MD System

TECHNICAL MANUAL, ENGLISH

8072040 Rev C, 2021-10-15

μ dialysis

Manufactured by:
M Dialysis AB
Hammarby Fabriksväg 43
S-120 30 Stockholm
Sweden
E-mail: Info@mdialysis.se
Tel. +46 8 470 10 20
Fax. +46 8 470 10 55
Web: http://www.mdialysis.com

Technical manual for MD System

Printed in Sweden

All devices from M Dialysis AB are intended for use by qualified medical personnel only.

For MDD Use

Precautions:

No installation of non-M Dialysis software permitted.

Technical Manual (REF 8072040)
MD System

Contents

MD SYSTEM

1. OVERVIEW

1.1. GENERAL

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

1.2. INTENDED USE

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

1.2.1. **Intended user**

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

1.2.2. **Intended purpose**

The MD System 1.0 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.

1.2.3. **Intended use environment**

The MD System 1.0 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 1.0 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.

1.3. INDICATIONS FOR USE

1.3.1. **Condition**

The MD System 1.0 is indicated when the clinician decides there is a need to measure and display the metabolic changes via analyses of Glucose, Lactate and Pyruvate.

1.3.2. **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.

1.3.3. **Frequency of Use**

The MD System 1.0 is indicated for use when prescribed by a clinician.

1.3.4. **Physiological Purpose**

The MD System 1.0 is indicated when the purpose is to gain information for treatment, to assess adequacy of treatment, or to rule out causes of symptoms.

1.3.5. **Patient Population**

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

1.4. DESCRIPTION (OVERVIEW)

The dimensions of MD System are 220 mm x 220 mm x 332 mm (W × D × H) and the weight of the system is 5 kg. The analyser can be placed on a table or similar capable of carrying its weight.

The analyser is controlled via a web page presented on MD Monitor – a Windows 10 medical grade panel PC. The connection is via an internal Ethernet.

MD Unit – Main unit with a Raspberry pie computer that controls the pumping rods (Piezo motors), assesses the digital signals from MD Amplifier, handles calibrations and calculates results, updates the web page and has an overall control of everything executed.

MD Sensor – MD Sensor contains the biosensor and connections to the catheter in use and the calibration fluid. MD Sensor is connected to MD Amplifier.

MD Amplifier – Connects to MD Sensor and thus the biosensor, amplifies the signals and sends them digitally to MD Unit.

106 Syringe – Container for perfusion fluid, attached to MD Cartridge for dispensing of perfusion fluid

Perfusion Fluid – Carrier fluid passing the catheter membrane enabling microdialysis.

Catheter Extension – Extension allowing the MD Unit to be placed at a convenient location and still be connected to the catheter.

Syringe Orange – Container for MD Calibrator, attached to MD Cartridge for dispensing of calibrator fluid.

MD Calibrator – Fluid with specified amounts of Glucose, Lactate and Pyruvate to enable calibration of the analysing system. The fluid should be stored in a fridge, +2 - +8 °C.

MD Cartridge – Holder for 106 Syringe and Syringe Orange enabling the pumping of the contained fluids through the System.

2. DESCRIPTION

2.1. SPECIFICATIONS AND CLASSIFICATION

See User's Manual.

2.2. 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 10s < t < 1min.

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 analysing 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 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.

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.

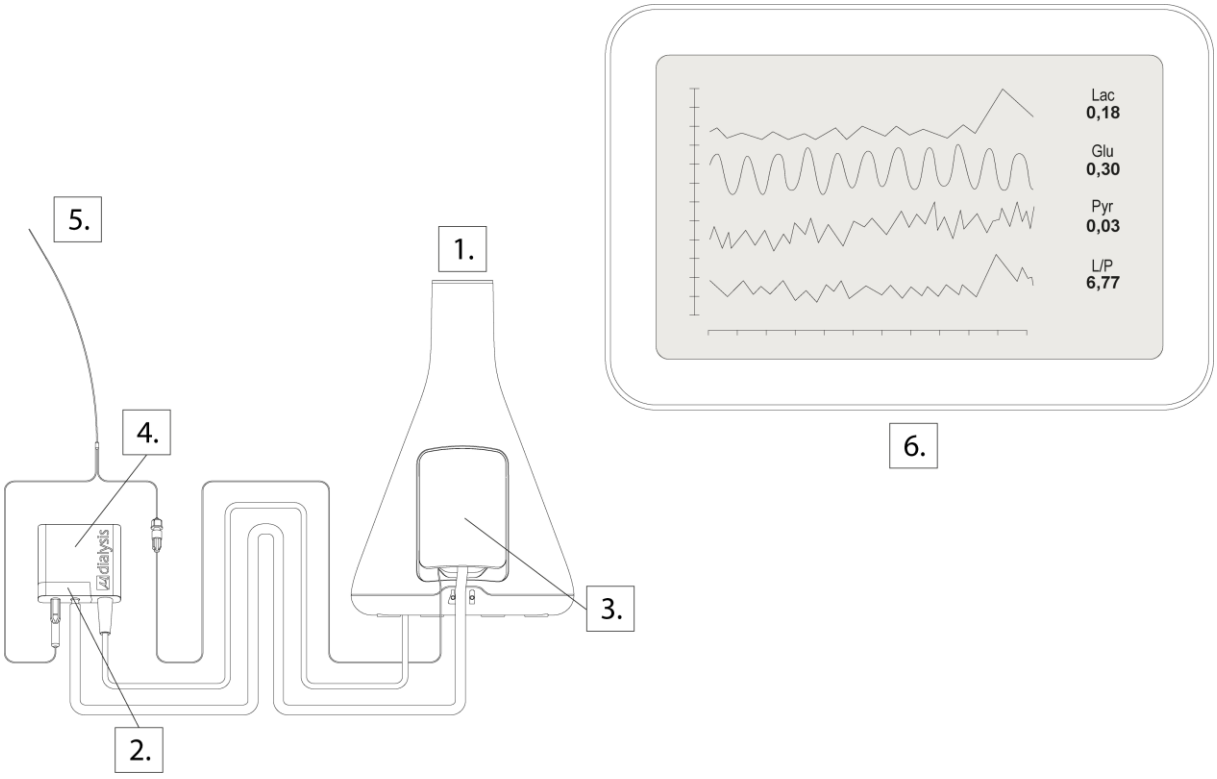
MD Catheter – Microdialysis catheter supplied by M Dialysis. For example, the 70 Brain Microdialysis Catheter, 63 Microdialysis Catheter and others. For handling of the MD Catheter read the MD Catheter IFU.

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.

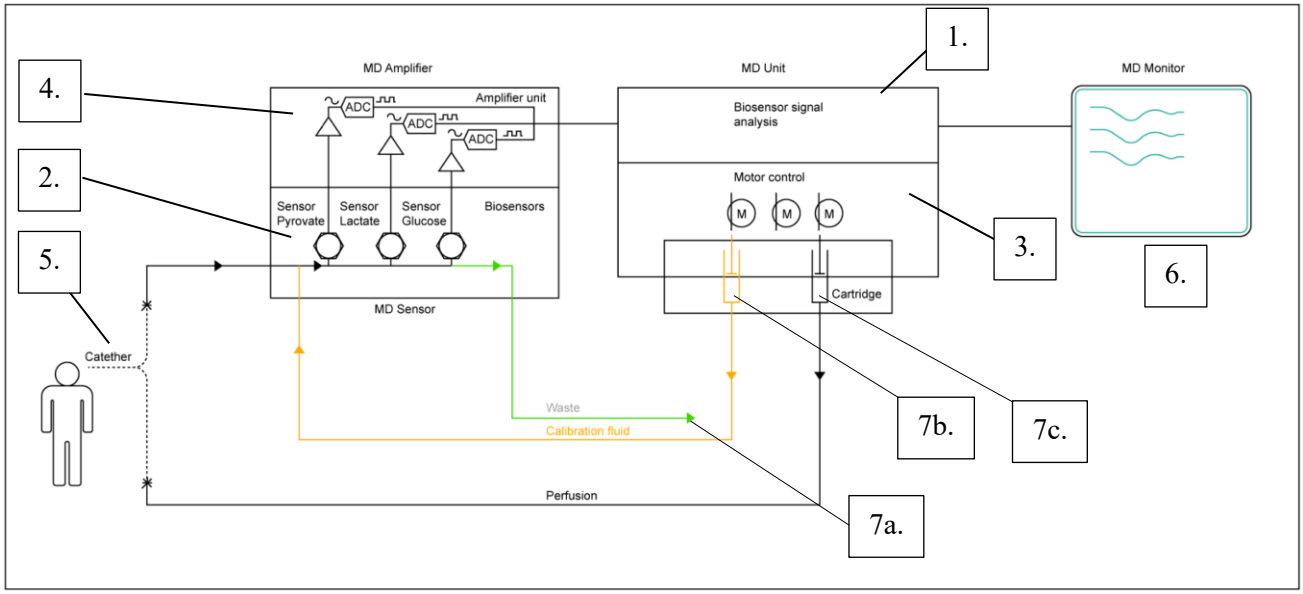
2.3. SYSTEM OVERVIEW

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, consisting of a variety of Microdialysis catheters supplied by M Dialysis, for example the 70 Microdialysis Brain Catheter, 63 Microdialysis Catheter and others.
6. MD Monitor, consisting of a pre-configured Windows PC with integrated monitor and a power supply unit.



