for use, the instructions rendered there shall be applicable.
- No liquids or fluids shall enter the device. If this should happen nonetheless, first remove the main adapter from the port and switch off the system using the power switch. Provide the device to the after-sales service department for inspection. Subsequently a safety-related check is necessary.

- The MD System has been designed in conformity with IEC 60601-1. It is a class II product with an internal power source, an external main power adapter and has been allocated to class IIa (MPG).
- The MD System must not be used in conjunction with the MRI.
- To avoid leakage currents the following instructions should be observed for the installation of the system:
    - Moveable multiple sockets must not lay on the floor.
    - Additional moveable multiple sockets or extension cables must not be connected directly to the device.
    - Devices, which are not part of the system, must not be connected.
    - The moveable multiple sockets have to be appropriate for the load of the system.

Warning! MD System is an adjunct analytical device which must always be used together with other means of assessing the patient's clinical condition. Diagnosis and change in therapy must not be based solely on data from MD System.

Warning! The MD System is intended to be used in hospital environments except:
- near active HF surgical equipment.
- during magnetic resonance imaging (MRI).
- during hyperbaric oxygen therapy.
- in rooms warmer than +38°C

- Cyber security information:
    - Patient information: Patient name is not required; it is possible to replace the true name with an alias.
    - USB ports on MD Monitor are intended for export of patient data or request for remote support.
      Mouse, keyboard and scanner may be connected only if necessary for intended use or for service purposes.
      Connecting any device for any other purpose is strictly prohibited.
    - Ethernet port "Service" on MD Unit is intended for service connection by authorized service technician. Connecting for any other purpose is strictly prohibited.

2. Description of the device

2.1. Intended use

MD System is a microdialysis analyzing system, which is used in conjunction only with M Dialysis catheters, performing continuous monitoring of Glucose, Lactate and Pyruvate levels in microdialysates.

2.1.1. Intended user

The MD System is intended to be used by experienced health care professionals

2.1.2. Intended purpose

The MD System is a monitoring device for measuring and displaying the levels of concentration for Glucose, Lactate and Pyruvate in tissue or blood. This information support clinical decisions or can be of use for clinical research. The device provides the information only when connected to the MD Catheter.

2.1.3. Intended use environment

The MD System is intended to be used in a clinical environment by experienced healthcare professionals and also in clinical research environment. The product is not intended for outside hospital use such as helicopters or ambulances. The MD System is not intended for home use. Qualified physicians experienced in the field of application must always assess whether the use of MD System is appropriate for a specific patient or not.

2.2. Indications for use

2.2.1. Condition

The MD System is indicated when the clinician decides there is a need to measure and display the metabolic changes via analyses of Glucose, Lactate and Pyruvate.

2.2.2. Part of Body or Type of Tissue with Which the Device Interacts

The MD Catheter is in vivo. MD Amplifier is not intended to come in contact with the body of the patient and shall be attached with padding between the MD Amplifier and the skin.

2.2.3. Frequency of Use

The MD System is indicated for use when prescribed by a clinician.

2.2.4. Physiological Purpose

The MD System is indicated when the purpose is to gain information for treatment, to assess adequacy of treatment, or to rule out causes of symptoms.

2.2.5. Patient Population

The MD System should be used on non-ambulatory patients. The user should refer to each Microdialysis catheter´s instructions for use.

2.3. Terminology and definitions

Applied parts – MD Amplifier and MD Sensor are applied parts, placed close to the patient. MD Unit is regarded as applied part with a contact duration of 10 seconds < t < 1 minute.

Biosensor – Coated electrodes which generate the raw current from the different analytes in the microdialysate. The biosensor is included in the MD Sensor.

MD Unit – Central unit containing process control and analyzing unit

MD Amplifier – Non-consumable part (multiple use) placed close to the patient. Contains amplifier and A/D converter. Amplifies the raw signal from the biosensor and sends digital values to the MD Unit

MD Calibrator – MD Calibrator is fluid especially developed for calibrating the MD system regularly for Glucose, Lactate and Pyruvate. The fluid should be stored in a fridge, +2 - +8 °C.

MD Cartridge – Part containing filled syringes connected to the MD Sensor. The MD Cartridge is, prepared with syringes, inserted in the MD Unit and the syringes are actuated by the syringe motors. MD Cartridge is for multiple use.

MD Sensor – Part to which the patient Microdialysis catheter outflow is connected to. Contains a biosensor and connective tubing to the MD Cartridge. MD Sensor is a single use part.

 **Warning!** Be sure to check that MD Sensor package is undamaged prior use.

106 Syringe – Special syringe for Microdialysis supplied by M Dialysis AB. 106 Syringe is for single use.

Syringe Orange – Special syringe for calibration of MD System, supplied by M Dialysis. Syringe orange is for single use.

Perfusion Fluid CNS – Perfusion Fluid is a sterile, isotonic fluid especially developed for brain Microdialysis.

Perfusion Fluid T1 – Perfusion Fluid is a sterile, isotonic fluid especially developed for Microdialysis in peripheral tissues.

Sensor docking – Where the MD Sensor is connected to the MD Amplifier.

MD Catheter - Microdialysis catheter supplied by M Dialysis. For example, the 70 Brain Microdialysis Catheter, 63 Microdialysis Catheter and others. For handling of the MD Catheter read the MD Catheter IFU.
Note! The MD System must only be used with Microdialysis catheters with 20 kDalton membrane pore size.

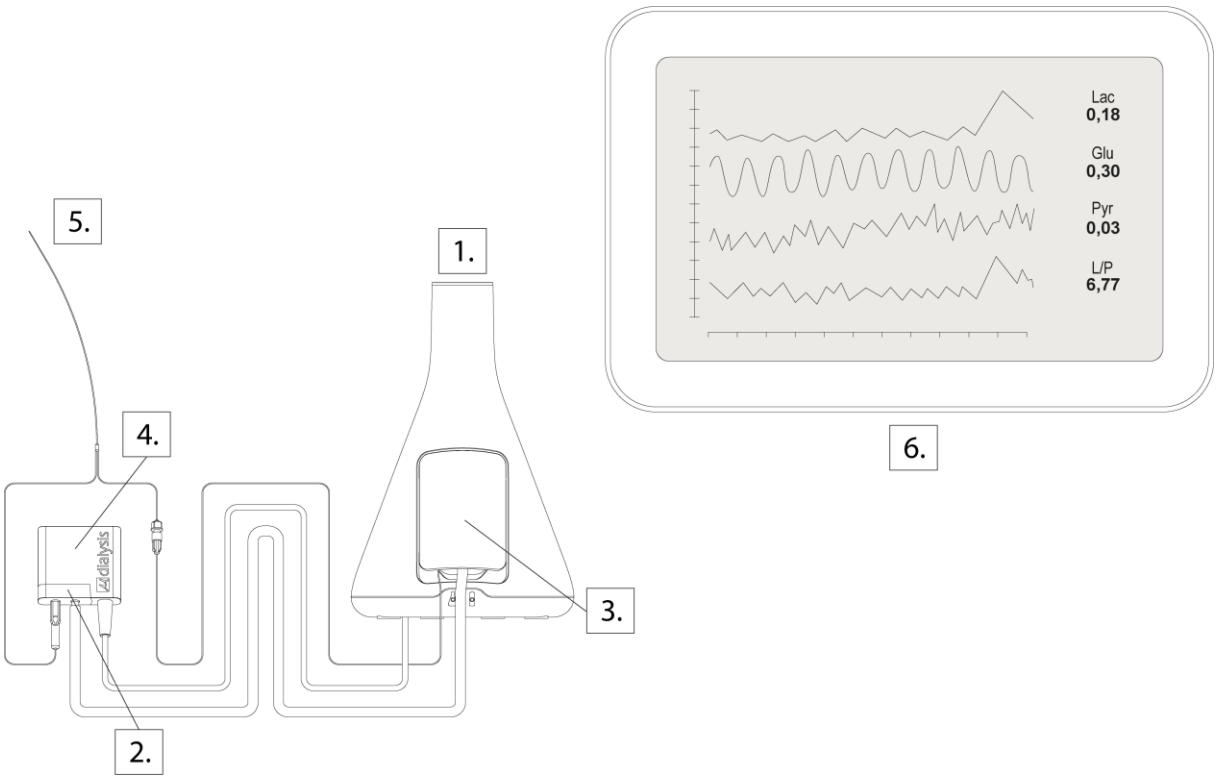
Catheter Extension - Sterile disposable extension tubing with luer lock connections connected between the 106 Syringe and the Microdialysis Catheter. The Catheter Extension is for single use.

2.4. System overview

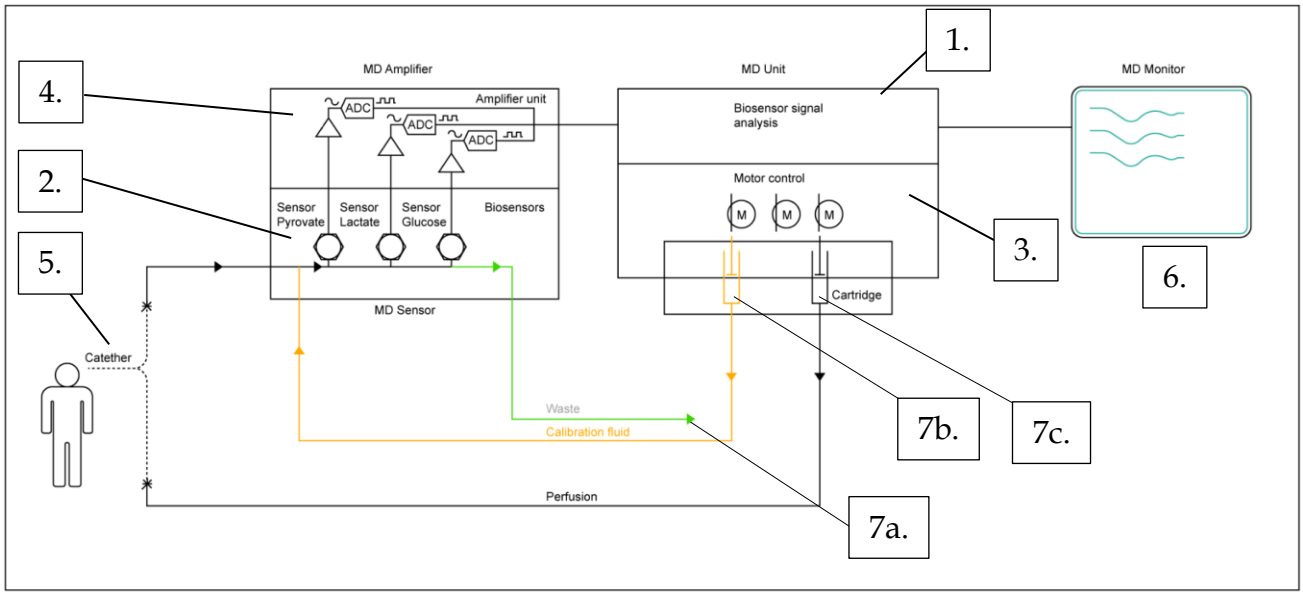
MD System consists of:

1. MD Unit, consisting of a power supply unit, syringe pumps and a computer.
2. MD Sensor, consisting of a Biosensor and tubing
3. MD Cartridge, consisting of an interface for the MD Unit and a syringe retainer.
4. MD Amplifier, consisting of an amplifier with cable.
5. MD Catheter, refers to a variety of Microdialysis catheters supplied by M Dialysis, for example the 70 Microdialysis Brain Catheter, 63 Microdialysis Catheter and others.

   Note! The MD System must only be used with Microdialysis catheters with 20 kDalton membrane pore size.
6. MD Monitor, consisting of a pre-configured Windows PC with integrated monitor and a power supply unit.



2.5. System block diagram



MD System has five main functions:

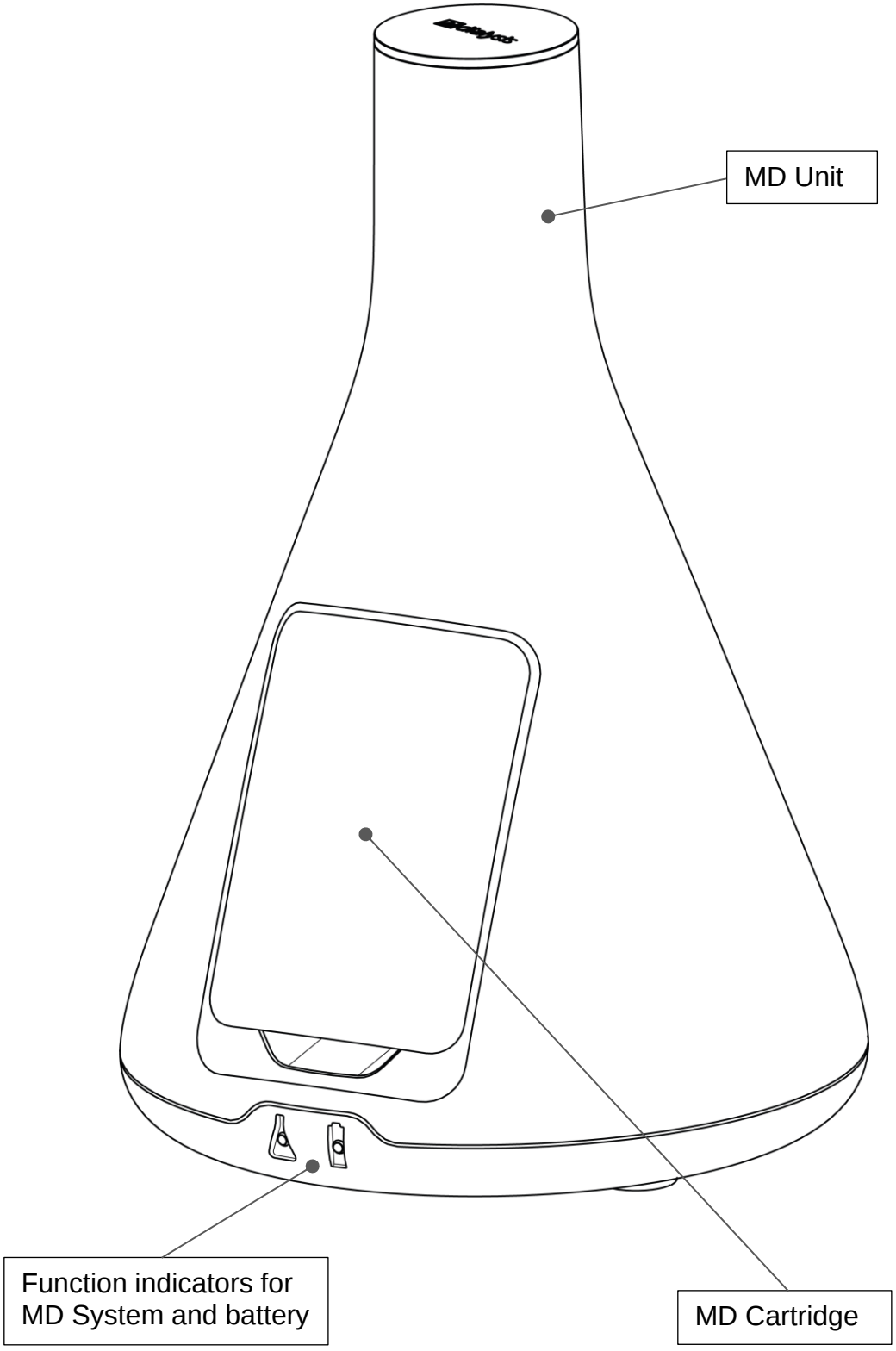
- A controlled flow of perfusion liquid to the MD Catheter.
- A controlled flow for Calibration fluid to perform recurring calibrations.
- A Biosensor that converts the content in the microdialysate to an electric current.
- An amplifier that amplifies the signal from the biosensor.
- Analysis software that displays the signal from the biosensor.

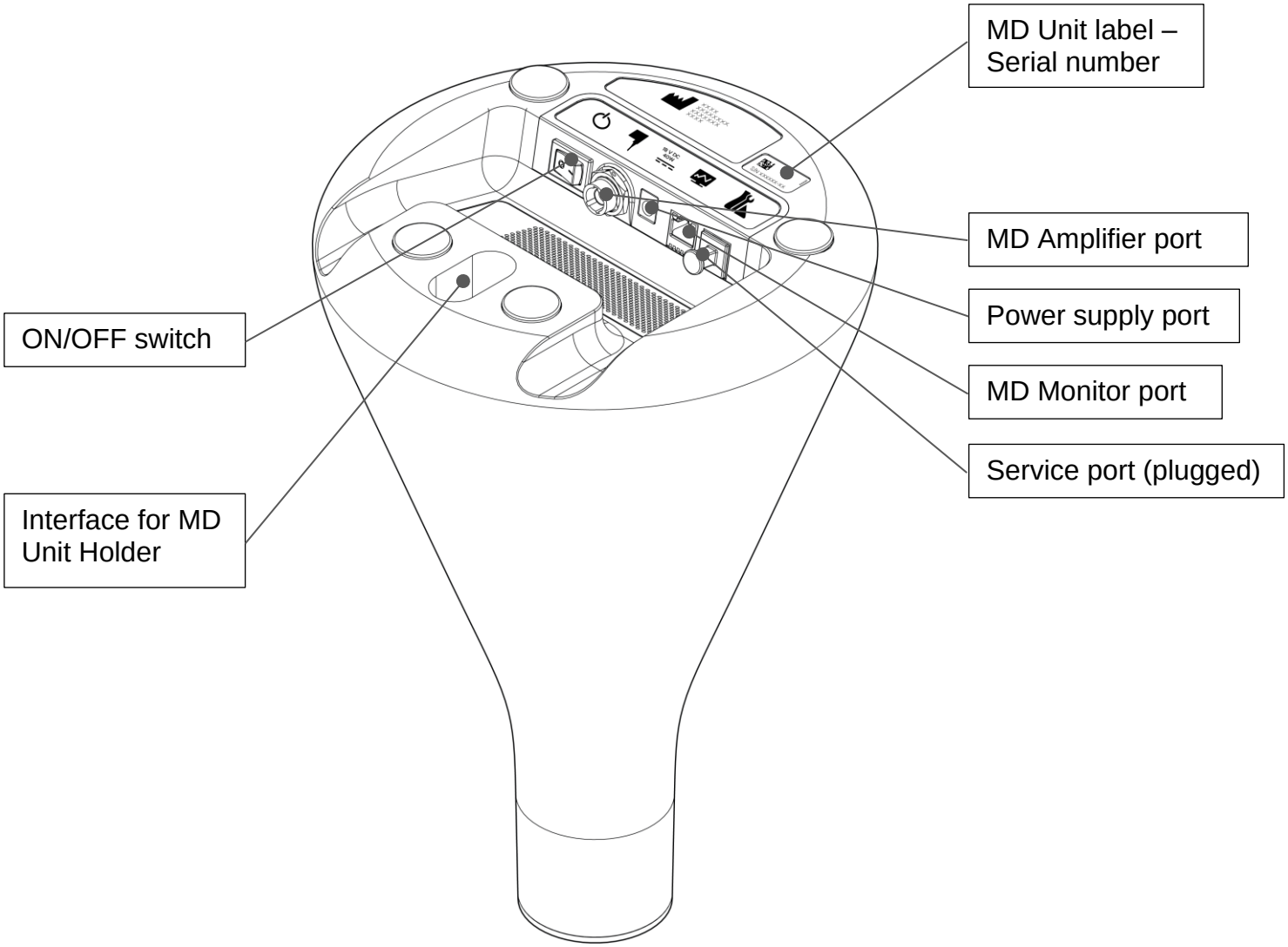
To facilitate the perfusion flow of 0.3 µl/min – 2.0 µl/min, one standard 106 Syringe (7c) is actuated by a Piezo motor with sufficient resolution. The 106 syringe supplies the MD catheter (5) with perfusion fluid that allows molecules to diffuse through the catheter dialysis membrane from the surrounding tissue, creating the so called microdialysate or dialysate.
Note! The MD System must only be used with Microdialysis catheters with 20 kDalton membrane pore size.

The dialysate passes through the Biosensor in the MD Sensor (2) where enzyme coated electrodes each generate a current that is proportional to the number of endogenous molecules of the specific analyte. After the Biosensor, the dialysate continues to the housing tubing as waste (7a). The MD Amplifier (4) amplifies and converts the analogue signal to a digital signal which is processed in the MD Unit (1) and displayed on the MD Monitor (6).

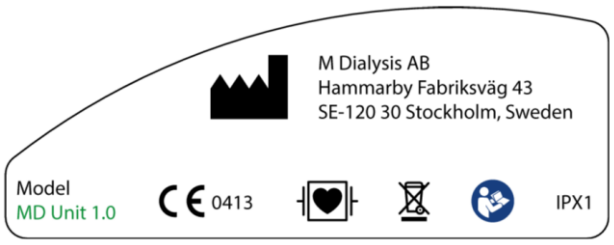
Recurring calibrations where Calibration Fluid is pumped through the MD Sensor, instead of the regular microdialysis perfusate, will ensure that any drift in the analyte signals is compensated for.

2.6. MD Unit parts

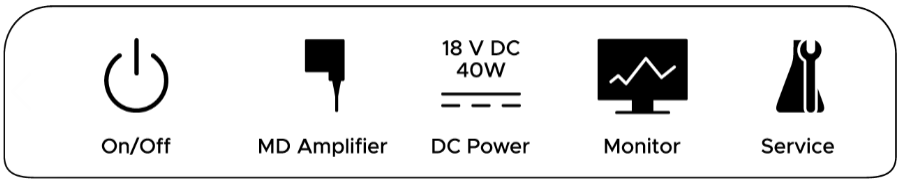




MD Unit label

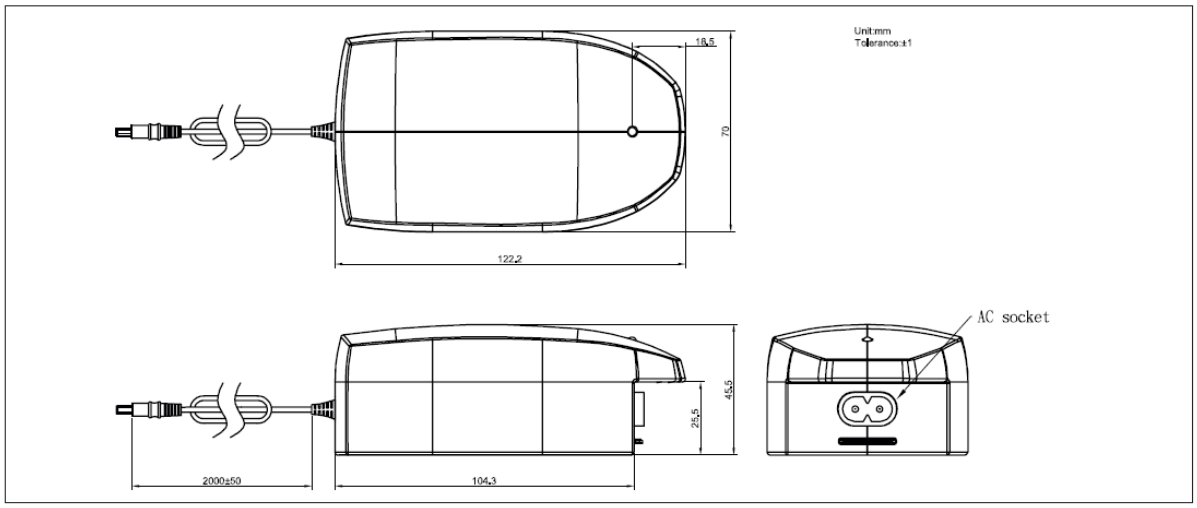


MD Unit label – Port explanation



2.7. MD Unit power supply

The MD Unit comes with a power supply, 18V DC.
Manufacturer: Powerbox
Model code: EXM 80 5120



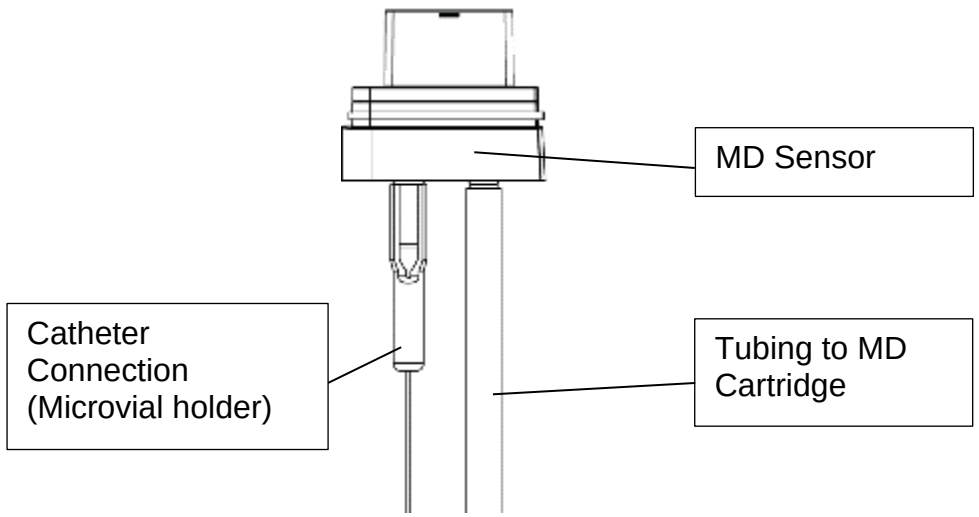
Warning! Use only specified power supply identified on the power inlet. If any suspicion of damage or other fault of power supply replace with new. If in doubt consult M Dialysis AB.

