US

CMA 600 Microdialysis Analyzer

XP/Vista/Windows 7

User's manual

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cma

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User manual for CMA 600 Microdialysis Analyser
Software version 1.45

Printed in Sweden

All devices from CMA Microdialysis AB are intended for use by qualified medical personnel only.

For In Vitro Diagnostic Use

Contents

1. Introduction

1.1. Introduction

CMA 600 Microdialysis Analyser was developed for the small sample volumes of dialysates obtained when sampling by microdialysis. The CMA 600 uses colorimetric measurement with enzyme reagents. The CMA 600 should only be used for microdialysates. Samples can be analyzed one at a time or in batch.

CMA 600 Microdialysis Analyser is computer controlled and can be integrated in a mobile system. The software (operating under Microsoft Windows™) is dedicated for microdialysis samples and the results are displayed graphically.
The CMA 600 comes with software that facilitates quick and easy graphical analysis of the results.
Samples from up to three individuals each with one to three catheters can be analyzed simultaneously. Note that no reference values have been established for microdialysates.
There are two combinations of CMA 600; "CMA 600 Microdialysis Analyser for bedside use", this is the mobile system, and "CMA 600 Microdialysis Analyser for laboratory use" (see Figure 4 and Figure 5).

Methods for analysis of a number of substances have been developed by CMA/ Microdialysis.

CMA 600 is easy to use: The microvial is transferred from the sample holder to the analyzer, one button is pushed, the result appears as a new point on the trend curve within a minute.
Clinical staff is expected to operate CMA 600 routinely after adequate training.

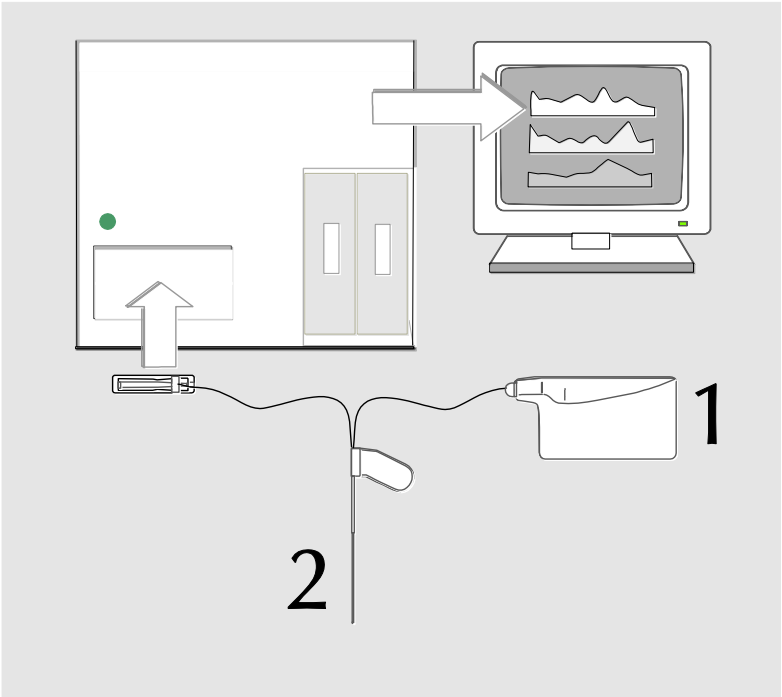
The dialysing properties of the microdialysis catheter can be expressed as its recovery for a particular substance. By comparing the concentration of the substance in the microdialysis catheter effluent with the concentration of the medium it is possible to calculate the recovery of the substance. The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

In the CMA Cerebral Tissue Monitoring System, the main factors influencing recovery are fixed, including the microdialysis catheter membrane length (10 mm) and diameter (0.6 mm) and the perfusate flow rate (0.3 µl/ min). In vitro tests have demonstrated that these design parameters provide average recoveries of 100% plus or minus 10%

CMA 600 Microdialysis Analyser is part of the CMA Cerebral Tissue Monitoring System (Figure 1) consisting of:
1. CMA 106 Microdialysis Pump: portable and battery powered, microdialysis syringe pump.
2. CMA 70 Microdialysis Catheter: microdialysis catheters with inlet tubing connected to the pump syringe and outlet tubing connected to –
3. a microvial for collecting the small sample volumes.
4. The CMA 600 Analyser, to which the sample is transferred for analysis.
5. Monitoring screen, where the analyses results are displayed.

See the respective manual for more information.

Figure 1



1.2. Intended Use

The CMA Cerebral Tissue Monitoring System measures intracranial glucose, lactate, pyruvate, glycerol and glutamate levels and is intended as an adjunct monitor of trends in these parameters indicating the perfusion status of cerebral tissue local to catheter placement. Because the CMA System values are relative within an individual, these should not be used as the sole basis for decisions as to diagnosis or therapy. It is intended to provide additional data to that obtained by current clinical practice in cases where ischemia or hypoxia is a concern.

1.3. Precautions

The CMA Cerebral Tissue Monitoring System's measurements of glucose, lactate, pyruvate, glycerol and glutamate are intended as adjunct to other monitoring information as well as standard clinical practice for the care of head injured patients. At the discretion of the physician, this may include ICP, pO_2, pCO_2, laboratory values, and clinical examination.

Reference values for markers of intracranial ischemia, such as glucose, lactate, pyruvate, glycerol, glutamate, tissue pO_2, ICP, etc., have not been established. Therefore, the intracranial glucose, lactate, pyruvate, glycerol and glutamate values provided by the CMA System are intended to show trends, not absolute measures, and are relative within a patient.

The measurements of glucose, lactate, pyruvate, glycerol and glutamate obtained with the system reflect the environment local to catheter placement and should not be taken as global indications of cerebral status.

1.4. Description of CMA 600 Microdialysis Analyser

Figure 2. CMA 600 front view.

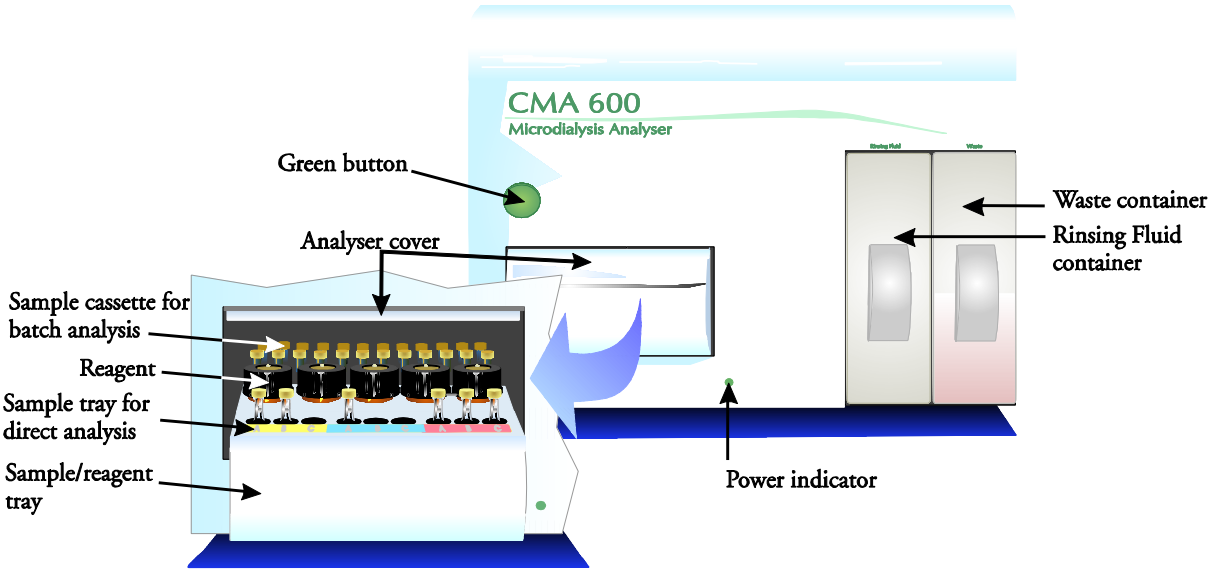


Figure 3. CMA 600 rear panel

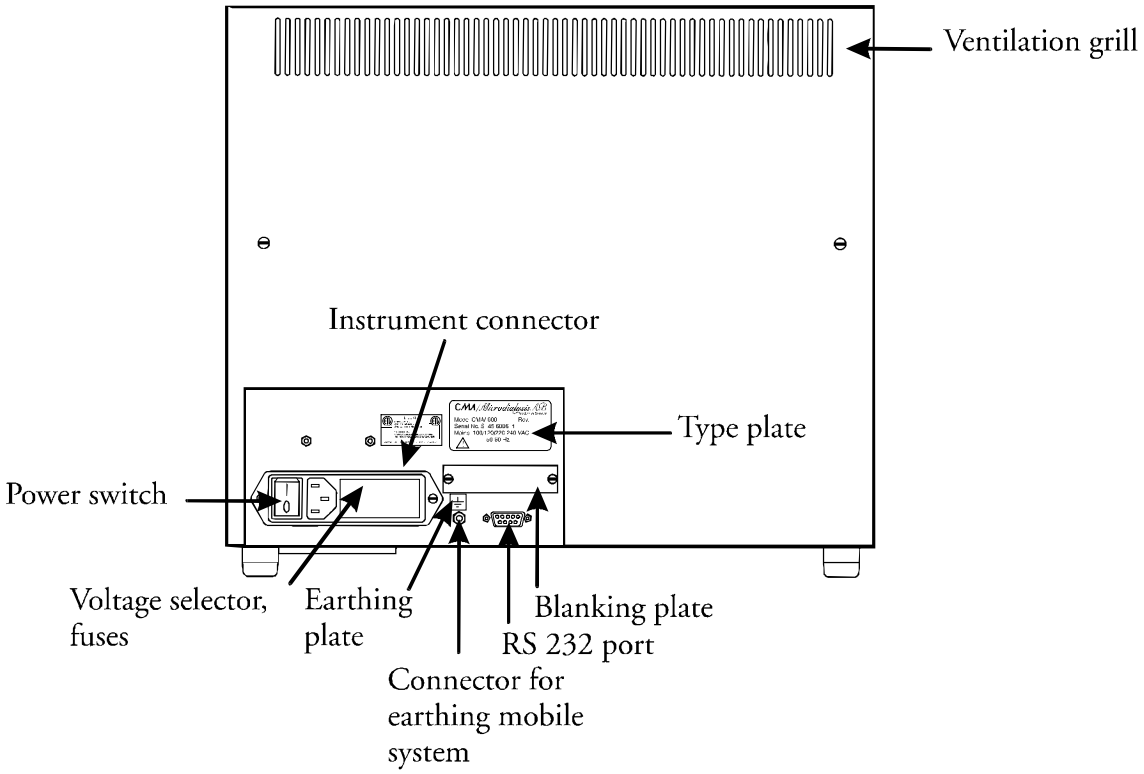


Figure 4. CMA 600 Microdialysis Analyser in a mobile system.

