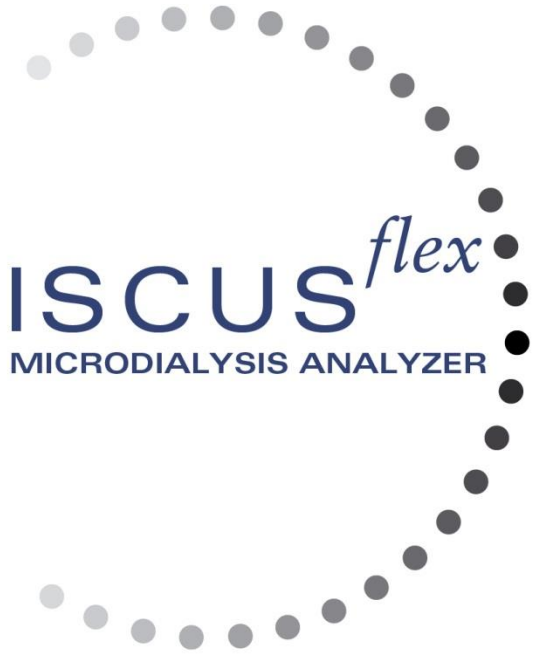
User's manual



Ref No 80033400

μdialysis

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

M Dialysis AB is only responsible for the reliability and performance of the device if the following is strictly observed:

- Authorized personnel (see end of manual for authorized service centers) carry out all service, repairs and modifications.
- The device must be used in accordance with the intended use and the instructions put forth in the Safety Information section.
- M Dialysis AB offers one-year warranty, from the day of delivery, on defective material and assembly. The warranty does not cover damage resulting from incorrect use or user maintenance or from non-authorized software modification.
- 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 analyzer.

If the above points are not strictly observed, the warranty will be considered invalid.

Contents

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Safety Information

ISCUS*flex* is CE marked for two different intended uses:

Intended for Medical Purpose according to IVDD, The In Vitro Diagnostic Directive 98/79/EC
and
Intended for Research Purposes according to LVD, The Low Voltage Directive (2006/95/EC) and the EMC Directive, Electro Magnetic Compatibility Directive (2004/108/EC)

Adhere to the following recommendations for safe and proper operation of the device:

Read this user manual before using the device. M Dialysis AB reserves the right to modify the design and specifications contained herein without prior notice. Please contact M Dialysis AB or one of our distributors for the most current information

Follow the un-packaging procedure to avoid personal injuries, equipment damage or property damage

Never use the device near mobile telephones, CB radios or other forms of radio communication, and/or electromagnetic fields. These may affect the performance of the device. The analyzer conforms to IEC 60601-1-2, IEC 61326 and shall not be exposed to higher levels of disturbance

Regarding emitting electronic fields, ISCUS*flex* fulfills Class B according to IEC 60601-1-2, IEC 61326 if the Ethernet cable is not longer than 3 m

Do not attempt to open the device or any cover unless it is described within this manual

Do not immerse the device in water or any other liquid (See the Maintenance/Cleaning section page 40 for specific details)

Medical electrical equipment needs special precautions regarding EMC and need to be installed and put into service according to the EMC information provided in the section “Technical Information”

Unplug the power connector from its power source before cleaning or servicing. Failure to do so could result in equipment damage and personal injury

Ensure that the power cord does not become pinched during normal operation of ISCUS*flex*. Failure to do so can result in equipment damage and personal injury

To avoid virus attacks, ISCUS*flex* should only be connected to a controlled network environment protected by firewall and antivirus software

CAUTION

It is possible to connect ISCUS*flex* to other equipment via the Ethernet connector. If other equipment is connected to ISCUS*flex* in a patient environment, the installation must fulfill leakage current and electrical separation requirements according to IEC 60601-1-1, e.g. by using a separation device

The Ethernet port is galvanically isolated from the internal secondary circuits of ISCUS*flex* with basic insulation according to the requirements of IEC 60950, withstanding 1500V. The USB port is not galvanically isolated from the internal circuits within ISCUS*flex*.

The USB port shall only be used for a USB Memory or an external keyboard

The device is not intended for use with flammable anesthetic gases. A possible explosion hazard exists and personal injury or equipment damage could occur

The analyzer shall not be exposed to direct sunlight nor be placed in a draught environment

Use only M Dialysis spare parts, accessories and consumables

All service shall be performed by M Dialysis authorized personnel

Handling of samples, waste fluid and cannula shall follow hospital infection risk procedures

Single measurements can fail due to air in the liquid system

To shut down ISCUS*flex* before any transportation the “Turn off” button must be used. Follow the instructions on the screen; empty wash/waste bottles, remove reagent cassette and vials

Introduction

ISCUS*flex* is used for analyzing microdialysis samples with the purpose of supporting early diagnosis of ischemia and other complications in different tissues and organs where microdialysis catheters/probes have been implanted.

The user interface of ISCUS*flex* is easy to understand and operate. It displays the changes in tissue metabolism as trend curves, trend symbols (arrows) and numerical values. Data can be printed on paper as well as stored on an SD card, USB memory and a network share location and transferred to other computers.

ISCUS*flex* can be shut down, moved to another location and restarted for continued analysis of the same patients. It is possible to carry the instrument due to its relatively low weight. It may be placed bedside even in a general ward due to the low noise emitted during operation.

Intended Use

ISCUS*flex* is a multi-patient Microdialysis Analyzer, intended to support clinical decisions or research based on tissue chemistry. It is suitable for use in clinical routine and clinical research.

ISCUS*flex* data shall not be the sole basis for diagnosis. As with any chemical reaction, the user must be alert to the possible effect on the result due to unknown interference from medication or endogenous substances. All patient results must be evaluated considering the total clinical status of the patient.

The intended users of the analyzer are medical professionals as well as research fellows and laboratory staff. ISCUS*flex* is only intended for the analysis of Microdialysis samples obtained from Microdialysis catheters perfused with M Dialysis Microdialysis pumps and Perfusion fluids. ISCUS*flex* cannot analyze blood or plasma samples.

Application

ISCUS*flex* is used for analyzing microdialysis samples with the purpose of supporting early diagnosis of complications in various clinical applications as well as research based on the local chemistry in tissues and organs.

Clinical catheters are today available for brain, liver, subcutaneous adipose tissue, resting muscle, skin and for placement in the peritoneal cavity. The most common clinical applications are brain trauma, subarachnoid hemorrhage, plastic and reconstructive surgery, liver transplantation and post surgical monitoring of gastrointestinal complications.

Ischemia causes well-known changes in the Glucose metabolism lowering Glucose and elevating Lactate levels and more specifically elevating the Lactate/Pyruvate ratio. In brain tissue cell damage causes elevation of Glycerol and Glutamate. Reagents are available for the analysis of Glucose, Lactate, Pyruvate, Glycerol, Glutamate and Urea.

The measurements obtained with the system reflect the environment local to catheter placement and should not be taken as a global indication.

The dialyzing properties of the microdialysis catheter can be expressed as its recovery for a particular substance. By comparing the concentration of the substance in the microdialysis catheter effluent with the concentration of the medium it is possible to calculate the recovery of the substance. The main factors influencing recovery is the surface area of the microdialysis catheter membrane (diameter and length) and the flow rate of perfusate through the catheter. The greater the surface area of the catheter, the greater the recovery will be and vice versa. Similarly, the lower the flow rate, the greater the recovery will be.

Un-packing Procedure

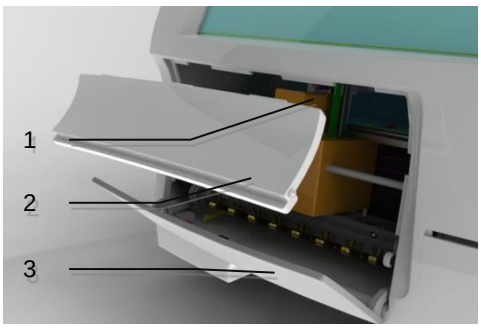
⚠ **CAUTION**

Use proper lifting methods when moving or lifting the aluminum case (REF 8002921); failure to do so can result in personal injury, equipment damage and property damage. Do not use any sharp tools when removing protective wrapping from the device. Failure to do so can result in equipment damage.

Inspect the package for transport damage, if damaged contact your representative Use proper lifting methods when lifting the ISCUS*flex* out of the aluminum case. **Save the aluminum case and the plastic wrapping for future need.**

Open lower hatch (3) manually. Remove the service lid (2). Remove the shock absorber (1) and save it for future use.

1. Shock absorber
2. Service lid
3. Reagent hatch



Inspect the parts for damage and verify completeness against package checklist. Make sure that all parts ordered are included, if not contact your M Dialysis representative.

For transportation and packaging see page 46.

