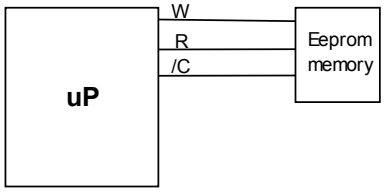
HOSPITEX DIAGNOSTICS

Quick Reference Manual
Firmware release 3.4 Software release 3.6

1 SERVICE PROGRAM

INTRODUCTION

The following paragraphs describe how to use Service program. Service functions allow to set all calibrations for instrument (offsets), to check photometer unit, to control pumps and hydraulic circuit, to set barcode reader, to monitor temperature level and to create your printing format.
When you set a new calibration, all offsets and permanent data are stored in EEPROM memory on main CPU board.



At start up, eprom data are uploaded in CPU RAM memory so that instrument can work properly.

1 ADJUST LAMP

Lamp adjustment has been done at Hospitex Diagnostics factory. The correct lamp position is achieved by producer. Only when the lamp has been defective, it's necessary to replace it with a new lamp, in this occasion it is very important to test lamp filament before to insert the new lamp.

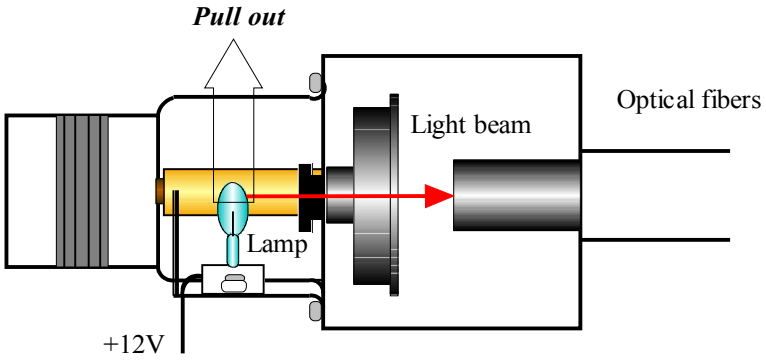


Figure 1 Optical group

1.1 NEEDLE ARM ADJUSTMENT

Needle adjustment has been done at Hospitex Diagnostics factory. After needle disassembly, you have to control vertical and horizontal needle positions.
Needle arm must be adjusted in such a way that the needle position is in the centre of washing well, see Figure 2:

1. Shut down instrument;

2. To loosen screw A and B, see figure 2, in such a way you can move by hand needle arm can freely ;

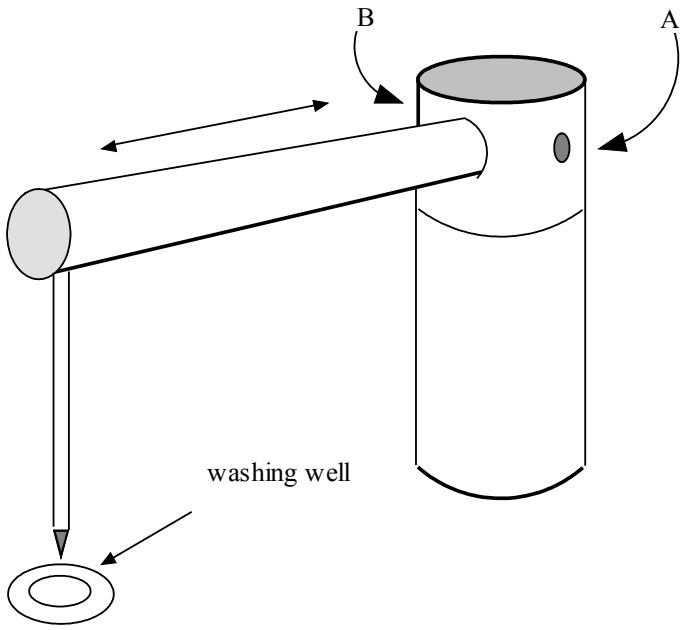


Figure 2: needle arm

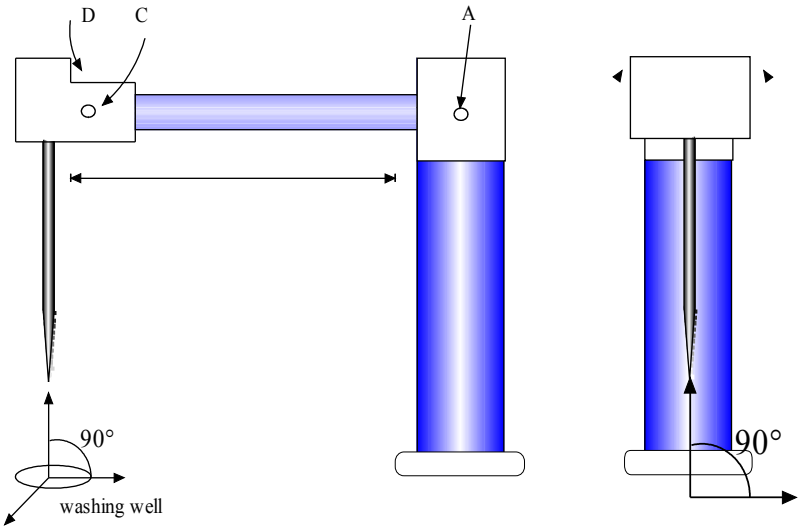
3. Moving by hand, adjust needle arm length so that the needle is in the centre of the wash position;

4. Tighten screw A and B;

1.1.1 Small vertical arm adjustment

Check if the needle vertical axis is set perpendicularly to the plate below, Figure 3:

1. Loosen screw C and D, see Figure 3, in such a way that the needle can be moved freely;



5. **Figure 3: needle settings**

6. Turn the needle by little movement and set it in perpendicular position;
7. Tighten screw C and D;

1.2 Service program

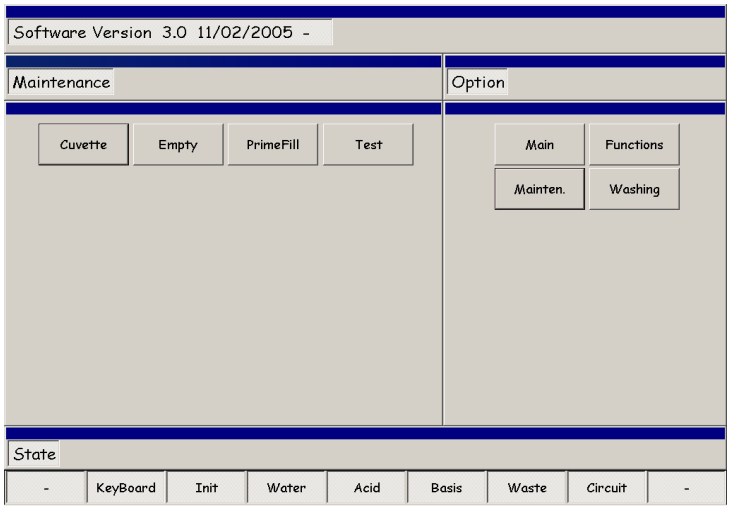


Figure 4 maintenance menu

To enter in Service program, from "Option" sub menu select "Mainten." button and then press "Test" button, see Figure 4.
Service program is divided in 11 menus listed here below:

Item	Description
Calibration	By this menu you can set all the mechanical calibrations for the instrument
Eprom	By this menu you can display Eeprom memory configurations
Dispenser	By this menu you can run preparations
Washing station	By this menu you can check washing station unit
Pumps	By this menu you can check washing well pumps
Temperature	By this menu you can set and monitor temperature level on instrument
Reader	By this menu you can check photometer unit
Cans	Only for producer
Barcode	By this menu you can calibrate barcode unit
Functions	By this menu you can change language interface
Printer	By this menu you can edit and customize your printer setup

To come back in main program press "Exit" button. Note that after Exit instrument will reset itself.

1.2.1Calibration menu

Using calibration menu is possible to set or modify mechanical calibrations.
The calibration procedure means: to find the offset for tray first position under needle and the offsets for vertical and radial needle arm positions in order to found a correct aspiring and dispensing action.