2.4. SYSTEM BLOCK DIAGRAM



MD System has four main functions:

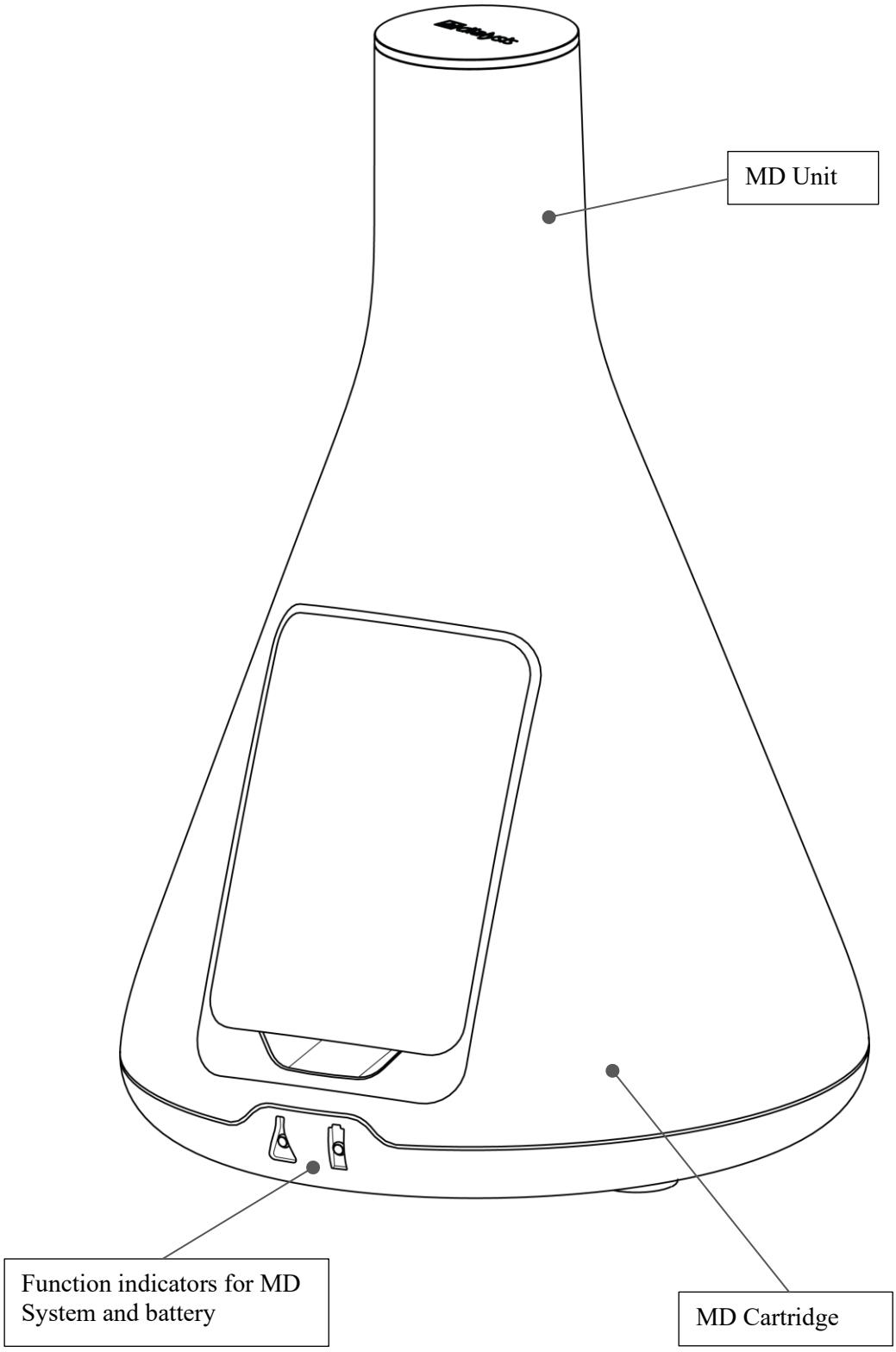
- A controlled flow of perfusion liquid to the MD Catheter.
- A controlled flow for Calibration fluid to perform recurring calibrations.
- A Biosensor that converts the content in the microdialysate to an electric current.
- An amplifier that amplifies the signal from the biosensor.
- Analysis software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

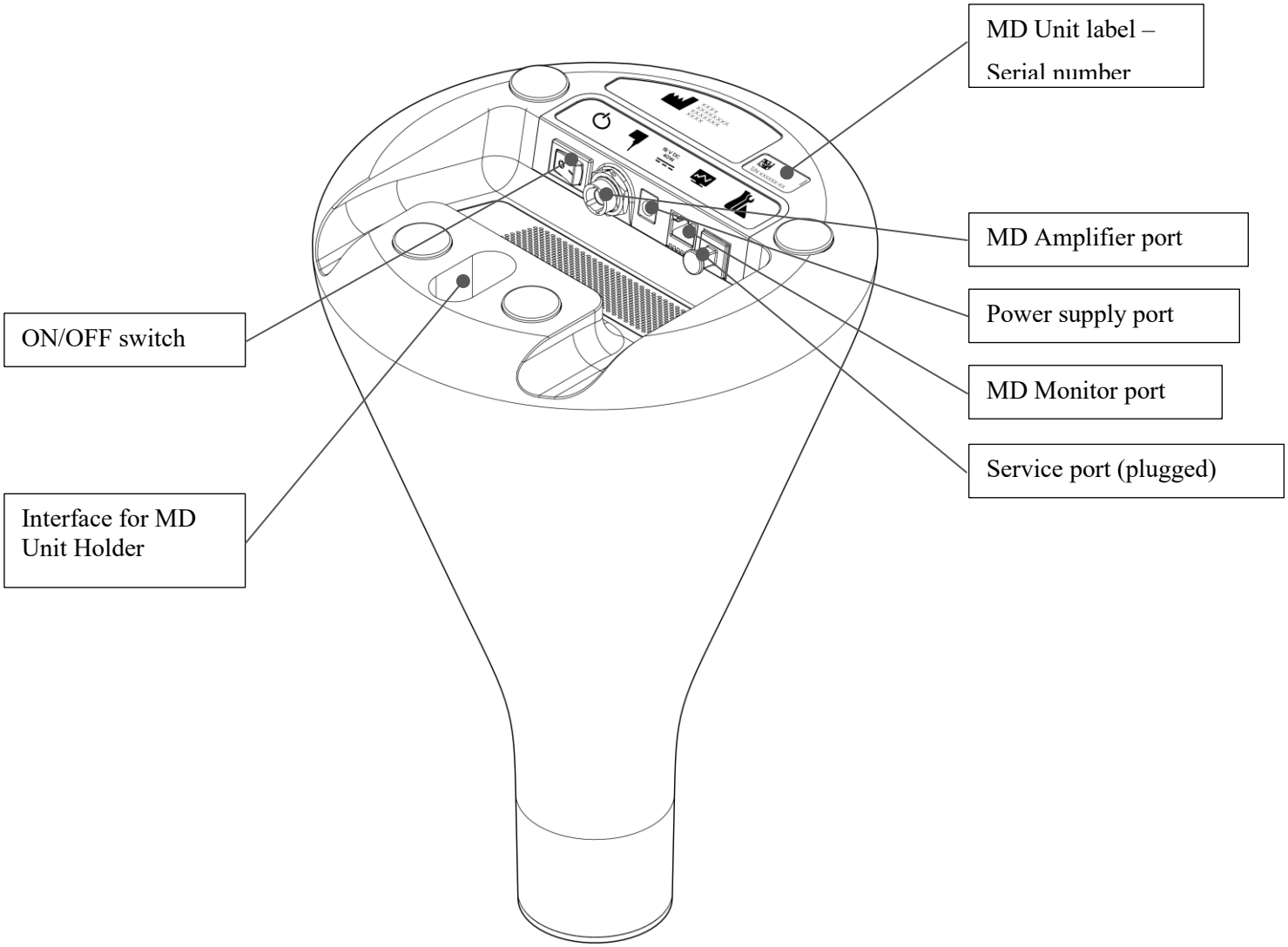
To facilitate the perfusion flow of 0.3 µl/min – 2.0 µl/min, one standard 106 Syringe (7c) is actuated by a Piezo motor with sufficient resolution. The 106 syringe supplies the MD catheter (5) with perfusion fluid that allows molecules to diffuse over the catheter dialysis membrane from the surrounding tissue, creating the so called microdialysate or dialysate.