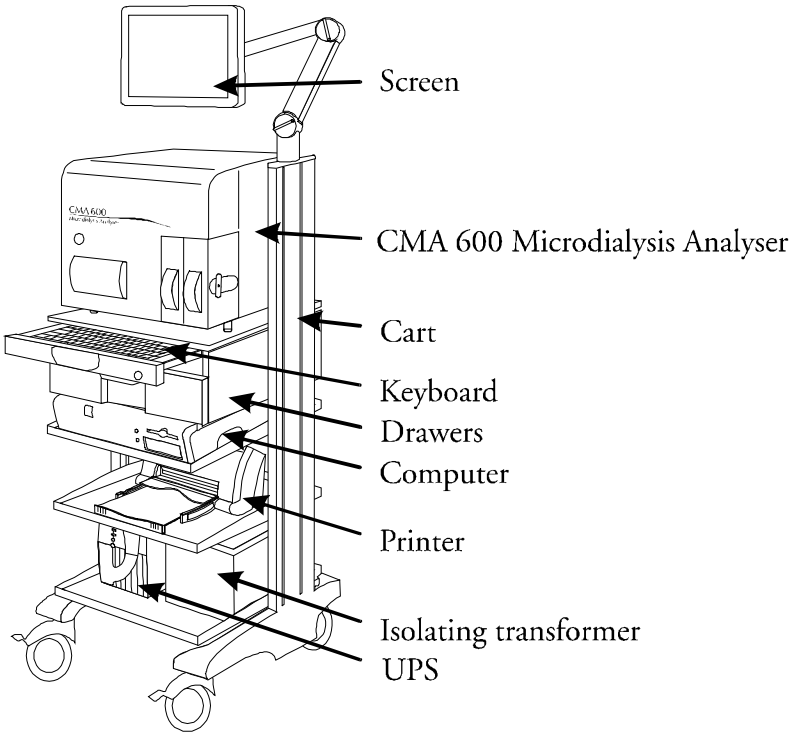
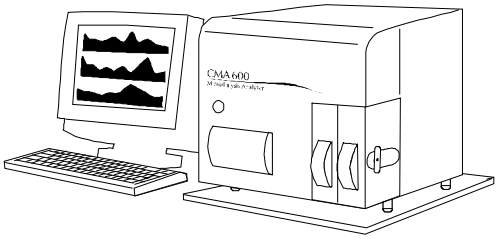


Figure 5: CMA 600 Microdialysis Analyser with computer



2. Safety, warranty and service

2.1. Safety

CMA is liable for the safety and reliability of its equipment only if:
a) maintenance, modifications, and repairs are carried out by authorized personnel;
b) components are replaced with CMA-approved spare parts;
c) devices are used only with CMA-approved accessories and consumables; and,
d) The devices are used in accordance with CMA´s operating instructions.

2.2. Warranty

CMA/ Microdialysis AB (CMA) offers one year warranty, from the day of purchase, on defective material and assembly.

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

CMA is only responsible for replacement of defect parts, not of wear parts. CMA is not responsible for any personal injury or any damage resulting from incorrect use of the analyzer.

2.3. Service

CMA recommends routine service by authorized personnel with six months interval.

Routine service includes:
- Replacing pump tubing, cannula and syringe.
- Cleaning the fluid pathway.
- Cleaning those parts of the instrument in contact with fluids, externally and internally.
- Checking lamp- and cell-house temperatures.
- General inspection of the analyzer.
- Function test.

Post warranty a service agreement may be purchased.

For more information, please contact the service department:

Sweden:
CMA/ Microdialysis AB
Box 2
SE-171 18 Solna
Phone: +46 8 470 10 00
Fax: +46 8 470 10 50
E-mail: cma.service@microdialysis.com
Web: http:/ / www.microdialysis.com

USA:
CMA/ Microdialysis, Inc
73 Princeton Street
N. Chelmsford, MA 01863
Phone 800 440 4980, 978 251 1940,
Fax 978 251 1950
E-mail: cma.service@microdialysis.com
Web: http:/ / www.microdialysis.com

3. Installation

3.1. Unpacking and installation.

CMA service personnel or personnel designated by CMA must perform all unpacking, installation and function tests of the instrument.

When moving the analyzer, avoid damaging the analyzer cover.

The analyzer should be placed on a table or rack allowing 20 mm air space under the instrument. The instrument should be placed in a draft free place and not in direct sun light. For ranges of acceptable temperature and humidity, see the technical specifications.

3.2. EN 60601 requirements

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

4. Technical specifications

4.1. Technical data

Voltage	100 / 120 / 220 / 240 VAC 50 / 60 Hz
Power consumption:	100 VA
Fuses:	220/ 240VAC - 2 x T2.5AL 110/ 120 VAC - 1 x T6.3A 6.3 x 32 mm, CSA and UL approved
Power cord:	For USA/ Canada - UL544 "Green dot" Hospital grade power cord.
Dimensions W x D x H:	393 mm x 445 mm x 345 mm
Weight:	23 kg
Principle:	Kinetic enzymatic analyzer
Samples:	Microdialysates
Sample vials:	Microvial
Sample volume, used:	≤ 1.0 µL/ analysis (typical 0.5 µL/ analysis, depending on analyte and conc.)
Minimum sample volume:	Sum of sample volumes per analyte + 2.0 µL
Reagent consumption:	≤ 15 µL / analysis
Imprecision:	≤ 6 % CV (within run)
Calibration:	Automatic (manual possible)
Warm-up time:	60 minutes
Measuring time:	30 sec
Throughput time / test:	60 - 90 sec
Detector:	Single beam filter photometer
Light source:	Hg-lamp
Wavelengths:	365 and 546 nm
Detector cell:	Capillary flow cell 10 mm, 2 µL
Reaction temperature:	37 °C

CMA Microdialysis AB reserves the right to make changes in the specifications without prior notice.

4.2. Operating environment

- The analyzer is manufactured for indoor use and should be placed in a draft free place and not in direct sunlight.
- No radio transmitters, cellular phones or other wireless communication devices should be used in the vicinity of the analyzer.
- The analyzer should not be submitted to higher levels of disturbance as specified in
  IEC 60601-1-2 Medical electrical equipment - Part 1: General requirements for safety - 2. Collateral Standard: Electromagnetic compatibility - Requirements and tests and
  IEC 61010 Safety requirements for Electrical Equipment for Measurement, Control and Laboratory use.

Transport and storage

Temperature at transport: -40 to +70 °C. NB. If transportation is done at a temperature at or below 0 °C the CMA 600 liquid system must be empty of any liquid.
Temperature at storage: +5 to +45 °C.
Relative humidity at transport and storage: 10% to 100% RH, non-condensing.
Atmospheric pressure: 50 till 106 kPa.

Operation

Ambient temperature: +18 to +28 °C.
Relative humidity: 30% to 75%.
Atmospheric pressure: 70 to 106 kPa.
Voltage variation: Max. ± 10% of nominal voltage.

5. Classification and Regulations

CMA 600 Microdialysis Analyser meets international standard *EN 60601-1 Medical Electrical Equipment - General Requirements for Safety*:

Paragraph 5.1: ”CLASS I EQUIPMENT”

Paragraph 5.3: ”Ordinary EQUIPMENT”

Paragraph 5.4: Disinfection: the outside of the instrument is cleaned with disinfectant (70% ethanol or equivalent).

Paragraph 5.5: ”Equipment not suitable for use in the presence of a FLAMMABLE ANAESTHETIC MIXTURE WITH AIR OR WITH OXYGEN OR NITROUS OXIDE”.

Paragraph 5.6 ”CONTINUOUS OPERATION”

CMA 600 Microdialysis Analyser meets international standard *EN 61010 class II Safety requirements for Electrical Equipment for Measurement, Control and Laboratory use* .

The CMA 600 Microdialysis Analyser bears the CE label in accordance with the provisions of the European Directives for LVD (Low Voltage, 73/ 23/ EEC and 93/ 68/ EEC) and EMC (89/ 336/ EEC, 92/ 31/ EEC and 93/ 68/ EEC)) and IVDD (98/ 79/ EC).

The CMA 600 Microdialysis Analyser is ETL listed according to
UL No 2601-1 and CAN/ CSA-C22.2 No. 601.1-M90
UL No 3101-1 and CAN/ CSA-C22.2 No. 1010.1-92.

6. Text and symbol explanation

Rinsing Fluid Marks place for Rinsing Fluid container. (Figure 2)

Waste Marks place for Waste container. (Figure 2)

 User must consult user manual before handling.

 Functional earth for mobile system

 The product meets EU directives for EMC and LVD. (See section 5 above).

Before June 30 2004 The product is ETL listed. (See section 5 above)

After July 1 2004 The product is ETL Listed (See section 5 above)

7. Instructions for use

7.1. General

CMA 600 Microdialysis Analyser is controlled by PC-software operating under Windows.
The instrument functions are represented as icons. The user runs the instrument using the mouse and the keyboard. We recommend that the user read this manual before operating the instrument.

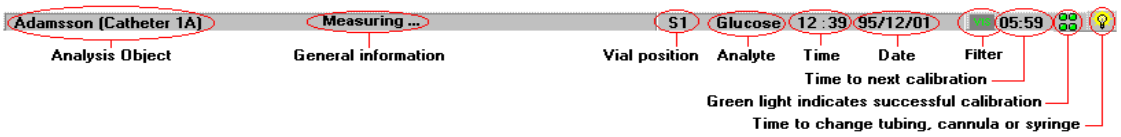
7.2. Green button

Pressing the **green button** (Figure 2) causes the sample / reagent tray to extend. Samples can then be loaded. The green button pressed again retracts the sample / reagent tray and commences the analysis.

The green button lamp:
1. Not illuminated: The analyzer is not ready for use.
2. Illuminated: The analyzer is on and mechanically initialized.
3. Flashing: The button has been pressed.

7.3. Status bar

The status bar shows the current status: the person from whom samples are being analyzed, catheter, analysis phase, vial position, analyte, time and date, filter, time interval to next calibration, calibration results and an indication whether it is time to replace peristaltic pump tubing, cannula or syringe.