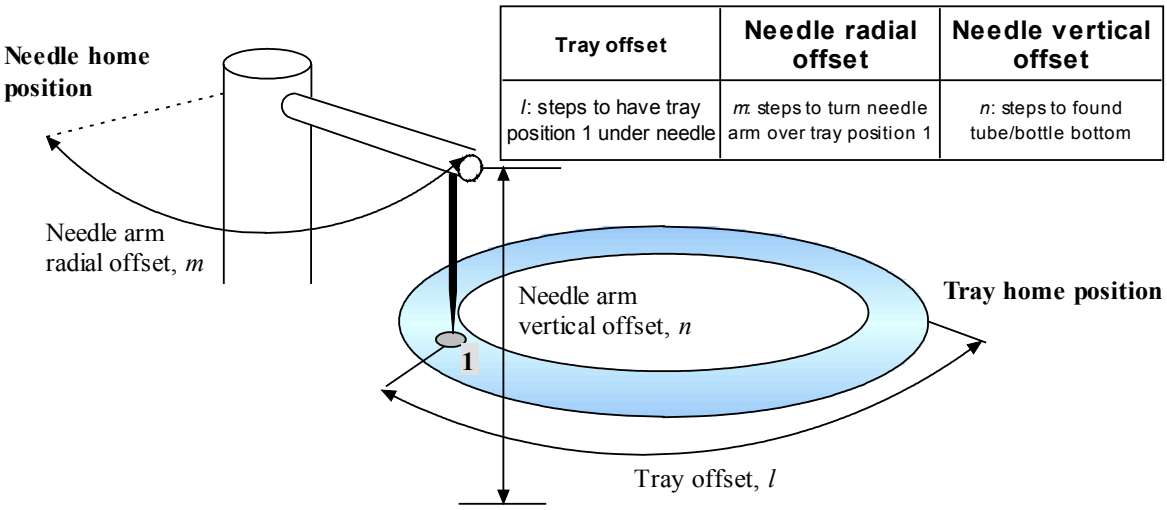


Figure 5: mechanical calibration

Every offset are expressed in steps and are not a physical measure. Calibration menu has the following graphical interface, see figure Figure 6:

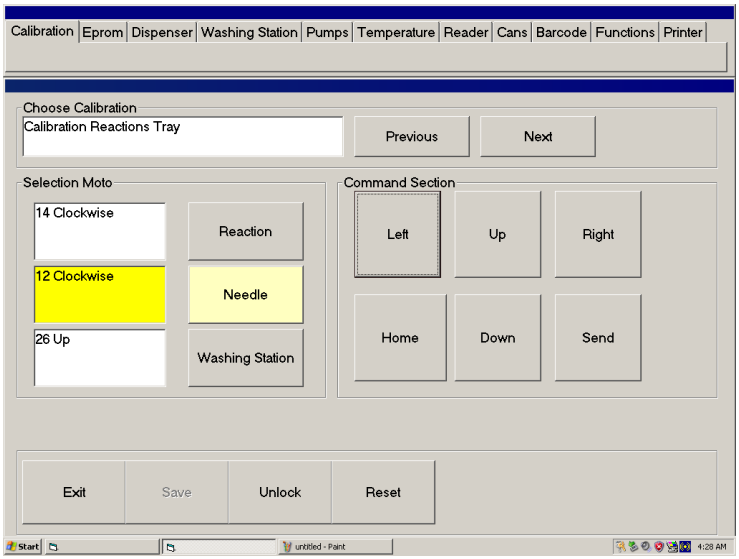


Figure 6 calibration menu

By “Previous”/”Next” buttons you can select calibration for all the parts, Figure 6 shows calibration for reaction tray.
The upper button in “Selection Motor” sub menu select tray motor, “Needle” button select needle arm motors.
In “Command section” pressing “Left/Right” buttons you can choose direction movement and how many steps to move the selected motor. The same is for “Up/Down” buttons, they are used for up and down needle arm movement.
Note that the actual motor selected is yellow highlighted.
“Send” button dispatches the command to the instrument. “Home” button recover the home position for the selected motor.
Instrument has 3 main trays to calibrate, however consider that serum and reagent trays have two different position to calibrate one for the external ring and the other one for inner ring, see Figure 7, this means that instrument needs 5 logical calibration points for trays + 1 for washing well.

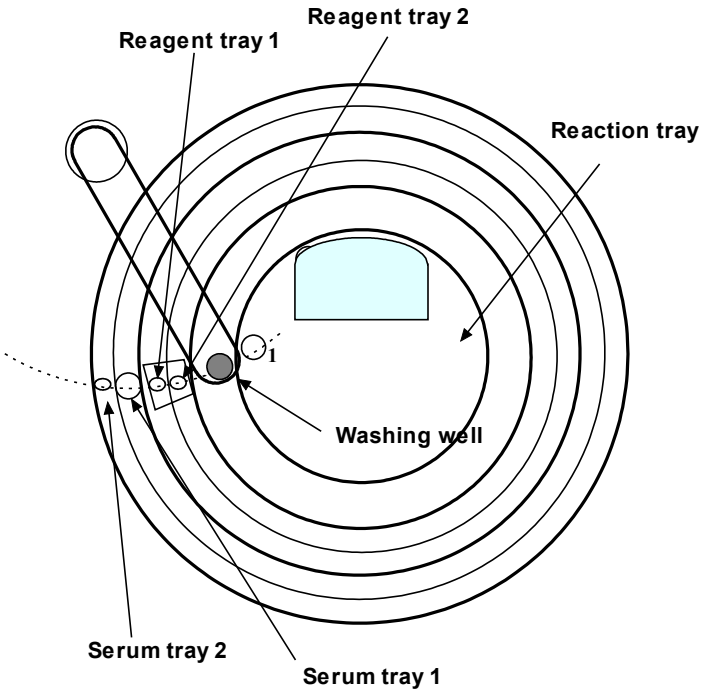


Figure 7 trays map

How to calibrate

The first tray to calibrate is Serum tray 1 (inner ring). You can skip to another calibration using “Next” and “Previous” buttons. The procedure to perform are the following.

Serum and reagent trays calibration

1. Move serum tray so that the first position is under needle arm: press “Serum” button for selecting the tray motor and move it by “Left/Right” and “Send” buttons, see Figure 8;
2. Turn needle arm to match the centre of first serum tray position: press “Needle” button for selecting the arm motor and move it by “Left/Right” and “Send” buttons;

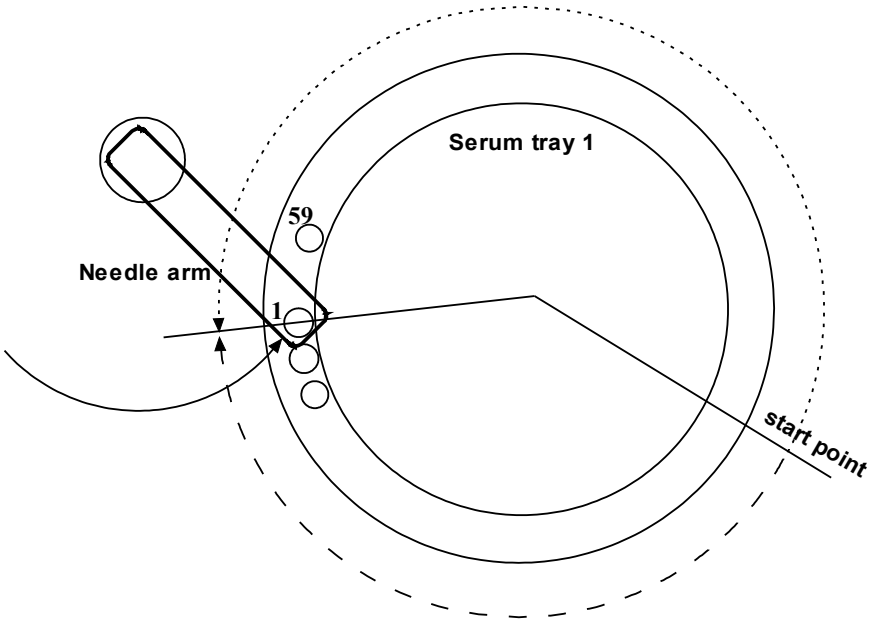


Figure 8 sample tray calibration

3. Move needle inside the first serum position up to find the bottom. To acting in this way press “Needle” button for selecting the motor and move it by “Up/Down” and “Send” buttons. Note that needle height inside the serum tube must be 1 mm over bottom level.
4. Press “Save” button to save offsets configuration in eeprom memory, (see Figure 6).
5. Press “Home” to recover needle in home position.