2.8. MD Sensor

MD Sensors are for single use only and should be disposed, according to the hospital routines, as biohazardous waste after used.

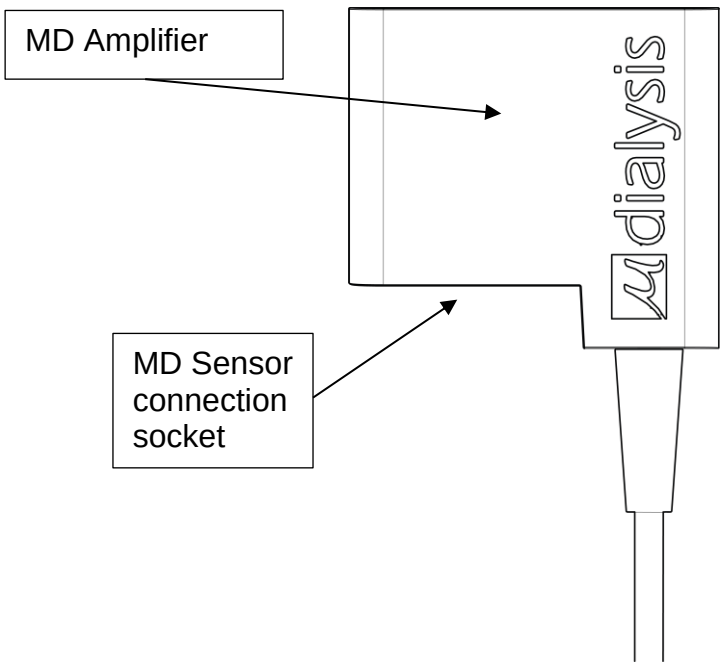
Warning! Don’t use if package is broken or damaged.

Warning! The MD Sensor is single use only.



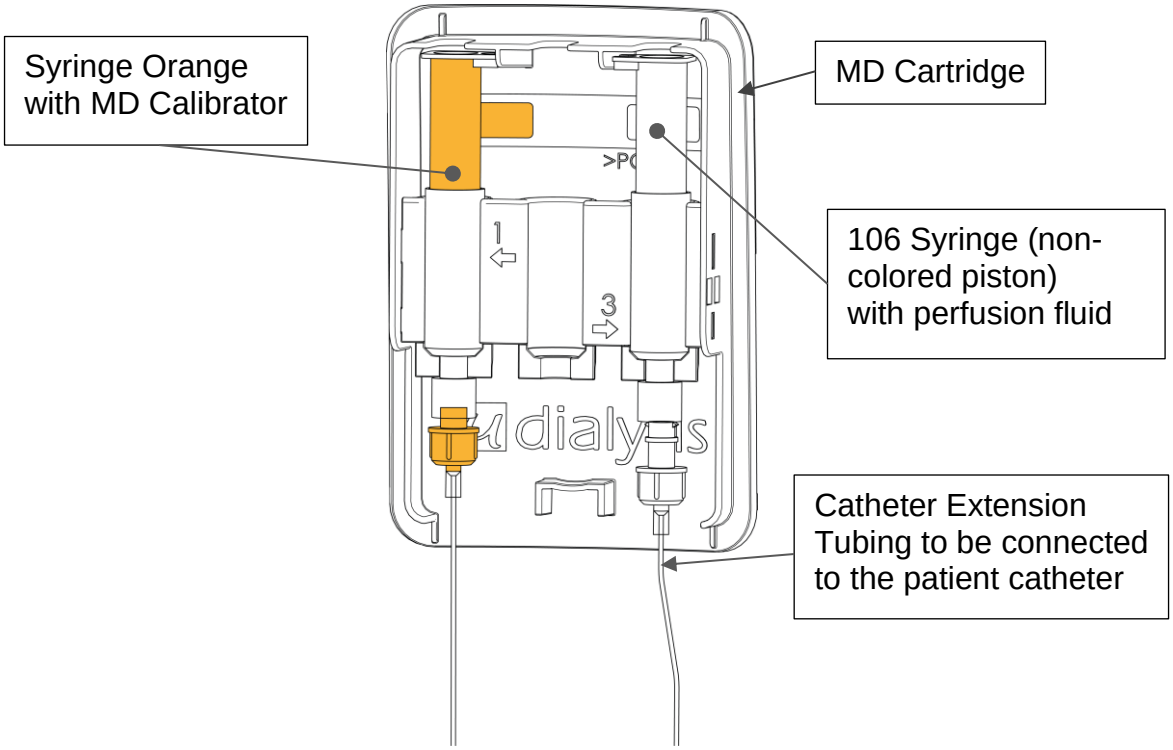
2.9. MD Amplifier

The MD Amplifier can be reused for a period of up to 1 year.



Warning! Only clean housing with disinfectant (70% ethanol or equivalent).Do not clean or touch MD Sensor connection socket. Do not clean using sharp objects.

2.10. MD Cartridge

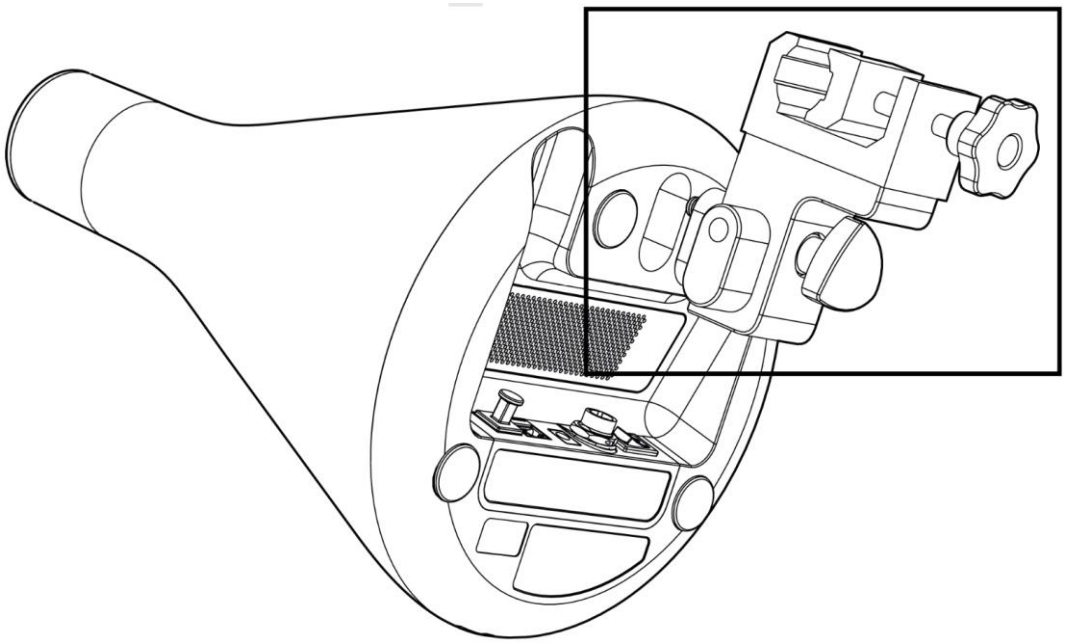


2.11. Battery back-up

The MD Unit contains a battery back-up if MD System should be disconnected from the mains power supply. Also, a safety feature in case of mains power failure.

2.12. MD Unit holder

The MD Unit Holder is an accessory for mounting the MD Unit on an ICU-rail or pole.



3. Operation of MD System

3.1. General

MD Unit is controlled by MD Software. The user operates the MD Unit using the touch screen of the connected MD Monitor. The user shall read this manual before operating the instrument.

3.2. Manual and Help (On-line manual)

This manual describes the most important MD System functions and how to operate MD System.

3.3. Unpacking and installation

Trained clinical staff or personnel designated by M Dialysis must perform all installation of the MD Unit. The MD Unit should be placed on a table or rack or attached to any of the ICU-poles used for instruments at the intensive care unit using the MD Unit Holder.
Note! All communication ports and on/off switch are located on the bottom side of the MD Unit, make sure that these are easily accessible after installation. For ranges of acceptable temperature and humidity, see the technical specifications.

Warning! Make sure to use a trolley or table with sufficient stability for placement of the MD Unit. When mounting the MD unit shall only be done to a part with sufficient load capacity.

3.4. EN 60601 requirements

To fulfill the EN 60601 requirements for leakage current and electrical separation the installation must satisfy the EN 60601-1-1 standard.

Warning! Multiple socket-outlet or extension cord shall not be connected to the MD System.

3.5. Handling of MD Sensor

The MD Sensors are single use only and should be stored in a fridge, +2 - +8 °C. Before usage they should be taken out in room temperature about 20 minutes prior connecting to MD System.

3.6. Edit settings in the MD Software

Editing MD System settings should only be performed by trained personnel or designated by M Dialysis.

3.7. Exchange of MD Sensor

Warning! Exchange of MD Sensor must be done under clean conditions, use gloves.

Warning! MD Sensor and its parts, syringes and extension tubing, are for single use and should not be reused on other patients.

To exchange the MD Sensor first follow the procedure for temporary disconnecting of patient section 3.20. Prepare a new MD Sensor according to 3.17.2 (the MD Cartridge itself may be reused). The orange calibration fluid syringe, is usually not

depleted but cannot be reused. Neither can remaining perfusion fluid be reused. Reconnect the MD Sensor and start MD System as described in section 3.17.

3.8. Exchange of perfusion fluid and Calibration fluid

Exchange of fluids may be done in the same manner as described in section 3.7 but shifting fluids instead of MD Sensor.

3.9. Disconnecting and storage of the system

After ending the microdialysis process according to section 3.21, reconnect the empty MD Cartridge to the MD Unit, disconnect the power adaptor and the MD Amplifier. The unit is now ready for storage.

3.10. Calibration

The MD Unit will automatically perform calibration every 6 hours. This can be postponed 30 minutes.
Manual calibration can be performed from the settings menu.

3.11. Indicator lights MD Unit

3.11.1. MD System status

MD Unit status is indicated by LEDs on the MD Unit in the following way:

Steady green	MD Unit ready for patient, standby
Flashing green	MD Unit running
Steady blue	System startup
Steady orange	Measurement or technical error

Warning! MD System does not have an alarm system compliant with IEC 60601-1-8.

3.11.2. Battery status

Battery status is indicated by LEDs on the MD Unit in the following way:

Steady green	> 1 hour left, charging
Flashing green	> 1 hour left, not charging
Steady blue	< 1 hour left, charging
Flashing blue	< 1 hour left, not charging
Steady orange	< 15 minutes left, charging
Flashing orange	< 15 minutes left, not charging

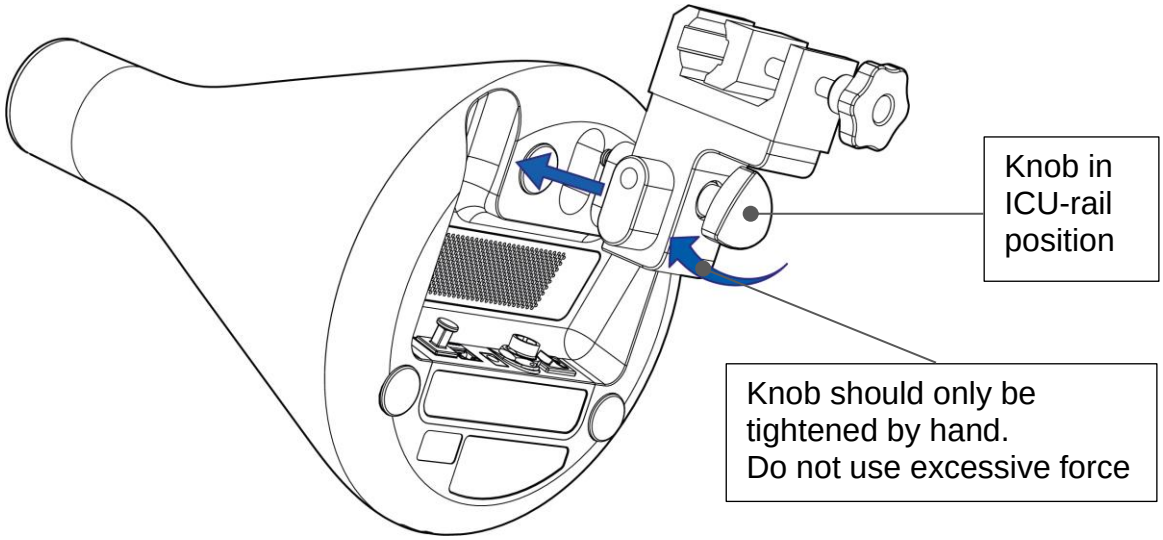
3.12. Installing the MD Unit holder

The MD Unit holder is attached to the bottom side of the MD Unit.

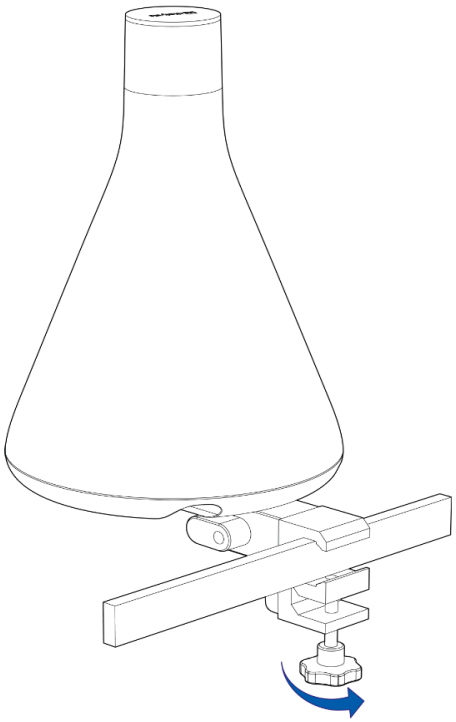
3.12.1. Installation on rail

The MD Unit holder is suitable for EU design rail (25x10mm) and shall only be attached to a rail with sufficient load capacity.
Note! If the knob is mounted for pole mounting, see below, unscrew the knob and reattach it as shown in the picture. Make sure that the clamp is attached in the right position on the rail.

Warning! If attached to other types of rails be sure to check that the MD Unit is firmly attached. If in doubt, do not attach to the rail.

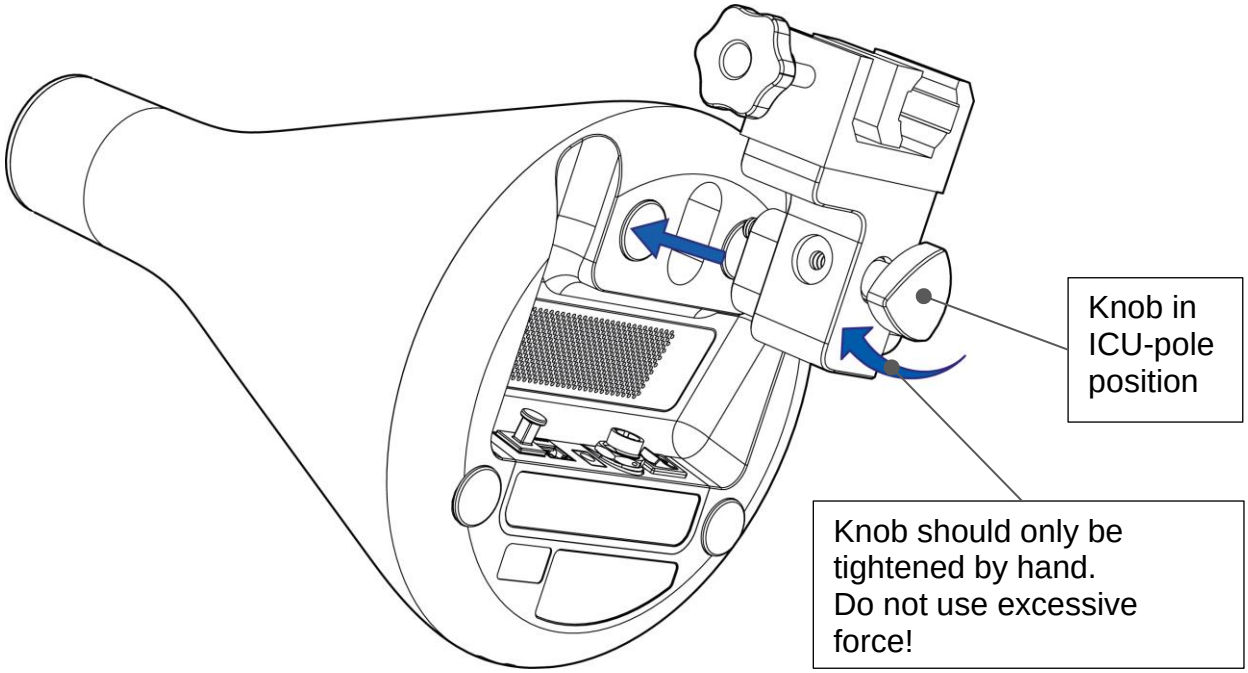


Attach the MD Unit to the rail. Lock knob firmly but tighten only by hand.

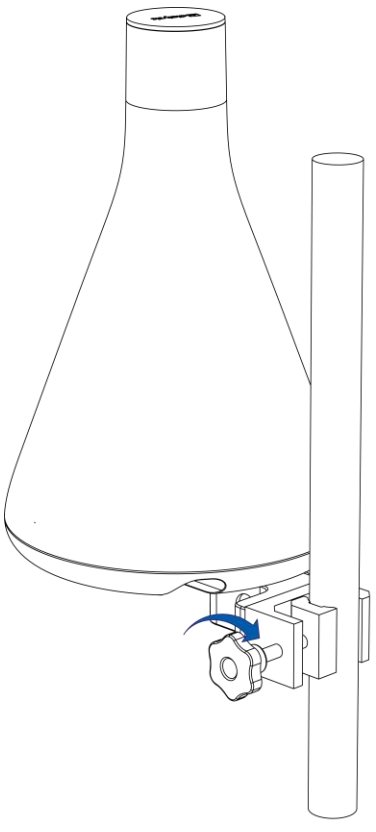


3.12.2. Installation on ICU-pole, diameter 24-30mm.

Note! If the knob is mounted for ICU-rail mounting, see above, unscrew the knob and reattach it as shown in the picture below.

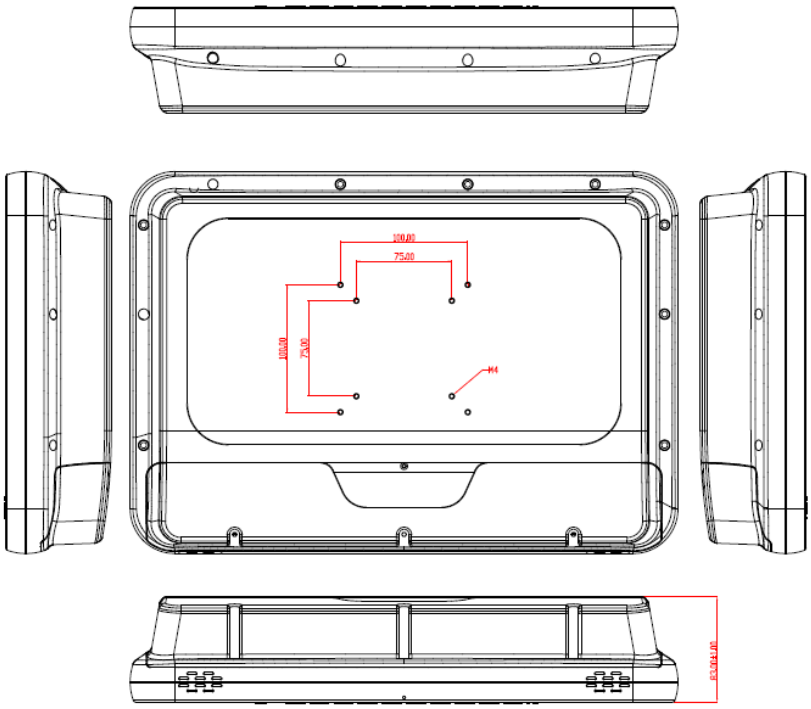


Attach the MD Unit to pole. Lock knob firmly but tighten only by hand.
Note! the MD Unit shall only be attached to a pole with sufficient load capacity.

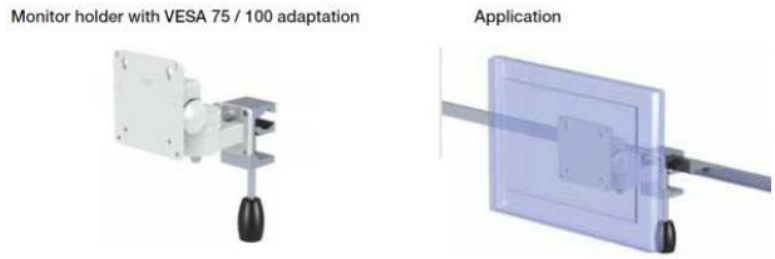


3.13. Installing the MD Monitor

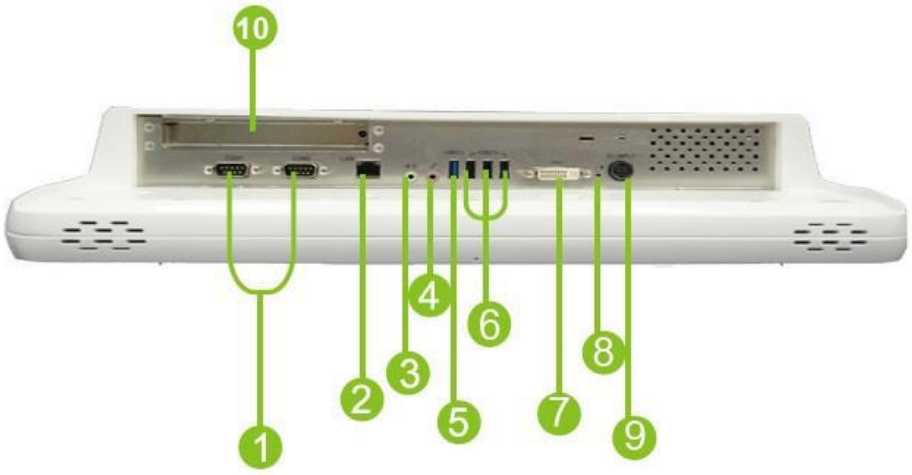
The MD Monitor has a standard VESA mount interface for installation in the vicinity of the patient. This product is certified as a Class I product per the MDD and IEC 60601-1, and must be installed on a distance outside the patients reach. MD Monitor must only be mounted to a part with sufficient load capacity.



There is also an MD Monitor Holder included. For MD Monitor Holder installation see MD Monitor Holder manual.