Installation

1. Place ISCUS*flex* on an appropriate shelf or table capable of carrying its load (13 kg). Make sure that there is enough clearance around the device, ensuring access to the main switch and inputs on the left side, lids at the front and the door to the right. The clearance on the backside must be sufficient enough to allow efficient cooling of the analyzer

2. Connect the mains cable to a wall socket (protective earth type)

3. Check that the Waste bottle is empty and place a new Rinse bottle in the fluid compartment (see page 29)

4. Turn on ISCUS*flex* by pressing the On/Off switch on the left side observing the power on indicator light

5. Wait for the Start screen to appear (see page 10). Touch the “Start” button to continue

6. Register a new patient (see page 13)

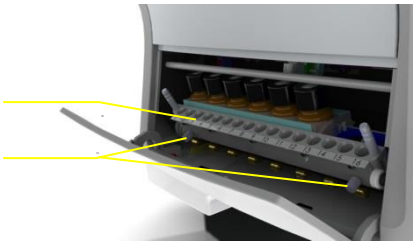
7. Unpack, mix and register a Reagent Cassette or separate Reagents (see page 15-18)

8. Check that the vial holder is pushed down firmly. Lock with the screws if necessary.

9. Insert a SD-card to enable safety copies of the patient data.

10. ISCUS*flex* is now ready to accept sample vials (see pages 25, 33 and 34). The analysis for a given analyte will start when the instrument is calibrated for that analyte

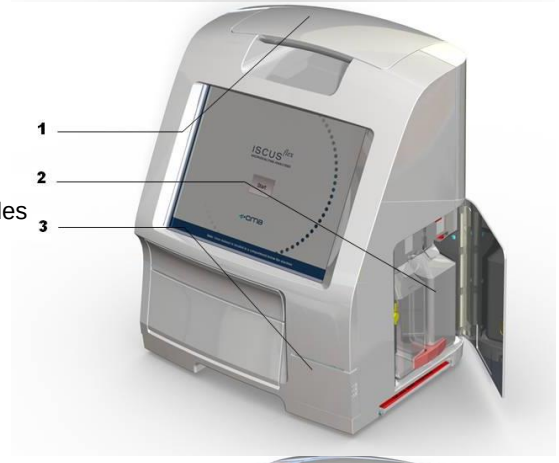
1. Vial holder
2. Lock screws



Overview

1. Touch screen
2. Display brightness control
3. SD Memory card
4. External connections
5. Mains and On/Off switch

1. Carrying handle
2. Rinse and waste bottles
3. Thermal printer



1. Reagent holder
2. Vial cassette

Operation

1. Insert the Mains cable into the Mains and to the ISCUSflex mains inlet
2. Use the on/off switch
3. Wait for the Start screen to appear
4. Touch the “Start” button

NOTE! There is no emergency stop!

User Interface

The ISCUS*flex* user interface consists of a few simple screens. You interact with them by touching the screen with your finger. To shift between the main screens you touch one of the main screen selection buttons in the lower right corner.

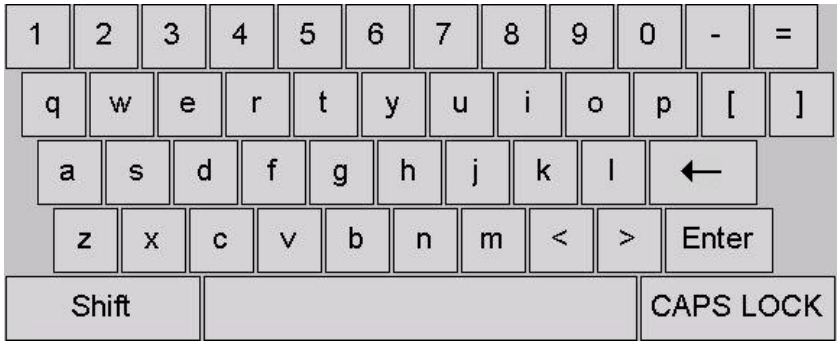
 Patient screen

 Settings and Controls screen

 Graphs screen

Touching the screen is like clicking with a mouse (touch to select)

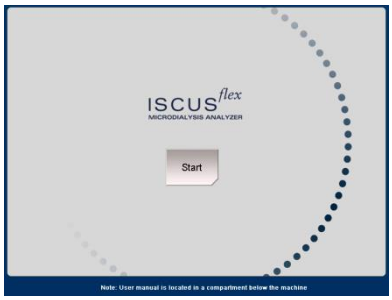
When you need to enter text or numbers just touch the text field and the on screen keyboard will appear. You can now touch-type your text and press the “Enter” button on the keyboard to move to the next text field.



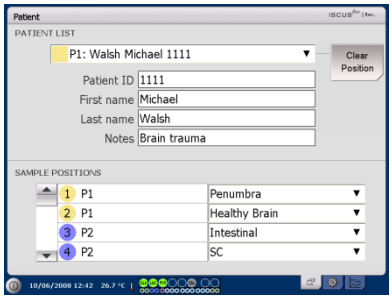
Main Screens

The Start screen appears after a few minutes. After pressing the Start button you can touch the main screen selection buttons to move between the different screens in order to enter data and examine the analysis results. In some windows there are buttons that will open other screens where you can enter information, define parameters and display data. Below you will see the Start screen and the three main screens you can shift between by touching the main screens selection buttons.

Start screen

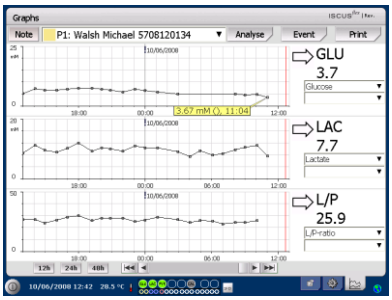


Patient screen



Settings and Controls screen

Graphs screen



Status Bar

Service maintenance status

Annual service is needed within less than 30 days! Please, contact a service engineer

Please, contact service engineer immediately!! Annual service is required

Error indicator

Rinse/Waste problems

Mechanical error

Printer error

Ongoing function

A/D conversion

Aspirating sample

Aspirating wash liquid

Dispensing pipetting syringe

Dispensing wash syringe

Moving the cannula

Washing the system

Printer status

System is printing

External Storage Device

Data is always stored internally and on the SD card (or network storage).

SD Card storage

USB Memory stick storage

Network storage

Network storage not available

Internal temperature status

No indicator – Temperature is below 23 °C

Temperature is 23-27 °C

Temperature is 27-29 °C

Temperature is 29-35 °C

Temperature is above 35 °C

See page 41 for more information

Reagent status

Calibration OK

Calibration not OK

Calibration status unknown

Calibration not OK, further calibrations blocked


No reagent

Vial status


Analyzed and ready


Will be Analyzed

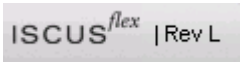

(blinking) Is being Analyzed


No vial inserted

Date and time

Main screen selection buttons

Software type and revision



* ISCUS^{flex} top Status Bar

NOTE! This manual is written for Revision L (Version 2.1.0.475) of the software. If you have a later revision of the software please check with your M Dialysis representative if a more recent user manual edition exists

Patient Screen

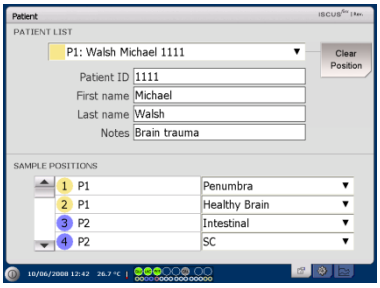
Add new patient

Select an empty patient position or touch “Clear position” button

Add Patient ID (**mandatory**), first and last name

If needed add a short note about the patient

Up to eight different patients can be added at the same time. The patient’s position is distinguished by colors and numbers



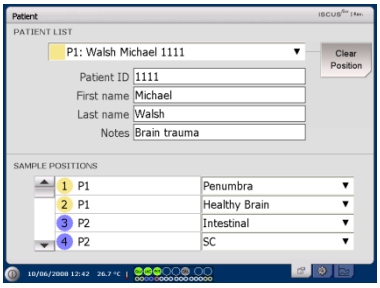
NOTE! Two patients can not have the same Patient ID

First time setup or change of patient sample position

Choose position of the vials for a specified patient position by adding a catheter name at the preferred sample position in the lower menu

Up to 16 different sample positions can be defined for one patient

Positions for Control samples can be defined at any free position and are valid for all patients.



NOTE! New catheter names can be added directly in the drop down menu or under the Settings - Catheter menu

NOTE! To change the sample positions you may have to unlock them in Settings - *Miscellaneous* (see page 22)

Settings and Controls Screen

Reagent Cassette

Patient Database

Settings

Batch Analysis

View Control Samples

Maintenance

Check mark the Maintenance check box to gain access to additional functionality

Sample Cannula

Set Time & Date

Show Service Log

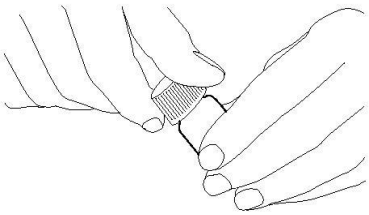
Service code

Reagent Cassette

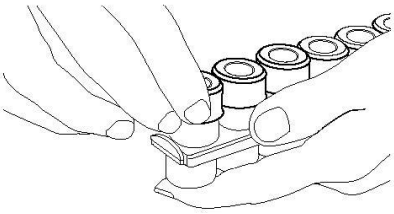
Touch the “Reagent Cassette” button on the Settings and Control screen and the Reagent Cassette screen will appear

Prepare the reagents

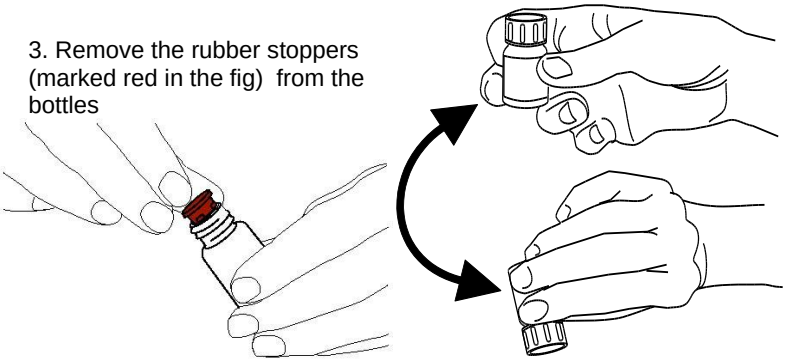
1. Unscrew the cap from the Buffer Solution bottle