After Serum tray calibration press "Next" to skip the next calibration. Reagent tray 1 (external) and 2 (inner) and Serum tray 2 calibration procedure are similar to Serum tray 1 calibration.
Note that when you move the needle inside the reagent bottle the maximum distance between needle edge and bottle bottom should be 2-3 mm, see Figure 9:

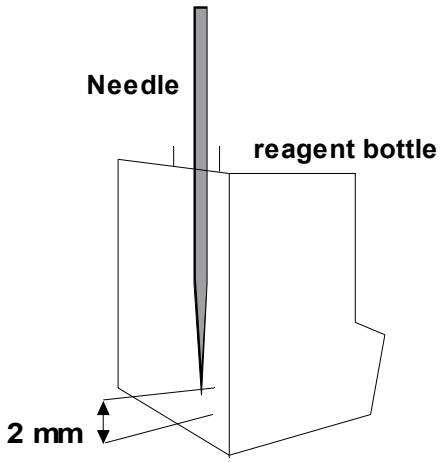


Figure 9 needle height

Needle calibration on washing well

1. Turn the needle arm on washing well and bring the needle in the centre of washing well: press "Needle" button for selecting the motor and move it by "Left/Right" and "Send" buttons;
2. By "Up" and "Send" button move down the needle to find the height as in the following drawing:

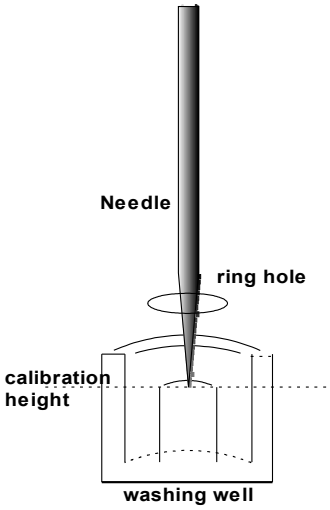


Figure 10 washing well needle height

3. Press “Save” button to freeze needle offset in eeprom memory.
4. Press “Home” to recover needle home position.

Reaction tray calibration

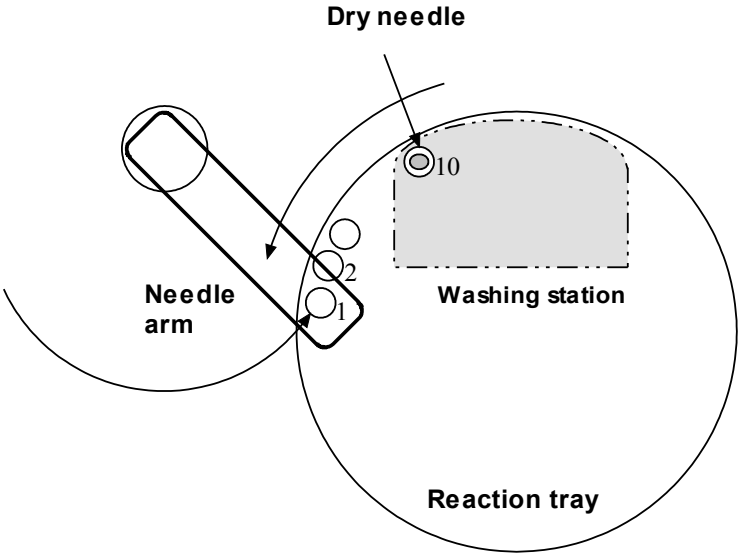


Figure 11 reaction tray calibration

1. Press “Reaction”, using “Left/Right” and “Send” buttons move reaction tray bringing cuvette position number 10 under dry needle, see Figure 11.
2. Press “Needle”, using “Left/Right” and “Send” buttons turn needle arm to adjust needle position over cuvette number 1 centre as in Figure 11.
3. With cuvette number 10 under dry needle, control that led D78 on instrument CPU board is lighted ON. If not, move step by step reaction tray in order to have led D78 lighted ON, Figure 12

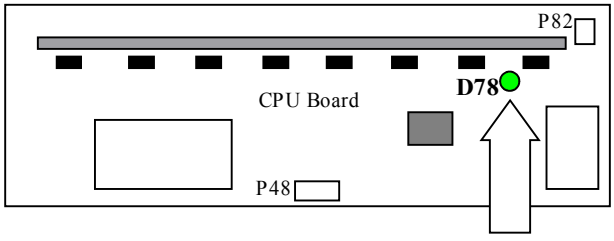


Figure 12 CPU Board

4. Using “Up” and “Send” buttons move down the arm to find the needle height, see Figure 13

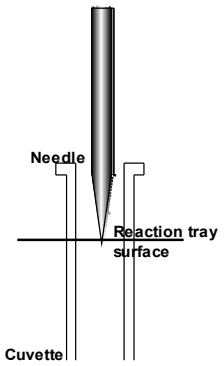


Figure 13 needle height inside cuvette

5. Press “Save” button to freeze needle offset in eeprom memory.
6. Press “Home” to recover needle home position.

When you have finished all calibrations or changed some of them press “Reset”. In this way the new offsets stored in eeprom memory will be charged in micro controller RAM memory.

1.2.2 Photometer calibration

Photometer unit is composed by 4 independents reading channels. This means that a set of 4 cuvette are read at the same time. After reaction tray calibration it needs to calibrate cuvette reading position aligned with photo battery cells. Photometer calibration, means to find the best reaction tray position to obtain the highest energy level for cuvette reading.

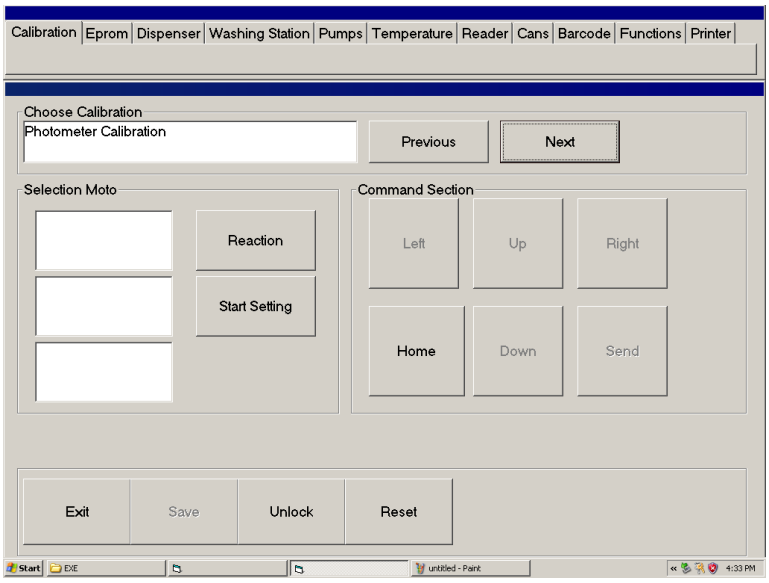


Figure 14 photometer calibration

Calibration procedure is fully automatic and it is composed by the following steps:

1. Fill with water cuvette number 1, 60, 59, 58.
2. Select “Reaction” button and align reaction tray so that the filled cuvettes are behind photometer channels. To obtain this, bring reaction tray cuvette position number 25 as shown in Figure 15, half covered by tray cover.