3.13.1. Connecting the MD Monitor

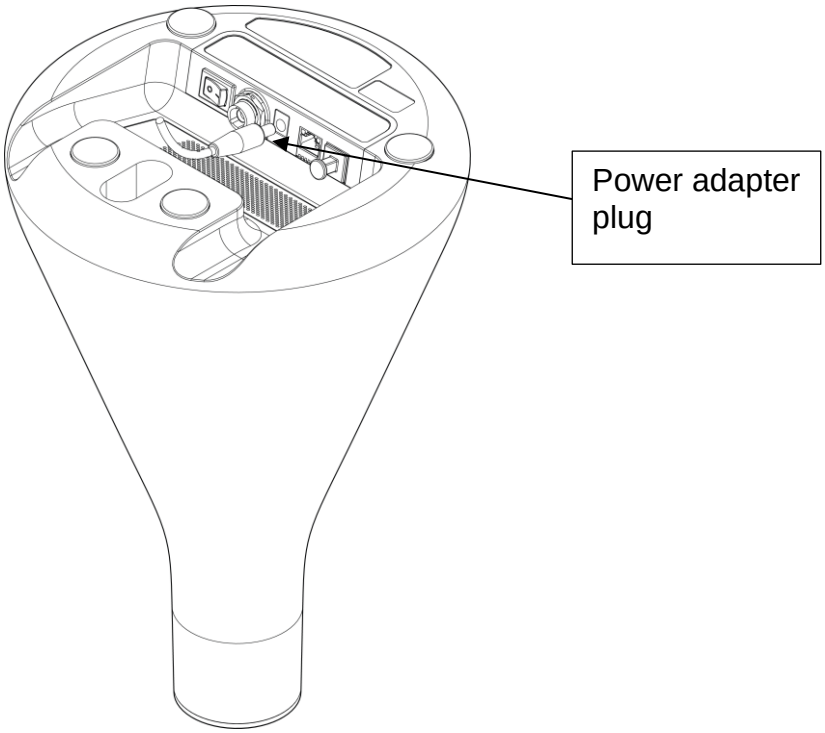


❶ COM x 2	❻ USB 2.0 x 3
❷ LAN x 1	❼ DVI-I output
❸ Line-out	❽ Reset
❹ Microphone-in	❾ DC-in
❺ USB 3.0 x 1	❿ PCI-E/PCI expansion

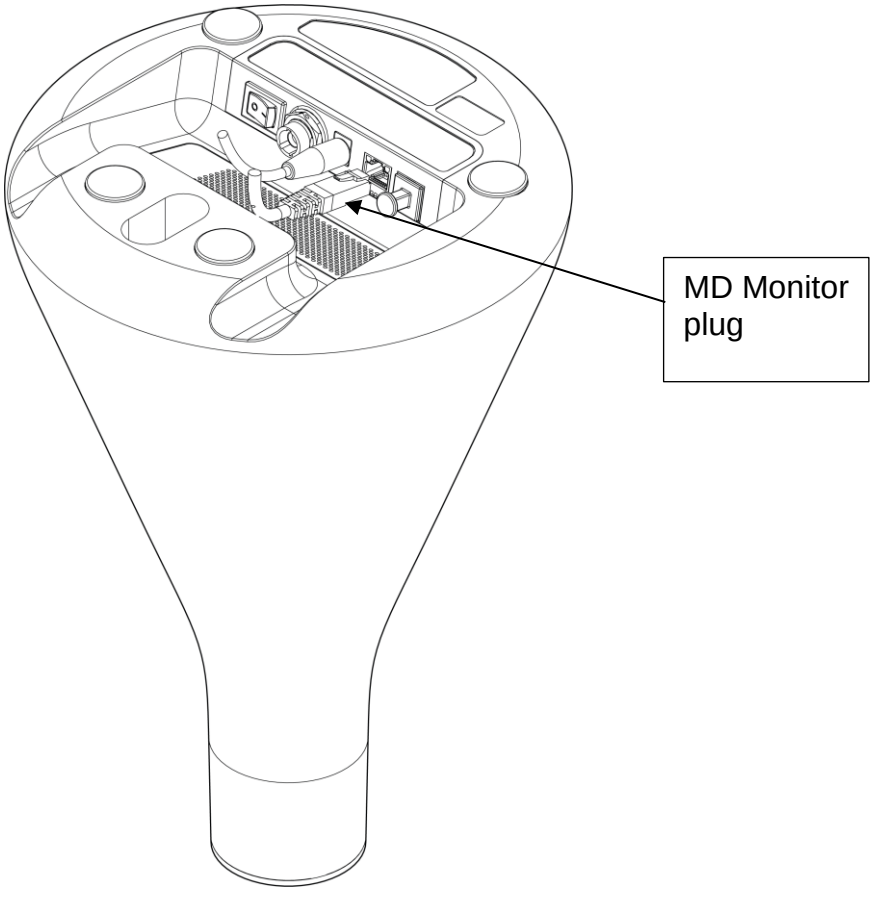
The power adaptor is connected to (9) DC-in, MD Monitor cable is connected to (2) and USB memory is connected to (6).

3.14. Turn on the MD Unit

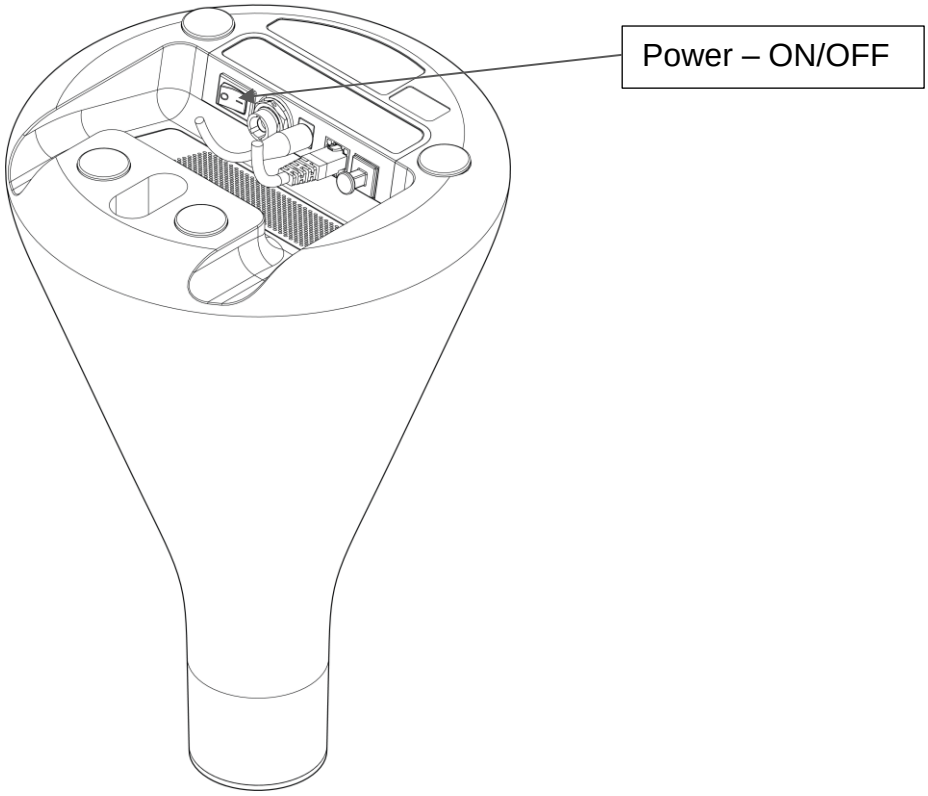
1. Connect the power adaptor to mains and the MD Unit.



2. Connect the MD Monitor to the MD Unit using the Ethernet cable.



3. Turn on the MD Unit by pushing the Power-ON/OFF switch underneath the unit.



3.15. Turn on the MD Monitor

Turn on the MD Monitor by pushing the Power-ON/OFF switch on the MD Monitor. MD Cartridge will be ejected.

Hotkey and LED definition at front panel

3.16. Using the GUI: Graphic User Interface

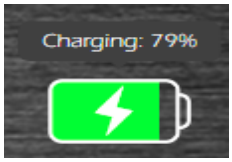
3.16.1. Home screen

MD Monitor graphic user interface:

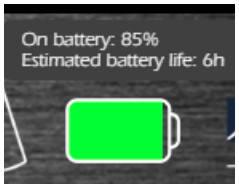
Home – Will display the main panel
View – Display of current measured microdialysis in graphs and figures
Settings – General settings such as date, time and location
Service – A password protected panel for MD System service
Patient data – Management of patient data
Start/Pause/Stop – For starting a new patient/, temporary pause in microdialysis and termination of patient session
Microvial Sample – Pause analysis to collect dialysate in a microvial.
Date/Time – Present date and time, synchronizes with setting in MD Unit.
MD System icon – Status of MD System
Battery icon – Current battery status
Logotype – Displays system software version

3.16.2. System status display on the home screen

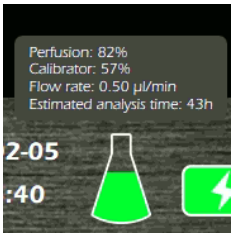
Tap the icons, current system status will be displayed.



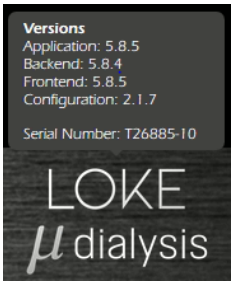
MD Unit connected to mains. Battery charging.



MD Unit disconnected from mains. Back-up battery in use.



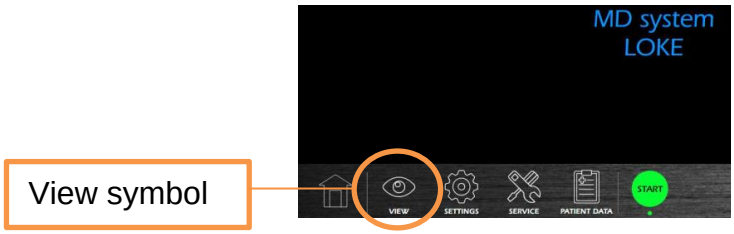
Remaining perfusion fluid in the cartridge and the set flow rate for the Microdialysis.



Current software version.

3.16.3. Display of analyte values

To display graphs of the microdialysis values tap the view symbol on the home screen.



This will display the analysis graphs

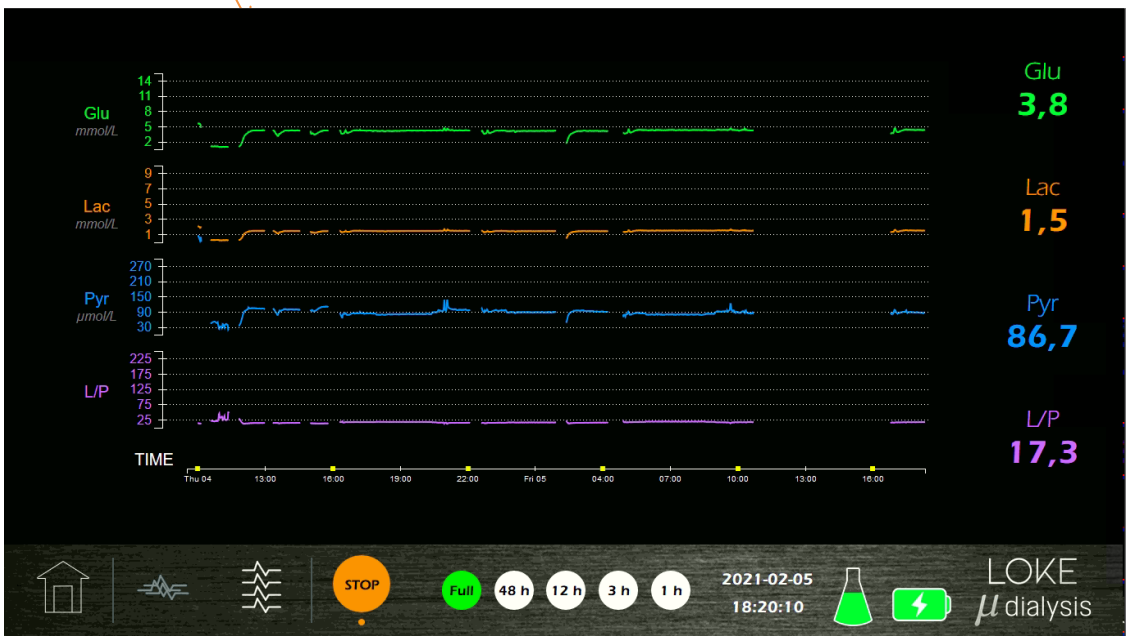
Numeric values

Displays each graph separated

Select time frame displayed in green

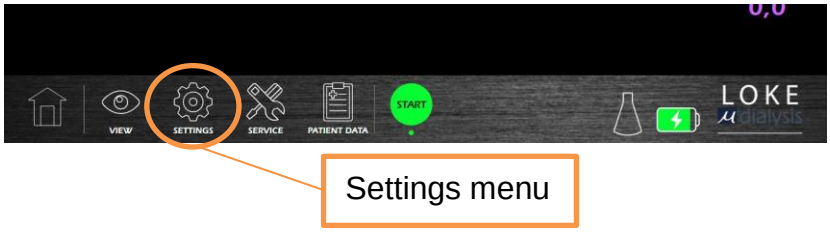
Time axis

Axis for each analyte



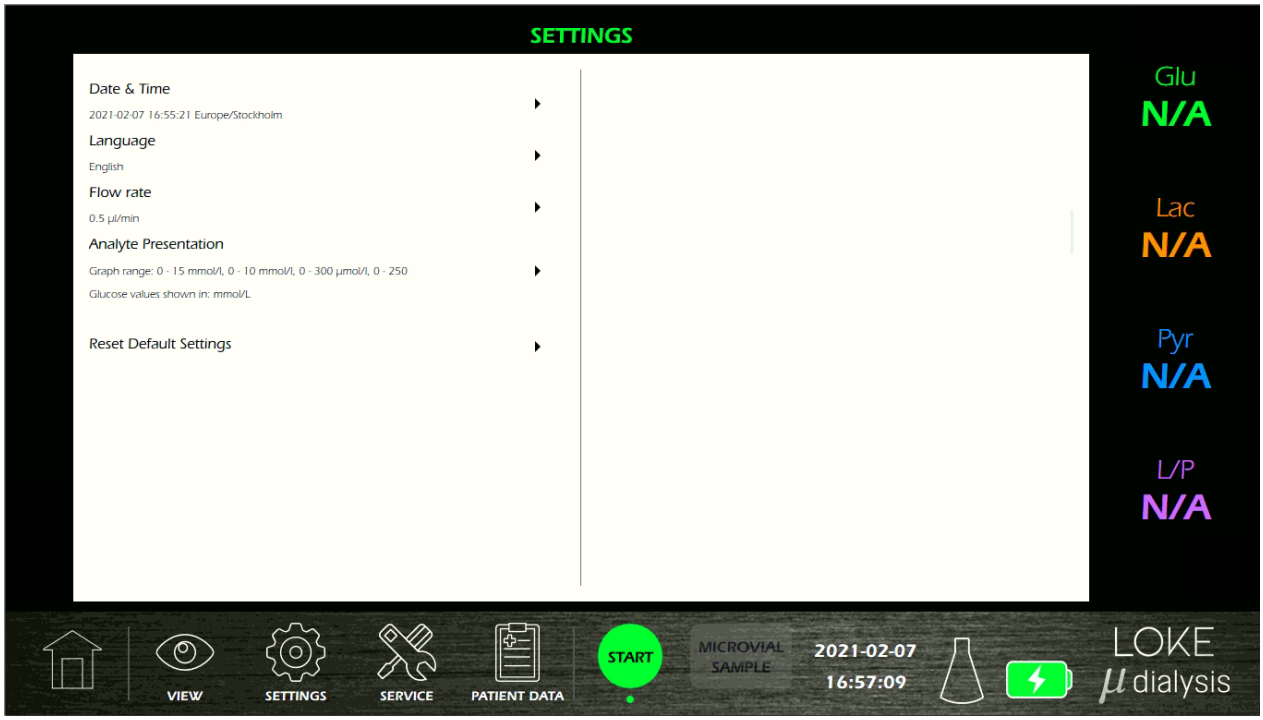
3.16.4. Change system settings

The Settings menu is password protected.



The Settings menu handles System settings.

3.16.4.1. System settings menu



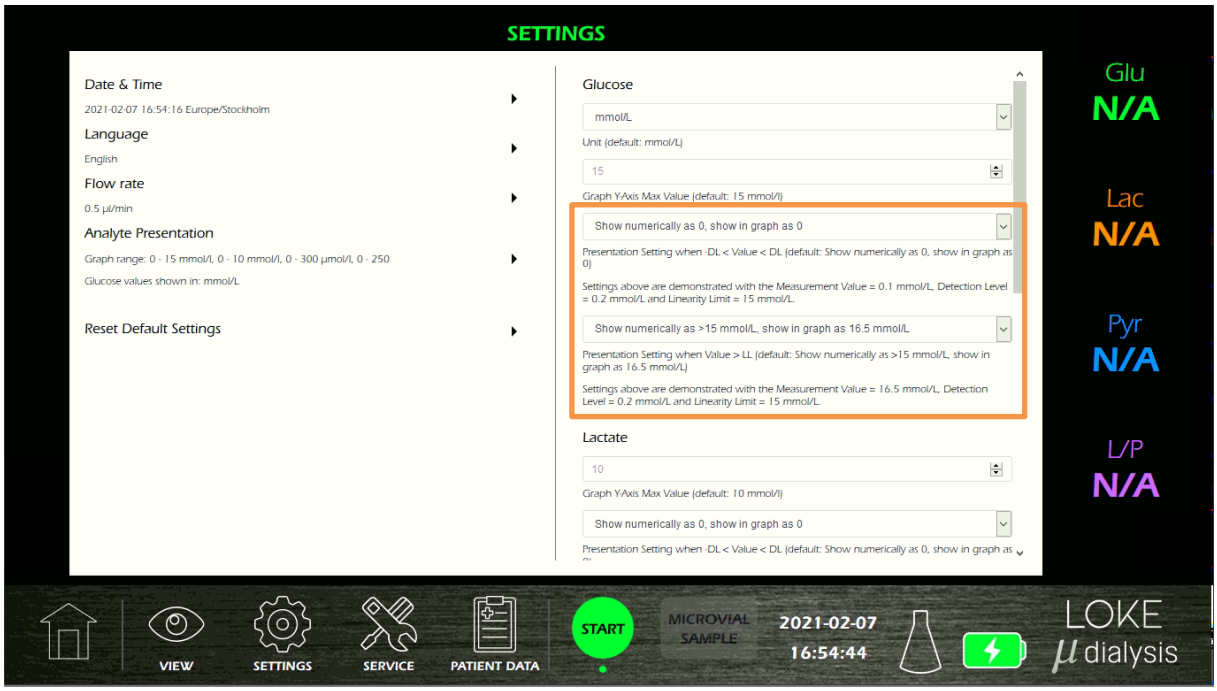
Settings menu

- Date and time
- Language
- Flow rate
  The dialysate is transported from the catheter to the Biosensor which will create a time delay. A higher flow rate will reduce the lag time but will shorten the total monitoring time. A flow of 0.5 µl/min will give a monitoring time of approx. 3 days whilst a flow of 2.0 µl/min gives a monitoring time of approx. 18 hours before the 106 Syringe in the MD Cartridge needs to be replaced.
- Analyte Presentation
  Graph interval and values display
- Reset Default Settings

3.16.4.2. Analyte presentation

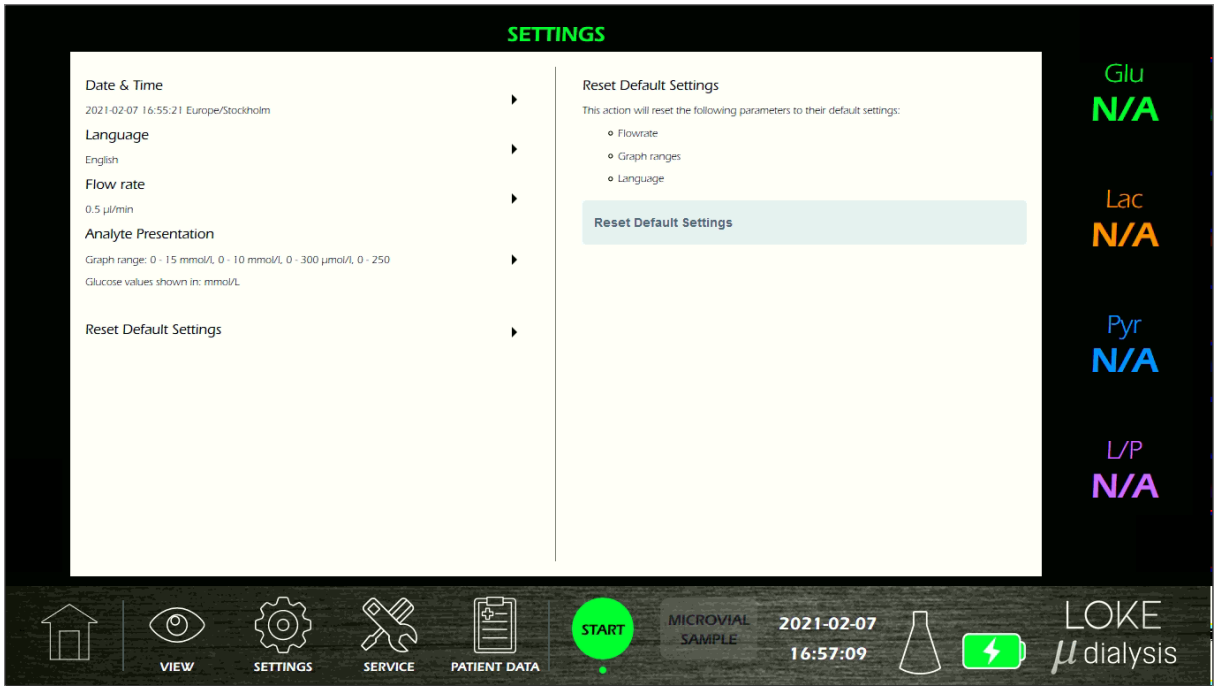
In the analyte presentation screen, it is possible to change the Y-axis max values in the graphs and the unit presentation for Glucose (mmol/L or mg/dL).

It is also possible to choose how values below the limit of detection (LD) and above the linearity limit (LL) will be presented on screen.



3.16.4.3. Reset to Default Settings

It is also possible to reset the parameters (flow rate, graph range and language) to their default settings.