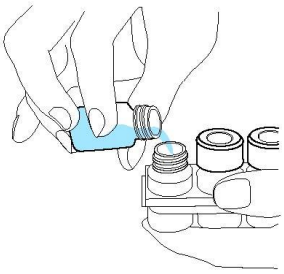
2. Unscrew the cap from the Reagent bottle



3. Remove the rubber stoppers (marked red in the fig) from the bottles



4. Gently empty the buffer solution into the corresponding Reagent bottle



5. Replace the cap with the white membrane on the Reagent bottle. Do **not** replace the rubber stopper

6. Repeat the steps above with all reagents included in the cassette

7. Remember to remove the rubber stopper from the Calibrator bottle

8. Dissolve contents completely by gently turning the bottles upside-down at least ten times.

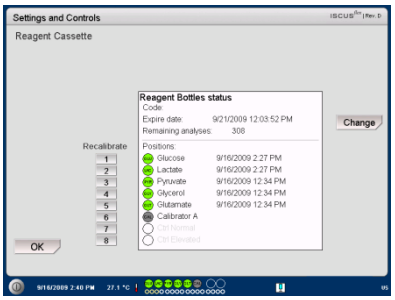
NOTE! Once reagents are mixed, they expire after five days. It is recommended that the Rinsing fluid is changed every time new reagents are inserted

Change reagent cassette

To change the reagents touch the “Change” button

The Reagent holder will extrude

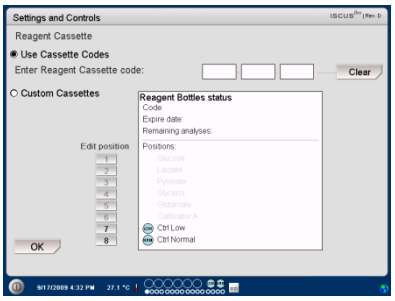
To return to main menu touch the “OK” button



Two options can be chosen by touching the radio button

- Use Cassette Codes
- Custom Cassettes

To return to main menu touch the “OK” button

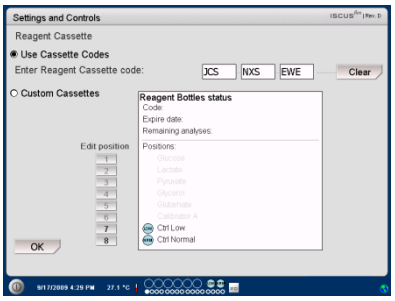


Use cassette codes

Enter the nine digit reagent cassette code found on the reagent cassette label

Place the reagent cassette to the left in the reagent holder

To start the calibration and return to the main menu touch the “OK” button

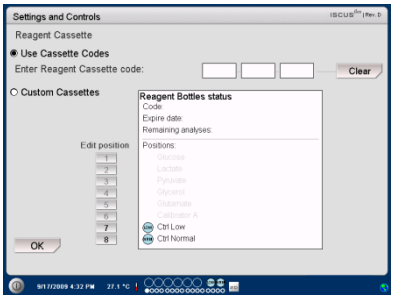


NOTE! Once reagents are mixed, they expire after five days

NOTE! The top position on the screen is the first position to the left in the reagent holder

The “Clear” button can be used to remove an expired cassette code

To return to the main menu without calibration touch the “OK” button

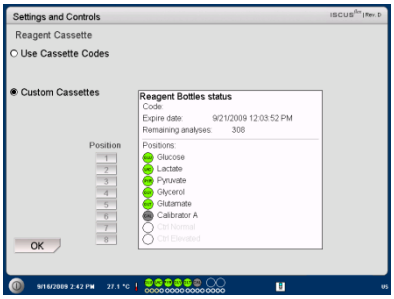


Custom cassette

This option shall only be used for separate reagent bottles, calibrator and control samples

Insert your reagent bottles in the reagent holder. Check that the correct reagent is indicated on the correct position. If needed change by touching the corresponding button under “Edit position”.

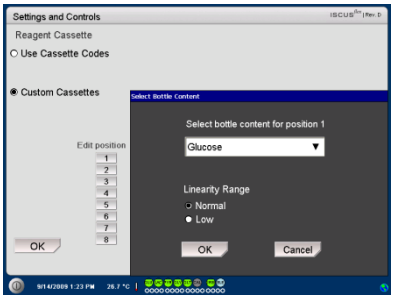
To start the calibration and return to the main menu touch the “OK” button



NOTE! All positions have a predefined default reagent:
1) Glucose
2) Lactate
3) Pyruvate
4) Glycerol
5) Glutamate
6) Calibrator A
7) Auto-control sample Low
8) Auto-control sample Elevated

NOTE! Once reagents have been mixed and registered they should not be removed from the analyzer unless they have expired or the system will be shut down for transportation

Change reagent position



Touch the desirable button under “Edit position”

Choose the wanted reagent for that position in the drop down menu

Change linear range

Touch the desirable button under “Edit position”

For Glucose, Lactate, Pyruvate and Glycerol normal or low linear range can be chosen

Recommendation: Use the lower range if the microdialysis samples have very low concentrations. See Technical Information – Linear range for more information

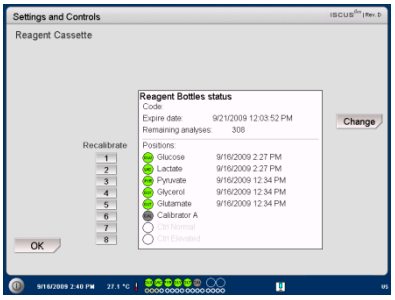
To return to the Reagent cassette screen and save changes, touch the “OK” button

To return to the Reagent cassette screen without saving touch the “Cancel” button

NOTE! For more information about Auto-control samples see Settings – QA

NOTE! Any changes in bottle content is restored to default settings when the ISCUS*flex* is restarted

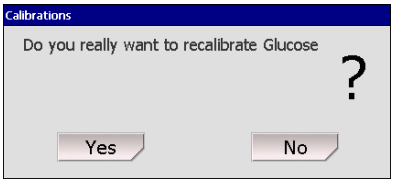
Calibration



The calibration will start when reagents are registered and you touch the “OK” button. After warming up of the reagents (30 minutes) the analyzer will calibrate once again

The analyzer will automatically calibrate the system every 6 hours

Recalibration



If a calibration fails you can recalibrate one or more reagents by touching the numbered button to the left of the reagent name

Touch the “Yes” button and the recalibration will start

Touch the “No” button to avoid recalibration and return to reagent cassette screen

Patient Database

Touch the “Patient Database” button on the Settings and Controls Screen and the Patient Database screen will appear

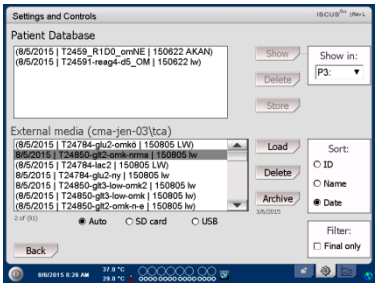
The top window shows patients added to the database. The External media list box appears when a SD card, a USB memory or a network location is available.

By highlighting the patient in the top window the “Show”, “Delete” and “Store” buttons appear.

Select a free position by using the drop down menu “Show in”. Touch the “Show“ button to show the patient data.

Touch the “Delete” button to delete the patient data from the database.

Touch the “Store” button to store the patient data on a SD card, a USB memory or a network location.



NOTE! Already active patients (P1-P8) cannot be stored, deleted or shown in a new position. Start by touching “Clear Position” in the Patient screen and then select the patient from the Patient database

NOTE! No sample data is stored in the database more than six weeks. Be sure to transfer your data to an external computer before that

The External media window shows the patients stored on the SD card, the USB memory or a network location.

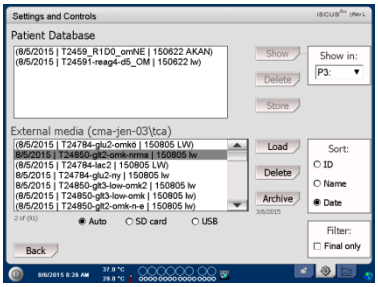
By highlighting the patient in the external media window the “Load” and “Delete” button appear

Touch the “Load” button to copy the patient data into the database

Touch the “Delete” button to delete the patient data from the SD card, the USB memory or the network location.

Touch the “Archive” button to archive (move) all patient data older than the date specified below the button.

Touch the “Back” button to save and return to Settings and Controls screen



NOTE! The USB memory is prioritized against the SD card. Some USB memory brands are not compatible with ISCUS*flex*

NOTE! It is not possible to delete or store a patient, which is still active. Start by touching “Clear Position” in the Patient screen

NOTE! Use the service code ARCHIVE to change the archive date.