The analytes pass 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 tube 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).

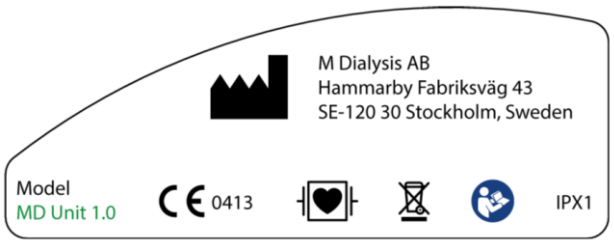
Recurring calibrations where Calibration Fluid is pumped through the MD Sensor, instead of the regular microdialysis perfusate, will ensure that any drift in the analyte signals is compensated for.

2.5. MD UNIT PARTS

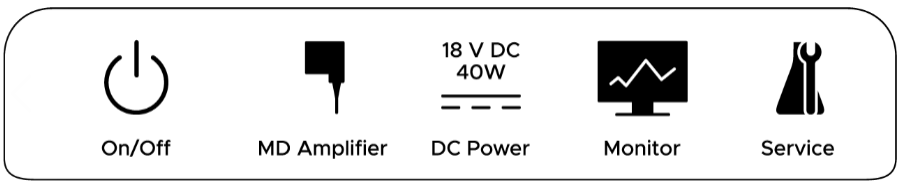




MD Unit label



MD Unit label – Port explanation

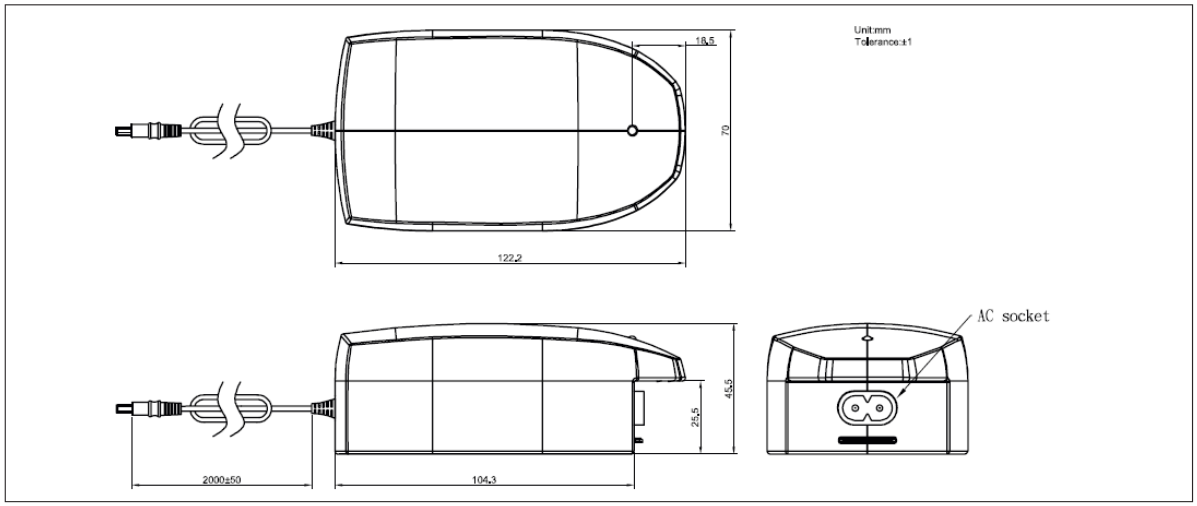


2.6. MD UNIT POWER SUPPLY

The MD Unit comes with a power supply, 18V DC.

Manufacturer: Powerbox

Model code: EXM 80 5120



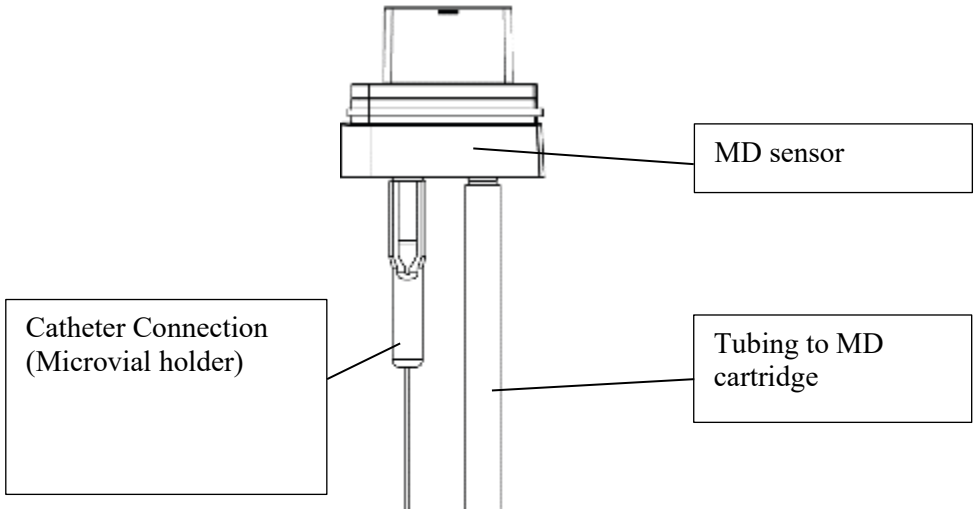
Warning! Use only specified power supply identified on the power inlet. If any suspicion of damage or other fault of power supply replace with new. If in doubt consult M Dialysis AB.

2.7. MD SENSOR

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

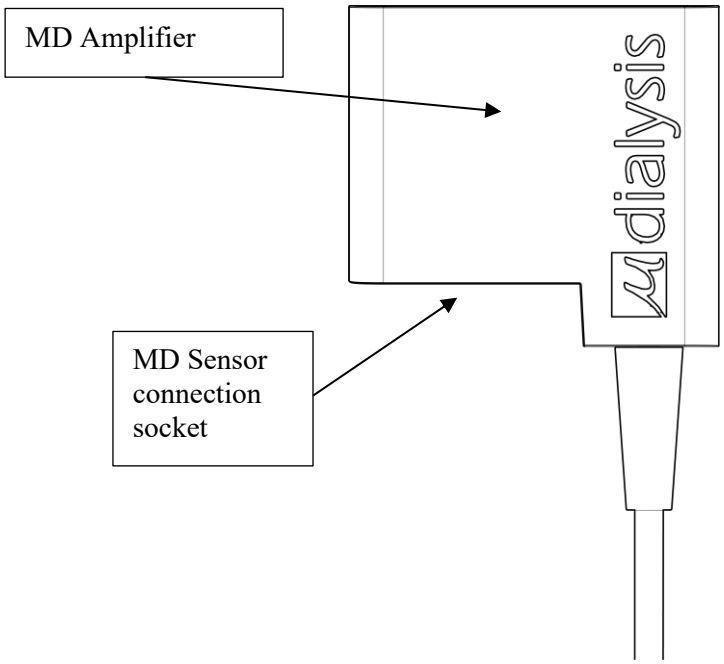
Warning! Don't use if package is broken or damaged.