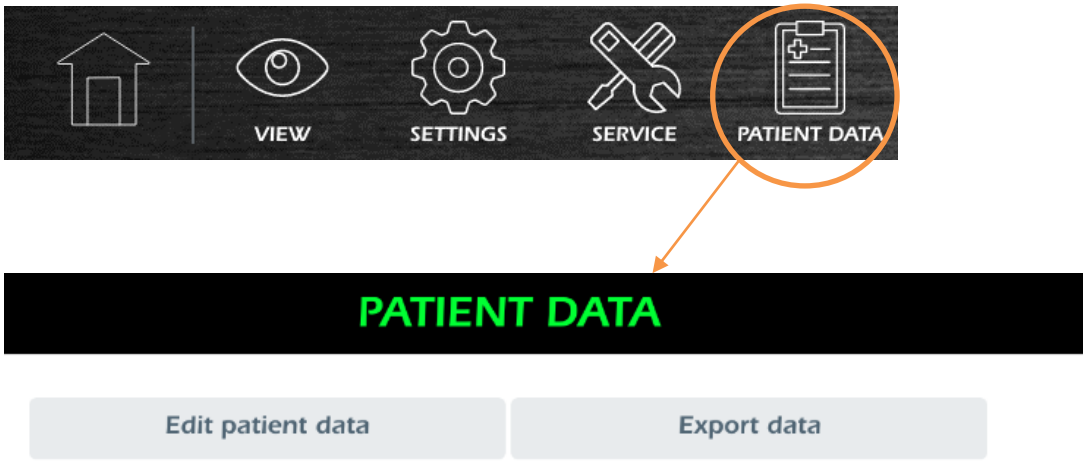


3.16.5. Service menu

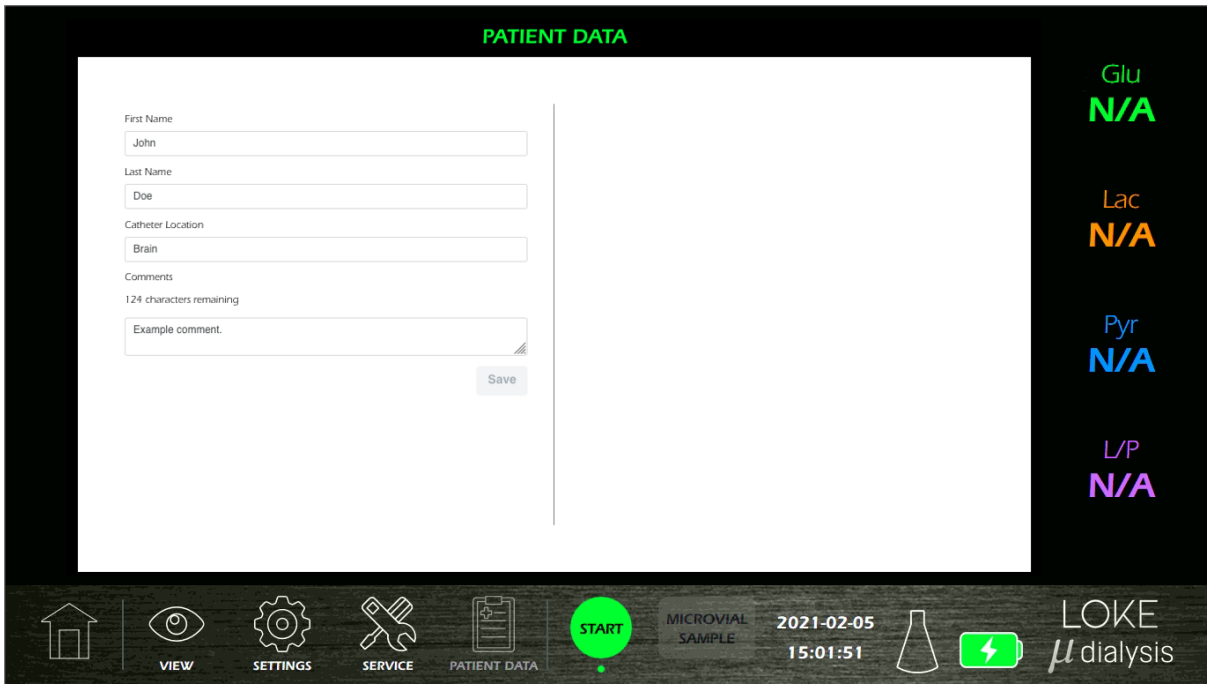
The Service menu is password protected and should only be accessed by M Dialysis authorized personnel. For further information, contact M Dialysis or your local representative.

3.16.6. Patient data

The patient data menu is for managing the analysis data that has been saved in the system. MD System only saves the current patient session, after each patient the data should be exported. Data saved in MD System is erased when patient session is terminated.

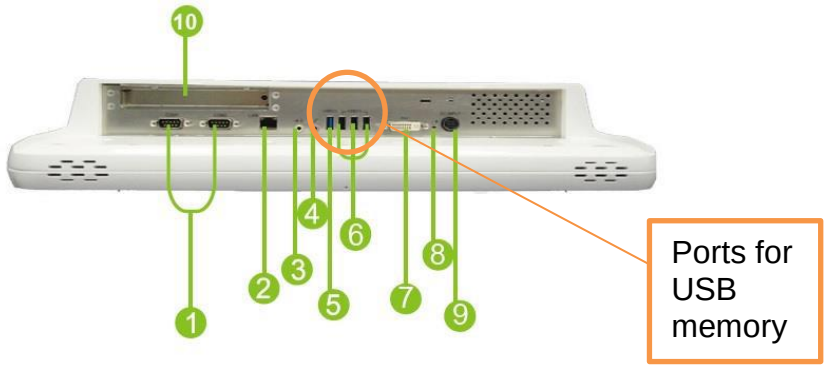


3.16.6.1. Edit patient data



3.16.6.2. Export patient data

Data can be exported by plugging in a portable USB memory to the MD Monitor using the ports in the picture below.



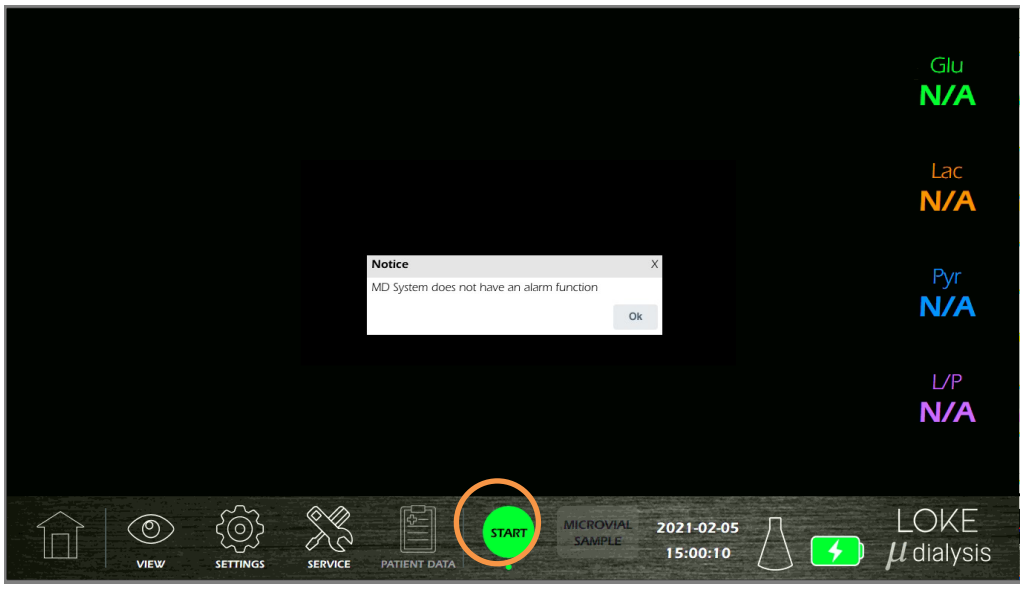
1. COM x 2
2. LAN x 1
3. Line-out
4. Microphone-in
5. USB 3.0 x 1
6. USB 2.0 x 3
7. DVI-I output
8. Reset
9. DC-in
10. PCI-E/PCI expansion

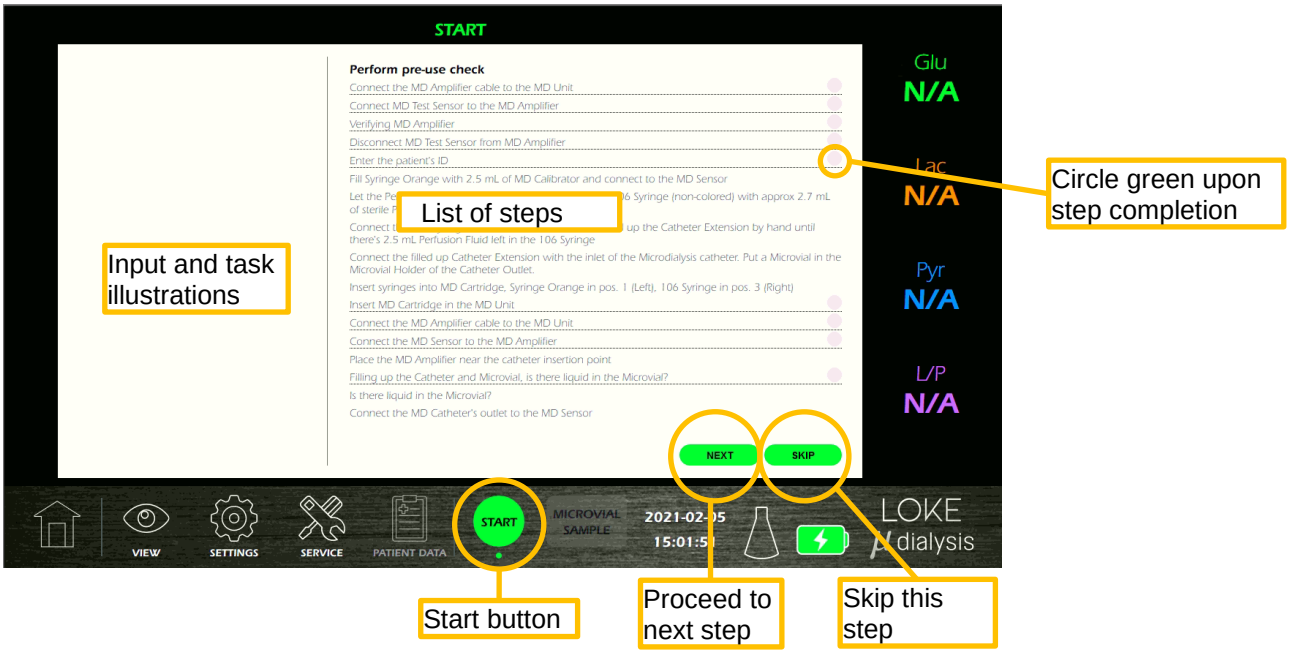
To export data, tap the [download or export the patient data as csv], found under Patient Data.

The save dialog will open in a separate window. Save the file to the USB memory.

3.17. Start-up process and connecting the MD System

Check flow setting, default 0.5 µL/min.
Tap the START button on the MD Monitor´s touch screen. Instructions of how to connect the complete MD System and the full starting procedure will then follow on the MD Monitor, follow these instructions. The instructions are also described below:





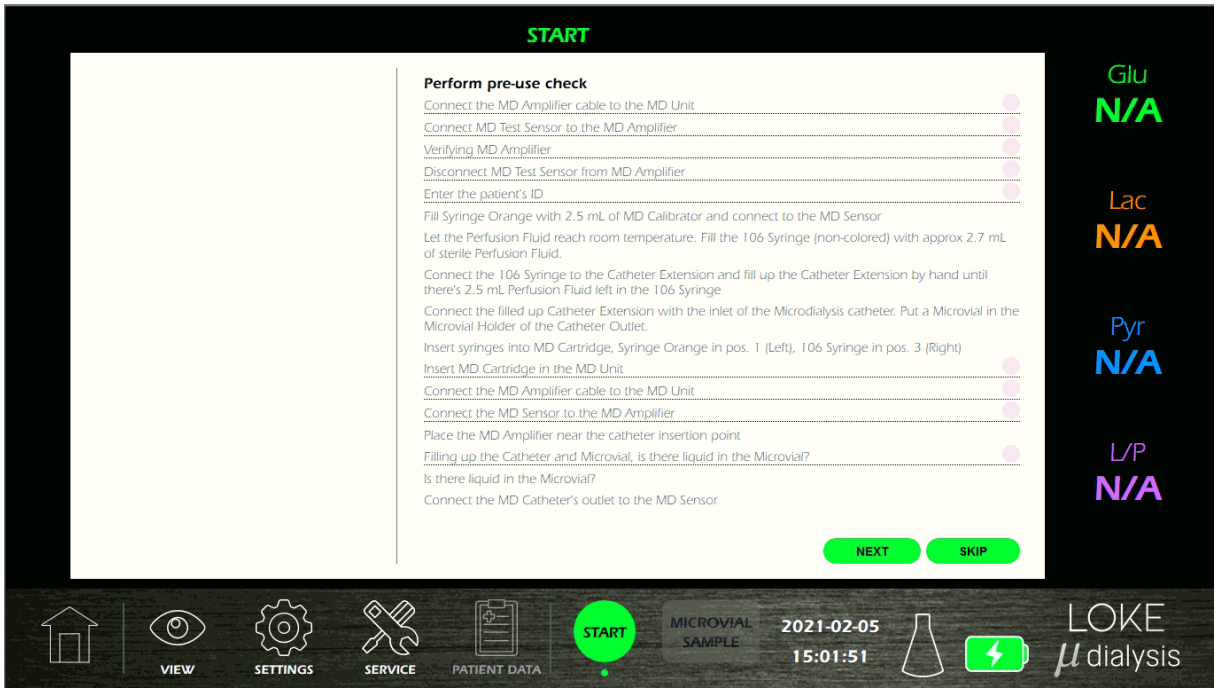
After each step is completed the circle to the top right will turn green. There is also an option to skip a step when applicable.

Note! The on-screen pictures are for guidance; always read the manual, and where appropriate up-to-date amendments, for detailed instructions.

Warning! Be sure to check for damages on MD System prior to each patient session.

3.17.1. Pre-use check

Pre-use check is described in step 1–5 on the Monitor Screen. Press ”SKIP” to go directly to step 6, ”Enter the patient ID”.
Note! Pre-use check should be done when starting a new patient



3.17.2. Preparation of MD Sensor and MD Cartridge

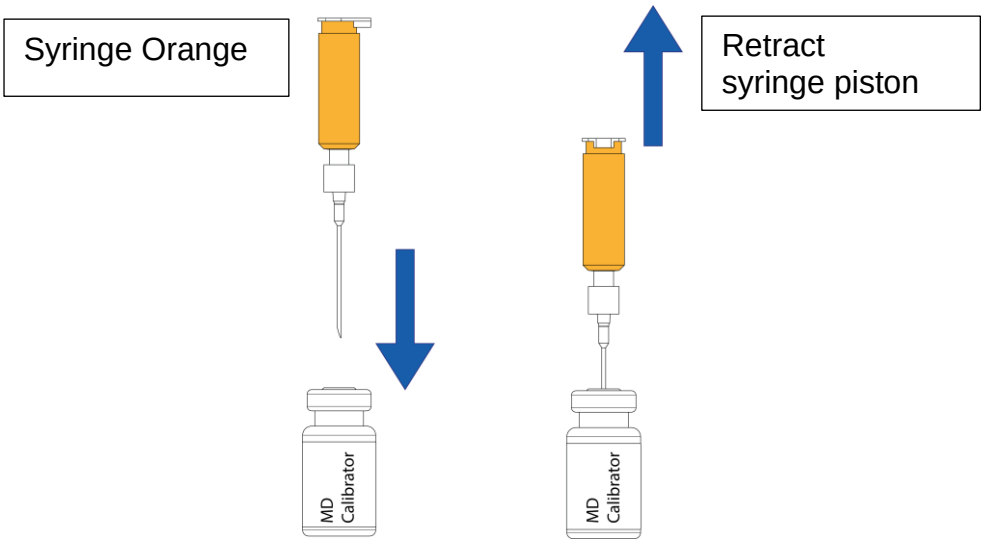
Note! The preparation of the MD Cartridge and sensor should be conducted under clean conditions. The preparation can be done prior to starting MD System.

The preparation requires the following items,
1 Bottle of Calibration Fluid
1 Syringe Orange (Orange colored piston)
1 single use MD Sensor
1 MD Cartridge
1 106 Syringe (non-colored piston)
1 pcs of Catheter Extension
1 Perfusion Fluid (see Microdialysis catheter IFU what perfusion fluid to use)
1 Microdialysis Catheter

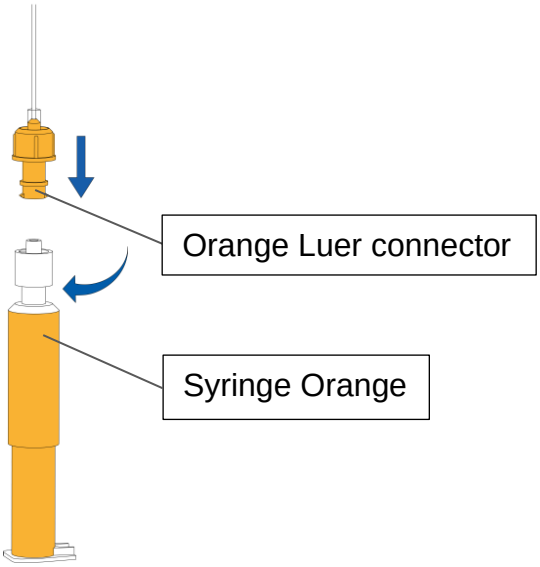
Warning! It is important that the color coding of syringes and Luer-connectors is followed throughout the whole process from filling syringes to connecting and placing the syringes in the MD Cartridge.

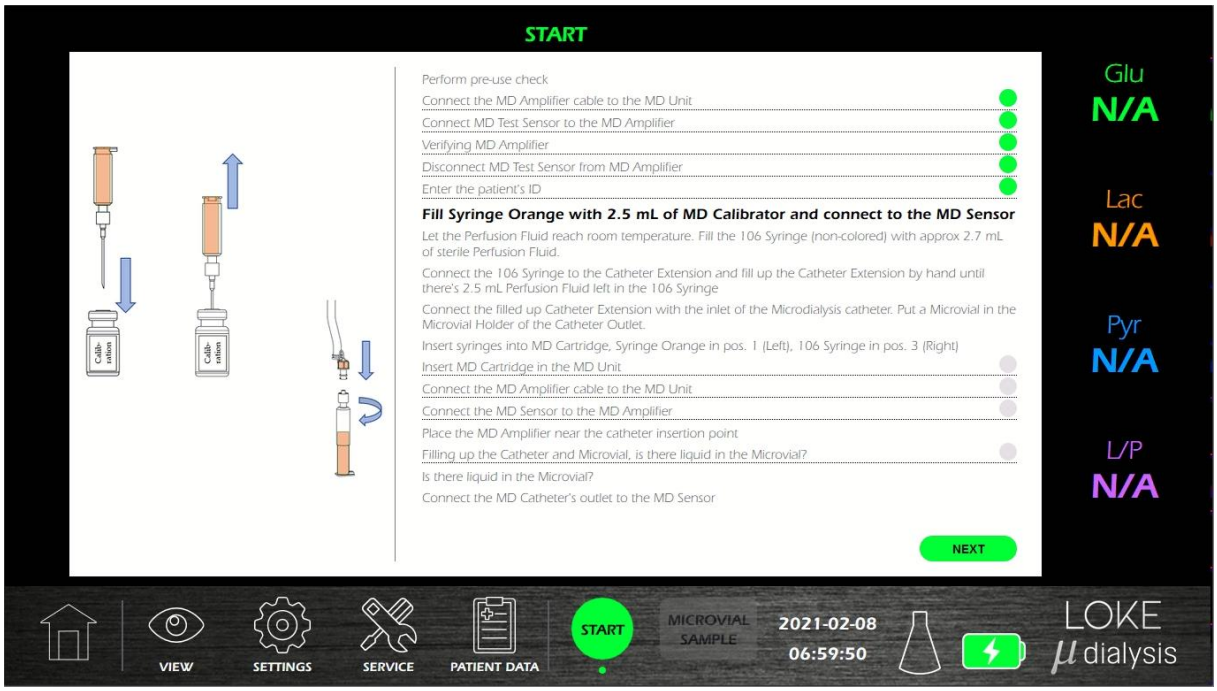
Warning! Be sure to check that MD Sensor package is undamaged prior to use.

1. Penetrate the membrane of the Calibration fluid vial with the cannula of the orange piston syringe and fill the syringe with 2.5 ml of Calibration fluid. Remove air bubbles.

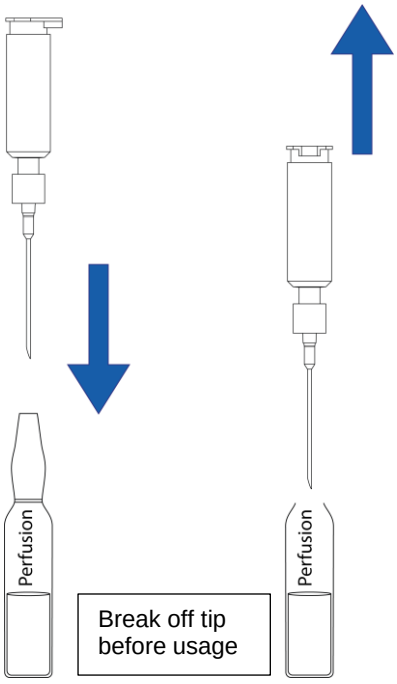


2. Connect Syringe Orange to orange Luer connector on the MD Sensor.



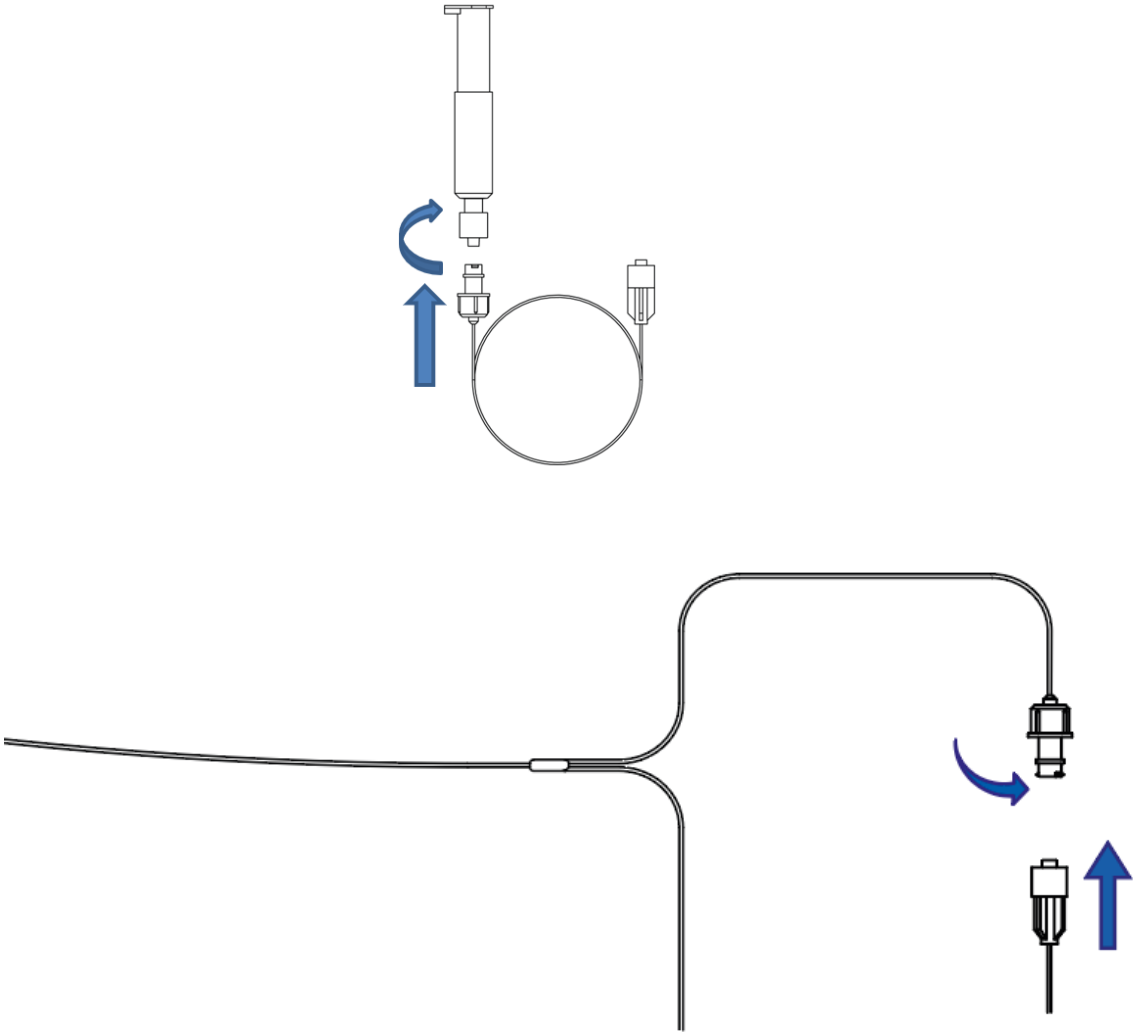


3. Fill the 106 Syringe (non-colored piston) with sterile 2.7 ml Perfusion Fluid. Make sure it is room tempered and that all air bubbles are removed.