Settings

Touch the “Settings” button on the Settings and Controls screen and the Settings screen will appear

Settings – *Scaling*

Scaling can be set for a specific analyte/catheter combination

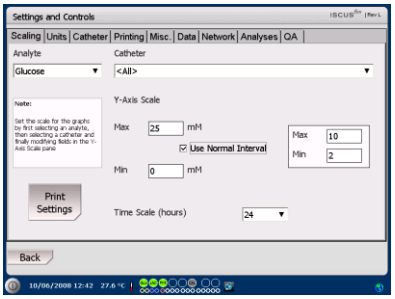
Chose analyte from the analyte drop down menu

Chose catheter from the catheter drop down menu

Chose max and min concentrations

Optionally a “Normal Interval” can be chosen

Touch the “Back” button to save and return to Settings and Controls screen



NOTE! The normal interval will appear as a blue background shade in the graphic window on the Graphs screen

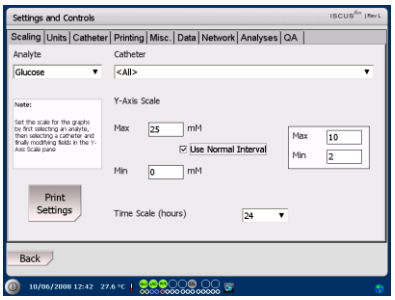
NOTE! If normal intervals are used, the biological variation between individuals must be considered. The user is responsible to set the normal interval and make sure that it is adequate

The time scale can be set in hours in the Time scale drop menu

The “Print Settings” button will print scale settings for all combinations of analytes and catheters

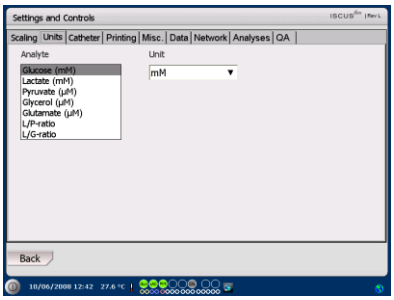
Touch the “Back” button to save and return to Settings and Controls screen

An audio signal can be chosen if the analytic result is outside the normal Interval (See Settings Misc.)



NOTE! During printing data is also copied to the SD card, USB memory and network location if available.

Settings – *Units*



A specific unit can be set for each analyte

Choose analyte from the Analyte drop down menu

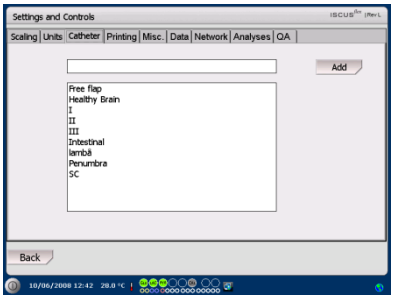
Choose unit from the Unit drop down menu

The unit choice will automatically apply to all catheters

Touch the “Back” button to save and return to Settings and Controls screen

NOTE! L/P-ratio and the L/G-ratio do not have a unit. For further information see the Technical manual

Settings – *Catheter*



Add a new catheter name

Touch the text field and type the new catheter name

Touch the “Add” button

The catheter name will now be added to the window and is ready to use

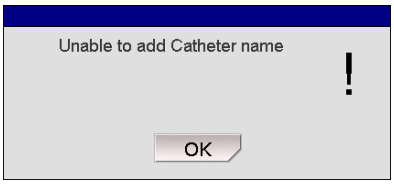
Remove a catheter name

Highlight the catheter name

Touch the “Delete” button and confirm the action

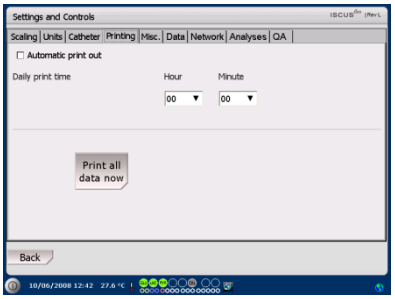
Touch the “Back” button to save and return to Settings and Controls screen

It is not possible to add a catheter name that already exists



It is not possible to delete a catheter name in use!

Settings – *Printing*



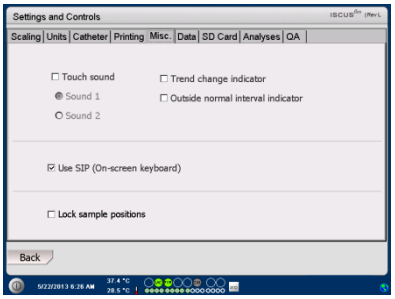
To print all available data for the active patient (visible on the Graphs screen) touch the “Print all data now” button

Check “Automatic print out”, to print all data for the active patient (Graphs screen), on a daily basis

Touch the “Back” button to save and return to Settings and Controls screen

NOTE! During printing data is also copied to the SD card, USB memory and network location if available.

Settings – *Miscellaneous*



If the “Touch Sound” box is checked a touch sound will appear. Two different sounds can be chosen

If the “Trend change indicator” box is checked a sound will indicate every time the trend of an analyte changes

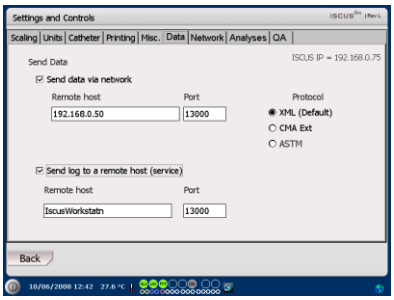
If the “Outside normal interval indicator” box is checked a sound will indicate every time an analytic result is outside the normal interval (See Settings - *Scaling)*

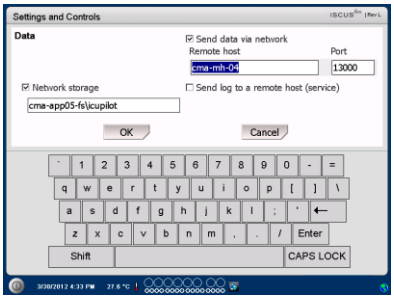
If an external keyboard is used it is recommended to uncheck the Use SIP check box to hide the on-screen keyboard.

If “Lock sample positions” is check marked it is not possible to change the sample positions in the patient screen.

Touch the “Back” button to save and return to Settings and Controls screen

Settings – *Data*





Insert a network cable to use these functions

"Send data via network" allows the user to collect all data on a central computer

Check the "Send data via network" box

Type the "Remote host" name and "Port"

Choose protocol (XML, CMAExt or ASTM)

The Network storage check box allows storage on a network share. Please refer to section 6.3 in the technical manual.
Check mark the Network storage check box. Enter the network location in the field displayed

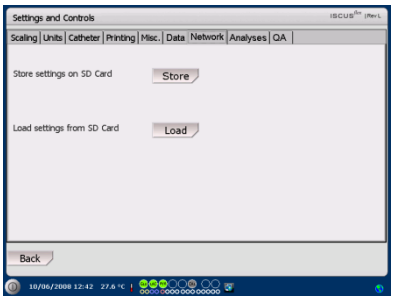
"Send log to a remote host (service)" allows the user to collect service information

Check the "Send log to a remote host (service)" box

Type the "Remote host" name and "Port"

Touch the "Back" button to save and return to Settings and Controls screen

Settings – *SD Card/USB/Network*



A SD card or a USB memory must be inserted in the machine or a valid network location must be specified to allow following options:

Touch the "Store" button to store the settings on the SD card, USB memory or network location.

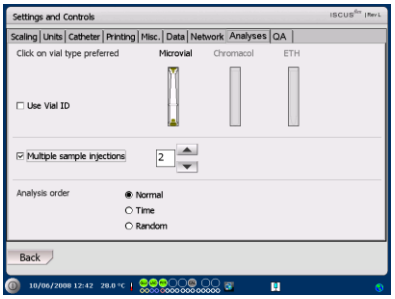
Touch the "Load" button to load the latest settings from the SD card, USB memory or network location.

Touch the "Back" button to save and return to Settings and Controls screen

NOTE! If the load button is still shaded after a SD card/USB memory is inserted there are no settings on the device to load

NOTE! Some USB memory brands are not compatible with ISCUS*flex*

Settings – *Analyses*



Choose vial type by touching the preferred one. Use vial adapters for the CMA Glass (CMA Microdialysis AB, Chromacol) The vial ID allows to type in a specific ID for each vial when analyzing

To do several analytical injections of a sample check the “Multiple sample injections” button and choose number (2-50)

Option to choose different analysis order by checking the radio button:

- Normal: Analyze the samples in sample position order
- Time: Analyze the samples in time order
- Random: Analyze the samples in random order

Touch the “Back” button to save and return to Settings and Controls screen

NOTE! The use of CMA Glass will disable the possibility to sense the vials automatically

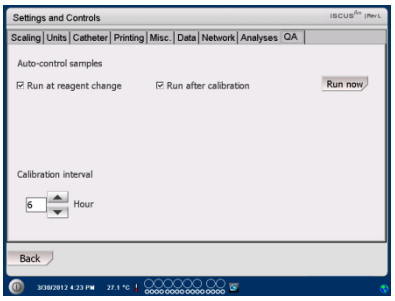
NOTE! CMA Glass need vial adapters placed in the vial cassette. Place the vial adapters in all positions of the vial rack before analyzing any samples

NOTE! Only one of the vial types can be used at the same time. The vial type applies to all sample positions

NOTE! Multiple sample injections need more sample volume

NOTE! If using capped CMA Glass vials, use REF 7432175 Cap/Seal Non-Reclosing (CMA Microdialysis AB)

Settings – *QA*



Auto-control samples can only be analyzed if an Auto-control bottle is added into the reagent holder. The results will appear on the “Control Sample” screen.

If the “Run at reagent change” box is checked the auto-control samples will be analyzed every time a new reagent has been added to the reagent holder.

The “Run now” button starts the analysis of the auto-control samples.

The calibration interval can be set to anything from 1 to 12 hours (6 hours is default).

Touch the “Back” button to save and return to Settings and Controls screen

NOTE! Auto-control samples are run after each calibration (default).

NOTE! If a result from an auto-control analysis is outside ±20 % of the nominal control sample value (±30 % for Low controls) a status message is displayed.

Batch Analysis

Touch the “Batch Analysis” button on the Settings and Controls screen and the Batch Analysis screen will appear

Touch on the first sample position in the batch sequence (ensure that the arrow icon contains a green right arrow). Batch positions are marked with a square frame (see picture)

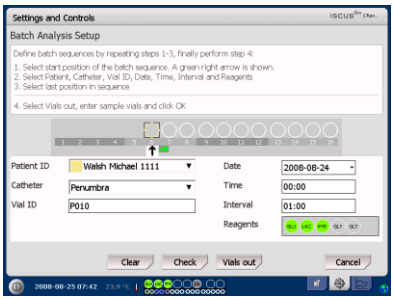
Select a patient from the Patient ID drop down list and select a catheter from the Catheter drop down list

If enabled enter a Vial ID in the Vial ID text box.