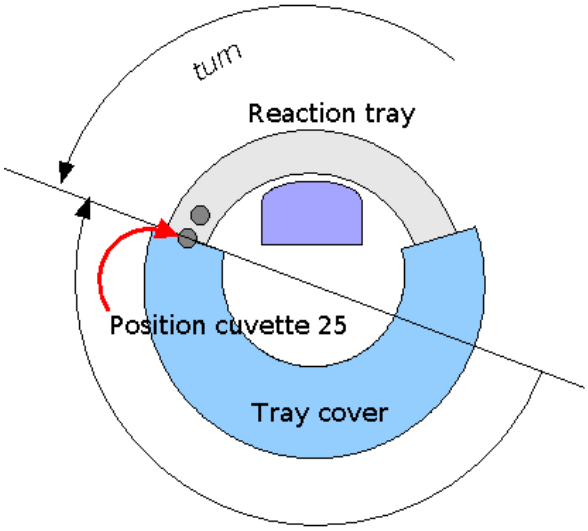


Figure 15 photometer calibration

3. Press “Start Setting” as shown in Figure 14. The automatic procedure will start displaying a message. At the end the found offset is stored in eeprom.
4. Press “Reset”.

The photometer calibration is completed. Note that if you change reaction tray calibration (only physical tray position) you have to recalibrate photometer reading point also.

1.3 Eprom

During calibration procedures all information are stored in a permanent memory on CPU board: eeprom.“Eprom” menu window is shown in Figure 16. Using Eprom menu you can:

1. Write instrument serial number using “Write S/N” button
2. Store actual eeprom information (offsets) in a local PC file (C:\EOSBF\FILE\LastEprom.PEP), using “Save Eprom on File” button
3. Download PC offsets file (LastEprom.PEP) in eeprom memory to recover the last eeprom memory configuration, using “Load Eprom from File” button
4. To display actual eeprom offsets , using “Eprom configuration” button
5. To display a complete instrument report, using “Calibration report” button
6. Erase eeprom information by “Clear Eprom” button

7. Erase AD channels offset to disable reaction tray temperature control by environment temperature sensor (Clear AD Offset)

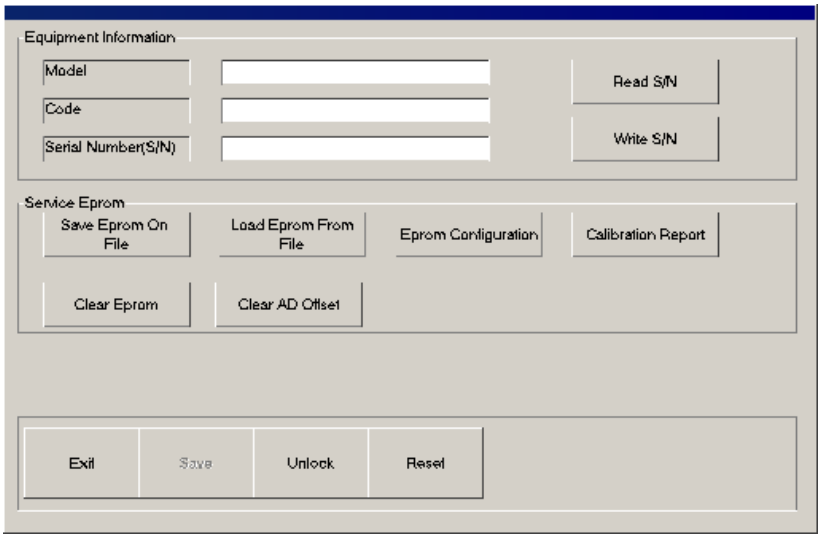


Figure 16 Eprom menu

1.4 Dispenser

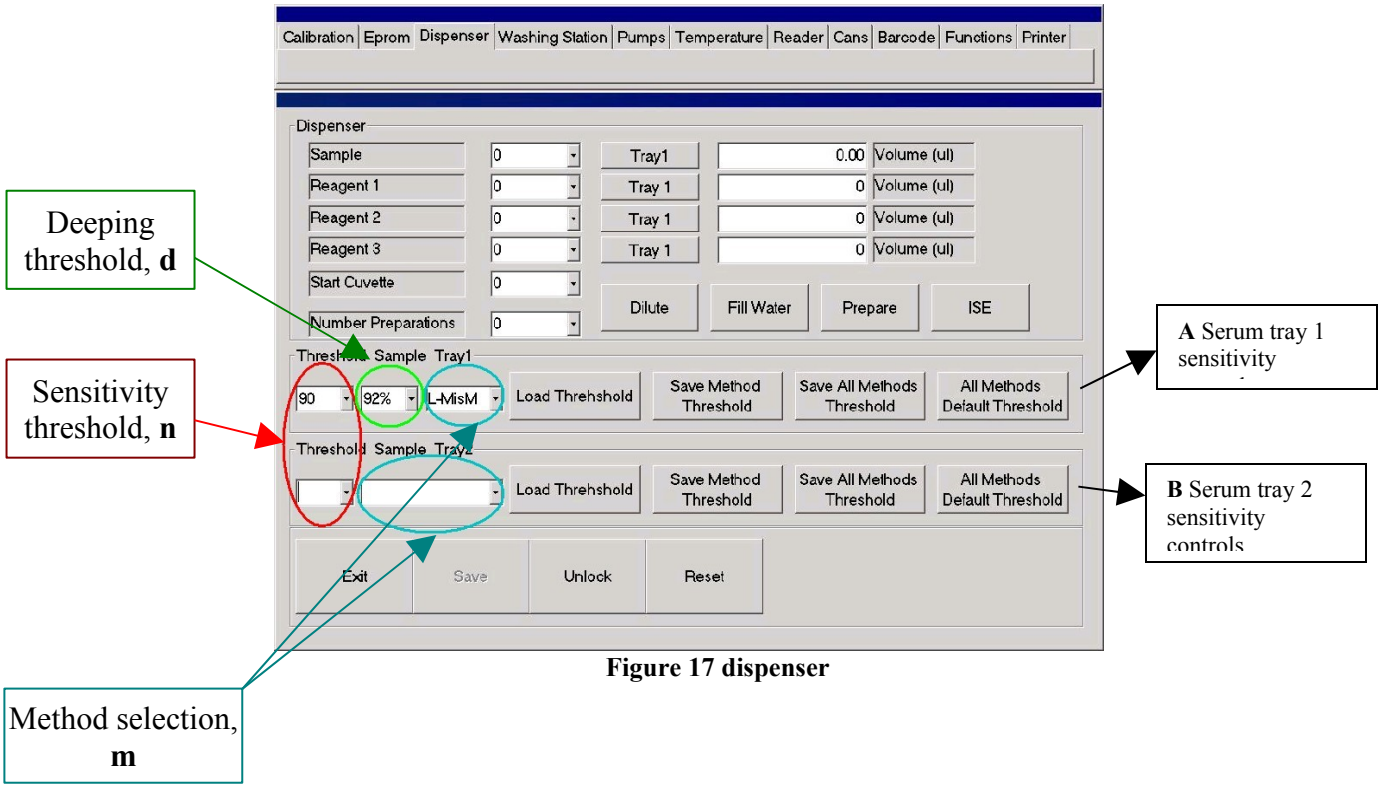


Figure 17 dispenser

Using Dispenser menu you can perform one or more preparations. During preparation the needle aspires reagent and serum volumes from their own trays positions and dispenses them in reaction cuvette. As shown in Figure 17, from "Sample" combo box you can select sample position from serum tray. Selecting "Tray1" button, sample position is on the inner ring. With "Tray2", sample position is on external ring.
To define how many sample volume to aspire, write it in "Volume" edit box.
During the same preparation you can add up to 3 different reagents, choose reagent positions from combo box "Reagent 1", "Reagent 2", "Reagent 3" and define their volumes in "Volume" edit box (Figure 17, right side).
Selecting "Tray1" button, reagent position is on external ring, with "Tray2" is on inner ring.
To select the cuvette to dispense in, use "Start cuvette" combo box. To choose how many preparations to perform use "Number Preparations" combo box.
As shown in Figure 17, there are 3 buttons:

1. "Dilute", to perform dilutions. During dilution, needle will dispense in serum tray external ring. To select cup position, use "Start cuvette" combo box.
2. "Fill water", to fill with water reaction cuvette. To select the first cuvette to fill use "Start cuvette" combo box, to select how many cuvettes to fill use and "Number Preparations" combo box.
3. "Prepare" to execute a preparation.
4. "ISE" to push samples inside ISE module position

Needle sensor thresholds

From firmware version 1.7 it is implemented a new function that allows to adjust needle sensor sensitivity threshold for one specific reagent when the needle are detecting the sample on serum tray 1 or serum tray 2 positions.
In this way it will be possible to set a specific sensitivity threshold for every different type of reagent. If adjustment sensitivity is not needed, the instrument works with default parameters.
In Dispenser menu, see Figure 17, there are **A** controls to set and modify threshold on serum tray 1 and **B** controls to set and modify sensitivity threshold on serum tray 2.
To modify sensitivity threshold for serum tray follow this steps:

1. From combo box ***m*** select the method (reagent) that needs threshold adjustment;
2. From combo box ***n,*** select sensitivity threshold level for relevant method indicated at point 1. The available threshold range is [70 –100], with threshold = 100 needle sensor has the highest sensitivity;
3. From combo box ***d***, select Deeping threshold level in the range [70%-99%]. Percentages is referred to the f_{Max} frequency, see Figure 19. The default value is 92%. If in your test the level sensor doesn't sense the sample level, sinking deeply into the test tube, increase the deeping threshold value.
4. Use "Load Threshold" button to activate the new threshold level indicated at point 2. Use Dispenser controls to run preparations and test threshold sensitivity level.

5. Use “Save Method Threshold” button to save the new threshold level selected from combo box ***n*** for method indicated in combo box ***m***.
6. Use “Save All Methods Threshold” to set every method with sensitivity threshold level shown in combo box ***n***.
7. Use “All Methods Default Threshold” button to recover all methods with default threshold sensitivity level. Default sensitivity level is 90 for serum tray 1 and 94 for serum tray 2.

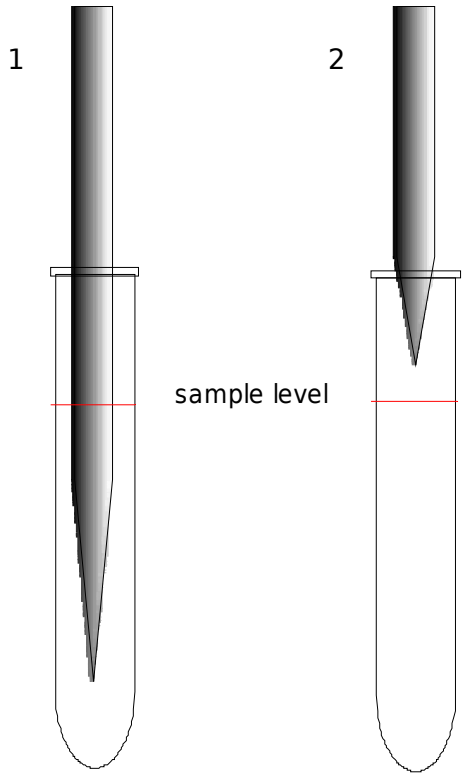


Figure 18

How to adjust thresholds

When the level sensor doesn't sense correctly the sample in serum tray 1 you have to adjust the following parameters: Deeping threshold and sensitivity threshold. The first parameter defines the percentage of maximum frequency f_{Max} from which the detection starts (maximum frequency is on needle home position, see Figure 19), sensitivity threshold is linked with the frequency variation from air to liquid.
If the level sensor fault condition is like in the case 1 of Figure 18 it means that the deeping threshold value is under the f_{Min} and you need to increase it, see Figure 19. When you modify deeping threshold move by 5% step units across the range.
If the level sensor fault condition is like in the case 2 of Figure 18 you have to make the following :

1. Decrease the deeping threshold until the needle goes down in the sample (case1) it means you have found the f_{Min} frequency. Then, increase the deeping threshold value f_{DTh}, it must be in the range of f_{Max} and f_{Min}.
2. After that you have fixed the deeping threshold decrease the sensitivity threshold (see point 2 page 14)

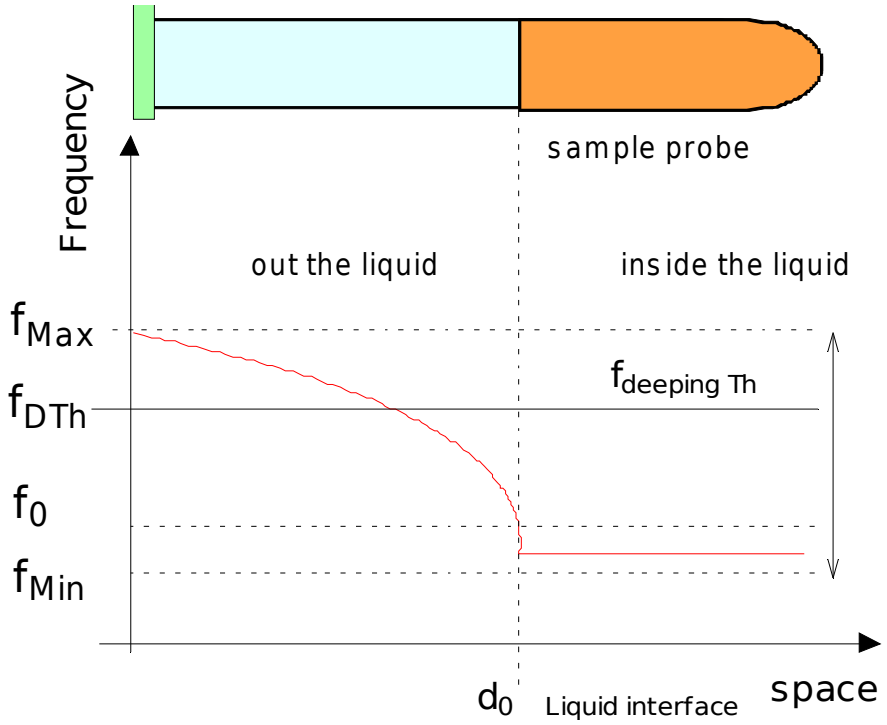


Figure 19:

Rem 1: f_{Max}, f_{Min} parameters are connected with the reagent that you are using and have not absolute values. You can only estimate f_{Max} and f_{Min} by test.

Rem 2: Let be THs the sensitivity threshold value, THs depends by reagent type Rx that you are using: THs(Rx). The level sensor stops the needle when:

$(\Delta f / \Delta s) > THs(Rx)$ where f is the frequency and s is the space

To modify sensitivity threshold level for serum tray 2 use **B** controls, the way to follow are same exposed for serum tray 1 (**A** controls). Deeping threshold are not available for serum tray 2.