Warning! Using wrong fluids could impair or give wrong analysis result

4. Connect the Catheter Extension to the 106 Syringe (non-colored piston), remove the sterile cap and fill up the tubing manually with perfusion fluid from the syringe until there is 2.5 mL left in the syringe. Connect the MD Catheter's inlet to the Catheter Extension and place an empty Microvial in the Microvial Holder on the Catheter



Warning! Ensure that all Luer-lock connections are firmly tightened.

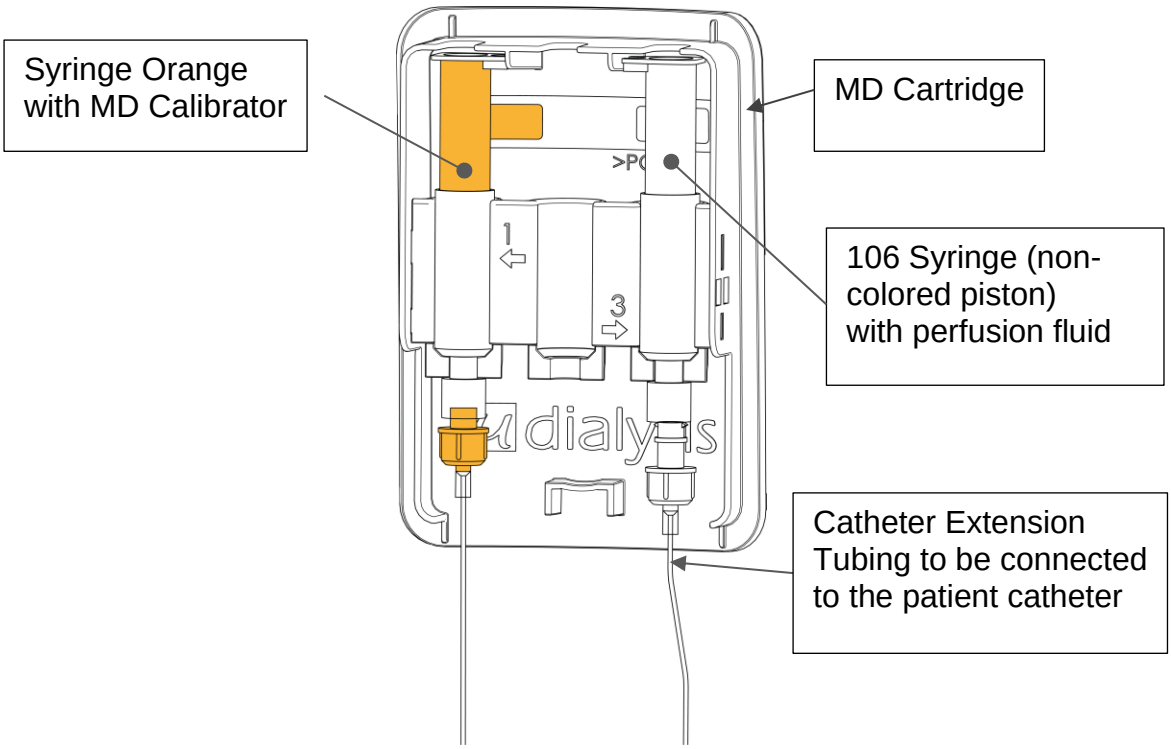
Warning! Ensure that there is enough slack on the Catheter Extension between the MD Cartridge and the MD Catheter

Warning! Pay close attention to the placement and handling of the MD Cartridge when not inserted to the MD Unit.

Warning! If the catheter is accidentally extracted from the patient, reinsertion must be done with a new catheter.

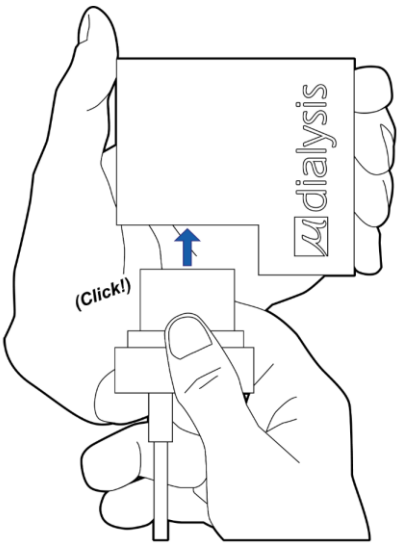
5. Place the Syringe Orange in the first (1) slot in the cartridge. The slots are color coded.

6. Place the 106 Syringe (non-colored piston) in the third (3) slot in the cartridge.

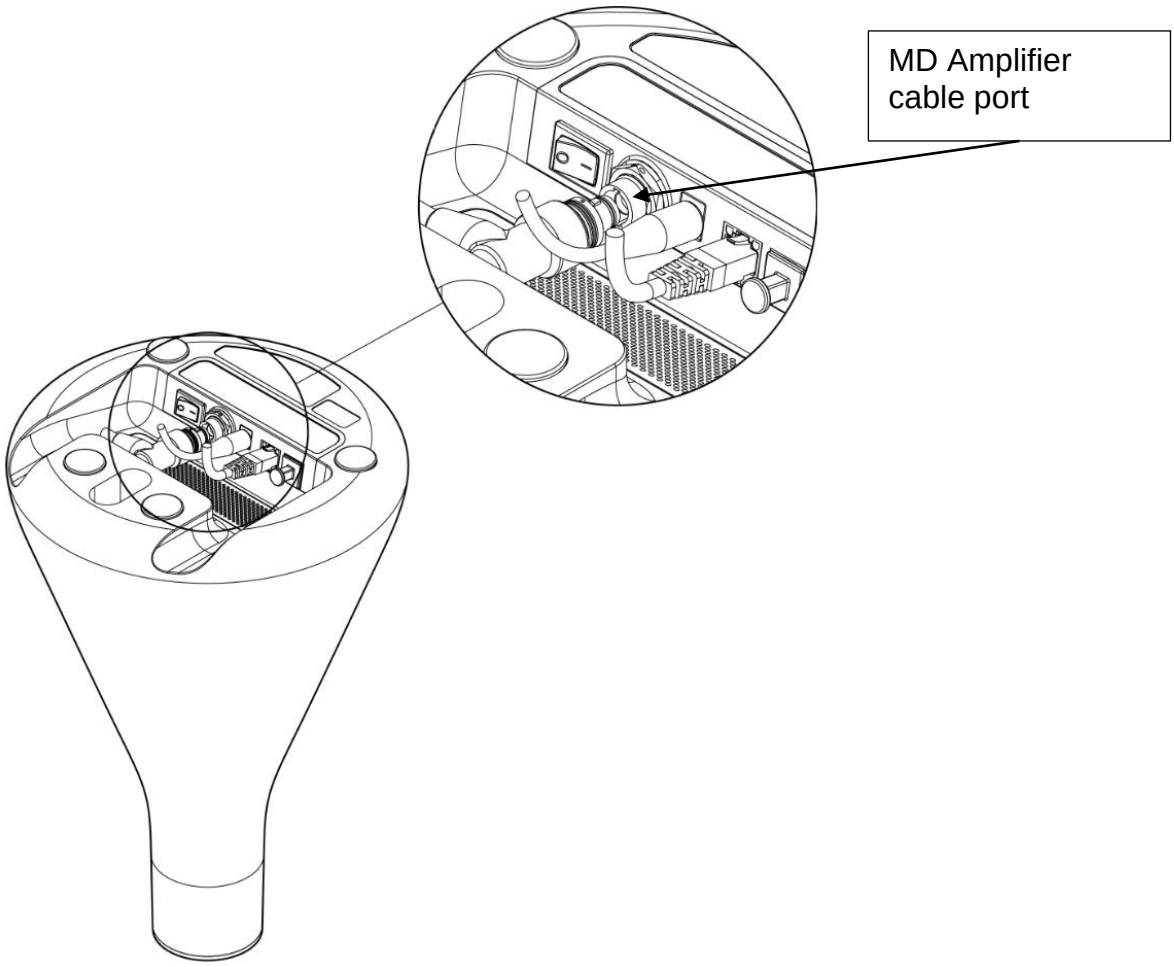


Warning! Ensure that all luer-lock connections are firmly tightened.

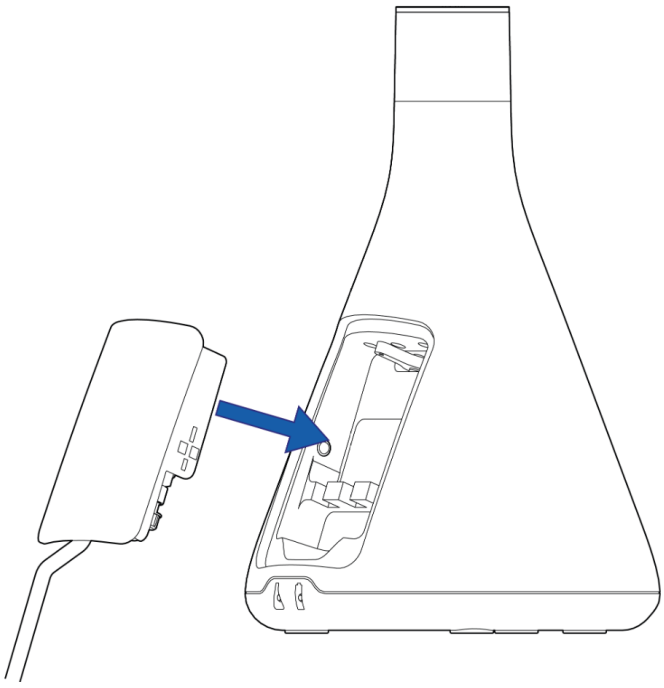
7. Connect the MD Sensor to the MD Amplifier.

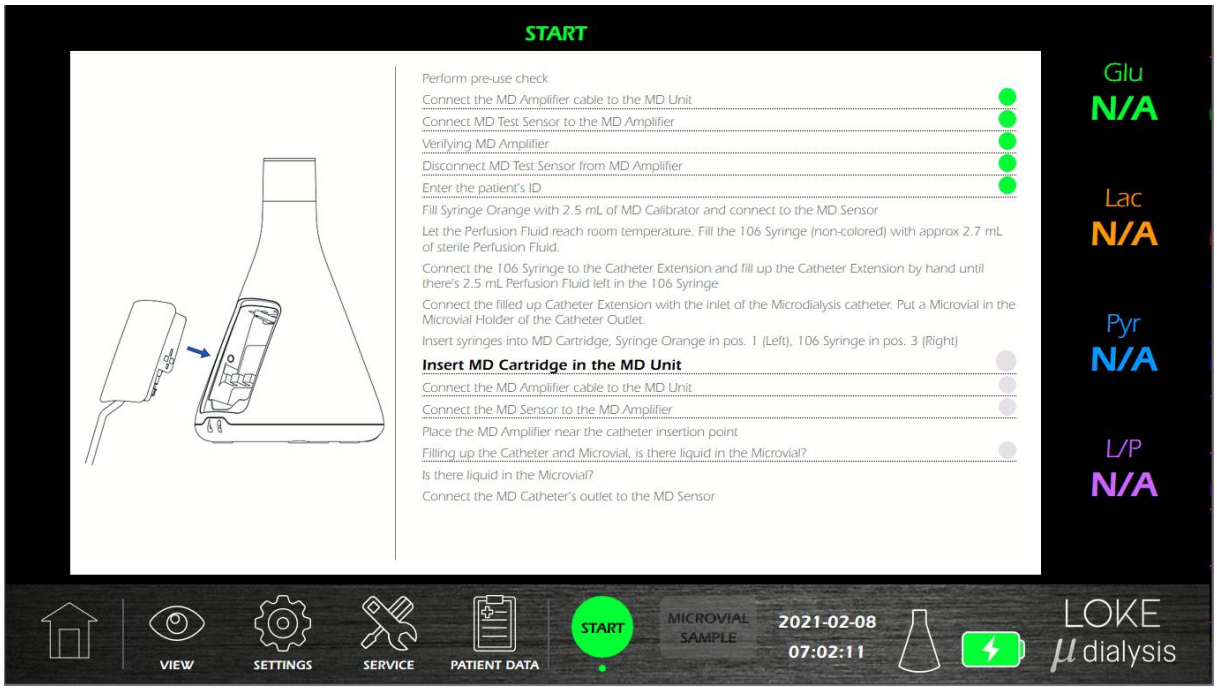


8. Connect the MD Amplifier cable to the MD Unit (if it is not already connected).



9. Insert the MD Cartridge in the MD Unit. Align the MD Cartridge in the center and insert it straight into the cavity.



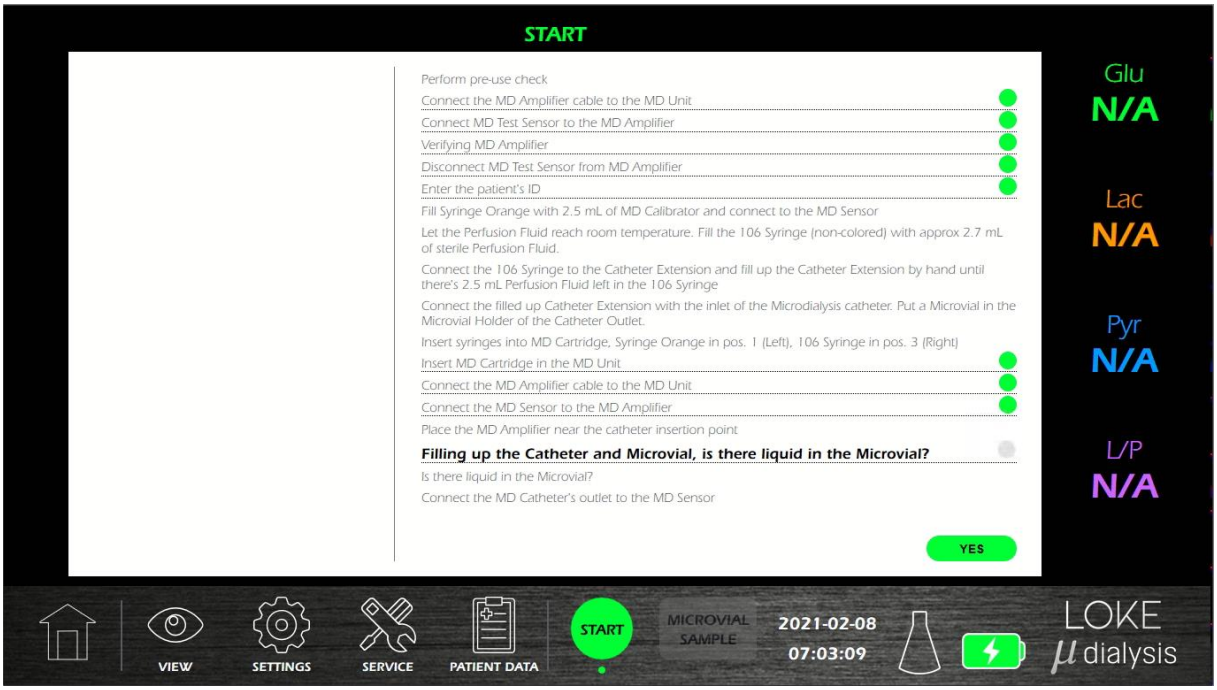


10. Press Next and follow the instructions on the MD Monitor to proceed.

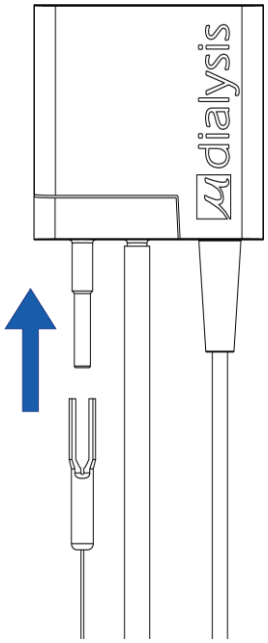
    Note! The MD Sensor should be connected to the MD Amplifier PRIOR to connecting the MD Catheter to the MD Sensor.

11. The system will automatically fill-up with liquid.

12. Flush check. Make sure that there is perfusion fluid in the Microvial holder on the outlet of the MD Catheter prior to connecting it to MD Sensor.



13. When liquid appears in the Microvial, connect the MD Catheter´s outlet to the MD Sensor, using the Microvial holder and press Yes.



14. The system will now automatically start to calibrate and warm up. This procedure could last up to 30 minutes. After the calibration process, the first values will be obtained. The data will be analyzed and presented on the MD Monitor.

Warning! Pay close attention to tubing and cables between the patient and MD Unit. Do not to squeeze the tubing.

Place the MD Amplifier near the catheter insertion point. Fix with bandage or other means. The distance is limited by the length of the catheter tubing.

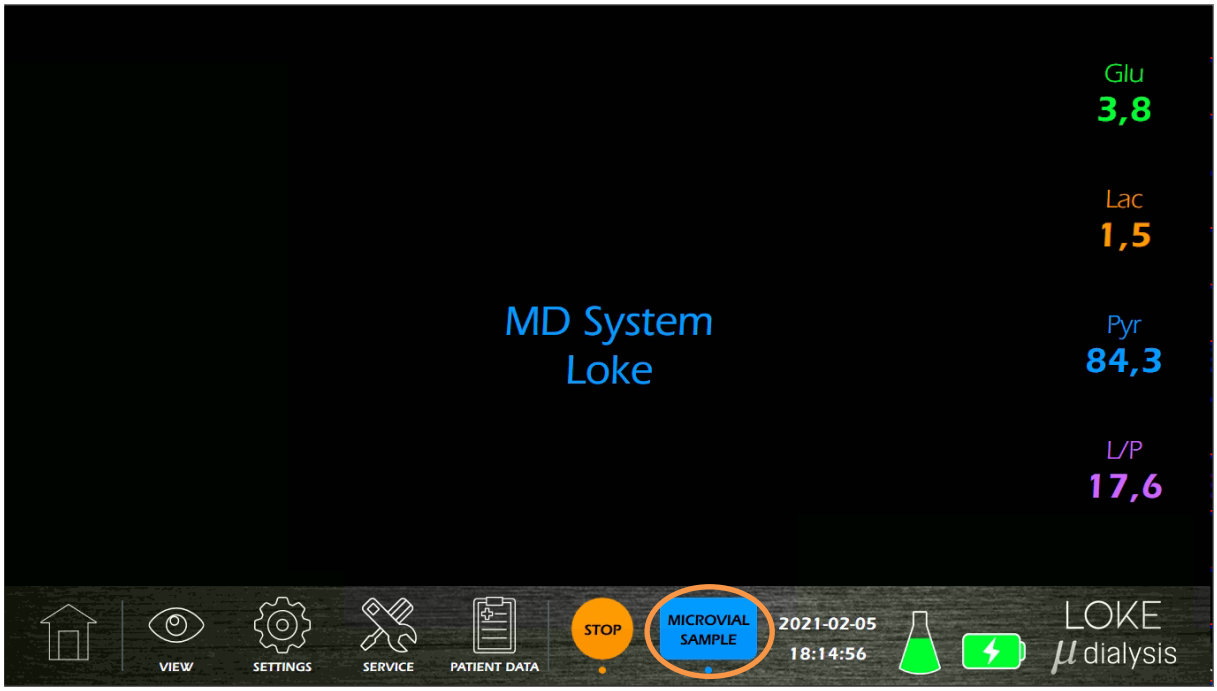
Note! Place MD Unit at a fixed level during measurements and MD Sensor shall always be placed lower than the catheter membrane
Note! Make sure that the MD Amplifier is not in direct contact with the patient (by padding) to avoid decubitus.
Note! Make sure that the MD Unit is at similar height level to the MD Catheter.
Note! Make sure that the MD Amplifier is properly secured to the patient.

Warning! Inspect skin condition beneath MD Amplifier mounting regularly with respect to infection and avoid decubitus. MD Amplifier shall not be continuously attached for a period longer than 5 days.

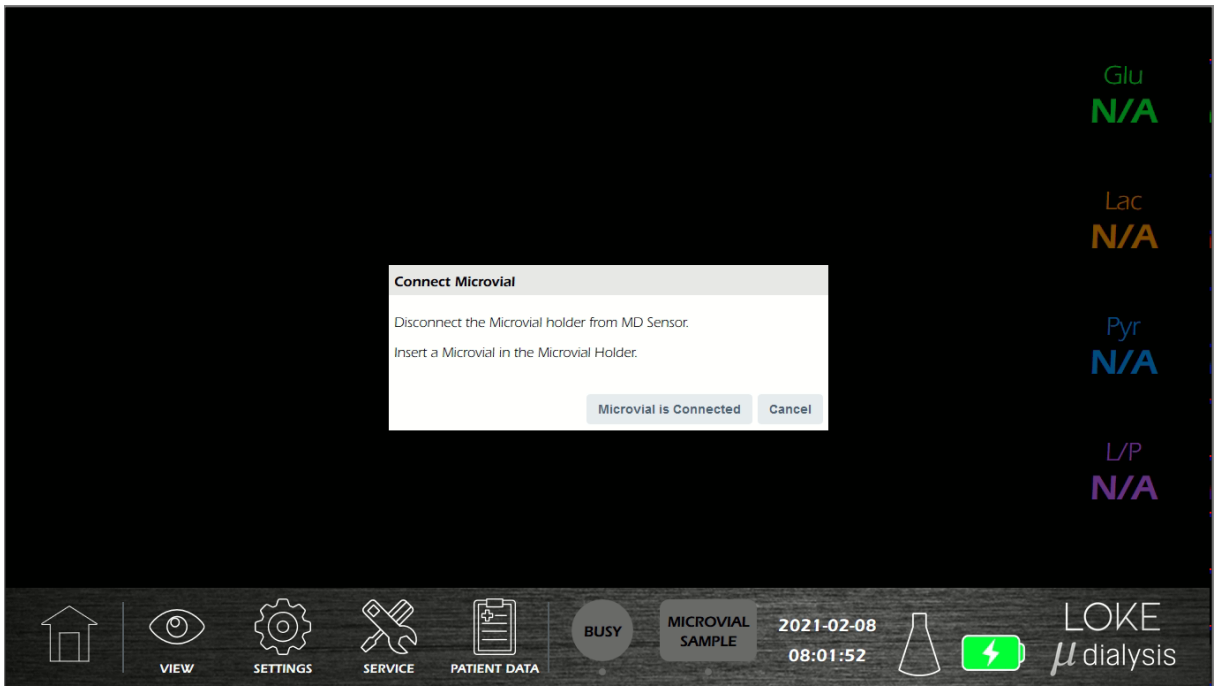
3.18. Taking a Microvial sample for external analysis

It is possible to take a sample in a Microvial for external analysis (the continuous monitoring will be temporarily paused).

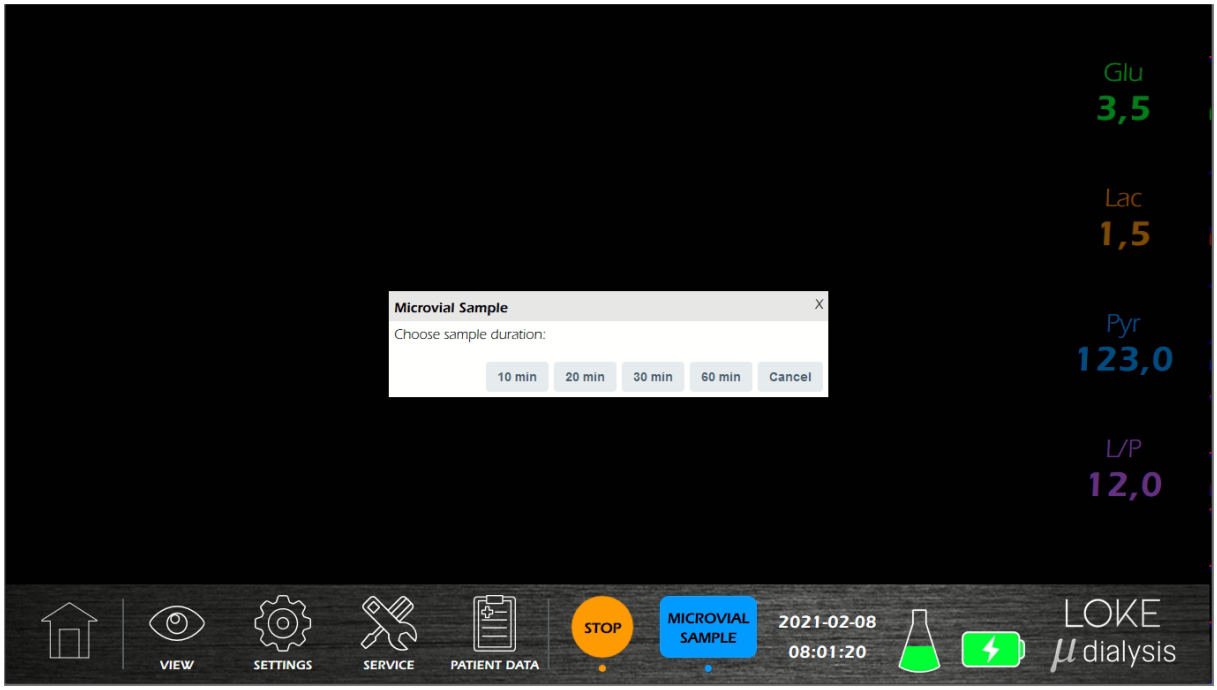
1. Press Microvial Sample and follow instructions.