7.4. Light indication

The lights, to the right on the status bar, indicate how the latest calibrations succeeded. Clicking on any of the lights is equivalent to clicking on

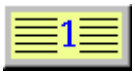
(see page 16). In the information window appearing, the same lights are shown, each one above the corresponding analyte position.
Green steady light indicates that the last calibration is OK.
Green blinking light indicates an ongoing calibration.
Red steady light indicates that more than 12 hours has elapsed since the last successful calibration.
Red blinking light indicates that the last calibration was not approved.

7.5. Icons

Normal menu

 Exit from CMA 600 program.

Check/ Change reagents and calibrator

 Registration

Analysis

 Print data

Shift graph 4 hours

Shift graph 24 hours

Shift graph to current time

 Export data to Excel file

 Analysis of control sample

 Show results for control sample

 To Instrument menu

 Help

Instrument menu

Mechanical initialization

 Rinse fluid pathway

 Extend sample/ reagent tray

Manual calibration

 Show logfile

 Utility Program. See help file for more information (click  or press F1).

 Database

 Show control graphs

Batch analysis

Back to Normal menu

 Help

7.6. Manual and Help (On-line manual)

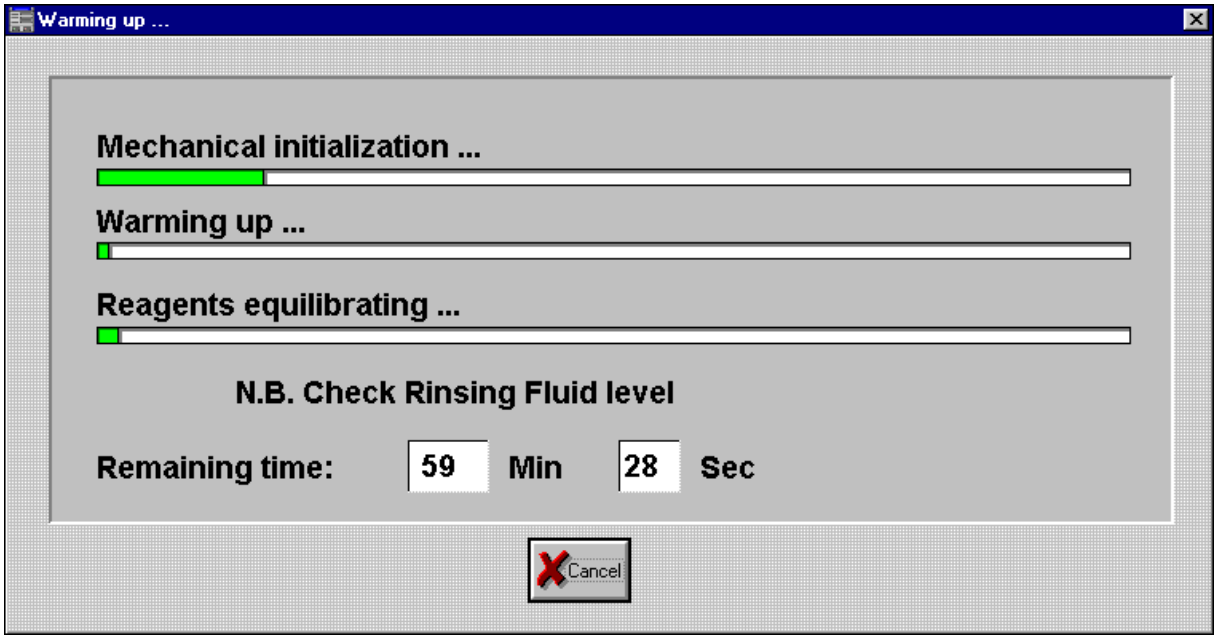
1. This manual describes the most important CMA 600 software functions. More information can be found in the on-line manual, opened by pressing F1 or clicking on *Help* or  .
2. If a system message appears, click on *Help* for instructions.

7.7. Starting the CMA 600.

CMA 600 requires a one-hour warm-up time to reach working temperature and lamp stabilization.

1. Turn on CMA 600, computer and screen.
2. If UPS (Uninterruptable Power Supply) is installed, turn on the instrument from the UPS.
3. The following window will open:

Figure 6



4. Check that the Rinsing Fluid container is at least 2/ 3 filled. To fill, see section 13.2.
5. Check that the Waste container is filled to no more than 1/ 3 capacity. To empty, see section 13.2.
6. Prepare reagents (see section 7.8). Remove the rubber stopper from the calibrator bottle. The warming up sequence can be interrupted but the reagents must be prepared and equilibrated before use and the CMA 600 electro-optical system must be stabilized.
7. Wait for mechanical initialization. Check that the green button is lit.

8. After the mechanical initialization, the analysis table extends and the following dialog appears (

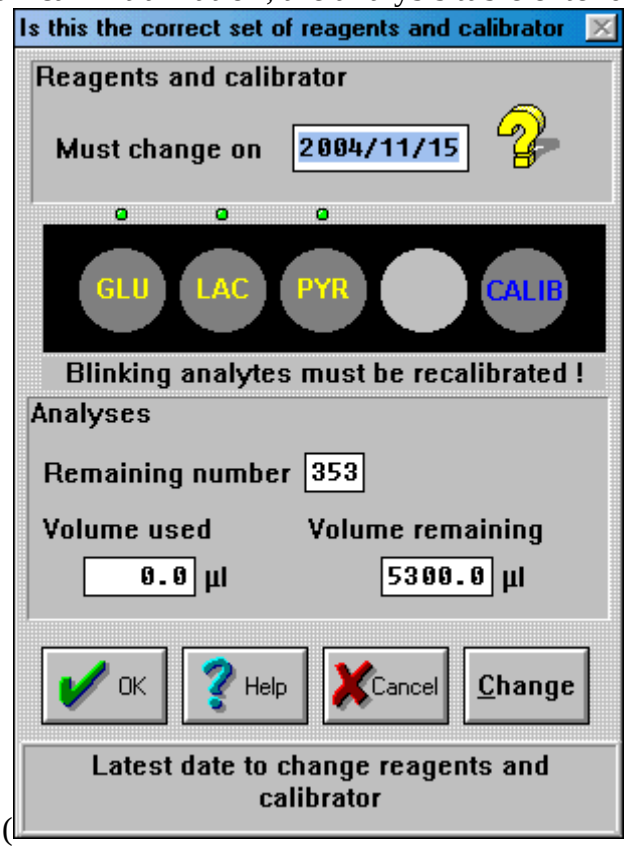


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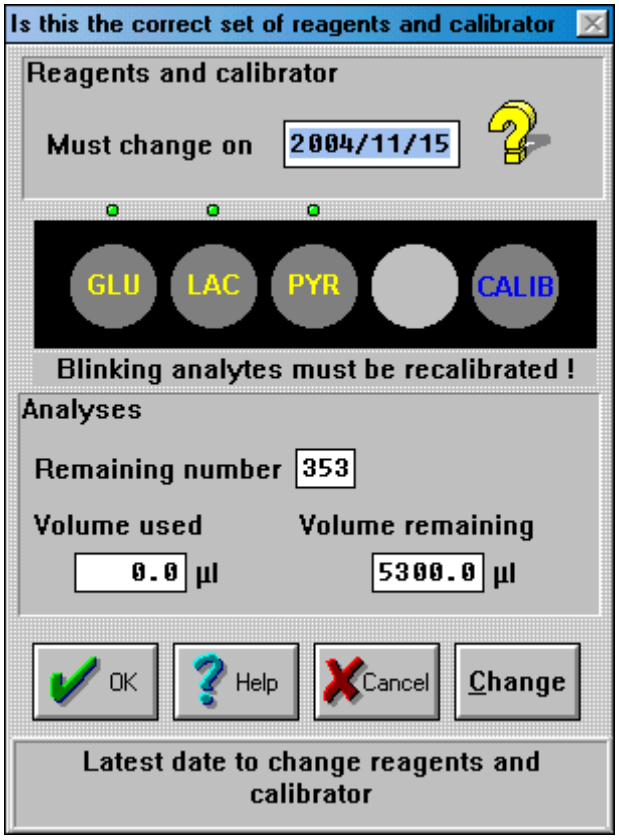
Figure 7

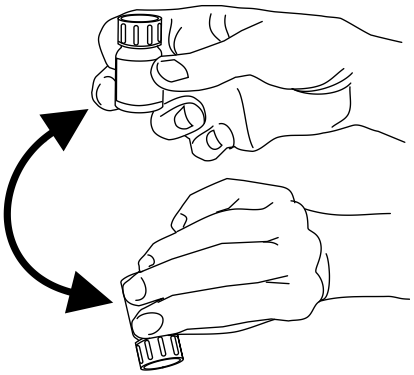


9. Click OK to accept current reagents set up or click *Change* to change the reagents set up (May require CLIA authorization). Put the reagent and calibrator bottles in the CMA 600 and finish with clicking OK.
10. A calibration is made as soon as the warming up period has elapsed (the warming up window, Figure 6, is automatically closed).
11. Register a person. See section 7.11.
12. The instrument is now ready for analysis of microdialysis samples.

7.8. Preparation of reagent solution

1. Unscrew the cap with the membrane from the reagent bottle. Remove and discard the rubber stopper.
2. Transfer the contents of the buffer bottle to the reagent bottle.
3. Replace the cap with the membrane on the reagent bottle.
4. Dissolve the reagent by gently turning the bottle upside-down (see Figure 8 below) at least ten times. Let the reagent stand and equilibrate in room temperature for at least 30 minutes. Turn the bottle twice upside-down before placing it in the CMA600.

Figure 8



7.9. Loading reagents and calibrator

1. Prepare the reagents (see section 7.8). NB. Remove the rubber stopper from the calibrator bottle. The warming up sequence can be interrupted but the reagents must be prepared and equilibrated before use and the CMA 600 electro-optical system must be stabilized.