Warning! The MD Sensor is single use only.



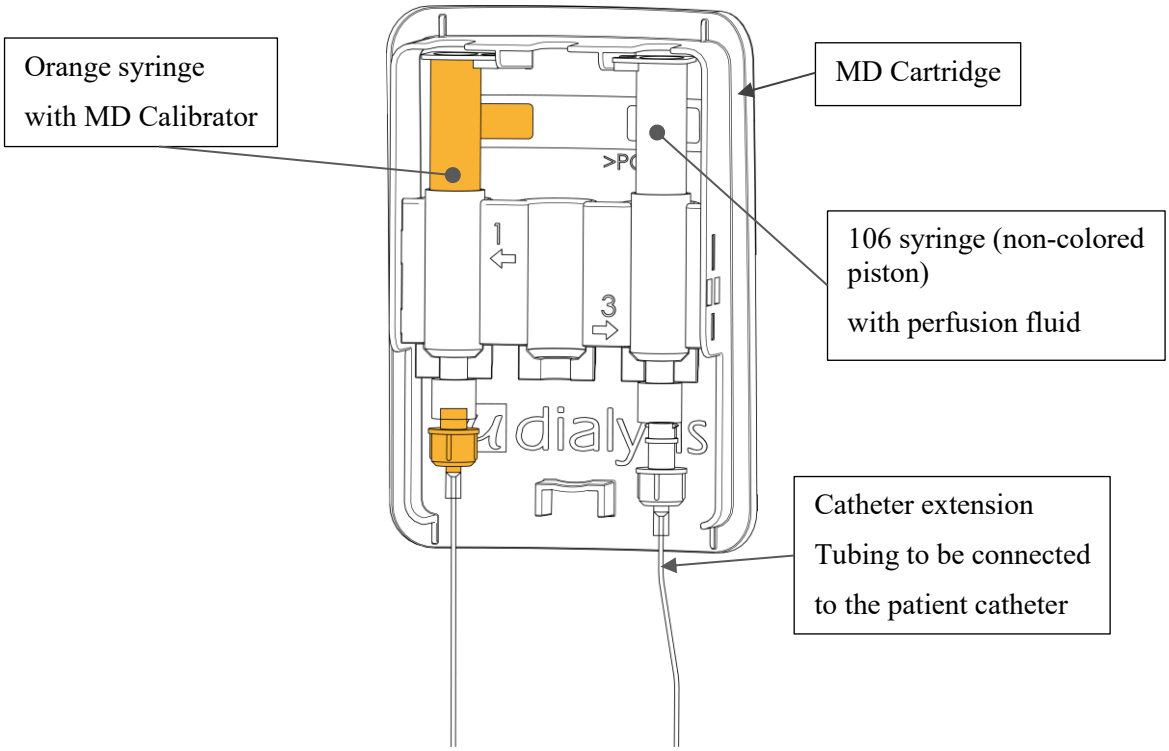
2.8. MD AMPLIFIER

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.

2.9. MD CARTRIDGE

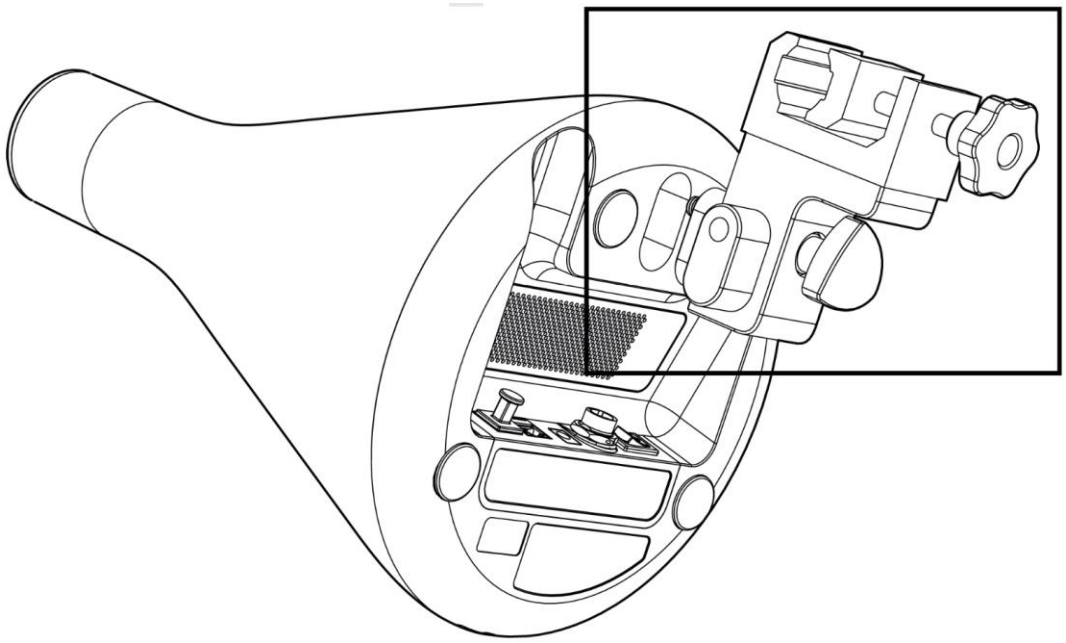


2.10. BATTERY BACK-UP

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.

2.11. MD UNIT HOLDER

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



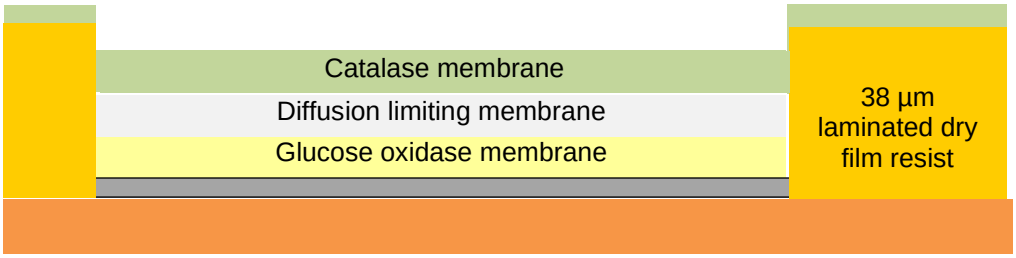
2.12. BIOSENSOR

The electrochemical biosensor used in the MD Sensor for analysis of the dialysate from the microdialysis catheter is a low volume flow through sensor. The biosensor is based on six platinum electrodes, one Ag/AgCl reference electrode and one counter electrode.

On top of each electrode there are different membrane layers, see figure below: catalase; in green, diffusion limiting layer; in light grey, oxidase enzyme; in yellow, and an electropolymerrized layer; in dark grey. The electropolymerized layer allows only H_2O_2 to react with the platinum electrodes; in brown in the figure. The oxidase enzymatic layer consists of either lactate oxidase, glucose oxidase or pyruvate oxidase depending on the targeted substance. The blank electrode lacks oxidase enzyme.

The sensitivity and the linear concentration range depend on the diffusion limiting membrane that is optimized for each application.

The top layer is the catalase membrane, which is preventing cross talk between the electrodes i.e. make sure that the signal from one substrate does not interfere with the signal from another substrate. This is a common problem with sensors measuring several substances in a similar way. In the sensor, the outer membrane layer contains immobilized catalase, which consumes H_2O_2 to prevent cross-talk.



The device compensates for electrochemical interference by subtracting the signal from the blank electrode.

Glucose is enzymatically oxidised by glucose oxidase (GOD). The produced H2O2 is subsequently oxidized at a platinum electrode and the current flowing through the electrode is proportional to the concentration of glucose;

$$\textbf{D-Glucose} + O_2 \rightarrow \textbf{gluconolactone} + H_2O_2$$
$$H_2O_2 \rightarrow O_2 + 2H^+ + 2e^-$$

and correspondingly for lactate;

$$\textbf{L-Lactate} + O_2 \rightarrow \textbf{Pyruvate} + H_2O_2$$
$$H_2O_2 \rightarrow O_2 + 2H^+ + 2e^-$$

and pyruvate;

$$\textbf{Pyruvate} + O_2 + H_2O + P_i \rightarrow \textbf{acetylphosphate} + CO_2 + H_2O_2$$
$$H_2O_2 \rightarrow O_2 + 2H^+ + 2e^-$$

(where Pi is inorganic phosphate)

The enzymatically catalyzed oxidation of glucose and lactate with subsequent amperometric detection of the generated hydrogen peroxide is a well-established technique in clinical chemistry. The technique is frequently used in blood-gas and bench-top analyzers as well as handheld point-of-care meters.