Select the sample date in the Date entry field and enter the sample time in the Time entry field

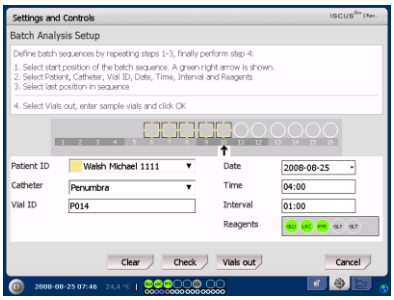
Enter the time interval between batch samples in the Interval entry field

Select which analytes to analyze by marking correct reagents



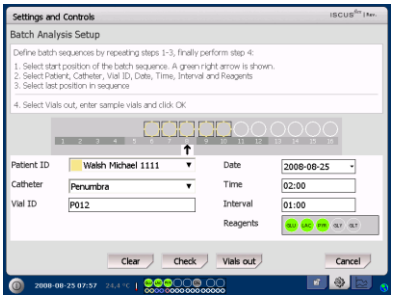
Touch on the last vial in the batch sequence. Note how the vials are marked with square frames to indicate batch analyses

Touch on “Check” button to see a list of defined batch vials or touch on any sample position in the batch sequence



Check that the information is correct. Adjust if needed

The ”Clear” button is used to clear **all** fields

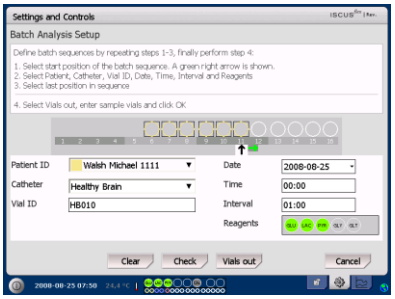


Load several batches

When done with the first batch start all over again by:

Touch on the first vial in the next batch sequence. Batch vials are marked with a square frame

Fill in the rest of the information as described above

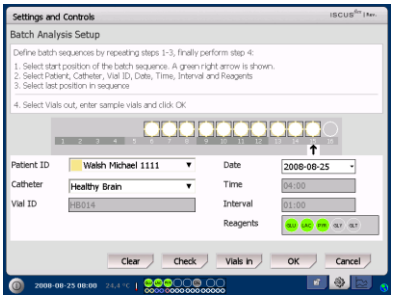


Touch on “Vials out” button

The vial cassette will be extruded

Add the vials in the preselected sample positions. For easier loading the vial cassette can be removed by lifting it upwards

To start the analysis touch on the “OK” button



NOTE! It is also possible to touch the sample positions on the screen to indicate vial presence. This is the only way when using CMA Glass Vials

NOTE! The results from the Batch analysis are found in the analysis window under the chosen patient, catheter and analyte

View Control Samples

Touch the “View Control Samples” button on the Settings and Controls screen and the Control Samples screen will appear

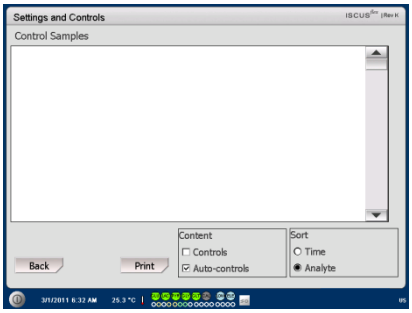
To show Control Samples check the “Controls” check box

To show Auto-control samples check the “Auto-controls” check box

The analysis can be sorted by Time or Analyte

Touch the “Back” button to save and return to Settings and Controls screen

For more information about Control samples see page 37



NOTE! Control samples are analyzed by using the “Analyze” button on the Graphs screen (See Graphs screen - Analyze)

NOTE! More information about Auto control samples see Settings - QA

Sample Cannula

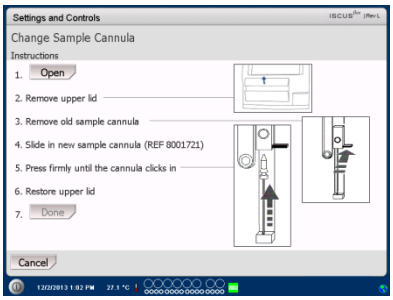
The sample cannula is a spare part that needs to be changed after extensive use. The user can easily change the cannula himself. When the sample cannula has been changed, ISCUS*flex* will automatically recalibrate

Check the Maintenance box on the Settings and Controls screen to show all buttons

Touch the “Sample Cannula” button and the Change Sample Cannula screen will appear

Follow the instructions on the screen (see below)

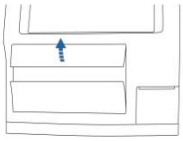
To cancel the process touch the “Cancel” button



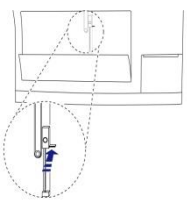
NOTE! Do not touch the tip of the cannula as it can cause needle injuries and be contaminated. Be sure to follow hospital infection risk procedures

1. Touch the ”Open” button. The lid covering the reagent and vial cassette opens

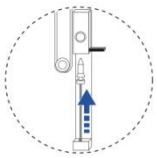
For the snap-in cannula (REF 8001721) do this:



2. Lift up and remove the upper lid. This will expose the interior of ISCUS*flex* and makes it possible to locate the position of the sample cannula

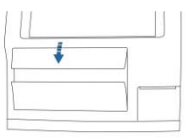


3. Detach the old cannula by moving the handle inwards



4. Slide in a new sample cannula

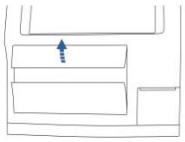
5. Press firmly until the cannula clicks in



6. Restore the upper lid

7. Press the “Done” button

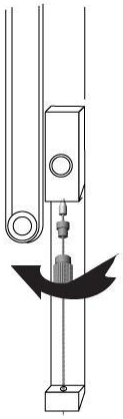
For the screw cannula (REF 8050012) do this:



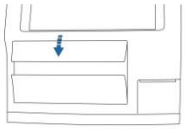
2. Lift up and remove the upper lid. This will expose the interior of ISCUS*flex* and makes it possible to locate the position of the sample cannula

4. Slide in a new sample cannula

5. Press firmly and screw the cannula in



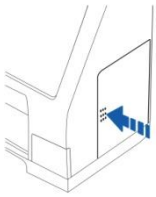
3. Detach the old cannula by unscrewing it



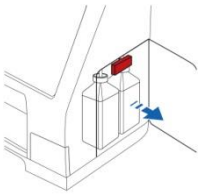
6. Restore the upper lid

7. Press the “Done” button

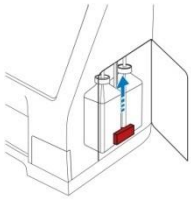
Empty Waste and Load Rinse bottle



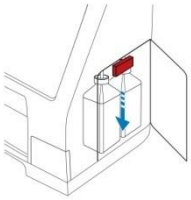
1. Open the door to the fluid compartment by slightly pressing it



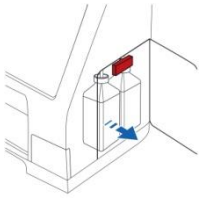
4. Empty the Waste bottle (narrow neck rear bottle) and put it back into the same position.



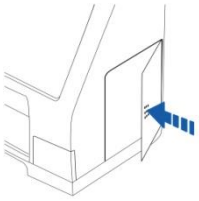
2. Move the handle (marked red) all the way up



5. Move the handle all the way down



3. Replace the Rinse bottle (wide neck front bottle) with a new bottle of Rinsing Fluid (REF 8002171)



6. Close the door

NOTE! The Waste fluid may be contaminated with e.g. hepatitis. Be sure to use normal hospital routines. If hospital requirements do not permit you to reuse the waste bottle, replace it with a new empty bottle using the cap of the new bottle to seal the old bottle (REF 8002161)

NOTE! It is recommended to change the rinsing fluid when changing the reagents for optimal result

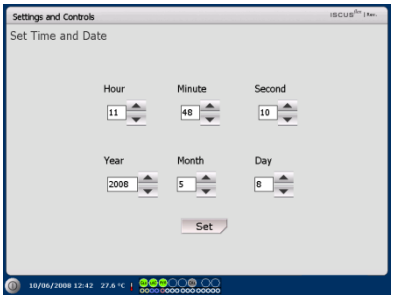
Set Time & Date

Check the Maintenance box on the Settings and Controls screen to show all buttons

Touch the “Set Time & Date” button and the Set Time & Date screen will appear

Set time and date with the up and down buttons

Touch the “Set” button to save and return to the Settings and Controls screen.