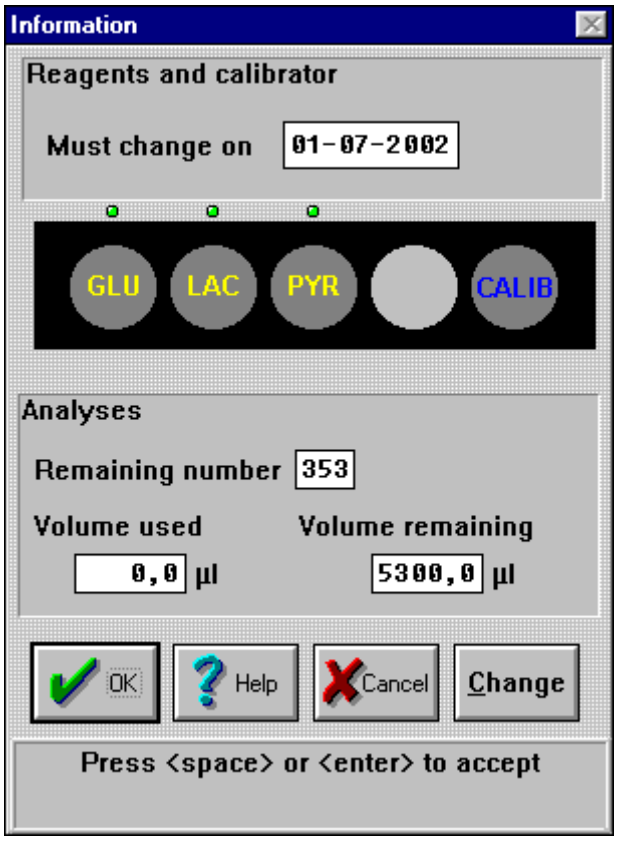
2. Click on *Reagents*. (Figure 9)

Figure 9

3. The window displays the present reagents and calibrator set-up. To change, click on *Change* (Figure 10) Click on *OK* or *Cancel* to close the information window.

(Click *OK* to accept reagents, Click *Cancel* if automatic calibration is not wanted now, click *Change* to change reagents).

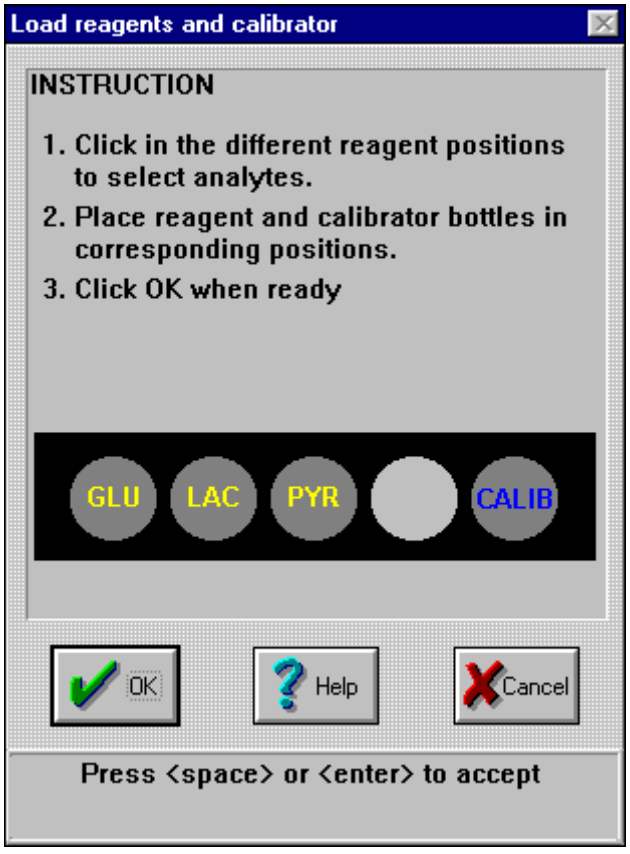
Figure 10



In the figure above the field notated as “Remaining number” indicates the number of analyses that can be made before the analyzer runs out of reagent.
The “Volume used” figure indicates the total amount of reagent that has been used since the last reagent/ calibrator switch.
The “Volume remaining” figure indicates the remaining amount of reagent since the last reagent/ calibrator switch.

4. The sample/ reagent tray extends. A window opens (Figure 11). Select reagents by clicking with the left mouse-button.
5. Place reagent and calibrator bottles on the sample/ reagent tray as shown. Calibrator should always be placed in the far right position.
6. When all bottles are in the correct position, click *OK*.
7. The warming up dialogue appears. If the Rinsing Fluid container is less than 2/ 3 full, see section 13.2.
8. The analyzer performs an automatic calibration as soon as Reagents equilibration has been carried out and the warming up dialogue has been closed automatically. The automatic calibration takes from 5 to 15 minutes depending on the number of reagents used, followed by *Calibration ready* appearing in the status bar.
9. An Error message will appear if the calibration is not accepted. For information click *Help*.

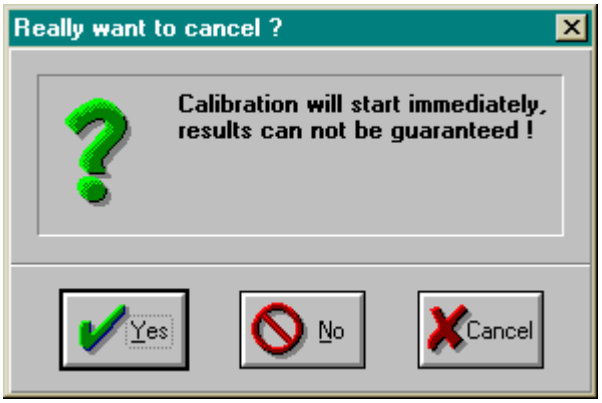
Figure 11



7.10. The interruption of the Warming up dialogue

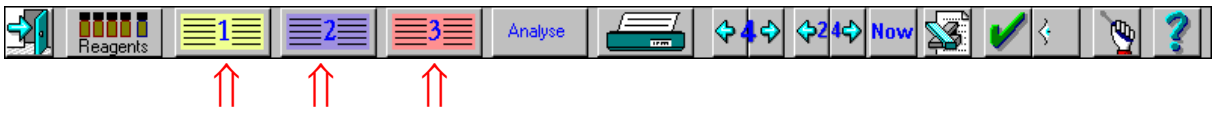
The warming up sequence can be interrupted but the reagents must be prepared earlier and equilibrated before use and the CMA 600 electro-optical system must be stabilized. Click Cancel in the Warming up dialogue and click Yes in the following dialogue that appears, (Figure 12)

Figure 12



7.11. Registration

Figure 13



1. Click on icon 1 (yellow), 2 (blue) or 3 (red) to register (see section 7.5), or click on icon for database to reregister a person from the database (see section 7.23).
2. To deregister a person for whom analysis is completed (see section 7.22).

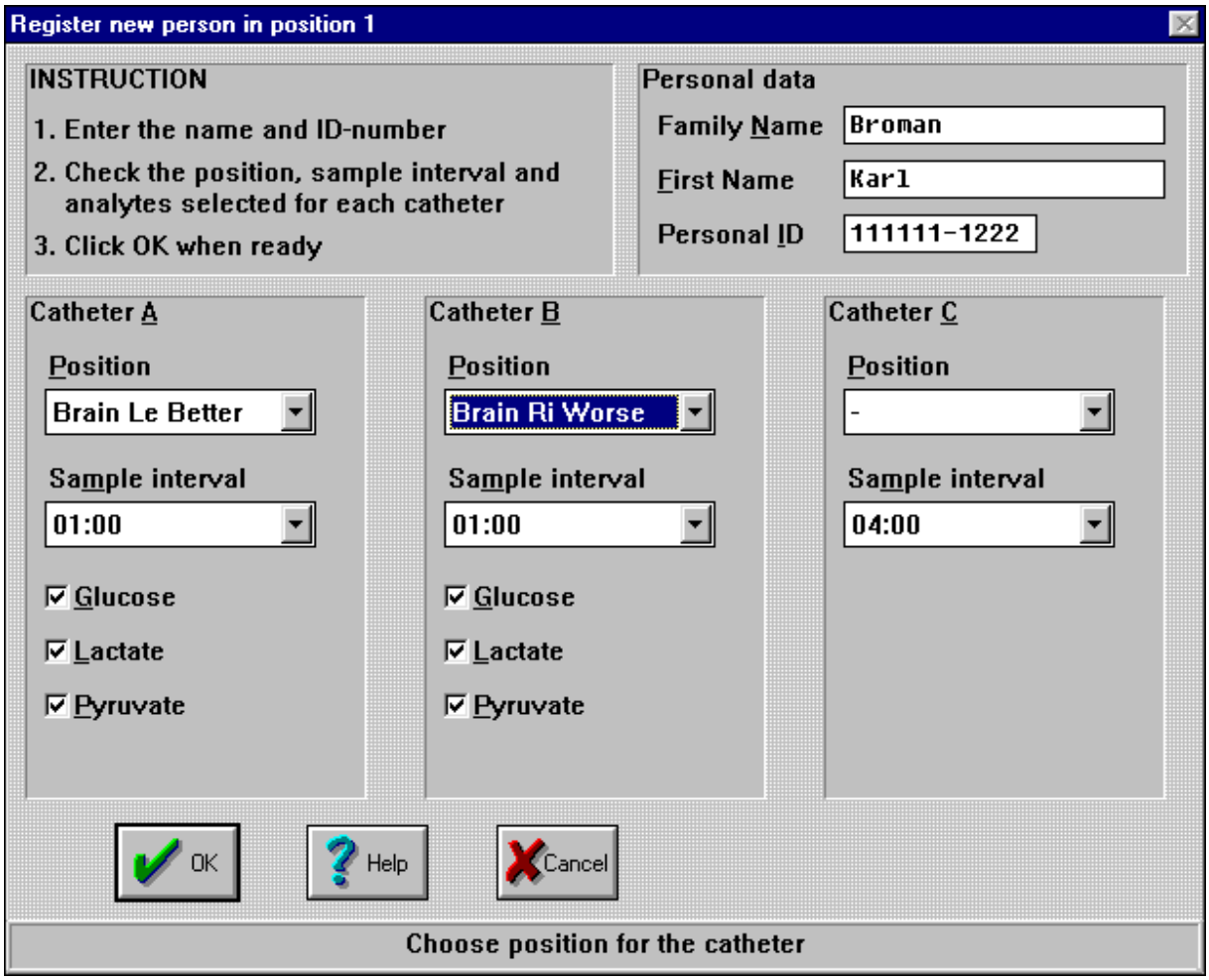


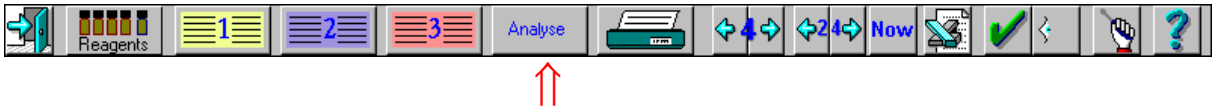
Figure 14

3. Enter family name, first name and ID in the appropriate fields. ID must be unique for each person!
4. Enter location of microdialysis catheter(s) and sampling interval.
5. Check-mark boxes for analyses to be performed.
6. When registration is completed, click *OK*.