2.13. INITIALISATION

2.13.1. Finding the mechanical home position

- At startup (switch on) the both Piezo motor rods will automatically move to their upmost position – this may take up to 30 seconds to perform.

2.13.2. MD Cartridge pops out – System is ready to start

- When the piezo motor rods upmost positions are reached MD Cartridge will pop out to indicate that the system is ready to be started for analyses of a new patient.

3. SENSOR MEASUREMENTS

3.1. D-GLUCOSE

3.1.1. **Measuring principle**

Glucose is enzymatically oxidised by glucose oxidase (GOD), which is coated on the biosensor electrode.

$$\text{D-Glucose} + O_2 \rightarrow \text{gluconolactone} + H_2O_2$$

The formed hydrogen peroxide is oxidised at the electrode according to:

$$H_2O_2 \rightarrow O_2 + 2H^+ + 2e^-$$

The released electrons generate a current that is measured.

3.1.2. **Measuring range**

Glucose can be measured in the range 0.2-15 mM with an accuracy of ± 30 % or 0.1 mM whichever is greatest.

3.1.3. **Stability**

The MD sensor in its unbroken package is stable up to expiry date when stored at +2 to +8 °C. Once the sensor package has been opened and the sensor used in the system it can be used for up to five days.

3.1.4. **Calibration**

3.1.4.1.Calibrator

The MD system is calibrated using MD Calibrator A.

3.1.4.2.Checks

A factory calibration response factor is programmed into the EEPROM in the MD sensor. The calibration is re-run once if calculated response factor obtained at calibration deviates by more than ± 67% from the factory value.

3.1.5. **Performance**

3.1.5.1.Linearity

The method is linear from 0.2 to 15 mmol/L (270 mg/L) with a deviation of < 10 % at 15 mmol/L.

3.1.5.2.Analytical Sensitivity

The average sensitivity of this method is 0.8 nA per mmol × L^{-1}.

3.1.5.3.Detection limit

The detection limit is 0.2 mmol/L.

3.1.5.4.Accuracy

The results below show the accuracy for the MD system compared to the ISCUS*flex* analyzer

The results are presented in following figure.

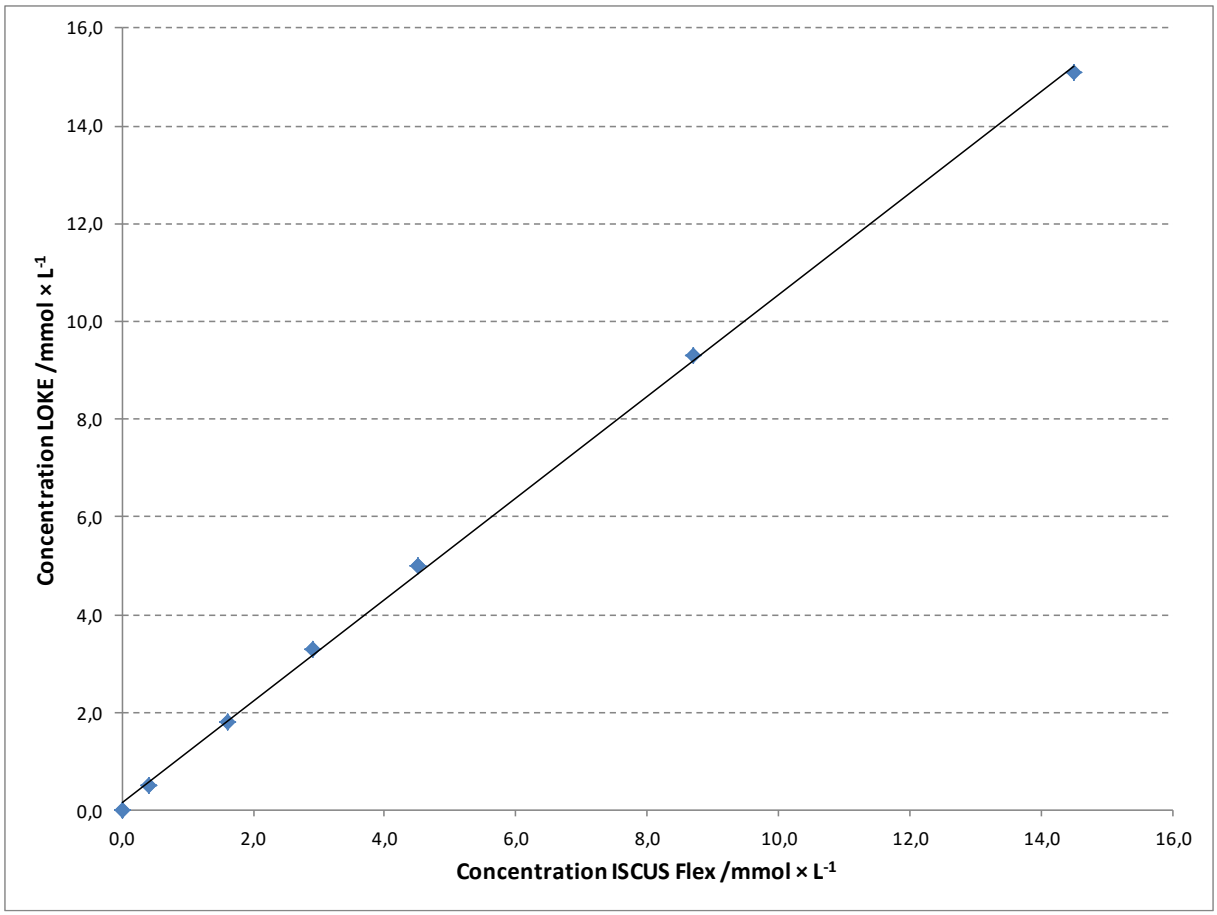


Figure 1. *Correlation between MD System (LOKE) and ISCUS^{flex}.*
$Glucose_{MD\ system}$ =1.04 × $Glucose_{ISCUS\ Flex}$ +0.16 mmol/L; R^2 = 0.9994;

3.2. L-LACTATE

3.2.1. Measuring principle

Lactate is enzymatically oxidised by lactate oxidase (LOD), which is coated on the biosensor electrode.

$$\text{L-Lactate} + O_2 \rightarrow \text{pyruvate} + H_2O_2$$

The formed hydrogen peroxide is oxidised at the electrode according to:

$$H_2O_2 \rightarrow O_2 + 2H^+ + 2e^-$$

The released electrons generate a current that is measured.

3.2.2. Measuring range

Lactate can be measured in the range 0.1-10 mM with an accuracy of ± 30 % or 0.1 mM whichever is greatest

3.2.3. Stability

The MD sensor in its unbroken package is stable up to expiry date when stored at +2 to +8 °C. Once the sensor package has been opened and the sensor used in the system it can be used for up to five days.

3.2.4. Calibration

3.2.4.1.Calibrator

The MD system is calibrated using MD Calibrator.

3.2.4.2.Checks

A factory calibration response factor is programmed into the EEPROM in the MD sensor. The calibration is re-run once if calculated response factor obtained at calibration deviates by more than ± 67% from the factory value

3.2.5. Performance

3.2.5.1.Linearity

The method is linear from 0.1 to 10 mmol/L (90 mg/dL lactic acid) with a deviation of < 10 % at 10 mmol/L.

3.2.5.2.Analytical Sensitivity

The average sensitivity of this method is 2.2 nA per mmol × L^{-1}.

3.2.5.3.Detection limit

The detection limit is 0.1 mmol/L.

3.2.5.4.Accuracy

The results below show the accuracy for the MD system compared to the ISCUS*flex* analyzer

The results are presented in the figure below.