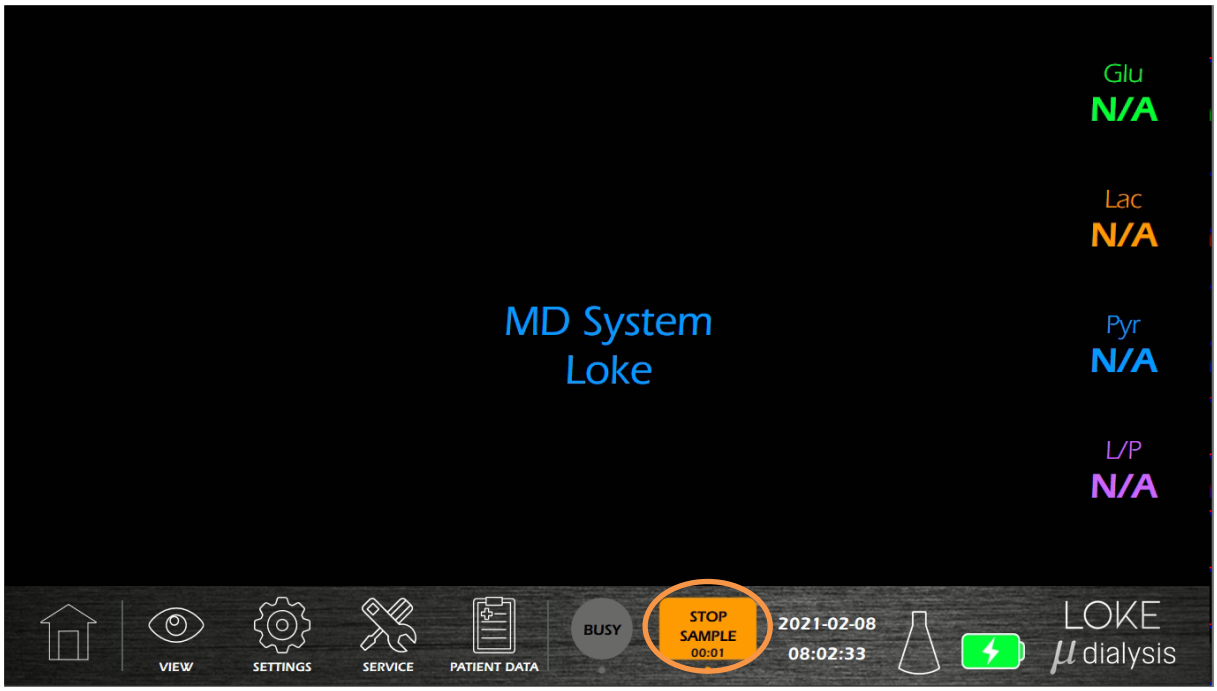
2. Disconnect the Microvial Holder from the MD Sensor and insert a Microvial in the Microvial Holder. Press Microvial is Connected.



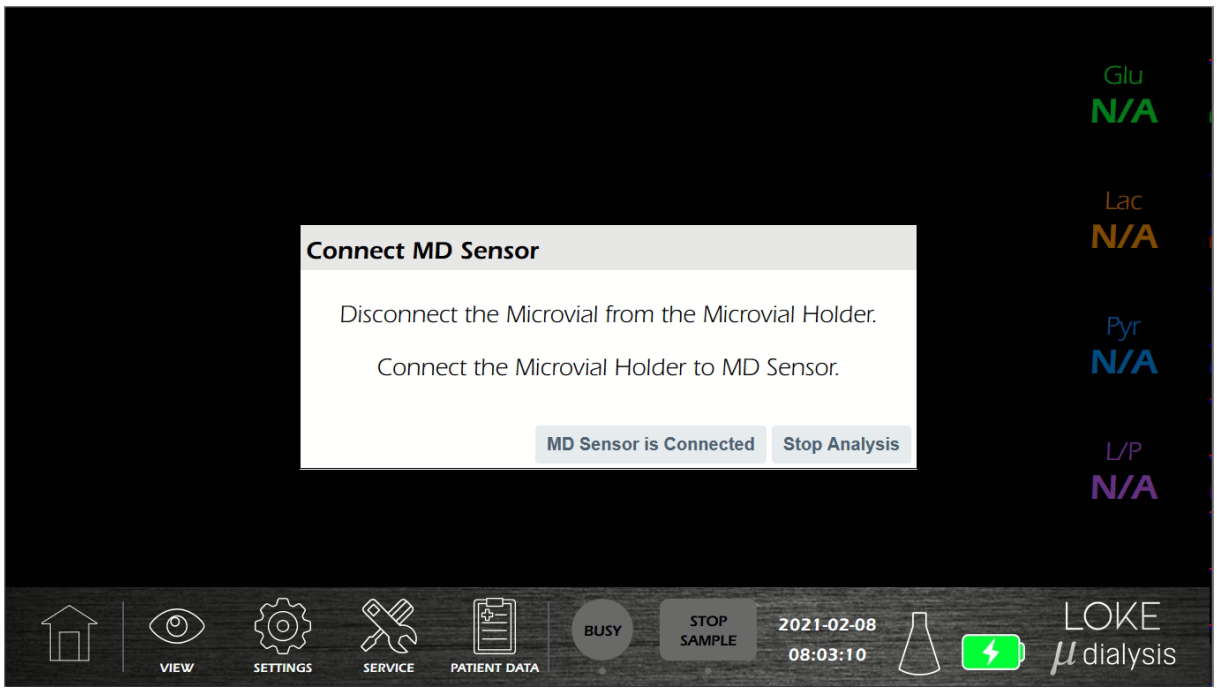
3. Choose Sample duration. It is always possible to stop sampling in advance or leave the Microvial inserted to continue sampling for a longer period.



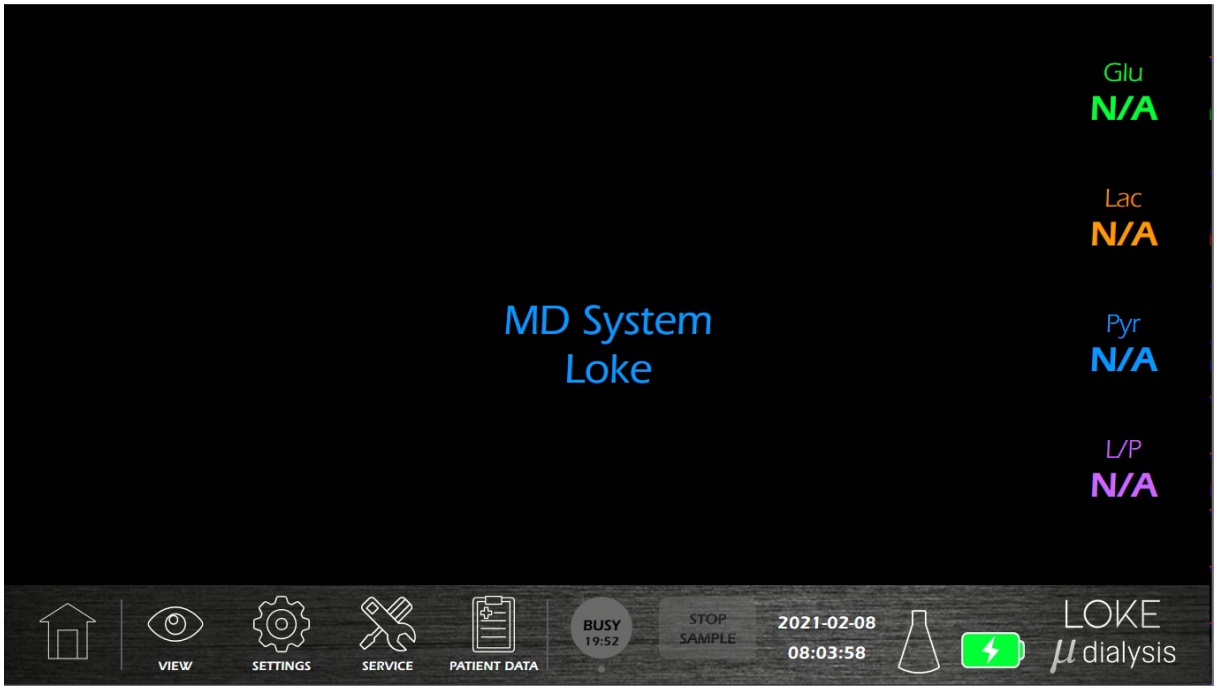
4. Wait while the sample is collected. The sampling can be interrupted by pressing Stop Sample.



5. When the sampling is finished, remove the Microvial from the Microvial Holder and reconnect the Microvial Holder to the MD Sensor. Press MD Sensor is Connected.

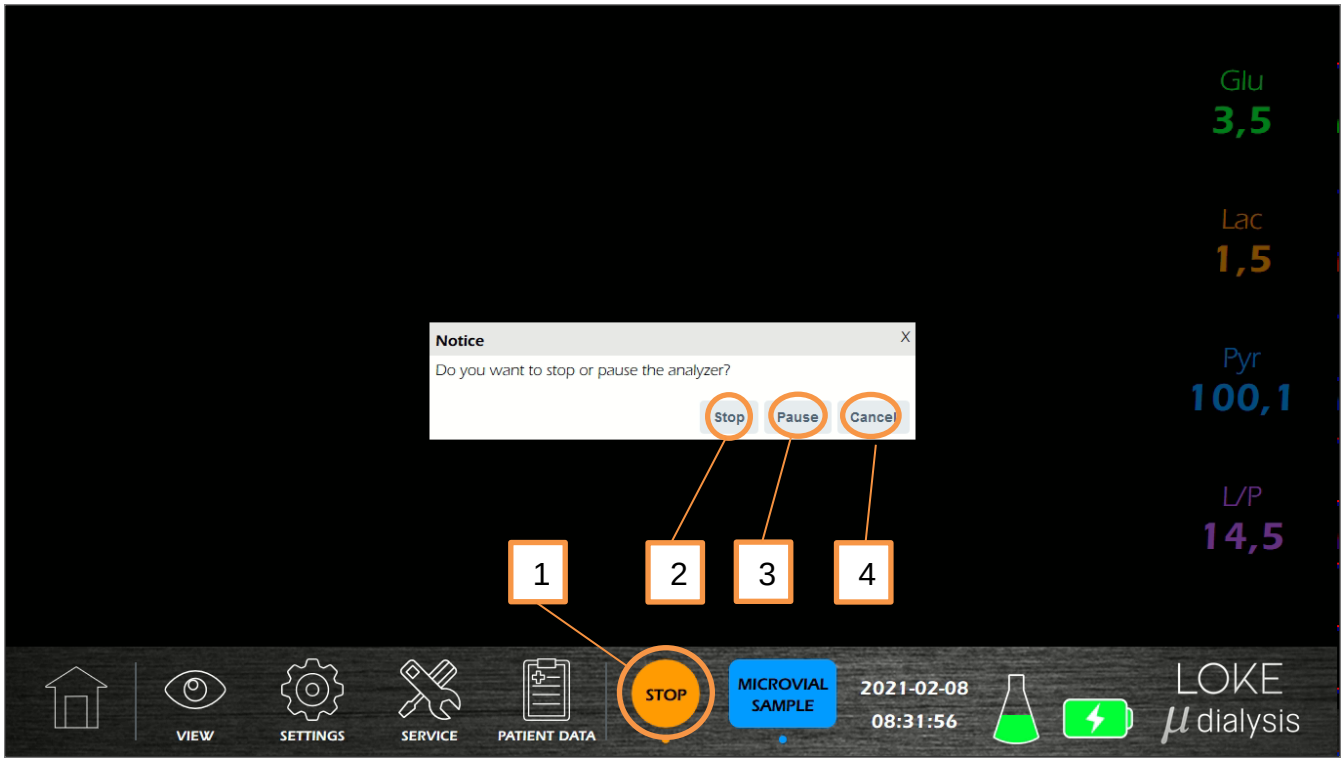


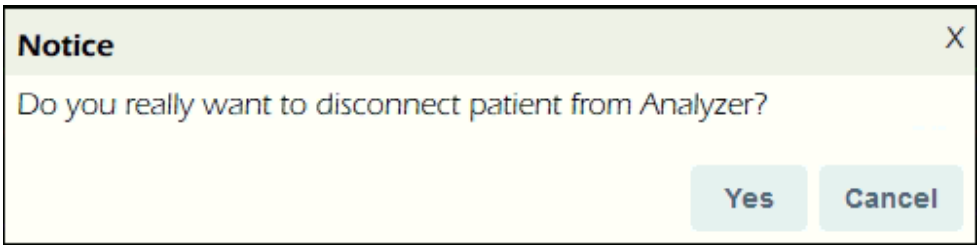
6. After the Microvial Holder has been reconnected to the MD Sensor, the system needs 20 minutes for the MD Sensor to get stable values. During this time no new values are displayed on screen.



3.19. Stop or pause microdialysis session

1. To stop the session, tap STOP (1).
2. To stop microdialysis and change patient, tap Stop (2) and confirm in next window by pressing “Yes”.
3. To temporary pause the analysis and reconnect same patient later, use the Pause option (3) and confirm in next window by pressing “Yes”
   Note! Current patient’s data remains stored in the system during pause.
4. To abort stop and continue microdialysis, tap Cancel (4).





Answer the question to proceed or Cancel

3.20. Temporary disconnection of the patient (Pause session)

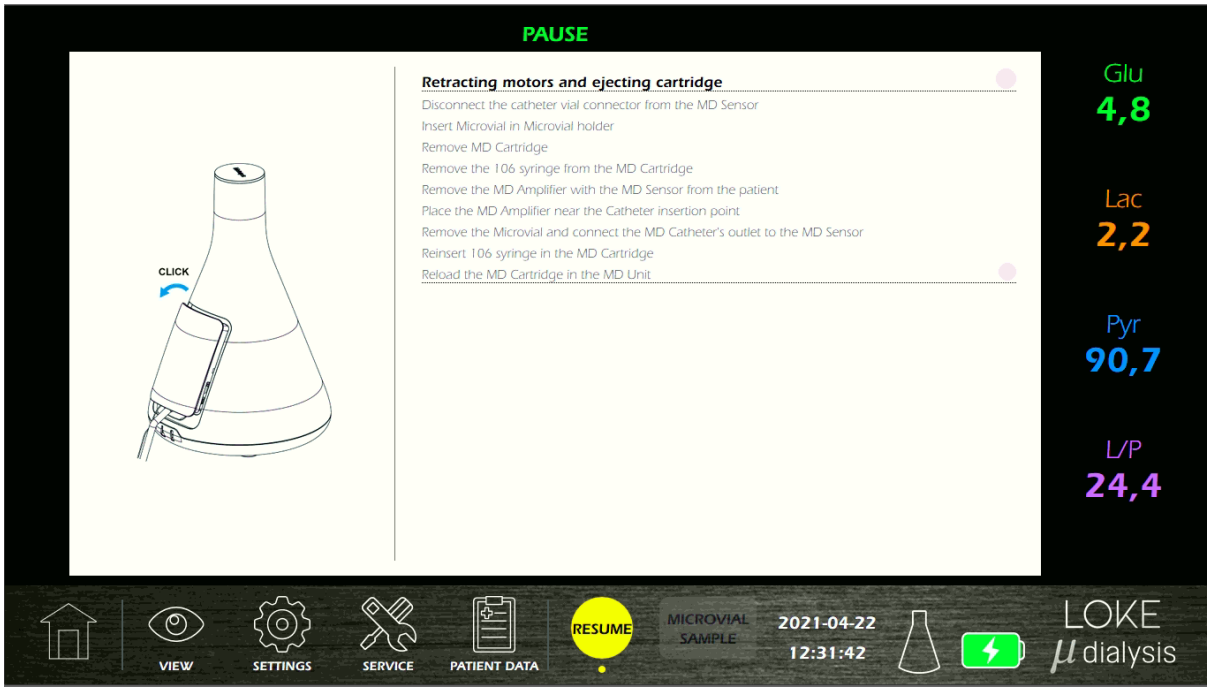
Note! Current patient's data remains stored in the system during pause.

3.20.1. Disconnecting the patient

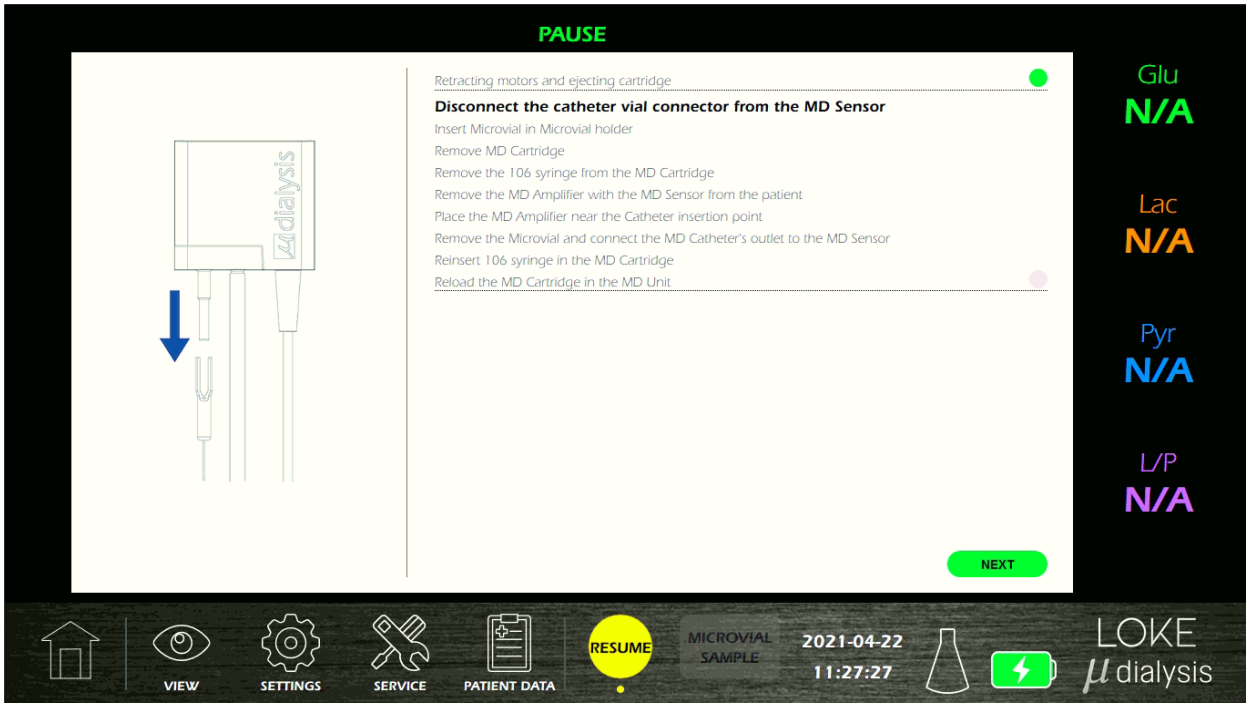
1. After tapping STOP (1) tap the pause button (3) on the MD Monitor and follow the instructions.

2. Wait until MD Cartridge is ejected.

Warning! Do not to squeeze the tubing when MD Cartridge is ejected from MD Unit.

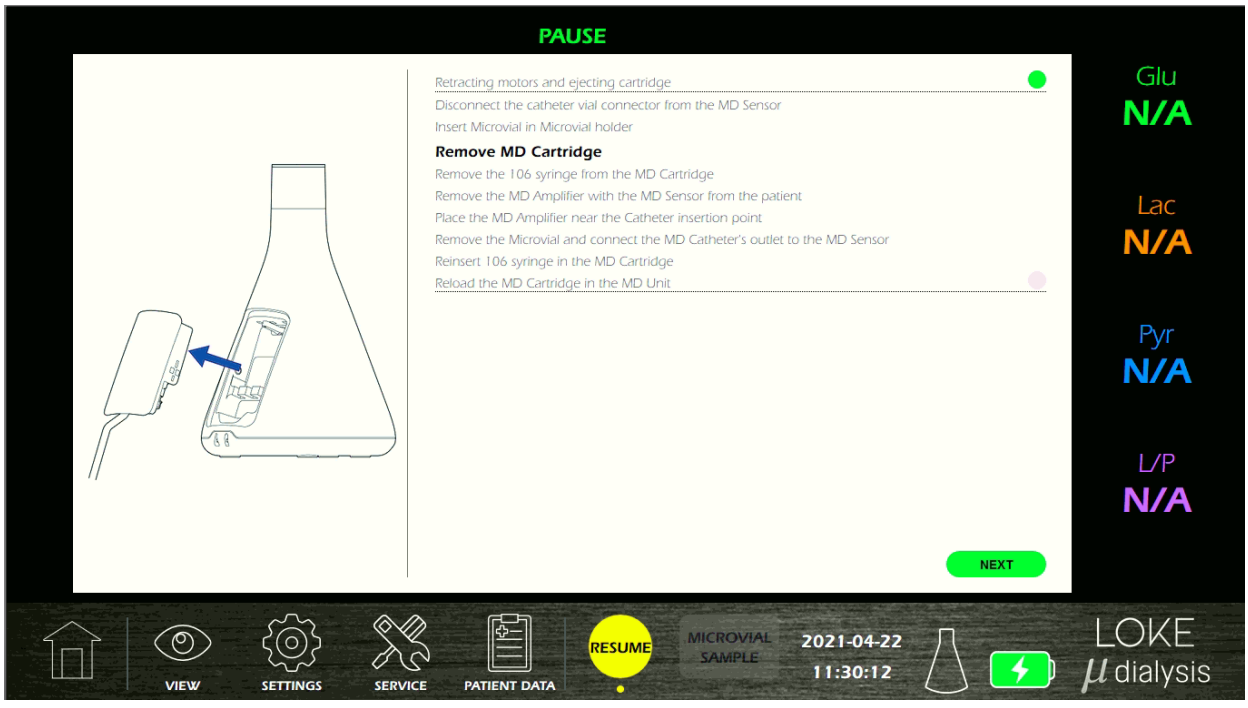


3. Disconnect the Microdialysis catheter vial holder from the MD Sensor and connect a Microvial to the vial holder.



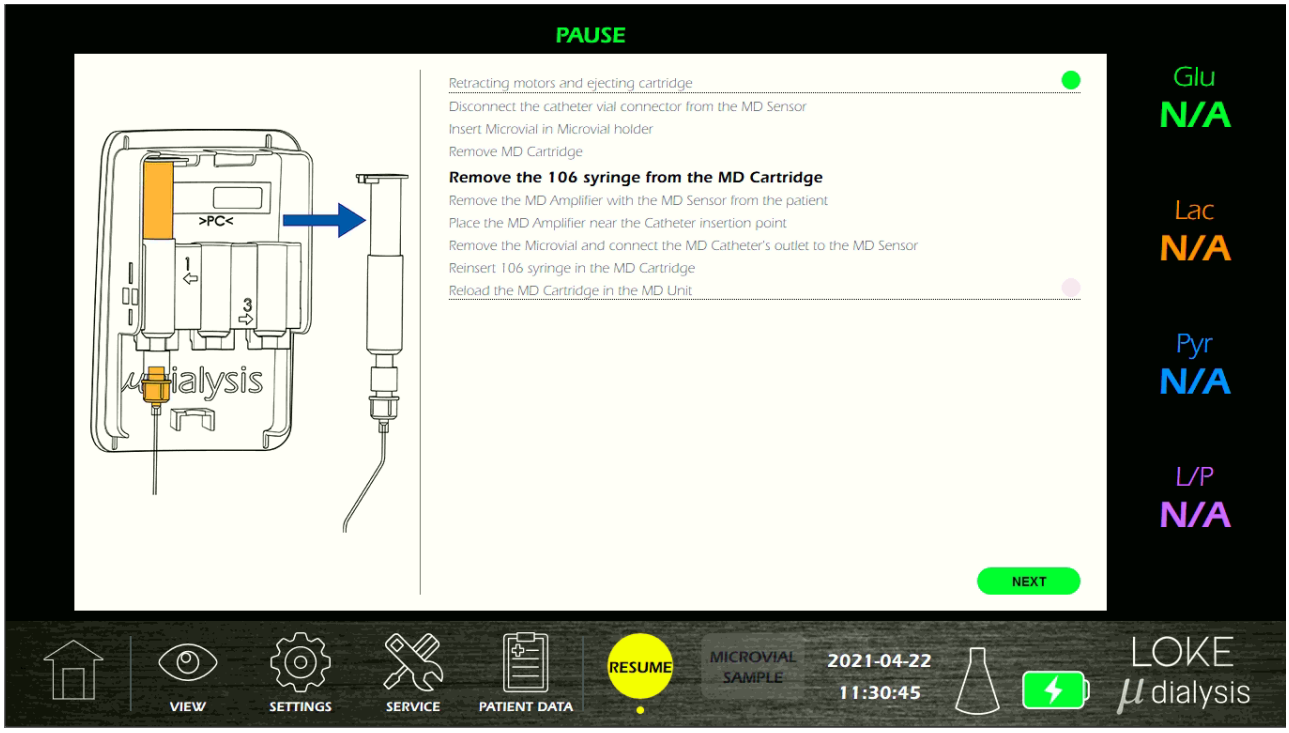
Warning! A Microvial must be connected to the MD Catheter's outlet.