7.12. Analysis of microdialysis samples (may require CLIA Authorization)

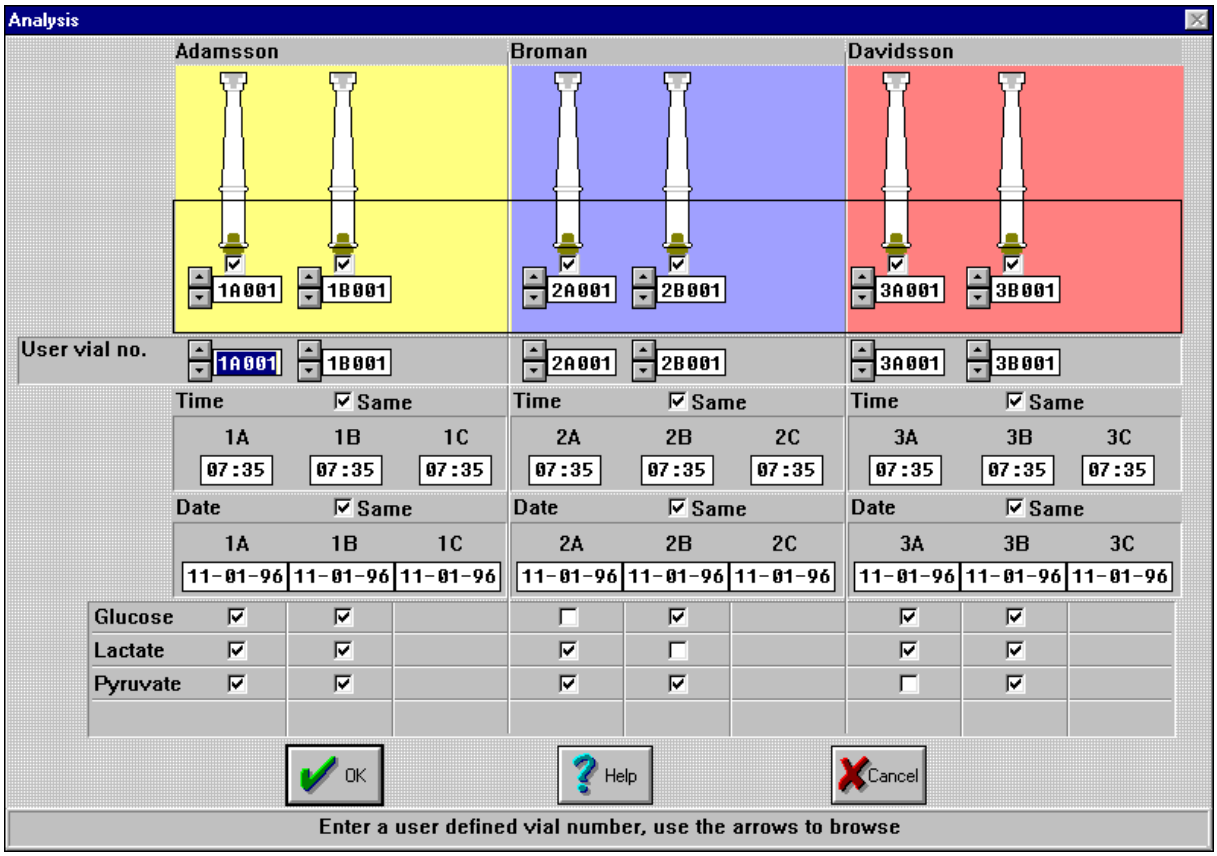
1. Push the Green button or click *Analyze*. (Figure 15)

Figure 15



2. The sample / reagent tray extends and the *Analysis* window opens with three sections, 1 (yellow), 2 (blue) or 3 (red), each with three sample positions for catheter A, B or C. (Figure 16) (For example, the third catheter for the second person would be designated 2(blue), C)

Figure 16



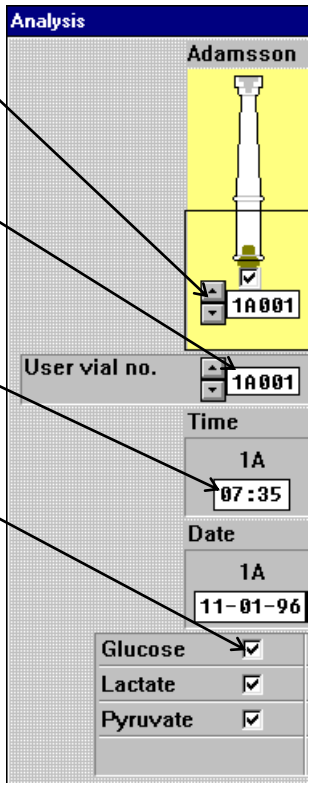
3. Place the microvials in the corresponding position on the analysis tray with the narrow end of the vial upwards. Each vial to be analyzed will be indicated in white on the screen and the box below it will be check-marked.
4. An ID-number will appear below each vial. In the example from Figure 16, 1A024, 1 is for position number, A for catheter and 024 a number which is updated for each vial. Each vial analyzed is assigned a unique ID-number, which can not be changed by the user.
5. Check that sampling time and date are correct, change, if necessary, by clicking on time or date and entering the correct value. If the box *"same"* is check-marked, the sampling time or the date for all catheters for this person will be changed.

6. Verify analytes for each catheter and, if necessary, change by check-marking/ clearing appropriate boxes.
7. Designate user vial numbers by typing the number or by clicking on the up or down arrows to the left of the user vial number. The number can be used for identification of vials provided that a unique number has been entered for each vial.
8. Press the green button again or click on *OK* to confirm that all data have been entered. The analysis begins.
   Note: The analysis will start automatically after two minutes even if no confirmation has been made.

7.13. Reanalysis

If reanalyzing a sample, start as described in 7.12.1-4. Use the up or down arrow keys to select the correct vial ID.
Check that the correct user vial no. is shown.
Proceed as above.
The reanalyzes will have the same vial ID but the sampling time will be increased by one minute to separate the two analyses.
Select analytes by clicking in the corresponding checkboxes.

Figure 17



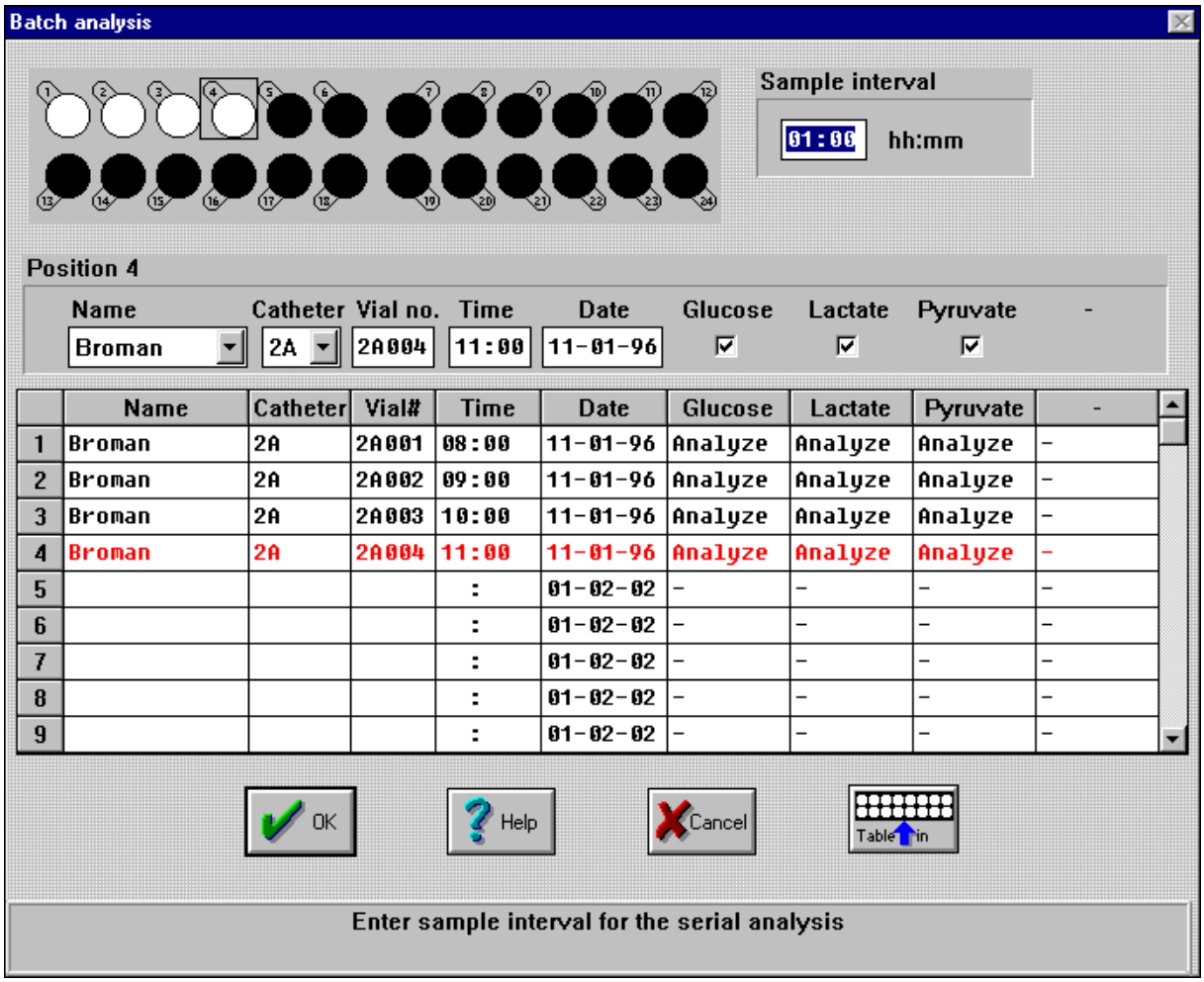
7.14. Batch analysis (may require CLIA Authorization)

1. Click on the Instrument menu icon and then on *Batch analysis* (Figure 18) producing the *Batch analysis* window. (Figure 19).