Show Service Log

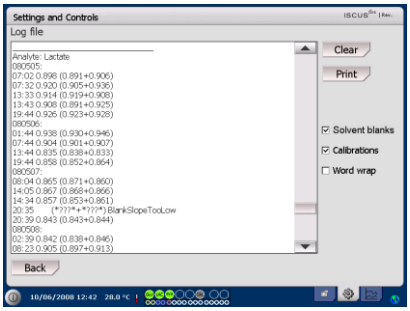
Check the Maintenance box on the Settings and Controls screen to show all buttons

Touch the “Show Service Log” button and the Show Service Log screen will appear

The Service Log shows calibration factors and solvent blanks. The Service Log also shows error messages and other important messages for Service engineers

The two check boxes “Solvent blanks” and “Calibrations” shows/hides information

The ”Word wrap” check box wrap the word in the printout



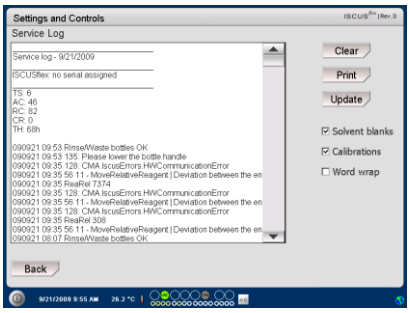
NOTE! The check box “Word wrap” makes it possible to read all information on the paper print out (otherwise max 32 characters will be printed on each row)

Touch the “Clear” button to clear all data except for calibrations and solvent blanks

Touch the “Print” button to print out the service log

Touch the “Update” button to update the service log

Touch the “Back” button to return to Settings and Controls screen



NOTE! Data is also copied to the SD card/USB memory/Network location if available
\BACKUP\LOGFILE.TXT

NOTE! The installation log file is also copied to the SD card/USB memory/Network location if available
\INSTALLATIONLOG.TXT

Service code

The service mode can be entered by authorized service engineers by entering a service code. For more information see page 39

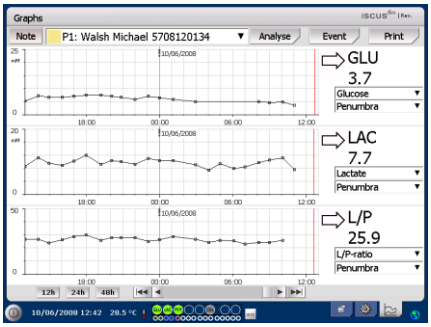
Graphs Screen

The Graphs screen shows the selected patients data

Use the top drop down list to select a patient

To add an event to the patient touch the “Event “ button (See Graphs screen – Event)

To analyze a microdialysis sample touch the “Analyze” button (See Graphs screen – Analyze)



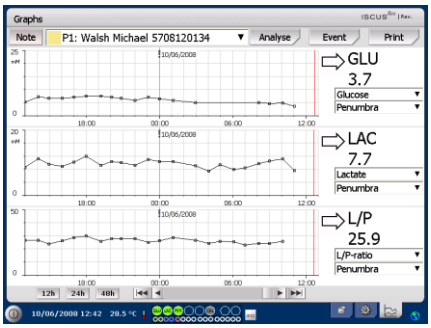
NOTE! After selecting a patient the color in the drop down window will change to the color of the patient position

Each graphic window can be individually set with a combination of reagent/ratio and catheter

Select a reagent/ratio in the drop down menu

Select the catheter in the drop down menu

The latest analyzed sample value is shown below the chosen reagent letter abbreviation (latest in time)

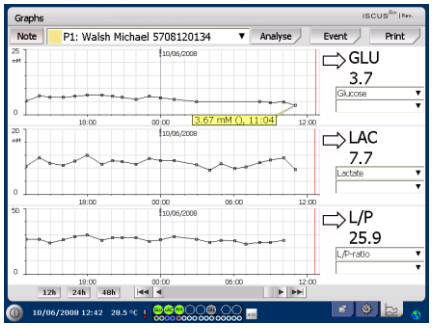


A microdialysis sample is marked with a small “ ▫ ” and an Event is marked with a “ ! ” in the graph

To get more detailed information about a sample or event touch the “ ▫ ” or “ ! ”

To get more detailed information about a sample series or events touch the yellow information bar

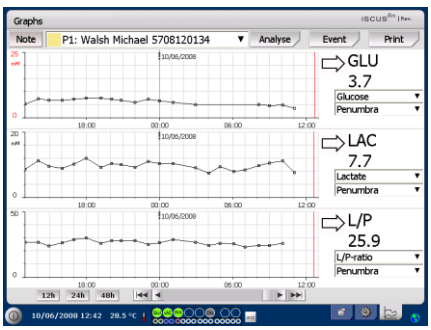
See Graphs screen – Data series/Events for more information

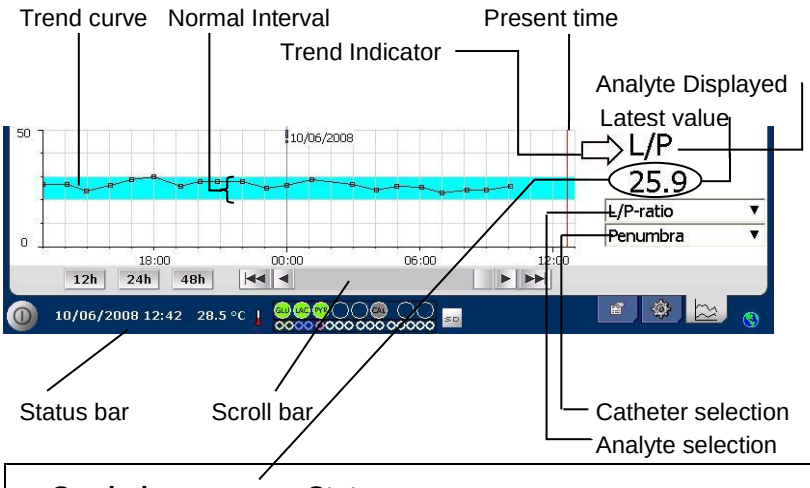


To change the y-axis temporarily for a better view, touch the y-axis area

To change the time-axis temporarily for a better view touch one of the 12h, 24h and 48h buttons at bottom left

The red vertical line indicates present time





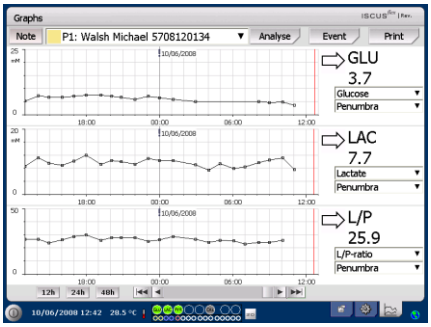
Symbols	Status
?	Measurement failed (e.g. due to air in the liquid system)
???	Undefined
+Inf	Positive infinity (e.g. for L/P-ratio if L>0 and P=0)
-Inf	Negative inifinity
1865 LL or >1865	Larger than (value above the linearity limit)
<12	Less than (e.g. for L/P-ratio if L is OK and P is above the linearity limit)
5.4 DL or *5.4	Under detection limit
20	Value OK

Graphs screen – *Event*

Touch the “Event” button on the Graphs screen and the Event screen will appear

or

Touch the “ ! ” and then touch the displayed yellow information bar to enter the Event screen

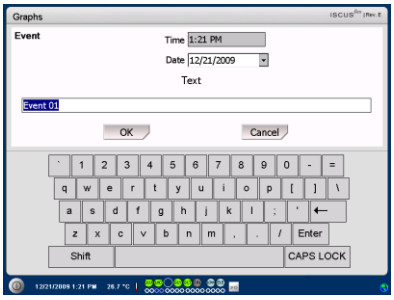


Highlight an event and touch the “Delete” button to delete the event

Touch the “New” button to enter a new event

Highlight an event and touch the “Change” button to Change the event

Touch the “Close” button to return to Graphs screen



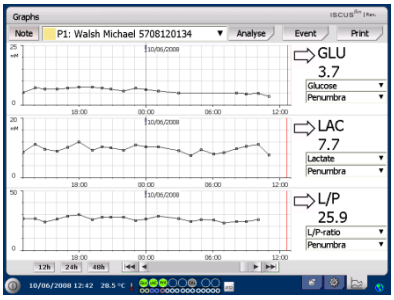
NOTE! The events are sorted by date and time for the selected patient

Load and Analyze a patient

Graphs screen – *Analyze*

Touch the “Analyze” button on the Graphs screen and the Analyze screen will appear

The vial cassette will be extruded



Add your vials at the pre-defined positions. The predefined catheter name appears when the microvial is inserted

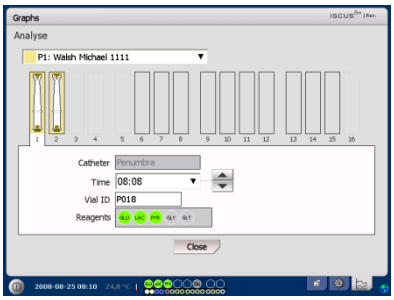
If needed add a new time

Optionally: Add Vial-ID (See Settings – Analyses)

Select what to analyze by marking and un-marking the reagents

Control samples can always be analyzed in their predefined positions

Touch “Close” to analyze the samples and return to the Graphs screen



NOTE! The background of the sample position will have the same color as the patient position

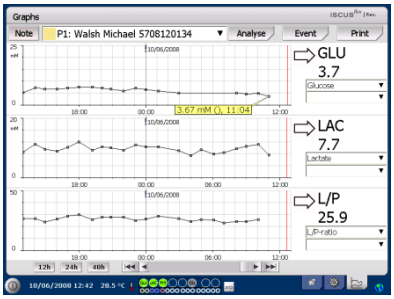
NOTE! If you add a vial in a position not defined for the patient a red cross over the vial will appear and the sample will not be analyzed

NOTE! The maximum number of measurements per hour is 30

Graphs screen – *Data series*

Touch the sample point “ ▫ ” and touch the yellow information bar displayed in the graphic window to enter the Data series screen

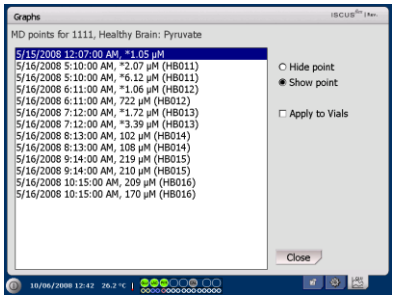
The window shows all analyzed Microdialysis points for the selected reagent and catheter combination sorted by time and date