2 Washing station

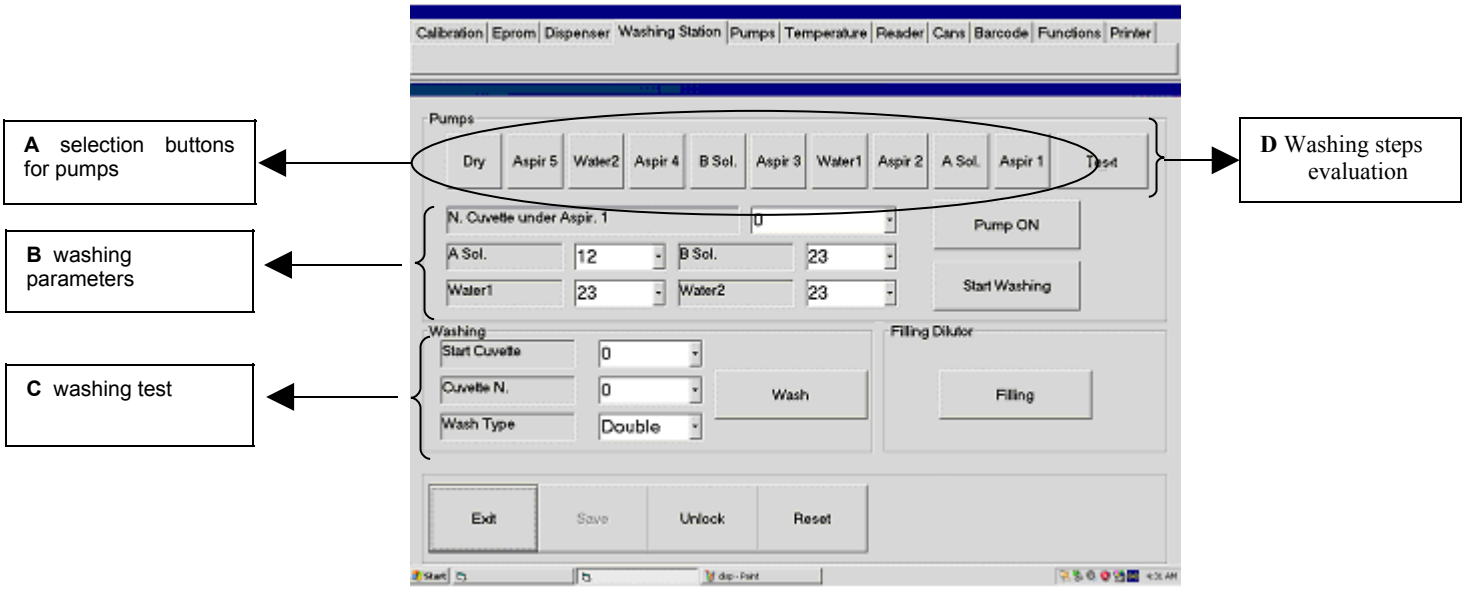


Figure 20 washing station menu

Use washing station menu to check all the hydraulic pumps. In "Pumps" sub menu (**A**) there are 10 buttons to select the washing station needles pump, see Figure 20.

A pump check

To switch on one of the pumps:

1. press one button from **A** section to choose the pump;
2. press "Pump ON" to activate the pump

To stop the pump, press "Pump OFF" button (it is "Pump ON" toggled button). The relation between buttons in **A** (Figure 20) section and washing tower needles is shown in Figure 21

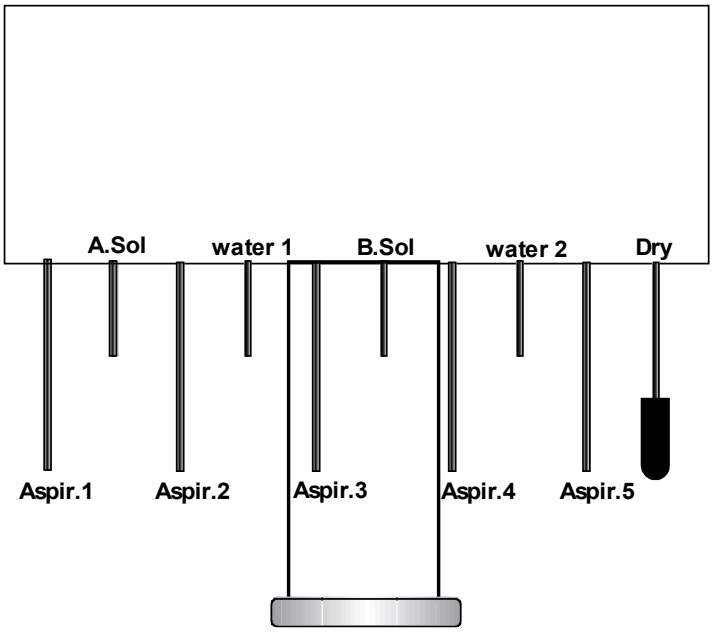


Figure 21 washing tower

B washing parameters

To test one washing cycle:

1. select the cuvette to bring under Aspr1 needle from "N. cuvette number under Aspir. 1" combo box
2. in "A sol", "B sol", "water1", "water2" combo boxes set the liquid volume for washing (remark: the default values are fixed by producer, it is recommended don not change them)
3. from A section button select the pumps that you want to test
4. press "Start Washing" button to start washing cycle

After this, reaction tray will bring under Aspr 1 needle the selected cuvette and the washing station moves down with selected pumps opened.

C washing test

Using "Washing" sub menu you can test a washing cuvettes:

1. From "Start Cuvette" combo box select the first cuvette to wash;
2. From "Cuvette N." combo box select how many cuvettes to wash;
3. From "Type" combo box select washing type, washing type is shown in Table 1.
4. To start washing press "Wash" button.

Press "Filling" button to fill with water needle hydraulic circuit or to wash needle.

Washing Type	Description
Neutral	Only with H_2O
A Solution	A sol + H_2O
B Solution	B sol + H_2O
Double	A sol + B sol + H_2O

Table 1

D washing steps evaluation

"Test" command allows to evaluate each single washing steps

The whole washing cycle can be divided in 6 steps (see Figure19) :

1. Aspir.1 + A.Sol + Aspir.2
2. Aspir.2 + Water 1 + Aspir.3
3. Aspir.3 + B.Sol + Aspir.4
4. Aspir.4 + Water 2 + Aspir.5
5. Aspir.4 + Water 2 + Aspir.5 + Dry
6. Dry

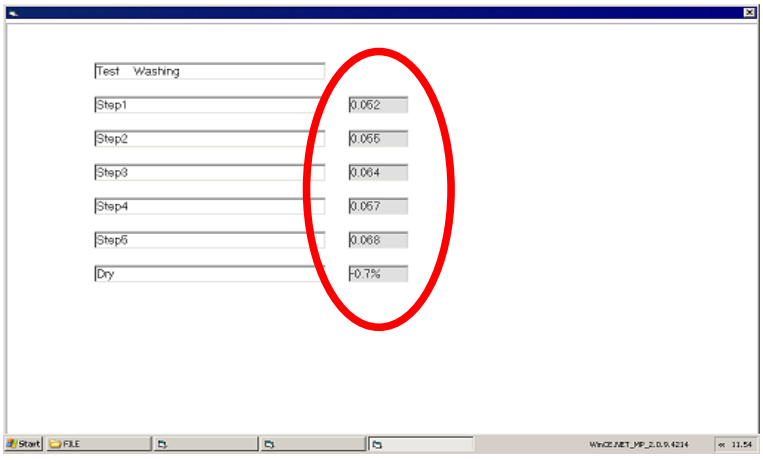
Steps 1,2,3,4,5 are evaluated by calculating the ABS of remaining coloured drops , left by washing step

Step 6 is evaluated by calculating the effect of water drops , left by dryer , towards ABS of a coloured solution

In order to use this procedure you have to :

- ✓ Fill position 1 of serum tray 1 with concentrate potassium bichromate (K2Cr2O7)
- ✓ Fill position 1 of reagent tray with a bottle full of water
- ✓ Insert on position 1 of serum tray 2 an empty cup

After automatic procedure results are shown in the following form:



An error on results is shown by colouring red the cell with wrong result .

Moreover form can be saved on file".bmp" by pressing F1 on keyboard (optional: user will be able to input a note in the file name), all files will be saved in "C:\EosBF\File" folder.