4. Remove the MD Cartridge from the MD Unit. Make sure that the MD Cartridge has been ejected by the MD Unit prior to removal.

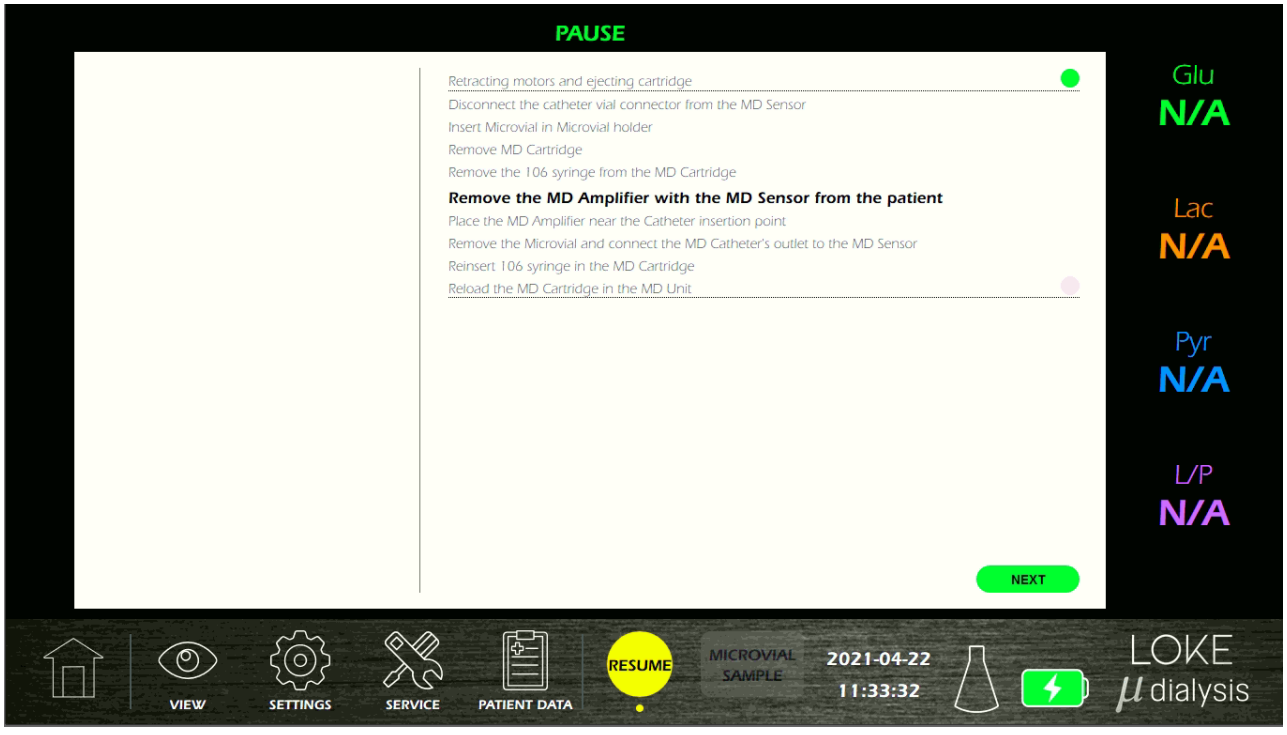


5. Remove the 106 Syringe with perfusion fluid from the MD Cartridge.

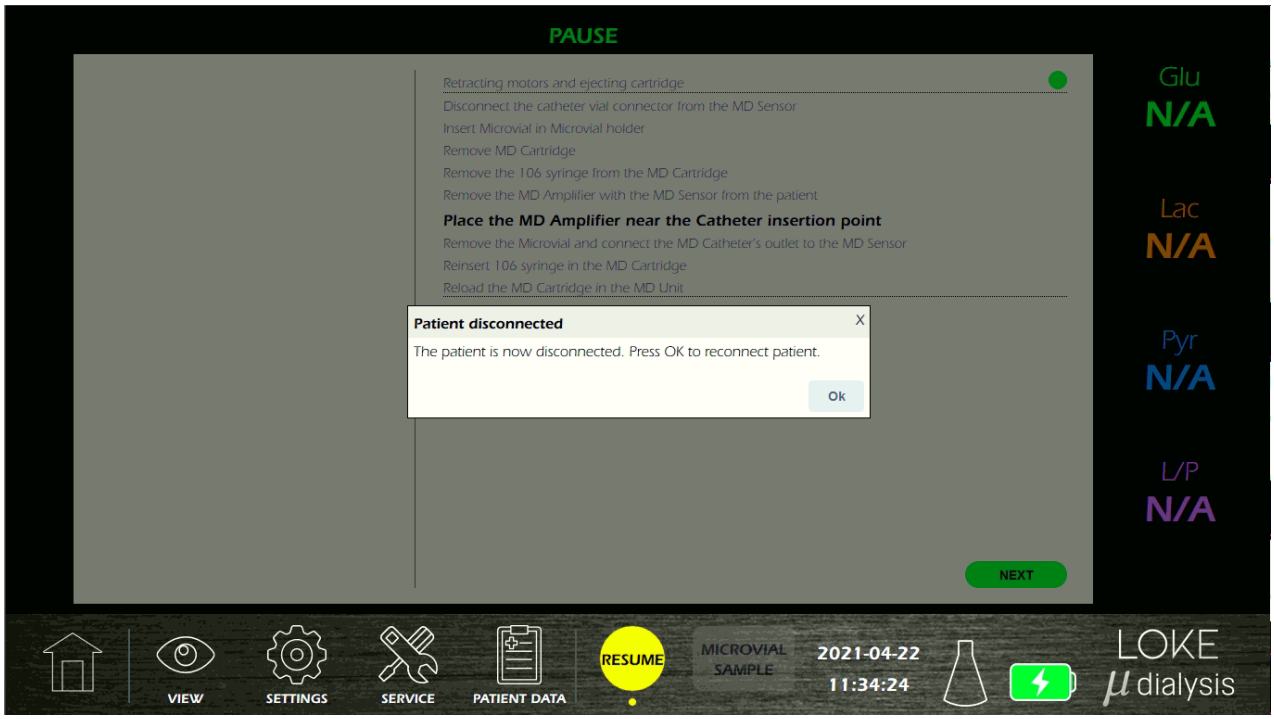
Warning! During e.g. MR investigation the 106 Syringe must be removed from the MD Cartridge but it shall not be disconnected from the Catheter Extension.



6. Remove the MD Amplifier with the MD Sensor from the patient.

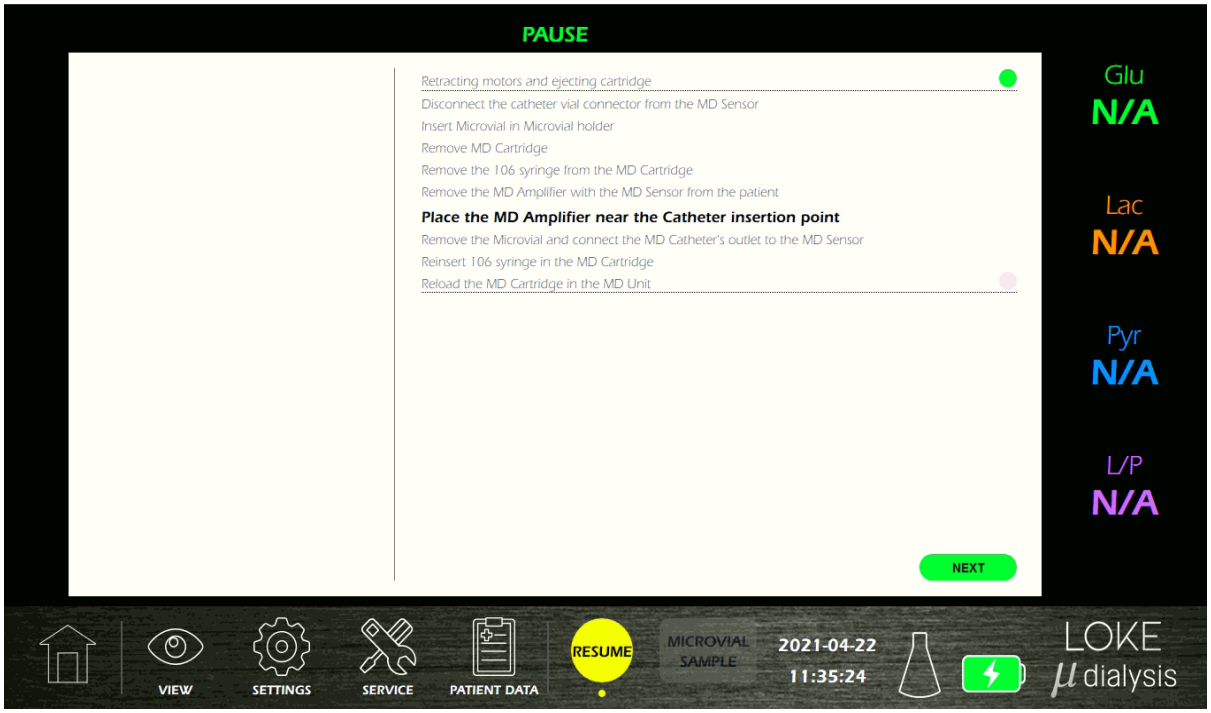


7. The patient is now disconnected from MD System.

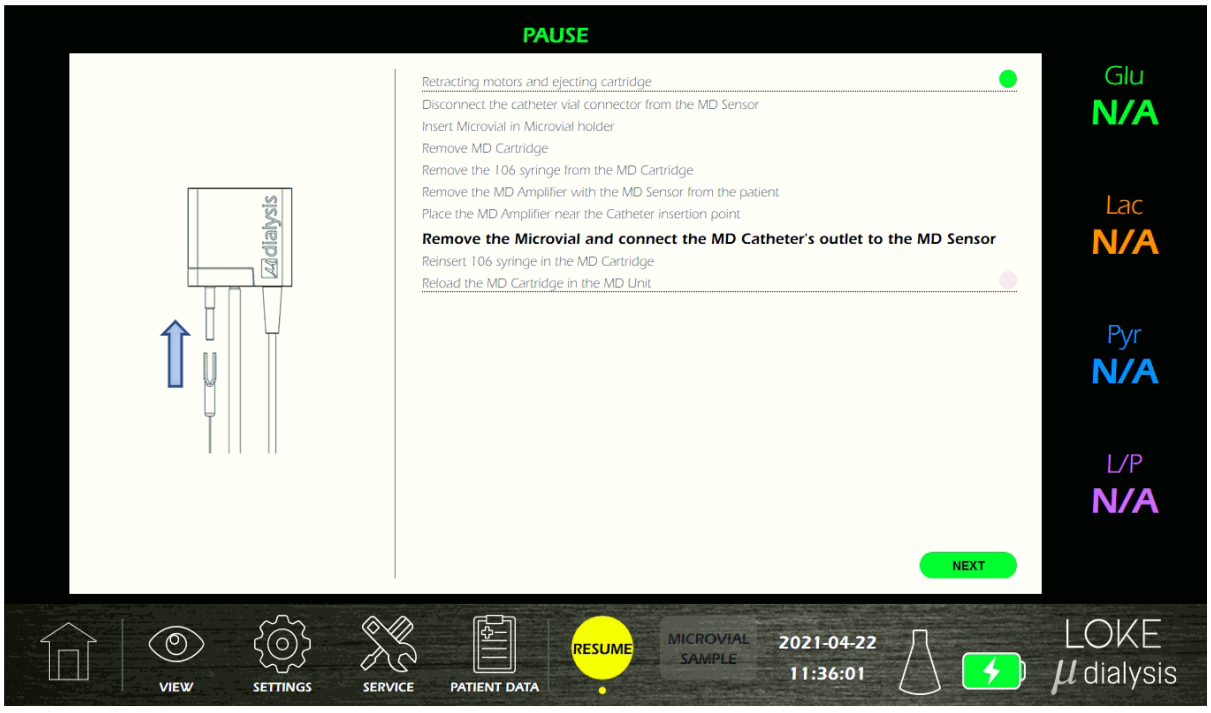


3.20.2. Reconnecting the patient

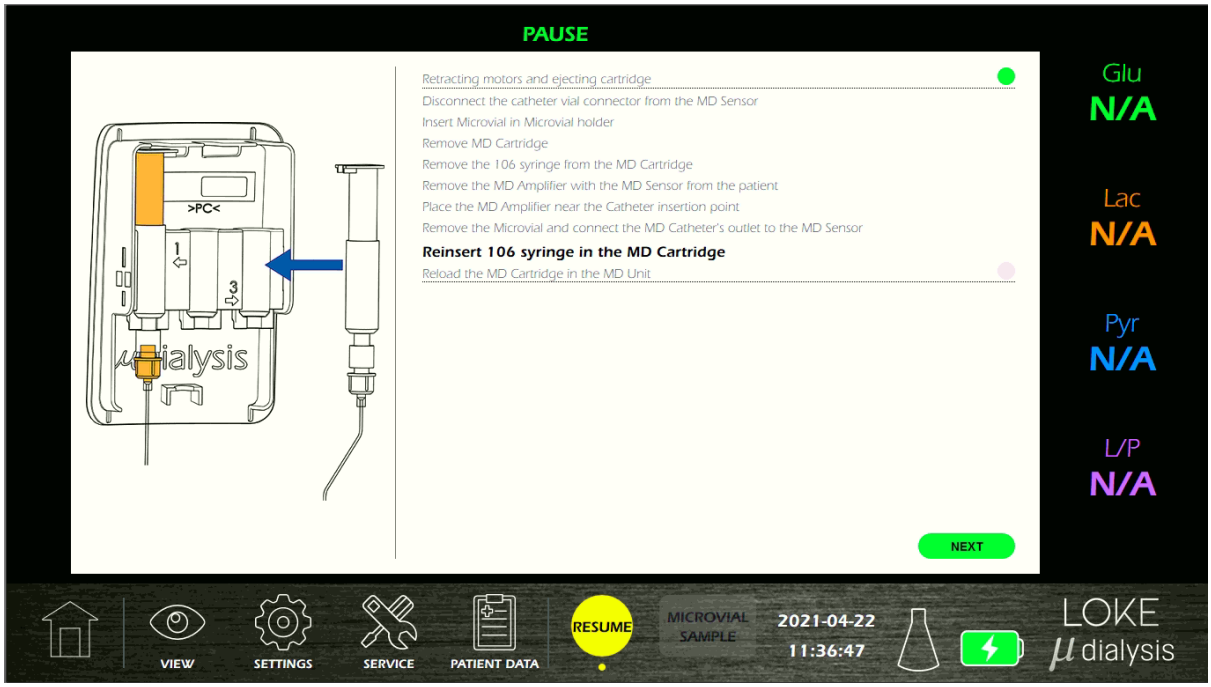
1. Place the MD Amplifier near the Catheter insertion point



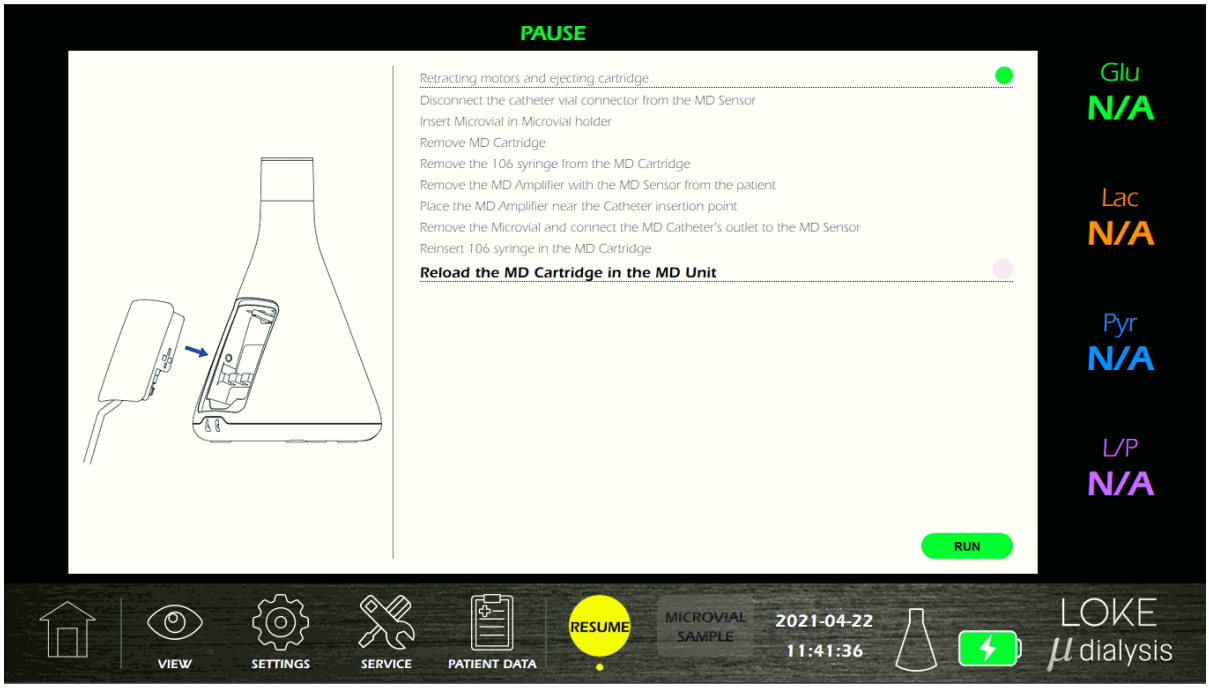
2. Remove the microvial and connect the MD catheter connector to the MD Sensor.



3. Reinsert the 106 Syringe with perfusion fluid into the MD Cartridge.



4. Insert the MD Cartridge in the MD Unit. Align the MD Cartridge in the center and insert it straight into the cavity.

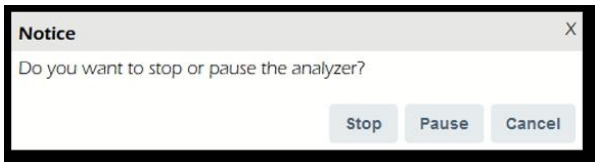


5. Press “RUN” on the MD Monitor and MD System will continue with the Microdialysis monitoring.

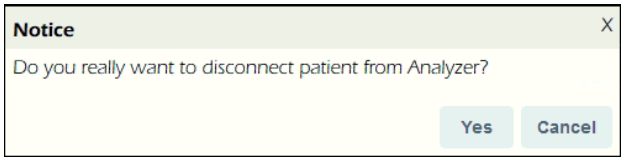
3.21. Ending the Microdialysis process

3.21.1. Shutting down the system

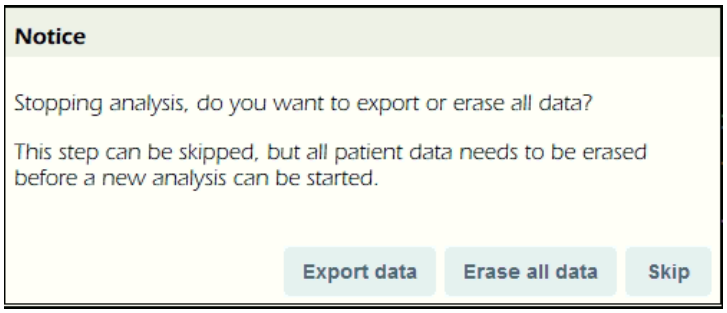
1. Press Stop on the MD Monitor and confirm (see section 3.19 above).



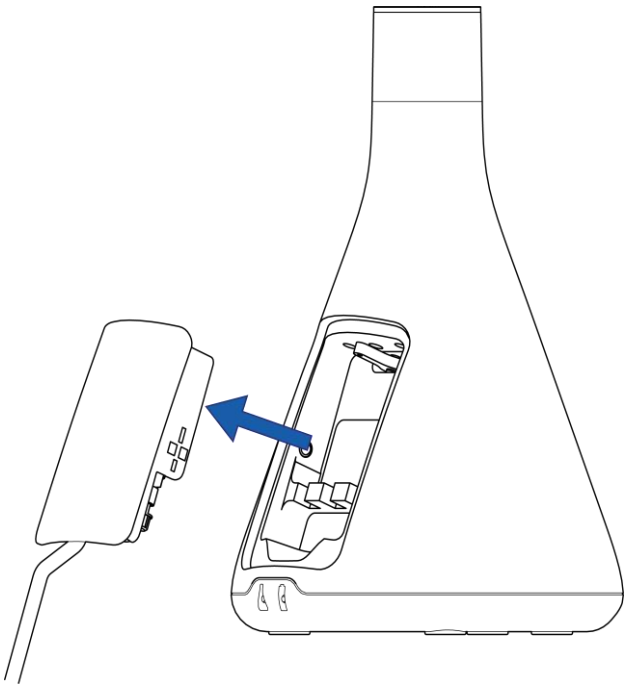
2. Press Yes to confirm



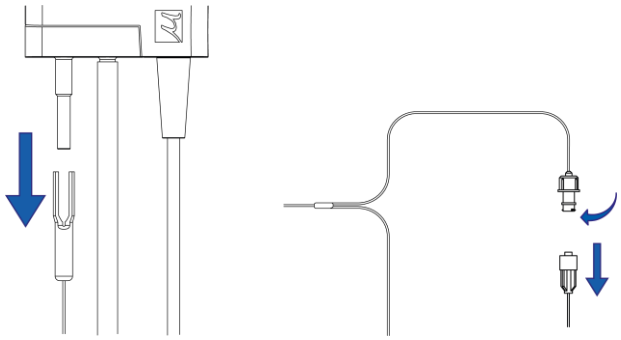
3. Stopping analysis, do you want to export or erase all data.
   This step can be skipped, but all patient data needs to be erased before a new analysis can be started. Select what to do.