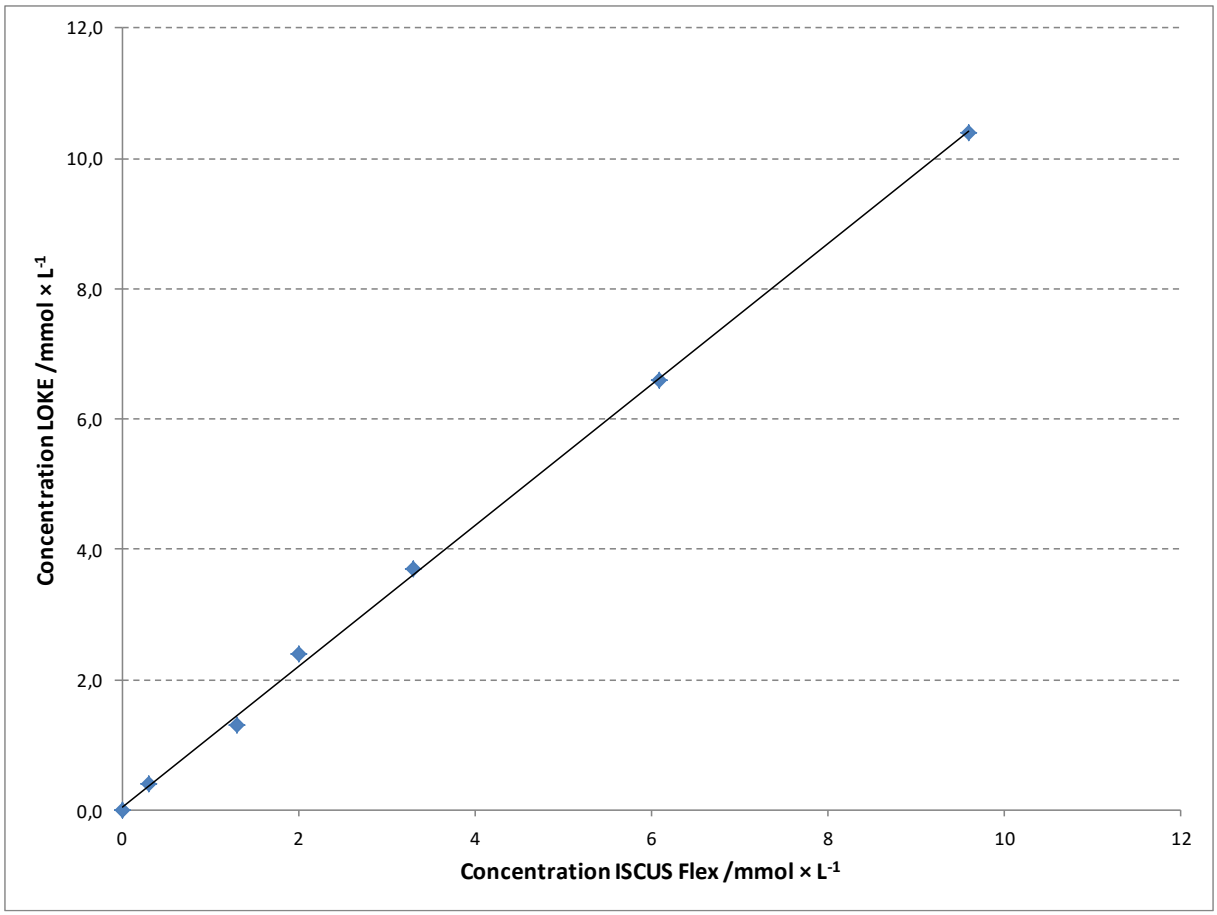


Figure 2. *Correlation between MD System and ISCUS^{flex}.*
$Lactate_{MD\ System}$ =1.08 × $Lactate_{ISCUS\ Flex}$ +0.06 mmol/L; R^2 = 0.9992

3.3. PYRUVATE

3.3.1. Measuring principle

Pyruvate is enzymatically oxidised by pyruvate oxidase (PyrOx), which is coated on the biosensor electrode; the reaction requires presence of inorganic phosphate (P_i).

$$\text{Pyruvate} + P_i + O_2 \rightarrow \text{acetylphosphate} + CO_2 + H_2O_2$$

The formed hydrogen peroxide is oxidised at the electrode according to

$$H_2O_2 \rightarrow O_2 + 2H^+ + 2e^-$$

The released electrons generate a current that is measured.

The enzymatic reaction requires inorganic phosphate which needs to be present in the dialysate. The level of inorganic phosphate is normally around 1 mmol/L in subcutaneous liquid, which is enough for the reaction to proceed. The figure below shows the phosphate dependency for three different levels of pyruvate.

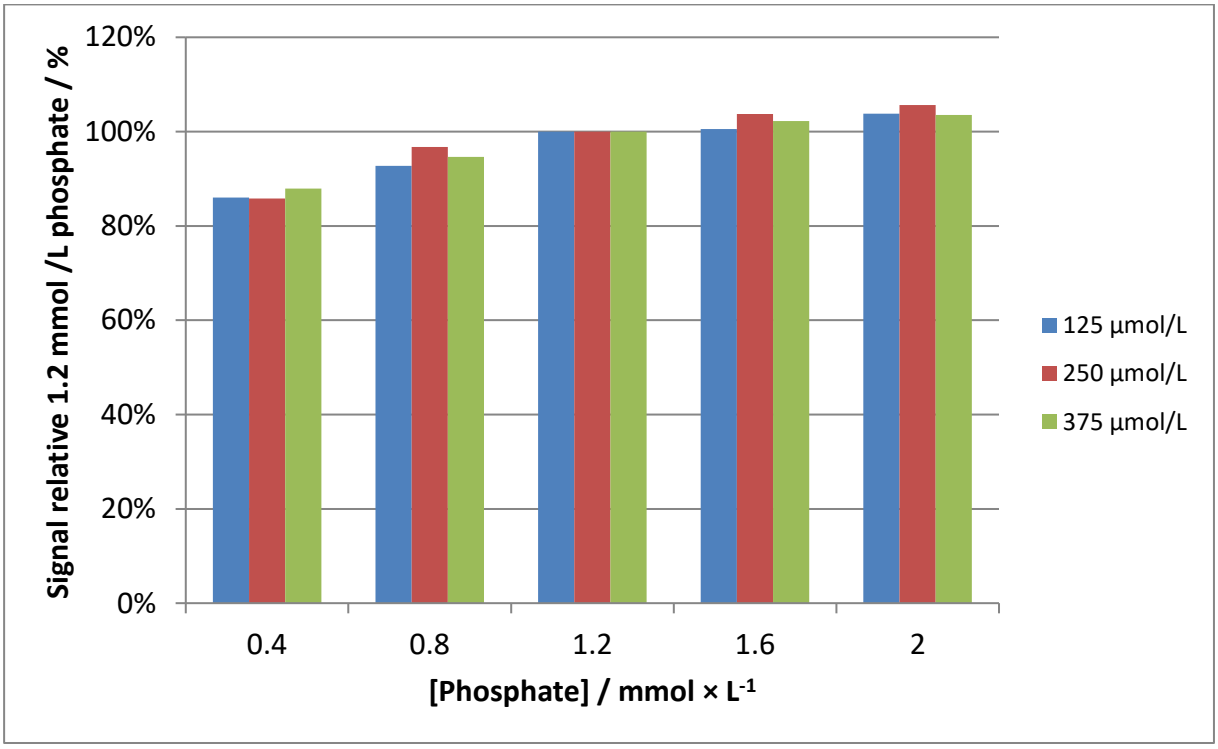


Figure 3. Phosphate dependence: Relative sensor signal at three levels of pyruvate (125, 250 and 375 µmol/L) as a function of the phosphate concentration (The signal at 1.2 mmol/L phosphate has been set to 100%).

A signal reduction of about 15% can be seen if the phosphate concentration drops from 1.2 to 0.4 mmol/L.

3.3.2. Measuring range

Pyruvate can be measured in the range 10-300 µM with an accuracy of ± 30 % or 10 µM, whichever is greatest.

3.3.3. Stability

The MD sensor in its unbroken package is stable up to expiry date when stored at +2 to +8 °C. Once the sensor package has been opened and the sensor used in the system, it can be used for up to five days.

3.3.4. Calibration

3.3.4.1.Calibrator

The MD system is calibrated using MD Calibrator A.