It is possible to hide a microdialysis measure point by highlighting the MD point in the window and checking the “Hide point” radio button

It is also possible to hide a complete vial by the same procedure, by checking the “Apply to Vials” box

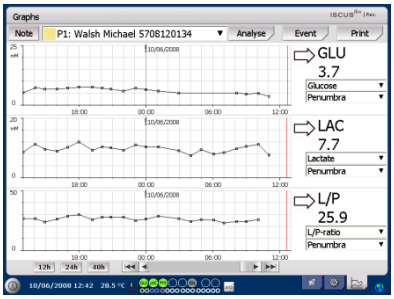
Touch the “Close” button to return to the Graphs screen



NOTE! Hidden points are light gray in the graph. A notification behind the MD point information is shown

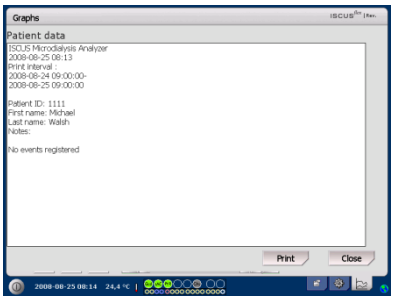
Graphs screen – *Print*

Touch the “Print” button



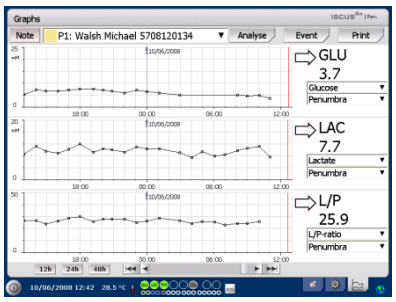
Information about the patient is shown and can be printed by touching the “Print” button.

Touch “Close” to return to the Graphs screen without printing



Load and Analyze several patients

Touch the Analyze button

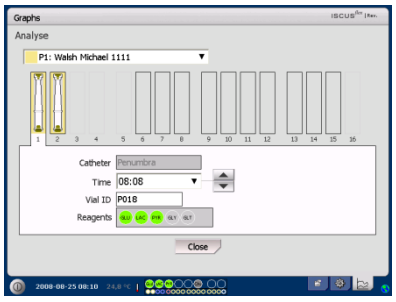


NOTE! After selecting a patient the color indicator in the drop down window will change to the color of that patient position

NOTE! The maximum number of measurements per hour is 30

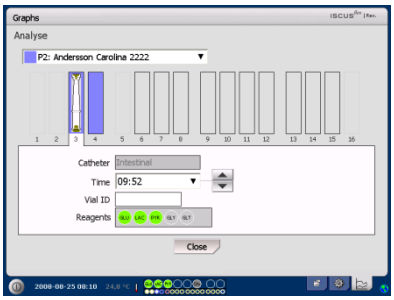
Graphs screen – Analyze patient 1

Add your vials at your predefined positions. The predefined catheter name appears when the microvial is inserted



NOTE! The background of the sample position will have the same color as the patient position

Graphs screen – Analyze next patient



Use the top drop down menu in the Analyze screen to select a new patient

Add your vials at your predefined positions of the new patient

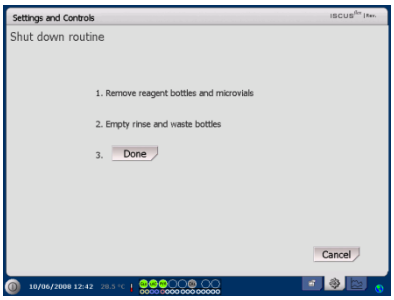
Touch “Close” to Analyze the samples (from all patients) and return to the Graphs screen

Shut Down Routine

To shut down the ISCUS*flex* touch the “Shut down” button in the bottom left corner and follow the instructions

NOTE! Empty the rinse/waste bottles and remove the reagents and the vial cassette to reduce the risk of equipment damage, which is not covered by any service or warranty agreement

Instructions



Remove reagents and vials

Empty rinse and waste bottles

Remove the vial cassette

Touch the “Done” button

It is now safe to turn the system off by using the On/Off switch on the left side of the analyzer

Printer Information

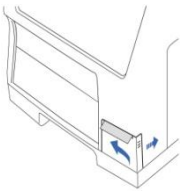
Printer information window

Please check the door and paper status of the printer!

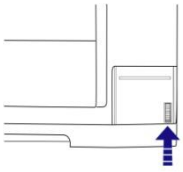
NOTE! If the printer seems to be off-line, please restart the ISCUS^{flex}, before next printout, by following the shut down routine

Load print paper

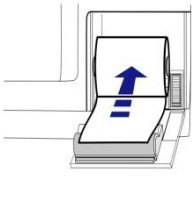
The printer is loaded with a roll of thermal print paper (REF 8002162)



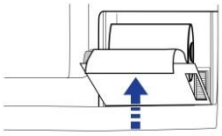
1. Open the cover lid



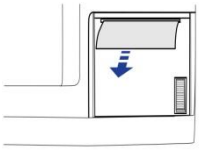
2. Open the printer lid



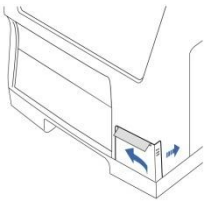
3. Replace the paper making sure that the free end of the paper comes out from the bottom of the paper roll



4. Close the printer lid



5. Pull out a small amount of paper from the roll



6. Close the cover lid

Control Samples

Intended use

The Control Samples are intended to be used as assayed quality control samples for the ISCUS*flex* Microdialysis Analyzer.

Usage

The use of quality control samples is often regulated by local quality assurance programs. Control samples are usually analyzed after change of reagents, after calibration and in connection with analysis of patient samples. By analyzing the control samples, performance of the analytical system, including everything from Analyzer, Reagents, Calibrator and calibration can be followed.

You can use Auto-control samples by placing the Control Sample bottles in the two outermost positions to the right in the reagent holder. The system will then automatically run controls every sixth hour (default). The interval can be changed under Settings – QA and the results can be found on the View Control Samples screen

If a result from an auto-control analysis is outside ±20 % of the nominal control sample value (±30 % for Low controls) a status message is displayed.

Another alternative is to run control samples in microvials. Please follow the instructions below:

• Predefine the positions for the controls on the Patient screen

• Remove and discard the stopper in the wide end of the microvial

• Using a pipette or a disposable syringe, fill the vial with 50-100 µL of control sample

• Remove the air from the narrow end of the microvial, preferably using a small centrifuge (30 s at 2000 g)

• Touch Analyze on the Graphs screen and place the microvials in the predefined positions of the vial cassette

• To display the results, touch “View Control Samples” on the Settings and Controls screen

• Satisfactory level of performance is achieved when the analyte values for the control are within the “Acceptable Control Range” given in the package insert for the Control Samples

Troubleshooting

Initial information

Begin gathering information about the problem (See Show Service Log above). Ask the operator to make it easier to find and verify the problem

⚠ Warning

Only authorized personnel should troubleshoot/service the ISCUS*flex* Microdialysis Analyzer. Troubleshooting by unauthorized personnel could result in personal injury, equipment damage or property damage

The user can handle replacement of consumables and spare parts (see page 45). If you need any help or have questions on how to perform these replacements, please contact your representative

Follow the instructions in this manual if replacing any part or correcting a problem that the user is allowed to correct without special training

NOTE! If the problem persists contact your representative for assistance

⚠ Class 1M LED product. LED placed in the detector module of ISCUS*flex*.

Service

ISCUS*flex* shall be serviced once every 12 months by a qualified service engineer certified by M Dialysis AB.

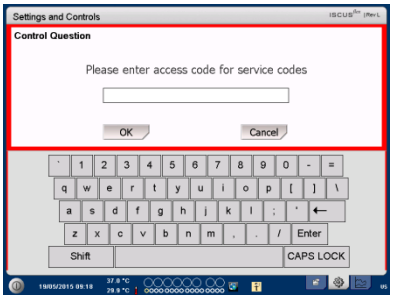
Enter Service mode

Check the Maintenance box on the Settings and Controls screen to show all buttons

Touch “Service Code” button

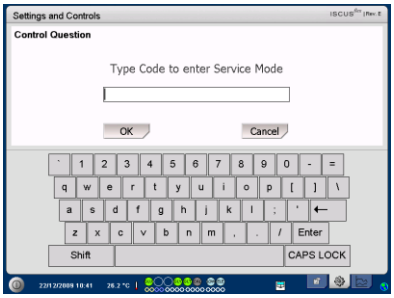
Control Question (1)

Enter the access code and touch OK to get access to ISCUS*flex* service codes.



Control Question (2)

Enter the service code and touch OK to enter ISCUS*flex* service mode.



Maintenance

Maintenance required between regular services is cleaning of the fan filter (see below) and the exchange of the Sample Cannula (see page 27)

Cleaning

The fan filter should be cleaned once a week with a soft cloth dampened with 70 % alcohol.

The outside of the instrument should be cleaned regularly with a soft dampened cloth using water and, if needed, a mild detergent and/or disinfectant (70 % ethanol or equivalent). The screen should be cleaned with a screen cleaner when needed.