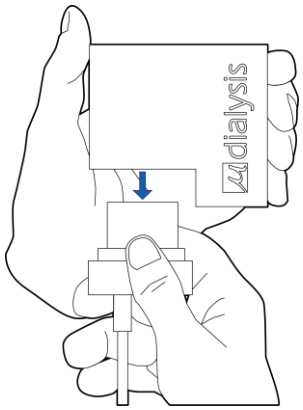
4. The MD Unit will eject the cartridge, after which it is possible to remove the MD Cartridge.
5. Remove the MD Cartridge from the MD Unit. Make sure that the MD Cartridge has been ejected by the MD Unit prior to removal.



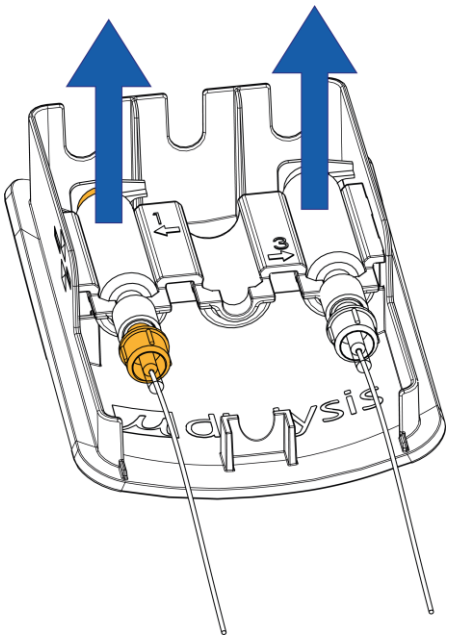
6. Disconnect the MD catheter from the MD Sensor and the extension tubing.



7. Remove MD Sensor and MD Amplifier from patient.

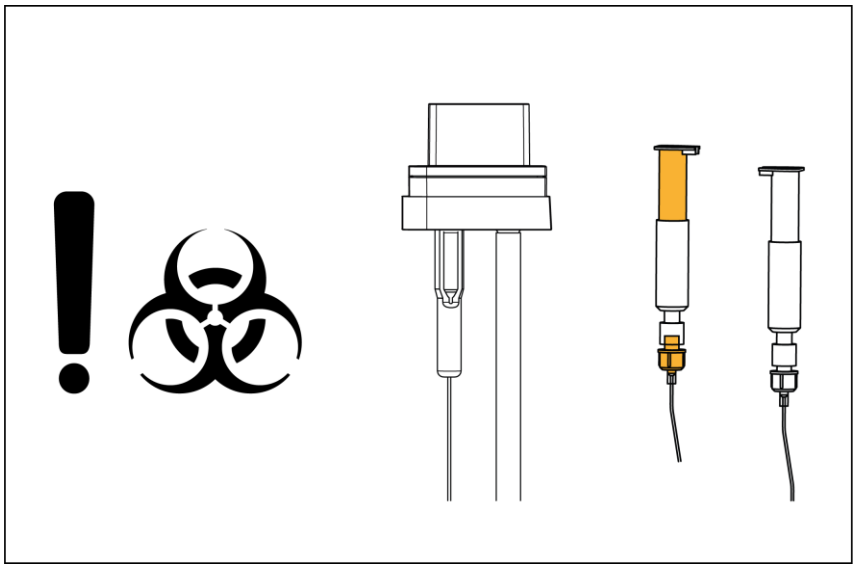


8. Remove all syringes from the MD Cartridge



3.21.2. Disposal of the MD Sensor

The MD Sensor should be taken care of as biological hazard waste.



The MD Cartridge can be reused.

Warning! Do not use a damaged MD Cartridge, replace a damaged cartridge immediately.

4. Routine maintenance

4.1. Cleaning the instrument

Wipe the outside of MD System components, except MD Sensor, with disinfectant (70% ethanol or equivalent).
Note! Sodium hypochlorite shall not be used on MD Unit.
Sodium hypochlorite may cause miss colorations on aluminum surfaces and should only be used to a limited extent.

Warning! Do not to use sharp objects for cleaning device or accessories

Warning! Do not to use excessive amounts of water or other liquids during cleaning

5. Troubleshooting

Error:	Message on MD Monitor; *Waiting for a connection*
Action:	• Check that MD Unit is on and is running • Check that ethernet cable between MD Unit and MD Monitor is properly connected and without visual damage • Restart MD Monitor • Restart MD Unit • If possible, try using another ethernet cable • If problem remains, please contact M Dialysis Service Center or your local distributor
Error:	Message on MD Monitor; *MD Sensor is not connected*
Action:	• Check that MD Sensor is properly connected to the MD Amplifier • Check that the cable between MD Unit and MD Amplifier is properly connected and without visual damage. • Check that MD Sensor is without visual damage • Check that MD Amplifier is without visual damage • If possible, try connecting another MD Sensor • If possible, try using another MD Amplifier • If problem remains, please contact M Dialysis Service Center or your local distributor
Error:	No message, system freeze
Action:	• Restart MD Monitor • Restart MD Unit • If problem remains, please contact M Dialysis Service Center or your local distributor

5.1. Error list

#	Text
-1	-1: "Unknown error",
0	0: "ADC Process: Unable to initialize ADC after {retries} attempts, disabling ADC.",
1	1: "Unable to connect to database - {e}.",
2	2: "Driver/Controller initialize error - {e}.",
3	3: "Waiting for processes to load timed out, exiting.",
4	4: "Cartridge Controller Eject: Error ejecting cartridge - {e}.",
5	5: "LED Controller LEDS1 Off: Error turning off LEDs - {e}.",
6	6: "LED Controller LEDS2 Off: Error turning off LEDs - {e}.",
7	7: "{module_name}: Calibration Error: Calibration factor needs to be cleared before gathering measurements for new calculation.",
8	8: "{module_name}: Calibration Error: No measurements stored.",
9	9: "{module_name}: Average signal from biosensor is 0, cannot calculate calibration factor.",
10	10: "{module_name}: Average signal from biosensor is less than 0 ({avg_snorm}), cannot calculate calibration factor.",
11	11: "{module_name}: Factory calibration factor is 0, cannot do comparison.",
12	12: "{module_name}: New calibration factor {calibration_factor} differs more than {cal_factory_cal_max_difference} from factory calibration: {factory_cal}.",
13	13: "Unable to parse test script file: {e}.",
14	14: "Patient Module Controller Biosensor Detect Callback: Could not read biosensor EEPROM, type of biosensor could not be determined.",
15	15: "Patient Module Controller Read EEPROM Data: {e}.",
16	16: "Patient Module Controller Measure Temperature - Could not measure temperature after {retries} retries: {e}.",
17	17: "Perfusion Flow rate not defined in Analysis Controller, cannot perform flush - aborting analysis.",
18	18: "A pump task for perfusion has already been defined in the script, cannot perform flush - aborting analysis.",
19	19: "Flush: Error in motor task list - aborting analysis.",
20	20: "Biosensor removed during flush, aborting analysis.",
21	21: "Cartridge forcibly ejected during flush, aborting analysis.",
22	22: "Unable to write start time to EEPROM: {e}.",
23	23: "Perfusion syringe empty. Re-fill syringe.",
24	24: "Error during pumping, aborting analysis.",
25	25: "Analysis Error - Biosensor expired on {expired_dt_str}.",
26	26: "Biosensor removed, aborting analysis.",
27	27: "Cartridge forcibly ejected, aborting analysis.",
28	28: "Sensor temperature sensor error, replace sensor.",
29	29: "Sensor Error - Short circuit detected, replace sensor.",
30	30: "Calibrator syringe empty. Re-fill syringe.",
31	31: "Calibration failed after {attempts} attempts. Check syringe placement or replace sensor.",
32	32: "Biosensor removed during calibration, aborting analysis.",
33	33: "Cartridge forcibly ejected during calibration, aborting analysis.",
34	34: "Invalid patient id/name ({patient_id} - {patient_name}) or flow rate {flow_rate}, aborting analysis.",
35	35: "Analysis Error - Error in motor task list during fill-up script.",
36	36: "Analysis Error - Timeout during fill up.",
37	37: "System error. Check syringes or replace sensor.",
38	38: "Analysis Error - Error in motor task list during fill up post script.",

#	Text
39	39: "Biosensor removed during fill-up sequence, aborting analysis.",
40	40: "Cartridge forcibly ejected during fill-up sequence, aborting analysis.",
41	41: "Biosensor removed, aborting start of analysis.",
42	42: "Cartridge forcibly ejected, aborting analysis.",
43	43: "Find Piston Error - Error in motor task list during find piston.",
44	44: "Timed out during Pre-Use Check while waiting for measurement data.",
45	45: "Biosensor Channel {channel} limit test failed, value: {ncurrent}.",
46	46: "Could not fully retract motors, remove cartridge carefully by hand and contact service.",
47	47: "Date/Time for MD Unit set incorrectly ({timestamp}), contact service.",
48	48: "Error during initialization of motors, contact service.",
49	49: "Flush Error - Error in motor task list.",
50	50: "Biosensor removed during flush, aborting analysis.",
51	51: "Cartridge forcibly ejected during flush, aborting analysis.",
52	52: "Could not fully retract motors, remove cartridge carefully by hand.",
53	53: "Could not fully retract motors.",
54	54: "Could not fully retract motors, aborting test mode.",
55	55: "Error in task list ID {task_list_id}: {task_list_errors}.",
56	56: "Error in task {task_motor_name} / {task_task_name}: {task_errors}.",
57	57: "Error in battery info thread: {e}.",
58	58: "Biosensor data signal missing check failed.",
59	59: "{key}: Signal missing - max value last {duration}s: {ncurrent} nA below limit {limit_na} nA.",
60	60: "{key}: Signal too high - average value last {duration}s: {ncurrent} nA over limit {limit_na} nA.",
61	61: "Biosensor data short circuit check failed.",
62	62: "Temperature below allowed low limit ({limit_low}) - average value last {temperature_sanity_length} measurements: {avg_temp:.2f}°C.",
63	63: "Temperature above allowed high limit ({limit_high}) - average value last {temperature_sanity_length} measurements: {avg_temp:.2f}°C.",
64	64: "Unable to get channel average ncurrent: {e}.",
65	65: "Resetting MD Amplifier by power cycle...",
66	66: "Already tried resetting MD Amplifier once, temperature cannot be read.",
67	67: "Pre-Use Check Failed, values: {channel_data}.",
68	68: "Error quering the max date: {e}.",
69	69: "Error inserting into database: {e}.",
70	70: "Unable to parse request data: {json_data}, error: {e}.",
71	71: "Unknown LogMessage level: {log_message}.",
72	72: "Unable to parse push data: {data}, error: {e}.",
73	73: "Socket Event Handler Exception: {e}, Event Data: {event_data}",
74	74: "Invalid socket request received: {request}.",
75	75: "Socket Request Handler Exception: {e}.",
76	76: "ADS1254 Driver: Unable to read at least 1 sample.",
77	77: "ADS1254 Driver: Max read sample attempts reached.",
78	78: "ADS1254 Driver: Error reading from ADC - {e}.",
79	79: "ADS1254 Driver: Read bits timeout, couldn't find DREADY signal pattern.",
80	80: "Exception: {e}.",
81	81: "Unable to merge user settings with default settings: {e}.",
82	82: "Could not copy fallback file to destination: {e}.",
83	83: "Unable to merge fallback user settings with default settings: {e}.",

#	Text
84	84: "Unable to merge user settings debug file with default settings: {e}.",
85	85: "Unable to load settings file: {e}.",
86	86: "Could not find path {element} in settings.",
87	87: "ADC Process: Error intializing ADC, retry count {init_retry_count} - {e}.",
88	88: "ADC Process: Unable to set ADC Registry Configuration, retry count {init_retry_count}.",
89	89: "Motor Process: Unable to initialize Serial Port Driver - {e}.",
90	90: "Possible air bubble detected - Difference between measurement type {mtype} and {reftype} greater than {max_diff}, minimum difference last {min_duration}s = {min_diff}. Current {reftype} measurement value: {ref_meas}mmol/L.",
91	91: "Unable to calculate biosensor reference levels - {e}.",
92	92: "{key}: Signal differs too much from reference level - max value last {duration}s: {ncurrent} nA over limit {limit_na} nA.",
93	93: "Reference level check has failed.",
94	94: "Sensor Error - Signal missing error detected, replace sensor.",
95	95: "Sensor Error - Possible air bubble detected, unable to automatically recover.",
96	96: "Sensor Error - Reference level error possibly due to stop in flow, unable to automatically recover.",
97	97: "{key}: Signal too high - min value last {duration}s: {ncurrent} nA over limit {limit_na} nA.",
98	98: "Post calibration check has failed.",
99	99: "Sensor Error - Error possibly due to stop in flow, unable to automatically recover.",
100	100: "Post calibration check failed for {name} - min value last {duration}s: {min_value} mmol/L over limit {limit} mmol/L.",
101	101: "Aborting analysis after {attempts} attempts at filling up the Microvial.",
102	102: "Take Sample duration invalid: {sample_duration}."

6. Classification and Regulations

6.1. In accordance with the MDD (Medical Device Directory)

In accordance with the MDD, Article 9, MD System is classified as a Class IIa medical device.

6.2. In accordance with EN 60601-1:2006

6.2.1. Type of protection against electric shock

Complete system except MD Monitor is Class II equipment. MD Monitor is a class I equipment.

6.2.2. Degree of protection against electric shock

Type CF equipment

6.2.3. Degree of protection against harmful ingress of water

IPX1 – Only with MD Cartridge mounted and MD Unit in upright position.

6.2.4. Mode of operation

Continuous operation

6.2.5. Mechanical strength

Portable equipment

6.2.6. Suitability for use in an oxygen rich environment

Not suitable for use in an oxygen rich environment

6.3. Regulations

MD unit meets international standard EN 60601 class IIa.

The MD Unit bears the CE label in accordance with the provisions of the European Directives for EU Directive 93/42/EC (MDD), EU Directive (2014/30/EU) (EMC), EU Directive 2012/19/EC (WEEE II) and EU Directive 2011/65/EC (RoHS II)

6.4. EMC - Electromagnetic compatibility

Warning! The use of accessories, transducers and cables other than those specified, with the exception of transducers and cables sold by M Dialysis AB as replacement parts for internal components, may result in increased EMISSIONS or decreased IMMUNITY of MD System.

Warning! MD System should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, MD System should be observed to verify normal operation in the configuration in which it will be used.

Warning! Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the MD System, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Warning! MD System should not be exposed to disturbance levels exceeding those given in IEC 60601-1-2.

NOTE! The Emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

List of cables:

Network cable – Max length 2 meters

Power cable – Powerbox PSU, length 1.8 m

Please see, EMC - Electromagnetic Compatibility, in MD System Technical manual for further information.

7. Technical specifications

7.1. Technical data

Voltage:	100 - 240, VAC 50 / 60 Hz
Power consumption:	max 40 VA
Compliance:	Power adaptor complies with 60601-1
Insulation:	MD Unit power adaptor is double isolated
Dimensions W x D x H:	220 mm x 220 mm x 332 mm
Weight:	5 kg
Principle:	Electrochemical biosensor
Samples:	Continuous on-line measurement of Microdialysate
Monitor cable:	Standard ethernet, shielded (Cat 5e or later)
Recovery time after exposure to defibrillation voltage:	5 minutes

Warning! MD Unit is heavier than it may appear. Exercise caution upon moving or lifting MD Unit.

MD System measures Glucose, Lactate and Pyruvate within the following intervals and with the following accuracies:
Glucose 0.2–15 mM, ± 30 % or 0.1 mM whichever is greatest
Lactate 0.1–10 mM, ± 30 % or 0.1 mM whichever is greatest
Pyruvate 10–300 µM, ± 30 % or 10 µM whichever is greatest
Calculated parameters: The Lactate-Pyruvate ratio

M Dialysis AB reserves the right to make changes in the specifications without prior notice.

7.2. Duration of contact for applied parts and accessible parts

MD Amplifier and MD Sensor are applied parts and have continuous contact with the patient for up to 5 days. MD Unit is regarded as applied part with a contact duration of 10 seconds < t < 1 minute.

Other components are regarded as accessible parts with a duration of contact 10 seconds < t < 1 minute.

7.3. Expected service life

Expected service life;
MD Unit 7 years
MD Amplifier 1 year
MD Cartridge 1 year

7.4. Operating environment

- The MD Unit is manufactured for indoor use and should be placed in a draught free place and not in direct sunlight.
- No radio transmitters, cellular phones or other wireless communication devices should be used in the vicinity of the MD Unit.

- The MD Unit should not be submitted to higher levels of disturbance as specified in EN 60601-1-2 and EN 61010.
- MD System should not be used with flammable anesthetics category AP or APG.

MD System excluding the MD Sensor shall be kept under the following environmental condition:

Operating
Temperature; +15 °C to +30 °C
Humidity; 10% to 90% (non-condensing)
Pressure; 700 hPa to 1060 hPa
Storage
Temperature; -10 °C to +60 °C
Humidity; 10% to 90% (non-condensing)
Pressure; 500 hPa to 1060 hPa
Transport
Temperature; -10 °C to +60 °C
Humidity; 10% to 90% (non-condensing)
Pressure; 500 hPa to 1060 hPa

MD Sensor shall be kept under the following environmental condition:

Operating
Temperature; +15 °C to +30 °C
Humidity; 10% to 90% (non-condensing)
Pressure; 700 hPa to 1060 hPa
Storage and transport
Temperature; +2 °C to +8 °C
Humidity; 10% to 90% (non-condensing)
Pressure; 500 hPa to 1060 hPa

 **Warning!** Do not operate/store/transport MD System and MD Sensor outside the above noted environmental conditions.

7.5. MD System materials and ingredients patient or operator is exposed to

MD Amplifier:	Medical grade PC, Poly Carbonate
MD Sensor cable:	PVC, Polyvinyl Chloride
MD Sensor:	Medical grade PC, Poly Carbonate
MD Sensor tubing:	Medical grade TPE, Thermo Plastic Elastomer
Perfusion fluid:	Perfusion Fluid is a non-toxic, sterile, isotonic fluid
Calibration fluid:	Fluid containing defined concentrations of Glucose, Lactate and Pyruvate to support sensor calibrations.

7.6. Disturbances

Devices transmitting on radio frequencies can affect the performance of MD System if used in close proximity of MD System.

8. Consumables

⚠ **Warning!** Only consumables from M Dialysis shall be used.

For up to date information, please visit our website: http://www.mdialysis.com

9. Spare Parts and accessories

⚠ **Warning!** Only Spare Parts and accessories from M Dialysis shall be used**.**

For up to date information on approved spare parts and accessories, please visit our website: http://www.mdialysis.com.

8050204 MD Sensor & Calibrators kit

- 8070203 MD Sensor LPG
- **8072009** MD Calibrators (2 bottles)

8050206 MD System Syringe Kit, Brain Tissue

- **8050200** MD System Syringes, Brain Tissue
  One 106 Syringe from **8010191** 106 Syringe 20/pkg
  One Syringe Orange from **8070081** Syringe Orange 20/pkg
  One ampoule from **P000151** Perfusion Fluid CNS 10x5 mL
- 8072001 Catheter Extension

8050207 MD System Syringe Kit, Peripheral Tissue

- **8050201** MD System Syringes, Peripheral Tissue
  One 106 Syringe from **8010191** 106 Syringe 20/pkg
  One Syringe Orange from **8070081** Syringe Orange 20/pkg
  One ampoule from **P000034** Perfusion Fluid T1 10x5 mL
- 8072001 Catheter Extension

The MD Sensor & Calibrators kit above (Ref 8050204) shall be stored in a fridge, +2 - +8 °C

10. Liability, warranty and service

10.1. Liability

M Dialysis AB is liable for the safety and reliability of its equipment only if:

a) repair, maintenance and modifications are carried out by authorized personnel;
b) components are replaced with M Dialysis approved spare parts;
c) devices are used only with M Dialysis approved accessories and consumables;
d) devices are used in accordance with M Dialysis´s operating instructions.
e) MD Unit is not repaired on site, unit should be replaced and sent to M Dialysis AB

10.2. Warranty

M Dialysis AB offers a one-year warranty from the day of purchase on defective material and assembly.

The warranty does not cover damage resulting from incorrect use or maintenance, or from unauthorized software modification.

M Dialysis AB is only responsible for replacement of defect parts, not of consumables or wear parts. M Dialysis AB is not responsible for any personal injury or any damage resulting from incorrect use of the MD Unit.

10.3. Service

Routine service by authorized personnel shall be done with a twelve-month interval. Routine service allows an expected service life of seven (7) years.

Routine service includes:
- General inspection of the MD Unit.
- Function test.
- Software upgrade, if applicable.

A service agreement may be purchased after the warranty period has ended.

For more information, please contact your local supplier or the M Dialysis service department:

M Dialysis AB
Hammarby Fabriksväg 43
SE-120 30 Stockholm
Sweden
E-mail: service@mdialysis.se
Tel. +46 8 470 10 20
Web: http://www.mdialysis.com

10.4. Arrival inspection

MD System must be inspected for damage upon arrival and unpacking according to the following points:
- Check the outer packaging for damage, any visible damage must be noted to the courier upon delivery.
- Any visible damage upon unpacking must be reported to M Dialysis immediately.

10.5. Functional test

There is an option to perform a pre-use check in the start guide (see section 3.17.1).

11. Text and symbol explanation

Follow instructions for use

Warning

Manufacturer information

Defibrillation-proof type CF applied part

Input DC Power

MD Amplifier

On/Off

Monitor socket

Service socket

Do not dispose as regular waste

IPX1

Protection class, protected against dripping water

Hazardous waste

Serial number

MR Unsafe

ETL- listed product.
Conforms to UL 60601-1:2003 Rev. 2006 and
Certified to CSA C22.2#601.1 (R2001)

CE marked according to the Medical Device Directive (MDD 93/42/EEC), EU Directive (2014/30/EU) (EMC), EU Directive 2012/19/EC (WEEE II) and EU Directive 2011/65/EC (RoHS II)

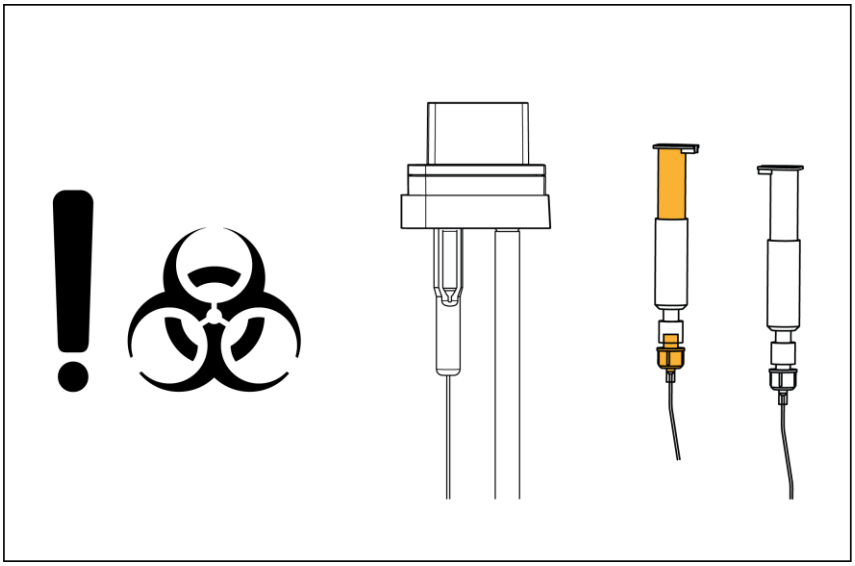
STERILE A Sterile using aseptic processing techniques

STERILE R Sterilized using irradiation

STERILE EO Sterilized using Ethylene Oxide

12. Disposal of product and accessories

Discontinued MD Sensors shall be handled according to the hospital routines for biohazard material.



Disposal of the MD Unit, or parts thereof, shall be in accordance with local regulations.