Figure 18

The following window is shown

Figure 19



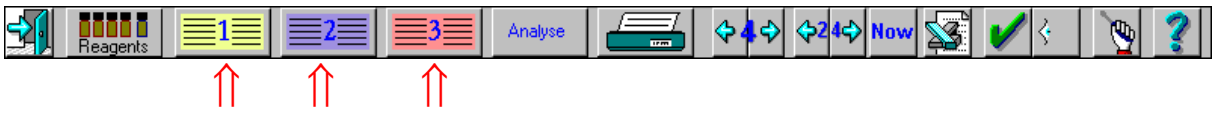
	Name	Catheter	Vial#	Time	Date	Glucose	Lactate	Pyruvate	-
1	Broman	2A	2A001	08:00	11-01-96	Analyze	Analyze	Analyze	-
2	Broman	2A	2A002	09:00	11-01-96	Analyze	Analyze	Analyze	-
3	Broman	2A	2A003	10:00	11-01-96	Analyze	Analyze	Analyze	-
4	Broman	2A	2A004	11:00	11-01-96	Analyze	Analyze	Analyze	-
5				:	01-02-02	-	-	-	-
6				:	01-02-02	-	-	-	-
7				:	01-02-02	-	-	-	-
8				:	01-02-02	-	-	-	-
9				:	01-02-02	-	-	-	-

2. Positions 1 to 24 are shown at the top: white indicates active, black inactive and gray already analyzed. Activate or deactivate by right-clicking.

3. To activate the first position, click on corresponding row in the table (or click on the first position on the diagram of the batch analysis cassette).
   Select a name from the list of registered persons.
   Choose catheter from the list
   Enter vial ID for the first vial.
   Enter time and date for sampling.
   Change analytes by clicking in appropriate box
4. By right-clicking on a vial position in the batch analysis cassette, several vials will be marked automatically. The sampling time assigned to each position is automatically incremented by the sampling interval. (If sampling interval has been changed from initial registration, before right-clicking, type new sampling interval in appropriate box).
5. Repeat steps 3 and 4 for each additional catheter and person from whom samples are to be analyzed. The first vial in any series can be placed in any free position.
6. To correct or remove already analyzed samples:
   -mark the first vial of the batch to be erased by right-clicking on the vial position to make it black
   -right-click on the last vial to be erased
7. It is also possible to edit in the table. Select the catheter and name from the drop down box above the table.
8. Select the desired analyte (s). Unless otherwise specified the analyses initially indicated will be performed. In each column A (Analyze) indicates that analysis is desired, R (ready) that it has been completed and a minus sign (-) for no analysis.
9. When all input data are correct click on *Table out* or press the **Green button**. Wait for the sample/ reagent tray to extend and place the microvials in the batch analysis cassette.
10. Start analysis by clicking *OK* (or press the **Green button**).

7.15. Record events

Figure 20



1. Method 1. Select 1 (yellow), 2 (blue) or 3 (red). (Figure 20)
   Click on *Events* (Figure 14) and a new window opens.
   Method 2. Right-click on the name in the graph.
2. Click on *New* and another window opens. Enter event and time and sign.
   Click *OK* in both windows.

7.16. Remove or change an event

1. Right-click on the name in the head of the graph and a window opens. Click on the event to be erased or edited.
2. Remove: Click on *Remove* and *OK*.
3. Edit: Click on *Edit* and another window opens. Enter changes. Click *OK* in both windows.

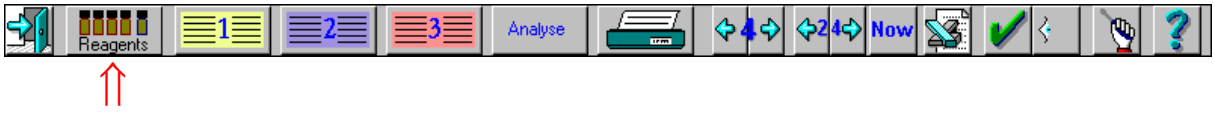
7.17. Edit data

1. Right-click on the analyte in the graph where data is to be edited.
2. In the window that opens, click on the row where data is to be edited. Click on *Edit*.
3. Date, time and vial-ID can be changed in the next window. A sample can also be marked as missing. Such a sample will not be shown in graphs and in printouts it will be shown as missing.

7.18. Exchange of reagent and calibrator

1. *Reagent too old or empty* appears when there is time to change reagents.
   Note: All reagents and calibrator must be exchanged at the same time.
2. Click on *Reagents*. (Figure 21)

Figure 21



3. A window opens showing remaining reagent volumes and number of samples for which the remaining reagent will suffice. (See Figure 10)
4. To load new reagents and calibrator, see section 7.9.

7.19. Editing graphs on the screen

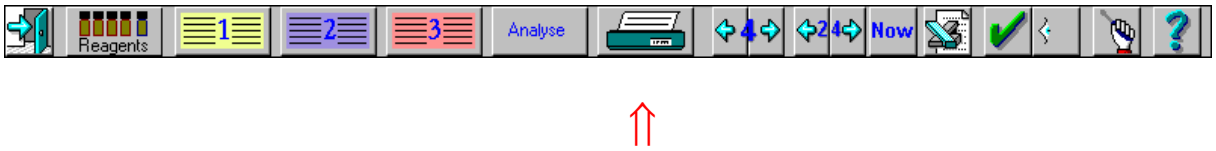
This table describes how graphs are edited. More information can be found in the electronic manual, see section 7.6 and *Help*.

Change	Mouse-position	Mouse-button	Result
Change of presentation	Head of graph	Left (circulating with repeated clicking)	Three alternatives where one or three persons are presented for one or three days
Change of catheter	Text catheter A, B, C in head of graph	Left	Browse among registered catheters with analyzed samples
Increase Y-scale	Upper arrow	Right	Stepwise increase of Y-scale
Decrease of Y-scale	Upper arrow	Left	Stepwise decrease of Y-scale
Change of Y-scale	Text Y-scale	Left	A window opens. Change interval, click OK.
Increase Y-offset	Lower arrow or Text Y-scale	Right	Stepwise increase of the value for time axis to cross Y-axis.
Decrease Y-offset	Lower arrow	Left	Stepwise decrease of the value for time axis to cross Y-axis.
	Text time-scale	Right	
Y-offset back to 0	In graph	Right	Offset returns to 0
Zooming an analyte	In graph	Left	Graph is zoomed to cover the entire screen
Zoom back to default	In graph	Left	Graph back to normal size
Change of date interval	Date interval in head of graph	Left Right	To display graph including first data point To display graph including last data point
Copy of graphs	Name in head of graph	Left	Data on the screen are copied
To edit data	Analyte	Right	Change date, time or mark missing sample

7.20. Printing

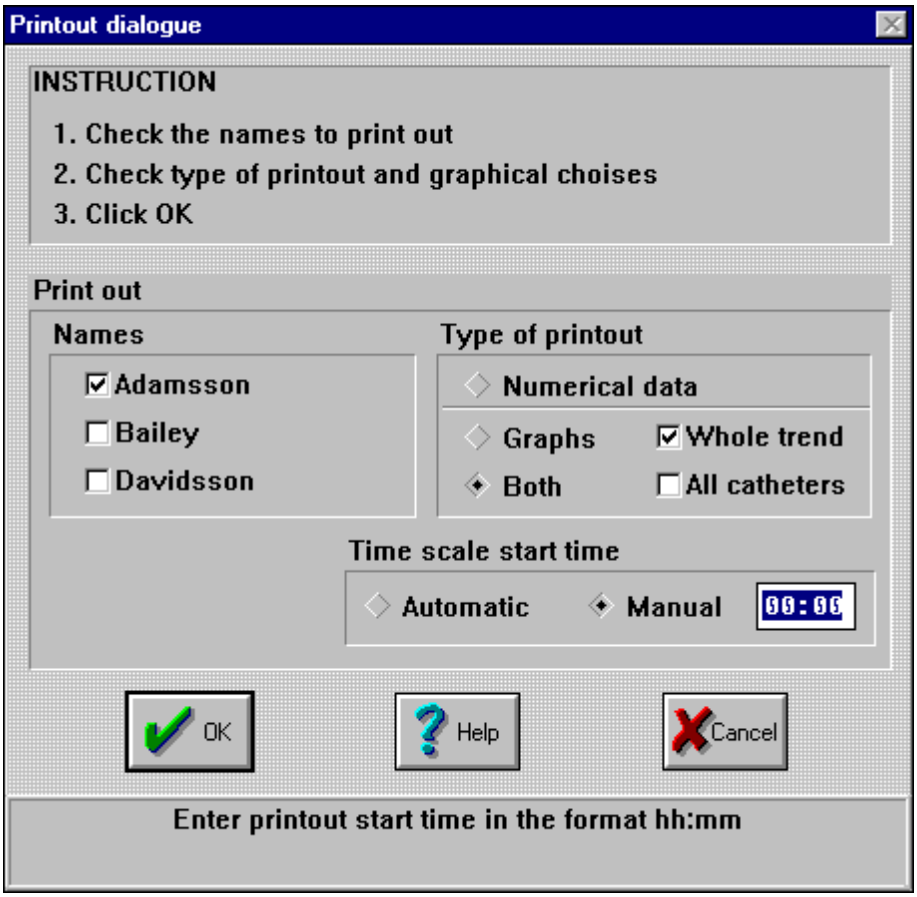
1. Click on *Printer*. (Figure 22)

Figure 22



2. A window is opened (Figure 23). Click on the name of the person for whom data are to be printed and select the desired data.
3. *"Numerical data"* gives a list of all results for selected persons.
4. By check marking the box *"Whole trend"* all graphs for the selected catheter will be printed. By check marking *"All catheters"* graphs for catheters not shown on the screen will also be printed.
5. If the entire graph is marked, starting time for graph printout can be chosen.
6. Automatic - the program selects a suitable starting time
7. Manual - insert desired start time
8. Click *OK* to start print out.

Figure 23



7.21. Preview of data

1. Click on the register icon for the person whose data is to be shown according to section 7.11.
2. Click on the magnifying glass (as shown in the dialogue in Figure 14) and data will be shown on the screen.

7.22. Deregister a person

After deregistering a person, data for this person is no longer available on the screen. (Such data can be retrieved from the database.)

1. Click on 1, 2 or 3 to select person to be deregistered (See Figure 13).
2. A window opens (Figure 14), click on 

, another window opens showing the person to be deregistered. Check that person ID corresponds. Click on *OK* to deregister.

7.23. Database

Data already analyzed can be retrieved, by using the database function. Using the database function it is possible to reregister a person and in this way be able to show or print "old" data and also make new analyses for that person.