2.1 Pumps

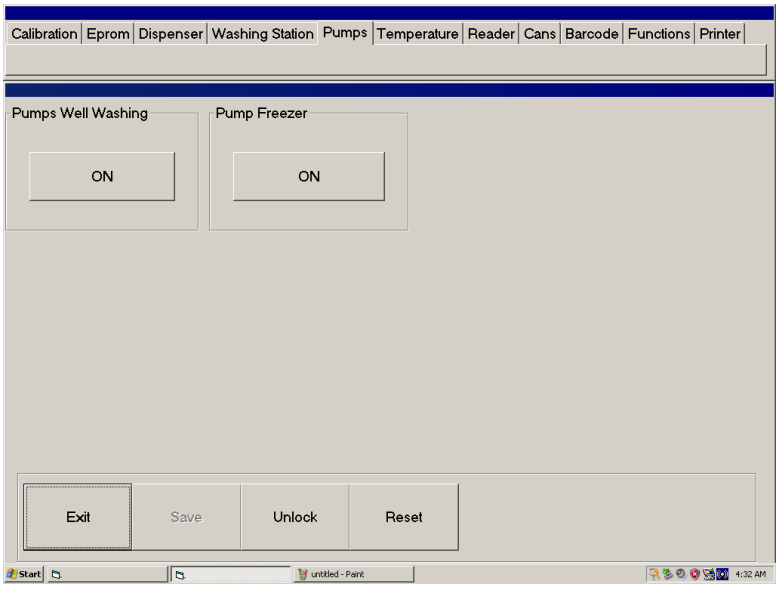


Figure 22 pumps menu

Using "Pumps" menu, shown in Figure 22, you can check all the washing well pumps and refrigerator pump:

1. Press "ON" button (toggle) in "Pumps Well washing" sub menu to turn on all the well pumps.
2. Press "ON" button (toggle) in "Pump Freezer" sub menu to turn on the refrigerator pump connected with reagent tray.

Washing well is connected with 3 peristaltic pumps: one to wash needle, the other ones to get out waste.

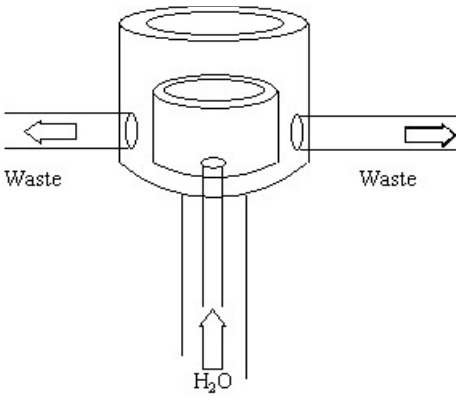


Figure 23 washing well

2.2 Temperature

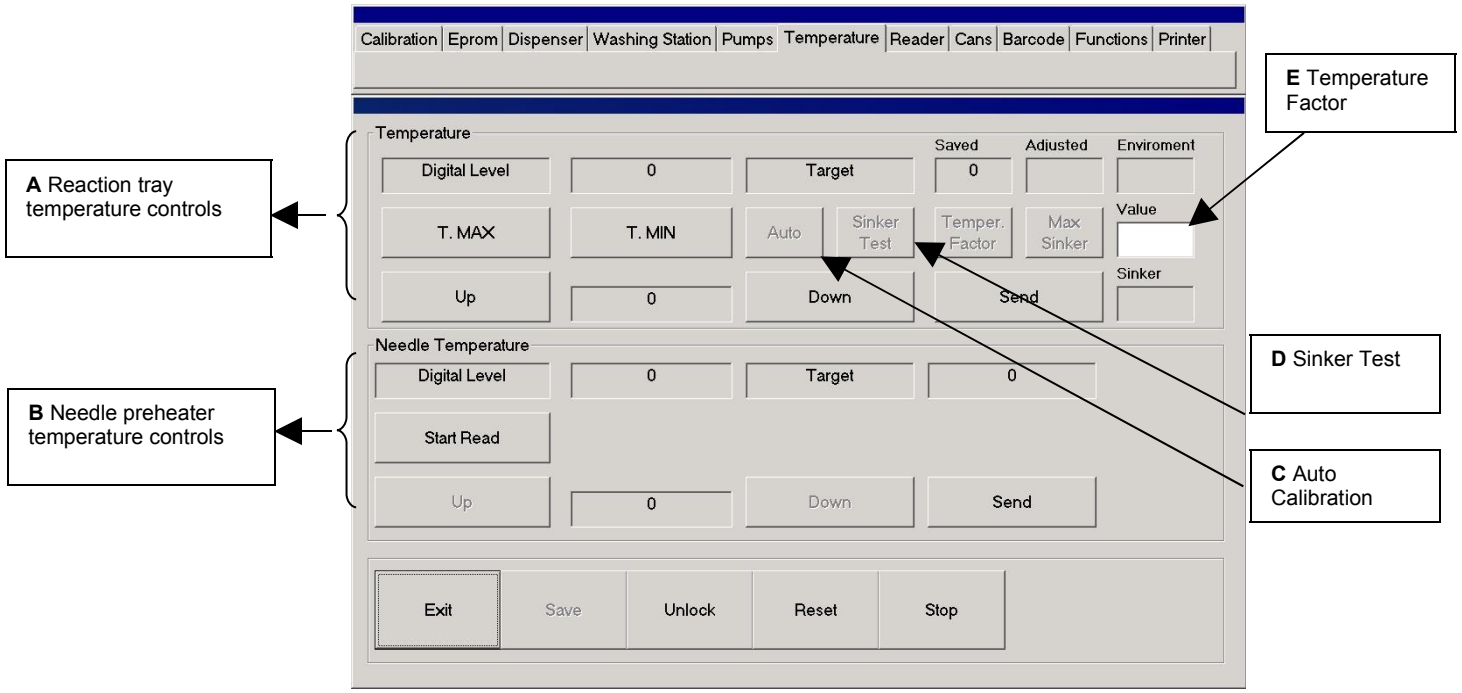


Figure 24 temperature menu

Using Temperature menu, Figure 24, you can monitor and calibrate temperature levels on reaction tray and needle arm preheater. "Temperature" sub menu controls reaction tray temperature. "Needle Temperature" sub menu controls preheater needles arm, see Figure 25.

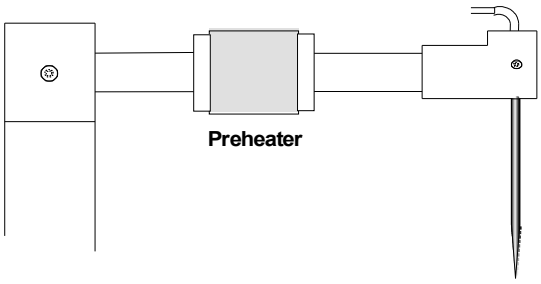
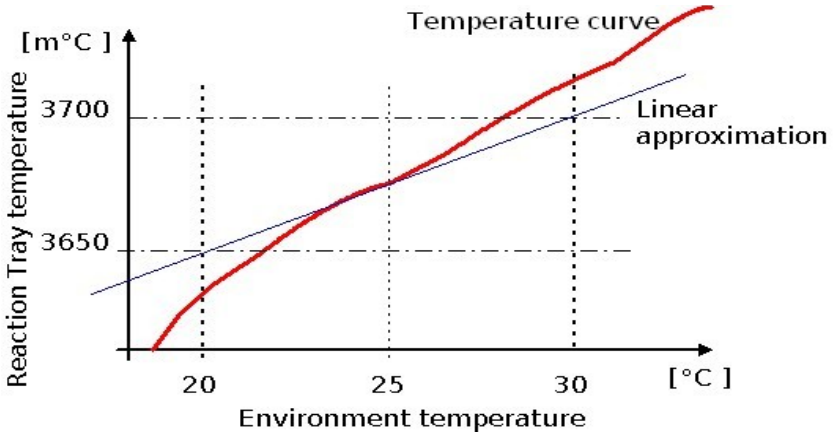


Figure 25 preheater

A Reaction tray temperature controls

To display actual reaction tray temperature press "T.MAX" button, software will show temperature digital level in "Digital level" edit box. To calibrate reaction tray temperature you have to define a digital level Target. To change "Target" level use "Up" button (to increase) "Down" (to reduce) and "Send" to modify the displayed target value. Actual "Digital Level" and "Target" values are expressed in digital units and are not physical degrees (°C).