3.3.4.2.Checks

A factory calibration response factor is programmed into the EEPROM in the MD sensor. The calibration is re-run once if calculated response factor obtained at calibration deviates by more than ± 84% from the factory value.

3.3.5. Performance

3.3.5.1.Linearity

The method is linear from 10 to 300 µmol/L with a deviation of < 10 % at 300 mmol/L.

3.3.5.2.Analytical Sensitivity

The average sensitivity of this method is 6 nA per mmol × L^{-1}.

3.3.5.3.Detection limit

The detection limit is 10 µmol/L.

3.3.5.4.Accuracy

The results below show the accuracy for the MD system compared to the ISCUS^{flex} analyzer

The results are presented in the figure below.

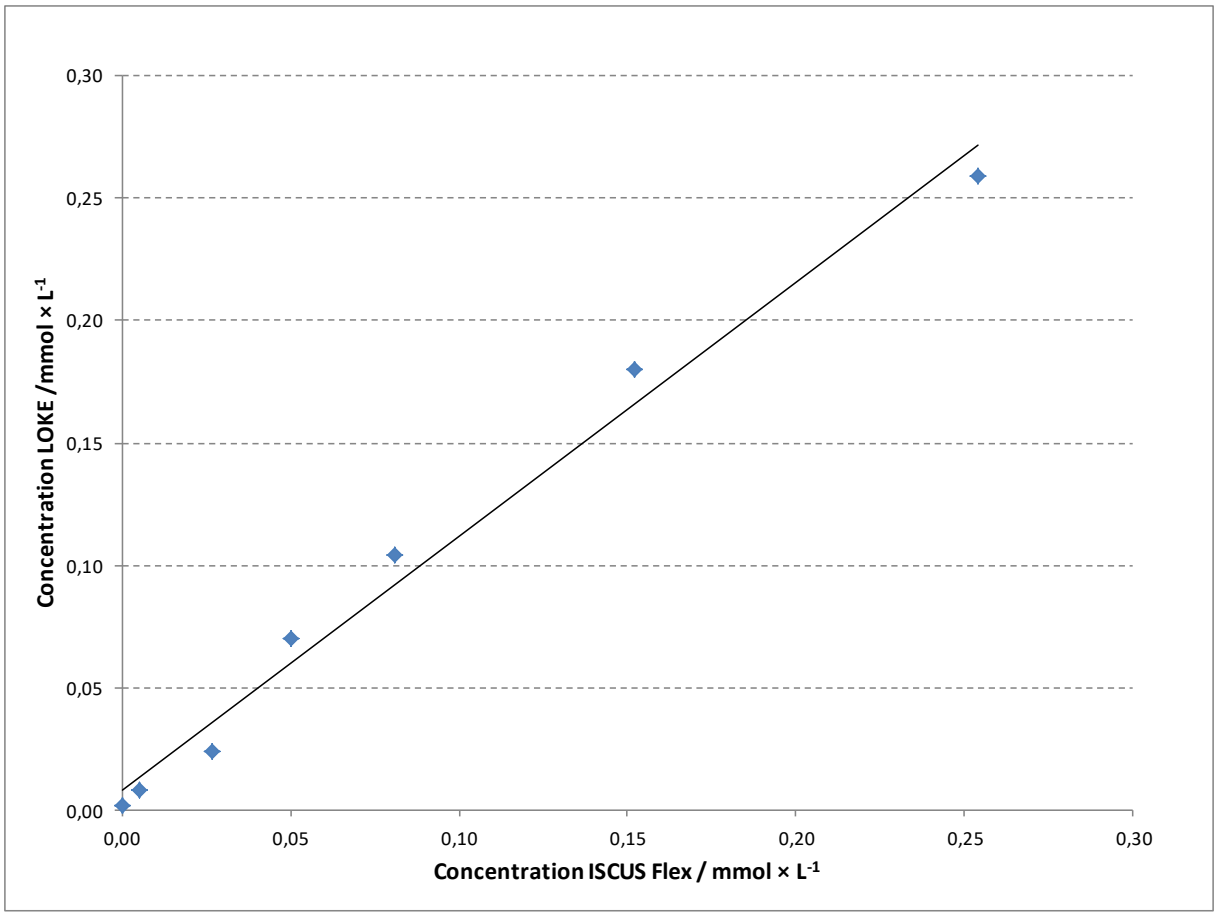


Figure 4. *Correlation between MD System and ISCUS ^{Flex}.*
$Pyruvate_{MD\ System}$ = 1.04 × $Pyruvate_{ISCUS\ Flex}$ + 0.008 mmol/L; R^2 = 0.9855

3.4. L/P RATIO

The L/P-ratio is calculated using current Lactate and Pyruvate data. For an L/P-ratio point to be calculated both a Lactate and a Pyruvate result must exist for a given time point. If one of Lactate and Pyruvate is missing for a given time point no L/P-ratio is calculated for that time point.

The L/P-ratio is always calculated using the mmol value for both analytes regardless of the selected presentation unit, thus no scaling errors exist.

Furthermore, the L/P-ratio is always calculated as a concentration ratio, which differs slightly from the mass ratio as Lactate and Pyruvate have different molecular weights. The difference between concentration and mass L/P-ratios is 2.2 %.

3.5. CALIBRATOR

3.5.1. MD Calibrator

3.5.1.1.Intended use

The MD Calibrator is intended for calibration of the Glucose, Lactate, and Pyruvate in the MD System.

3.5.1.2.Content and stability

Analyte	Assigned concentration
D-Glucose	5.55 mmol/L
L-Lactate	2.5 mmol/L
Pyruvate	250 µmol/L

The calibrator is prepared in a physiological salt solution similar to perfusion fluid CNS. It also contains 2.5 mM phosphate and is buffered to a pH of 7.4. The MD Calibrator is sterile.

Unopened Calibrator is stable up to expiry date when stored at +2 to +8 °C. The MD Calibrator is stable for five days in the instrument.

3.6. OPERATION

See User's manual.

4. DATA ANALYSIS

4.1. CALIBRATION AND CALCULATION OF RESULTS

The system calibrates at start-up and then every 6:th hour or upon user request.

The biosensor is calibrated by analysing a solution with known concentrations of the different analytes. During calibration the MD Unit starts to pump the calibration solution through the sensor at a high flow rate to flush out old solution which has been standing in the tubing since the last calibration. This takes six minutes.

Then, the MD unit decrease the flow rate of the calibrator (and stops perfusing the catheter) and perfuses the sensor with fresh calibrator solution during 12 minutes. During the last two minutes of the biosensor signals are measured and an average value is calculated. After subtraction of the signal from the blank electrode and adjustment for temperature a response factor for each analyte is calculated.

This response factor is used for calculating the sample concentration

$$C_{unknown} = signal_{unknown} / average\ signal_{\ calibrator} \times C_{\ calibrator}$$

Then the calibration has been accepted the MD Unit stop pumping calibrator and restart perfusing the catheter. Since the flow in the catheter has been stopped during the calibration, it will take about 20 minutes to obtain valid values from the catheter again. During this period no new values will appear on the monitor.

4.1.1. Checks for calibrator measurements

A factory calibration response factor is programmed into the EEPROM in the MD sensor. The calibration is re-run once if calculated response factor obtained at calibration deviates by more than

± 67% from the factory value for glucose and lactate and ± 84% for pyruvate.

5. SYSTEM DELAY AND FLUSHES

5.1. SYSTEM DELAY

The MD sensor is placed downstream the catheter and it will take some time for a change at the catheter membrane to be detected as a concentration change in the sensor.

The delay depends on the catheter length and length of the outlet tubing from the catheter, the internal volume of the MD sensor and the flow rate. At a flow rate of 0.5 µL/min and a catheter outlet of 220 mm this delay is around 20 minutes as shown in the figure below, where the delay was measured using a 63 catheter with 30 mm membrane and a flow rate of 0.5 µL/min.