1. Make sure that at least one of the register positions is free, i.e. not more than two persons are registered.
2. Select the Instrument menu by clicking on  .
3. Click on the database icon  , the database dialogue is shown.
4. Follow the instructions on the screen to reregister a person, i.e. double click on the person to register. NB only data for persons that are not registered are shown in this dialogue.
   In this dialogue it is also possible to erase data and copy data to or from diskette.

7.24. More than four analytes

To run more than four analytes the person must be registered twice. I.e. two different person ID:s must be used, as one person ID cannot contain more than four analytes.

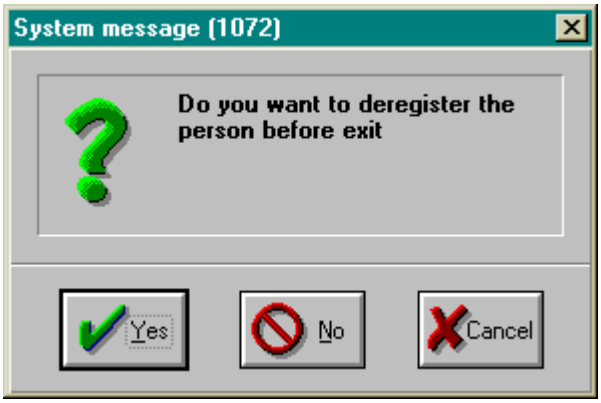
1. Run the first analytes as usual and save the Microvials (in the freezer if necessary).
2. When the analyses are ready, change reagent setup and let calibrate.
3. Register a new person with the new reagent setup.
4. Analyze all vials using batch analysis and remember the user vial number.

7.25. Shut down of CMA 600

1. Click on  .
2. A window opens with the question*: Really want to exit?* Click *Yes*. (Figure 24).

Figure 24

Figure 25



3. The dialogue above (Figure 25) will appear if there is at least one person registered upon exiting. Click Yes if you want to deregister the person(s) before exiting the CMA 600 program. If you don't want to deregister before exiting, click No and the persons will stay registered. The next time you start CMA 600 the registrations remain in the same positions as before exiting the program.
4. The sample/ reagent tray will extend. Reagents, calibrator and microvials can be removed. When this is done, click *OK*.
5. The CMA 600 program is now closed. Exit from Windows. Turn off the CMA 600, computer and screen. If UPS is installed, the UPS power switch turns off the entire system.

7.26. Emergency stop

If an activated command must be interrupted, press F2. A window opens with the question: *Really want to stop?* Click *Yes* and the system stops.

8. Calibration

The analyzer will automatically perform calibration every 6 hours. Manual calibration is also possible at any time. Click on *Manual calibration* (section 7.5).

9. Analysis of control samples

Select  *Instrument menu*. Click on  *Analysis of control sample* and follow the instructions on the screen. When the control samples are analyzed, click on  *Show results for control sample* and note the results (section 7.5).

10. Sample Handling (Frozen samples)

Frozen samples should be thawed in an incubator, not in a water bath, at 40 -50° C for maximum 10 minutes to reduce the risk for formation of air bubbles in the samples.
The tubes are centrifuged 10 - 15 seconds at 2000 g. During centrifugation the vial has to be placed so that it rests on the small stopper and not on the rim of the vial, otherwise there is a risk that the small stopper is pushed out of the vial.
The assays should be performed as soon as possible before cooling to room temperature.
The tubes ought not to be refrozen after analysis if the volume is < 15 µL.
Evaporation during freezing and thawing affects the volume which gives elevated values, up to 5% at small volumes (< 15 µL).

11. Disposal of consumables and accessories

1. Disposal of reagents and calibrator: See reagent manual regarding the disposal of reagents and calibrator.
2. Disposal of Rinsing Fluid: See section 13.2.
3. Microvials can be treated as normal waste unless there is risk for infection.
4. For disposal of the CMA 600 Analyser, or parts thereof, contact CMA / Microdialysis for more information

12. Trouble shooting

See section 7.6, Manual and *Help*.

13. Routine maintenance

13.1. Cleaning the instrument

Wipe the outside of the instrument with disinfectant (70% ethanol or equivalent).

13.2. Addition and emptying of rinsing fluid.

Check / Fill Rinsing Fluid and press OK indicates an empty Rinsing Fluid container. It is advisable to add Rinsing Fluid before the bottle is empty, as this otherwise could interrupt analysis. The level of the fluid is easily seen through the container.
The Rinsing fluid should be kept at room temperature and be at room temperature when added. It is recommended to replace the Rinsing Fluid when replacing reagents.

Addition: (If a mobile system is used, push in the keyboard). Pull the fluid container straight out until there is a stop and the filling hole is seen. Add Rinsing fluid to the upper mark on the left side of the container. Return the container to its original position.
Emptying: Emptying of the waste container should be done at the same time as Rinsing fluid is added. Turn the handle on the right side of the waste container to its horizontal position. Pull the waste container out until the handle reaches the hole in the container. Lift the container sideways out of the analyzer. Empty the container and flush with plenty of water. Return and lock the container in its original position.
Don't remove the Rinsing fluid container, as it is connected by tubes to the analyzer.

14. Consumables, Options and Spare Parts

For current information, please visit our website:
http:/ / www.microdialysis.com

15. Catheters, pumps and accessories

For current information, please visit our website:
http:/ / www.microdialysis.com

16. CLIA Considerations

The CMA 600 CLIA module is seamlessly integrated to the CMA 600 software.
General functionality of the CMA 600 CLIA Module is:

1. Tool for maintaining a list of users with definable privileges.
2. Tool for defining approved control samples results lower and upper limits.
3. User authorization for normal samples, batch samples, control samples and switching of reagents and calibrator.
4. Possibility to block normal and batch samples analyses if controls are out of range.
5. A CLIA log showing authorization events, samples results and controls results

17. CLIA Module administration

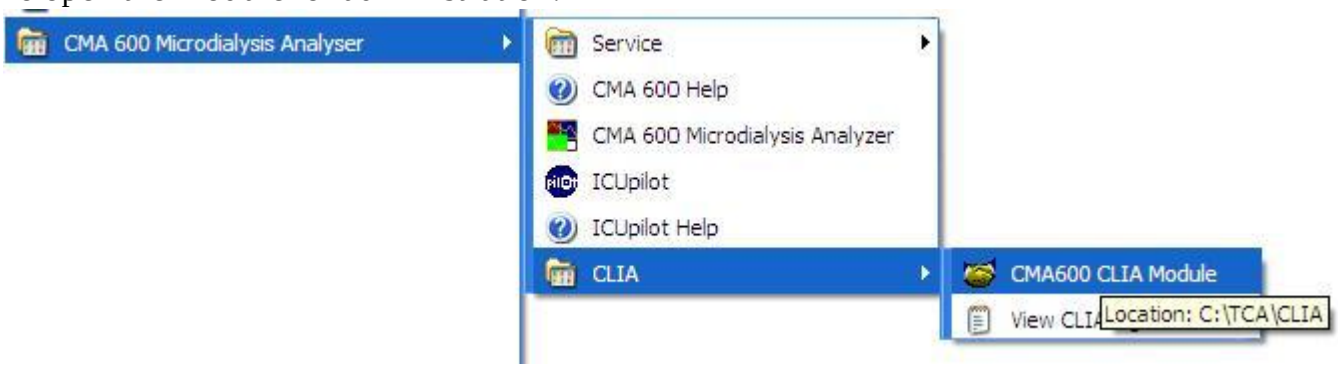
17.1. General:

The CLIA module provides accountability and ensures Controls are within established limits with limited user input, requiring user name and password prior to running any analyses, ensuring users are qualified to operate the operation selected.

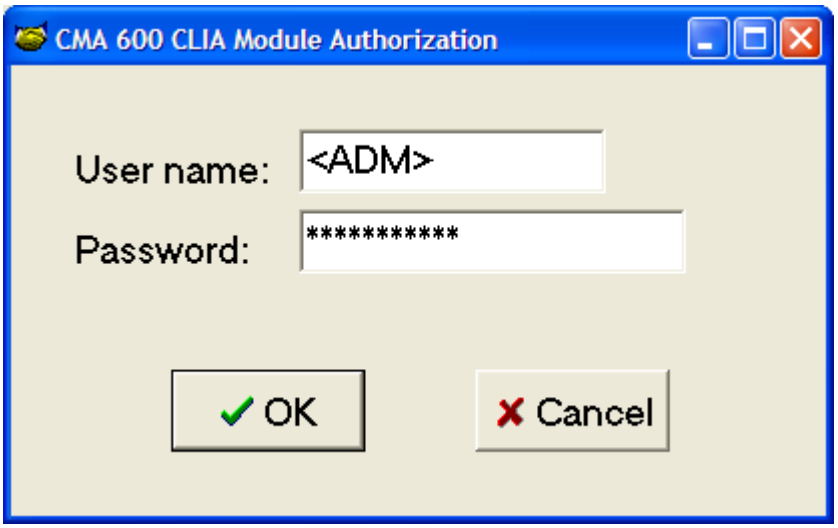
Operations requiring user name and password are:

A) Running patient samples
B) Running controls
C) Changing reagents
D) Running batch samples

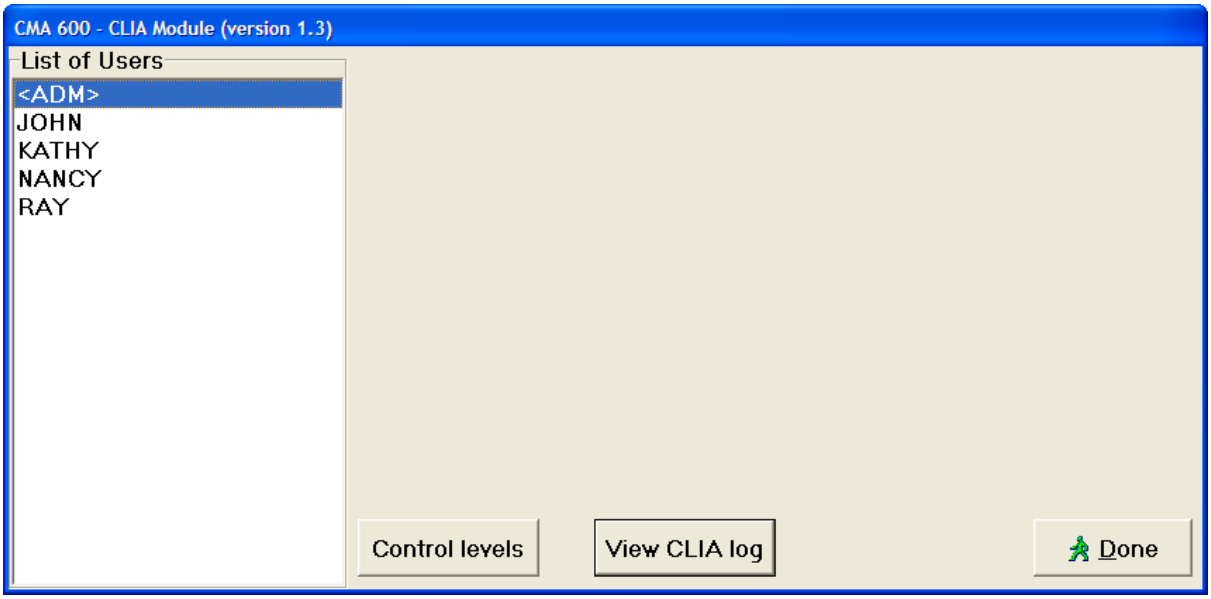
To open the Module for administration:



The Password Screen will appear



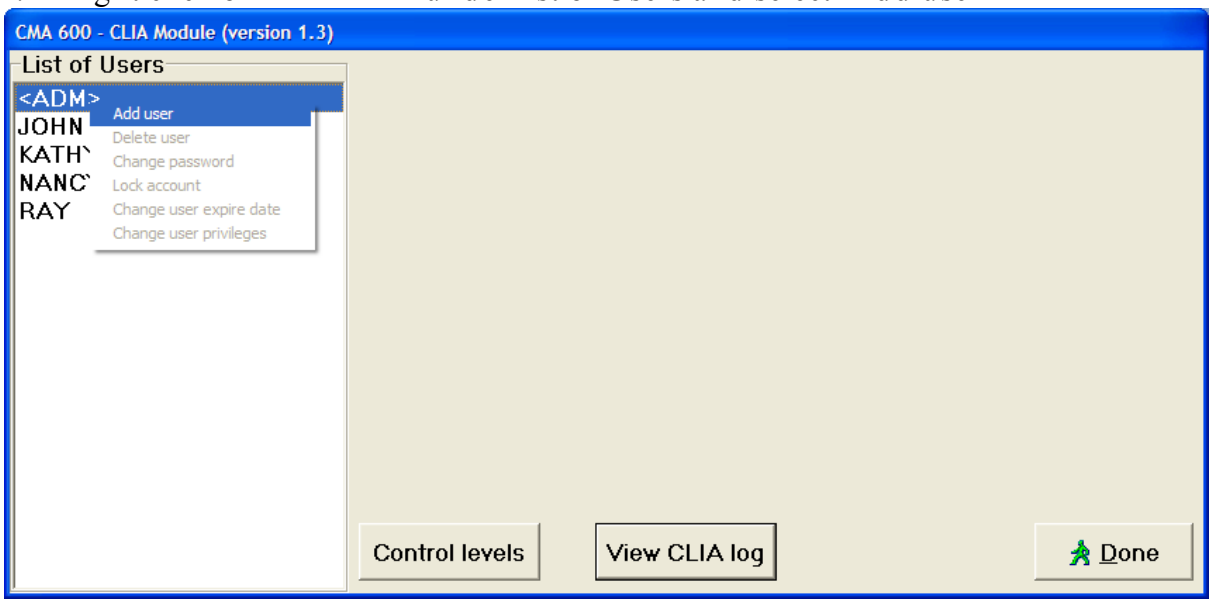
Type in your user name and password (Note: Only persons with administrative rights will be permitted to open the CLIA module). Click"OK". The Clia Module will open



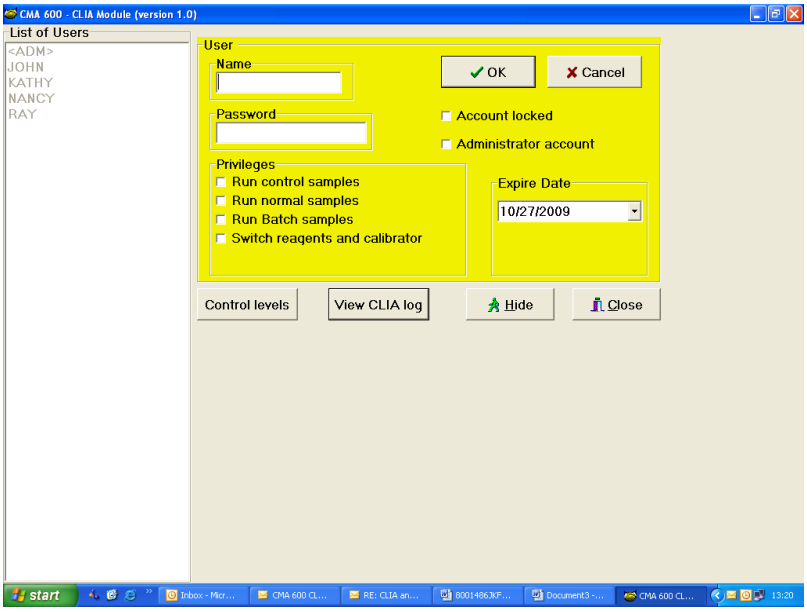
17.2. Adding a new User

Allows the administrator to add new user's and assign levels of competency

1. Right click on "<ADM>" under list of Users and select 'Add user'



2. The following box will appear in yellow:



Enter the new user's name and password. Place a check mark next to the privileges that the new user has passed competency tests for.

Note: If "Administrator account" is selected the user will have all privileges as well as the ability to administer the CLIA module.

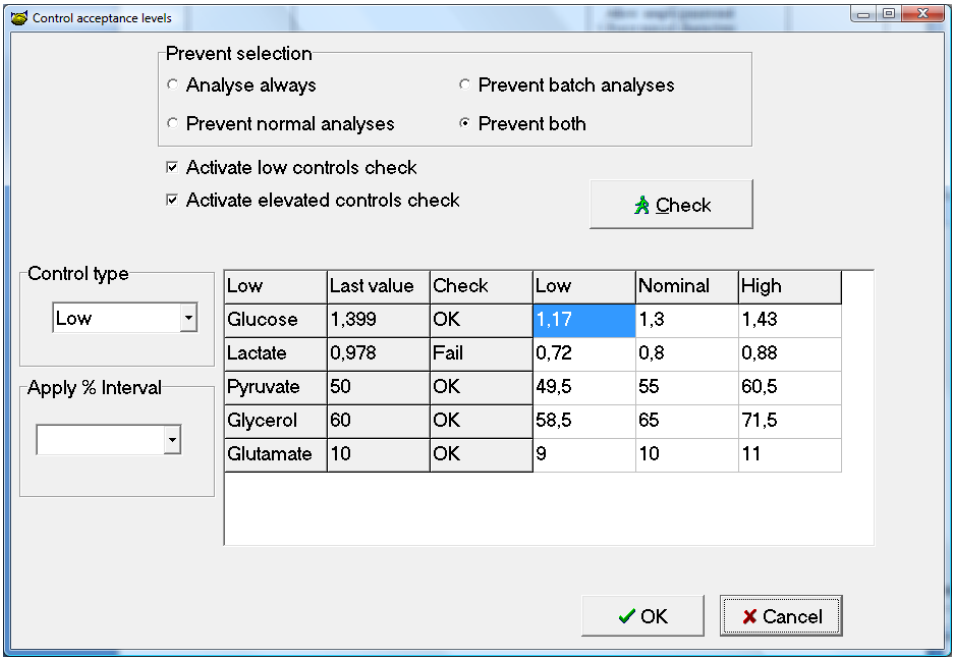
3. Click OK, the new user will be added to the "List of Users"

Note: The expiration date defaults to one year from the date entered. To change the default date click on the down arrow and select desired date of expiration.

17.3. Control Administration

Allows administrators to change control levels, tolerances, and "Lock out" the system, for controls that are outside the stated ranges.

1) Click on "Control Levels"
2) The following Box will appear:



2a) Prevent SelectionAnalyse

A) Analyze Always: Unit will analyze a sample even if controls fail
B) Prevent Normal analysis: will not analyze normal patient samples unless controls are within stated limits.
C) Prevent Batch Analysis: Will not run a batch if controls are not within stated ranges
D) Prevent Both: Will run no samples unless controls are within assigned limits

2b) Control Activation: Boxes that have been checked off will require that control to be run before samples can be analyzed. Should the control fall outside the set ranges for any control at any control level the system will ”lock out” the failed analyte.

2c) Setting control ranges: Select control type (Low or Elevated). Type in the high and low levels for each analyte at each control level (Low and High). The control levels are provided by lot # in each control kit.

2d) Click ”OK” and settings will be saved.

17.4. Viewing CLIA Log File:

The CLIA Log file keeps a permanent record of all data for patient samples, controls, reagent changes and batches that have been run on the system.

Click "View CLIA Log File" to view all samples and controls run by date, time and user.

Log Time	Authorization ID	CMA 600 ID	Analysis Position	Patient ID	Last Name	Analyte	Catheter	Original Sample Time
7/9/2008 15:43	USER1	T1234-00	1	Control		Glucose		
7/9/2008 15:43	USER1	T1234-00	1	Control		Glucose		
7/9/2008 15:43	USER2	T1234-00	1	123.$	Doe	Glucose	CNS	7/13/2008 03:00:00 PM
7/9/2008 15:43	USER2	T1234-00	1	123.$	Doe	Glucose	CNS	7/13/2008 03:00:00 PM
7/9/2008 15:44	USER3	T1234-00	1	123.$	Doe	Glucose	CNS	7/13/2008 03:00:00 PM

Actual sample time	Concentration	Unit	User ID	System ID	Analyzed system Result (OK/Fail)	Result within assigned limits (Pass/Fail)
	5.234	mmol/l			OK	
	5.132	mmol/l			OK	
7/13/2008 03:00:00 PM	3.234	mmol/l	1	1A001	OK	Pass
7/13/2008 03:00:00 PM	4.534	mmol/l	2	1A002	OK	Pass
7/13/2008 03:00:00 PM	3.976	mmol/l	3	1A003	OK	Pass

The log file records:

a) Date and time of operation
b) User ID of person whom ran the operation
c) System ID (System Serial Number)
d) Sample Postion
e) Patient ID number
f) Last Name of Patient being analyzed
g) Analyte analyzed
h) Catheter Position
i) Original Sample time
j) Actual sample time
k) Concentration of analyte
l) Unit of Measure
m) User ID
n) System ID
o) Analyzed system Result (OK/ Fail)
p) Result withinassigned limits (Pass/ Fail)