WARNING

Do not immerse the device or any input in any liquid or cleaning detergent

Do not pour any liquid or cleaning detergent on any device opening

Do not clean any input or communication ports with any liquid or cleaning detergents unless a representative or authorized personnel has approved that procedure

Waste disposal

Do not dispose this product as unsorted municipal waste

Follow local municipal waste ordinances for proper disposal provisions to reduce the environmental impact of waste electrical and electronic equipment (WEEE)

European Union customers

Contact your local M Dialysis AB representatives or your local authority for guidance

Biological hazard

Rinsing and waste fluid can be disposed as water unless there is a risk for infection

NOTE! The Waste fluid may be contaminated. Be sure to follow hospital infection risk procedures. If hospital requirements do not permit you to reuse the waste bottle, replace it with a new empty bottle and use the cap of the new bottle to seal the old bottle

Reagents and calibrator can be disposed as normal waste. Microvials and Plastic vials can be disposed as normal waste and Glass vials as glass waste unless there is a risk of infection

NOTE! The samples may be contaminated. Be sure to follow hospital infection risk procedures

Paper rolls can be disposed as normal waste

The Sample Cannula shall be disposed according to hospital routines for needles

NOTE! The cannula may be contaminated. Be sure to follow hospital infection risk procedures

Technical Information

Linear range

In research, microdialysis samples are generally acquired using higher flow rates (1-5 µL/min) which result in lower analyte recoveries. In order to facilitate the analysis of these samples, the ISCUS^{flex} can be configured to use more sensitive methods for low level analysis of the following compounds: Glucose, Lactate, Pyruvate and Glycerol.

To change the linear ranges see Reagent Cassette – Change linear range. Below you can find the specifications for the normal and low linear range.

Normal linear range

REAGENT	LINEAR RANGE	SAMPLE VOLUME	REAGENT VOLUME
Glucose	0.1 - 25 mmol/L	0.5 µL	14.5 µL
Lactate	0.1 - 12 mmol/L	0.2 µL	14.8 µL
Pyruvate *	10 - 1500 µmol/L	0.5 µL	14.5 µL
Glycerol	10 - 1500 µmol/L	0.5 µL	14.5 µL
Glutamate	1 - 150 µmol/L	1.5 µL	7.5 µL
Urea	0.5 - 25 mmol/L	0.5 µL	14.5 µL

Low linear range

REAGENT	LINEAR RANGE	SAMPLE VOLUME	REAGENT VOLUME
Glucose	0.02 - 6.0 mmol/L	2.0 µL	13.0 µL
Lactate	0.02 - 2.5 mmol/L	0.8 µL	14.2 µL
Pyruvate *	2 - 300 µmol/L	2.0 µL	13.0 µL
Glycerol	2 - 500 µmol/L	2.0 µL	13.0 µL

* Pyruvate default linear range is low linear range

Operating conditions

TEMPERATURE	HUMIDITY	ATMOSPHERIC PRESSURE
+18 °C to +28 °C	10 % - 70 % rh. non- condensation	500 - 1060 hPa

The internal temperature of the system is displayed beside the indicator  on the status bar

If the temperature rises above 35 °C, please clean the dust from the fan filter on the backside of the analyzer and make sure that there is enough clearance around the device to allow efficient cooling of the analyzer

If the temperature remains high we recommend that you try to decrease the surrounding temperature and start to run control samples

Storage and transport conditions

TEMPERATURE	HUMIDITY	ATMOSPHERIC PRESSURE
0 °C to +50 °C	10% - 80% rh. non-condensation	500 - 1060 hPa

Measures and weights

HEIGHT	WIDTH	DEPTH	WEIGHT
430 mm	350 mm	270 mm	13 Kg

Classification

ISCUS*flex* Microdialysis Analyzer is not intended to be connected to a patient

Degree of protection against electric shock:
Type B (Body). Equipment providing particular degree of protection against electric shock, particularly regarding allowable leakage current

Degree of protection against harmful ingress of water:
IP20

Degree of safety in presence of inflammable anesthetics:
The device is not intended for use with flammable anesthetic gases

Mode of operation:
Continuous operation

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 ISCUS*flex*

ISCUS*flex* should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, ISCUS*flex* should be observed to verify normal operation in the configuration in which it will be used

List of cables: Network cable – Max length 5 meters, Power cable – Max length 1.8 meters

Please see, EMC - Electromagnetic Compatibility, in ISCUS*flex* Technical manual for further information

Technical Specifications

NOTE! If there are additional questions please contact your M Dialysis representative.
Please note that M Dialysis AB reserves the right to make changes in the specifications without prior notice

REF	SPECIFICATION
Model	ISCUS*flex* Microdialysis Analyzer
Voltage	100-240 V ~50/60 Hz
Power consumption	100 VA
Fuses	T 1.25 A (L) 250 V. Shall be replaced with a UL recognized fuse.
Type of protection	Class1, Type B
Principle	Kinetic enzymatic analyzer
Vials	Microvials, CMA Glass vials
Samples	Microdialysates
Samples volume, used	0.2 – 2.0 µL/analyte
Minimum sample volume required	Sum of samples volumes per analyte + 2.0µL
Reagent consumption	≤15µL/analysis (depending on analyte)
Pipetting imprecision	≤2% (0.5µL) rel. standard deviation
Calibration	Automatic
Warm-up time	10 minutes
Measuring time	30 seconds
Time per test	60-90 seconds
Throughput	30 measurements per hour
Detector type	Single beam filter photometer
Light source	Class 1M LED
Wavelength(s)	375 and 530 nm
Detector cell	Capillary flow cell 10 mm, 2µL
Detector cell, working temp.	37 °C/98.6 °F
Rinsing bottle volume	500 mL
Waste bottle volume	500 mL
Printer type	Thermal printer
Printer paper type	Thermal paper
Printer paper dimensions	Width 50mm, diameter 48 mm, length 30,5 m
Assay imprecision	≤ 4% relative standard deviation within run for control samples Normal*
Assay inaccuracy	≤ 10% for Control Samples {Ref nr 8010201}
Assay range	See instructions for use for the Reagent sets {Ref nr 8002335, 8002336, 8002337}

* Control samples Normal contain:
5.2 mmol/L Glucose, 3.2 mmol/L Lactate, 73.3 µmol/L Pyruvate,
260 µmol/L Glycerol, 40 µmol/L Glutamate and 5.0 mmol/L Urea.

Symbols and Markings

Explanations of the symbols found on the device and in the User´s manual:

Symbol	Description
	Read the User's Manual
	Warning or Caution
	On
	Off
	Fuse
	SD card (Secure Digital Memory card)
	Universal Serial Bus (USB) port
	Ethernet port (network)
	Refer to instruction manual/booklet
	Intended for Medical Purpose according to IVDD, The In Vitro Diagnostic Directive 98/79/EC
	Temperature limitation

Symbol	Description
	Serial Number
	Catalogue number
	Manufacturer
	Storage Humidity
	Brightness control (Display)
	Rinsing fluid
	Waste fluid
	Printer
	Biological hazard
Class 1M LED product	Caution - Class 1M LED radiation when open (in detector module). Do not view directly or with optical instruments

Consumables and Spare parts

The analyzer has several consumables and spare parts which are installed, delivered or sold separately. These are described in the table below.

REF	Description	Incl. in Package	Consumable	Spare part	Qty.
8002171	Rinsing Fluid		√		8 x 0.5 L
8002161	Waste Bottles	1 bottle	√		8 x 0.5 L
8002162	Thermal Print Paper	1 roll	√		4 x 30.5 m roll
8002163	Reagent Set A		√		1
8002164	Reagent Set B		√		1
8002165	Reagent Set C		√		1
P000023	Reagent Glucose		√		5 x 6mL
P000024	Reagent Lactate		√		5 x 6mL
P000063	Reagent Pyruvate		√		5 x 6mL
P000025	Reagent Glycerol		√		5 x 6mL
P000064	Reagent Glutamate		√		5 x 4mL
P000026	Reagent Urea		√		5 x 6mL
P000057	Calibrator A		√		10 x 6mL
P000001	Microvials		√		250
7431100	Vial Plastic, 300µl (CMA Microdialysis AB/ETH)		√		1000
7431007	Vial Glass, 300µl (CMA Microdialysis AB/ Chromacol)		√		500
P000114	Vial Adapter		√		1
8010201	Control Samples		√		5 x 5 mL at 2 levels
8001721	Sample Cannula	√		√	1
8050012	Sample Cannula Screwed			√	1
8003806	ISCUSflex SDC (SD-card)	√	√		1
8002792	ISCUS Maintenance Kit			√	1
8003409	Vial Cassette	√	√		1
8002921	Aluminium Case	√	√		1
8001027	ICUpilot software	√			1

Transportation and Packaging

CAUTION!

MANDATORY ACTIONS BEFORE TRANSPORT.

PLEASE CHECK THAT ALL FLUIDS HAVE BEEN REMOVED BEFORE PACKAGING ISCUS*flex* IN THE CARRIER (RINSE/WASTE BOTTLES, REAGENT SET & SAMPLE VIALS).

PLEASE INSERT ISCUS IN THE CARRIER IN AN UPRIGHT POSITION WITH THE FRONT OF ISCUS*flex* TOWARDS THE HINGES OF THE CARRIER.

NOTE! If the fluids have not been removed from the analyzer or it is not placed correctly in the carrier it may be damaged by rough handling during transportation. Any damage to ISCUS*flex* as a result of not following these instructions will not be covered by warranty.

For transportation outside the hospital please use the aluminum case to transport the ISCUS*flex*

Insert the shock absorber over the reagent and vial holders. See picture on page 6.

Wrap the plastic bag around the analyzer

Use proper lifting methods when lifting the ISCUS*flex* into the aluminum case (REF 8002921)

Use proper lifting methods when moving or lifting the aluminum case; failure to do so can result in personal injury, equipment damage and property damage

The package shall be transported upright and carefully

Service and Training center

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