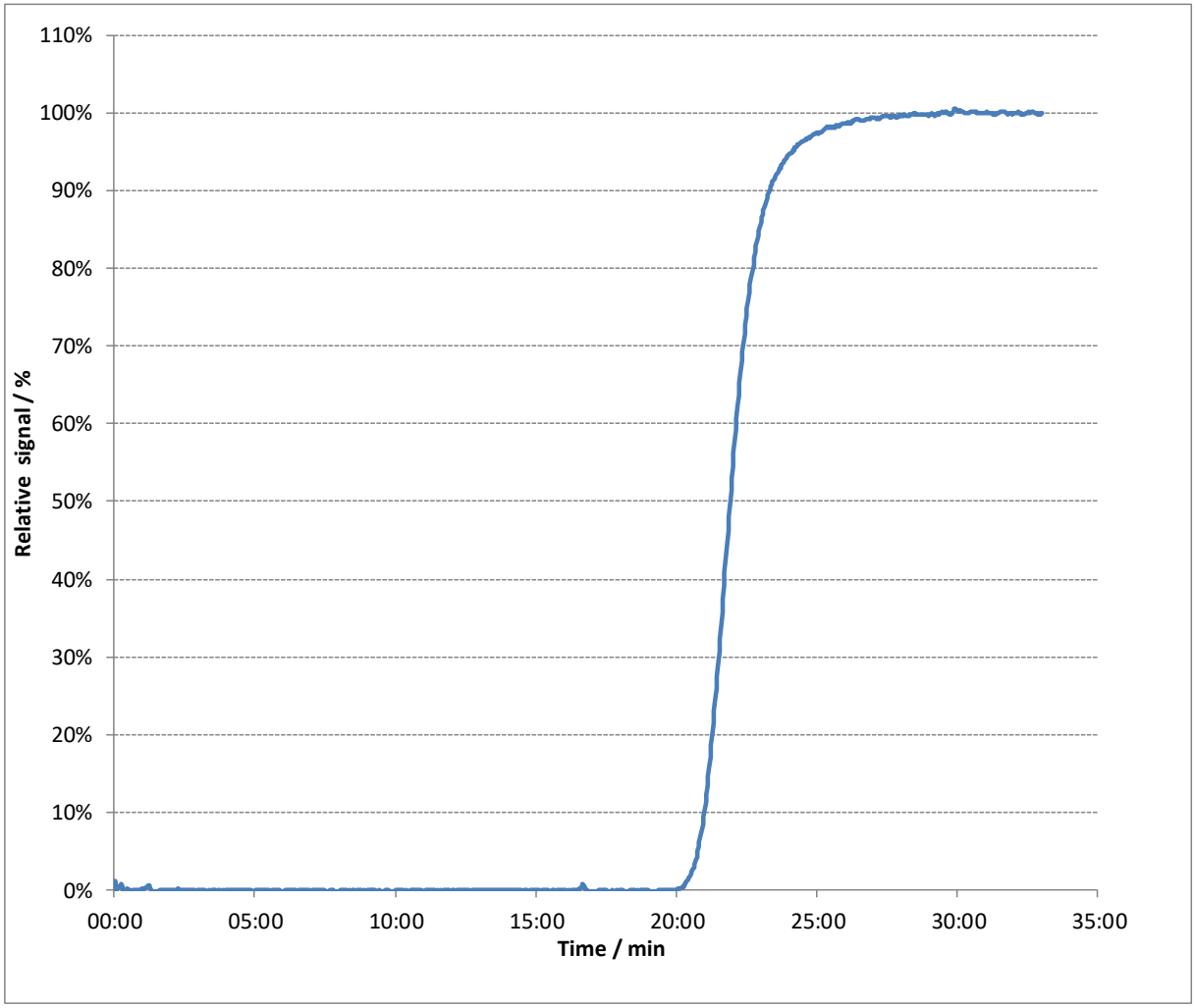


Figure 5. *System delay: System delay measured using a 63 catheter with a 30 mm membrane length at a flow rate of 0.5 µL/min. At time 00:00 the concentration outside the membrane is changed.*

5.2. FLUSHES

5.2.1. Stop in flow

It may happen that the flow through the catheter stops occasionally. If this happens there will be no fresh data for the monitor to display. By analysing the raw data from the sensor, the system is in most cases able to detect if this occurs. When the system detects a stop in flow, it will flush the catheter by increasing the perfusion flow rate to 15 µL/min for 5 minutes (i.e. the same flush that is performed when the syringe lid on the 106/107 Pump is closed). A "stop in flow flush" can also be executed by

the user manually through the service panel. During the flush and 20 minutes following the flush, no new values are displayed on the monitor.

5.2.2. **Air bubbles**

Occasionally, air bubbles may accumulate in the biosensor. If this happens the signal for one or more of the analytes drops. As in the case with stop in flow, the system is normally able to automatically detect if this occurs. When the system detects an air bubble in the sensor, it will flush the sensor by running calibrator solution through it at a flow rate to 50 µL/min for 2 minutes (In this case the calibrator is used since a higher more powerful flow rate can be used without risk of damaging the catheter membrane). An "air bubble flush" can also be executed by the user manually through the service panel. During the flush and 10 minutes following the flush, no new values are displayed on the monitor.

6. INFORMATION STORAGE AND DATA HANDLING

6.1. COMMON DATA

Common data is stored in the internal database.

6.2. SAMPLE DATA

Sample data is stored in the internal database. Sample data is stored during analysis only, as soon as next patient is started the patient data is reset.

If a USB memory is inserted in MD Monitor, data from the current patient may be saved to the USB stick.

6.3. EXPORTING DATA TO EXTERNAL COMPUTER

The patient file saved on the USB stick may be viewed inn LABpilot, ICUpilot or, for instance, Microsoft Excel.

6.3.1. Network share

Not implemented.

6.4. NETWORK DATA TRANSMISSION

Not implemented

6.4.1. Connecting MD System to a Windows computer with ICUpilot

Not implemented

6.5. FILE FORMAT

6.5.1. Description

The data is stored as a csv file. The first line is a header and the following lines are records which reflects the complete analyses session.

6.5.2. XML Schema

Not implemented

6.6. CONTINOUS DATA EXPORT FORMAT

Not implemented

6.6.1. XML Schema

Not implemented

6.6.2. ASTM Description

6.6.2.1.Supported ASTM messages

Not implemented

7. MAINTENANCE

7.1. MD SENSOR

7.1.1. Replacing or checking the MD Sensor

1. Follow the instructions on screen.

7.2. SYSTEM SHUT DOWN

1. Press the Stop button
2. Wait until the Cartridge pops out
3. Remove syringes with fluids
4. Reinsert the Cartridge
5. Press the Off button

8. EMC - ELECTROMAGNETIC COMPATIBILITY

8.1. ESSENTIAL PERFORMANCE:

MD System measurements shall not deviate more that ±30 % or Glucose ±0.1mmol/L, Lactate ±2 mmol/L and Pyruvate 10 µmol/L (whichever is greatest) from stable period, that is not related to circumstances in the environment or normal behavior of system (such as automatic calibrations being executed or slow trends).

8.2. WARNINGS

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.

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.

8.3. LIST OF CABLES

Network cable – Max length 2 meters

Power cable – Powerbox PSU, length 1.8 m

Guidance and manufacturer's declaration – electromagnetic emissions		
MD System is intended for use in the electromagnetic environment specified below. The customer or the user of MD System should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	MD System uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	MD System is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration – electromagnetic immunity			
MD System is intended for use in the electromagnetic environment specified below. The customer or the user of MD System should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment ─ Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 sec	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of MD System requires continued operation during power mains interruptions, it is recommended that MD System be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity

MD System is intended for use in the electromagnetic environment specified below. The customer or the user of MD System should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment ─ guidance
			Portable and mobile RF communications equipment should be used no closer to any part of MD System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	$d = 0,12\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	$d = 0,12\sqrt{P}$ 80 MHz to 800 MHz $d = 0,23\sqrt{P}$ 800 MHz to 2,5 GHz where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, [a] should be less than the compliance level in each frequency range. [b] Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which MD System is used exceeds the applicable RF compliance level above, MD System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating MD System.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and MD System

MD System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of MD System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and MD System as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d = 0,12\sqrt{P}$	80 MHz to 800 MHz $d = 0,12\sqrt{P}$	800 MHz to 2,5 GHz $d = 0,23\sqrt{P}$
0,01	0,12	0,12	0,23
0,1	0,37	0,37	0,74
1	1,2	1,2	2,3
10	3,7	3,7	7,4
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.