Note : **<u>When environment temperature sensor is set up on equipment</u> (see 1.5)**
When user press "Save" button , equipment will also store environment temperature and Reaction tray temperature target will be automatically modified according to that environment .During temperature calibration , by pressing F1 on keyboard , environment temperature , sinker temperature(if present) and adjusted target can be shown .
The automatic correction of target temperature is controlled by a **temperature factor** (default: 65 m°C/°C) that makes target decrease when environment temperature increase. The automatic correction uses a linear model , so, in order to perform good corrections, **it's strongly recommended to calibrate reaction tray temperature with an environment temperature from 22°C to 26.5°C** .
That's because the linear model is working good only with small variation (positive or negative) around a medium point , so it's recommended to fix this medium point not with too low temperature and not with too high temperature



Moreover in order to assure a right working of temperature control **sinker temperature must be around 30°C/40°C.**
In order to disable reaction tray temperature control by environment temperature , command "Clear AD Offset" on "Eprom" menu has to be used.

B Needle preheater temperature controls

To find the target value corresponding at 37,5 °C, fill with water a cuvette and insert inside a thermometer probe. You have to wait that reaction tray temperature reaches the target value, after this, control the Celsius degrees on tray with thermometer. If temperature is not 37,5°C you have to modify target value using "Up/Down" buttons.
When you have found the right target value save it in eeprom memory pressing "Save" button.

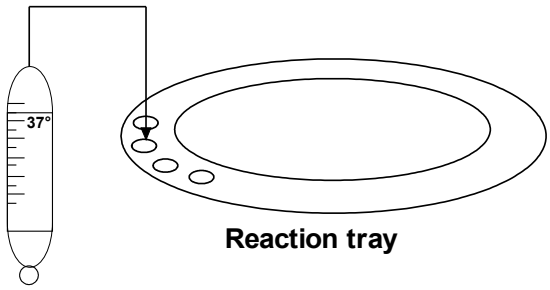


Figure 26 reaction tray temperature test

Press "Start Read" to monitor actual digital level on preheater and target value. About calibration you have to follow this procedure:

1. turn on reagent tray refrigerator and wait for a low temperature.
2. Wait for 37,5°C on reaction tray.
3. Using "Dispenser" menu, you have to run a preparation in which needle aspires 400 ul of water from reagent tray and 4 ul from serum tray and dispense it in a reaction tray cuvette. Repeat this operation 3 times.
4. Insert inside the last dispensed cuvette a thermometer probe.
5. For a good preheater target, water should reach 37 °C in 3 minutes
6. Using "Up" and "Down" buttons, modify target value if is not as point 5
7. Press "Save" button to save new target value.

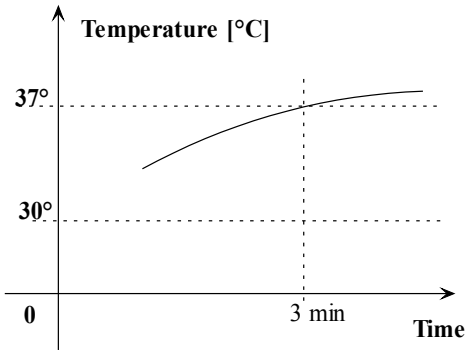
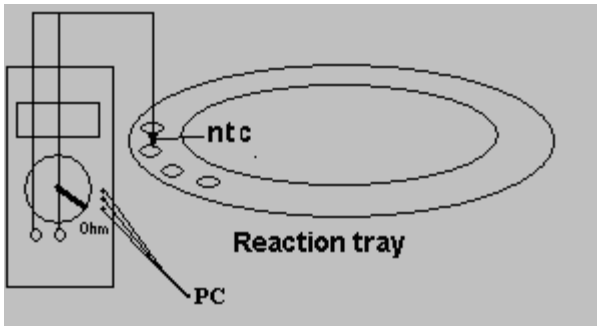


Figure 27 temperature rate

To exit from "Temperature" menu, press "Stop" button.

C Temperature auto calibration

In order to perform this procedure it's necessary to use tester "Lafayette MAS-345" with communication serial port RS232 connected with an NTC sensor.



- Fill a cuvette with 500uL of water
- Put this cuvette on reaction tray position under photometer mask
- Switch tester on Ohm mode
- Connect NTC with tester probes
- Connect Tester on PC Com1
- Push "Auto" on "Temperature" menu
- Wait for end of procedure (it can last from 40 min to 60 min)

During procedure, calibration can be stopped by pressing ESC on keyboard , **note that in this case current level and environment temperature will be saved.**
Moreover environment temperature and sinker temperature can be shown by pressing F1 on keyboard and current cuvette temperature is shown on a message.

If temperature calibration end with no error software will show :

- TEMPERATURE ON CUVETTE + SAVED DIGITAL TARGET

If temperature calibration end with error software will show an error code :

- TEMPERATURE CAN NOT BE CONTROLLED : after first correction temperature is not reaching for target
- TEMPERATURE CAN NOT REACH PLATEAU : after a correction temperature doesn't become stable but keeps on drift
- TEMPERATURE CAN NOT REACH TARGET : after maximum number of corrections target is not reached
- TEMPERATURE CAN NOT STAND BY ON TARGET: after target is reached temperature keeps on changing around target

D Sinker test

Sinker efficacy can be controlled with an automatic procedure.
Some temperature cycles are performed on sinker and the rising temperature time is monitored.
This procedure may last several minutes(from 40 to 60) and it's recommended to perform it when equipment has been just switched on.

Procedure can be stopped by pressing ESC on keyboard.

If sinker temperature test end with no error software will show :

- RISING TEMPERATURE SPEED+ LAST TEMPERATURE

If sinker temperature end with error software will show an error code :

- FREEZE ERROR+ LAST TEMPERATURE : sinker can not get cold
- WARM ERROR+ LAST TEMPERATURE : sinker can not get hot
- RISING TEMPERATURE SPEED+ LAST TEMPERATURE : the rising speed is too low

E Temperature factor

Temperature factor (m°C/°C) is the variation of reaction tray temperature (m°C) according to a 1°C variation of environment temperature.
The default factory value is **65 m°C/°C**

It's possible to change temperature factor on software by command on menu temperature

- If command is pressed when text box is cleared , current factor will be shown
- If command is pressed when text box is filled , written factor will be saved on board

It's strongly recommended to not change this factor .
This factor may be changed only in some particular cases :

- Special environment
- Special working conditions
- Special equipment configurations
- ……..

2.3 Reader

Using "Reader" menu you can check photometer channels and all the filters.

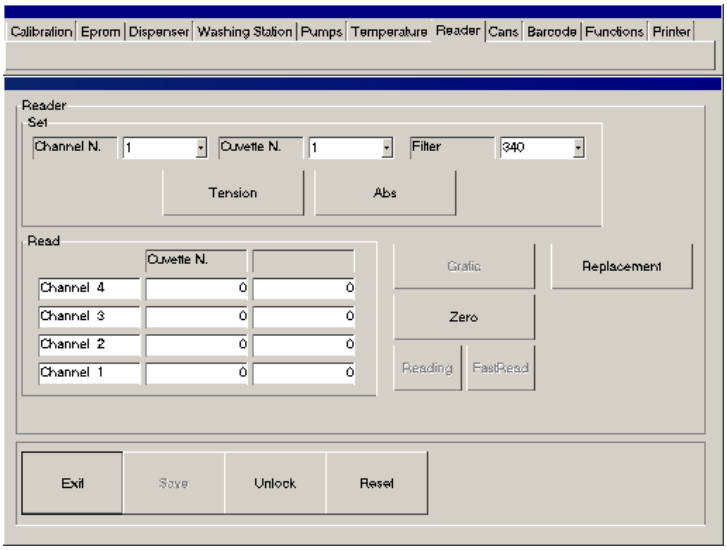


Figure 28 reader menu

In the "Set" sub menu you have the following input boxes and buttons:

1. "Channel N." to select the channel [1 ÷ 4] .
2. "Cuvette N." to select the cuvette [1 ÷ 60]. Reaction try will bring the cuvette aligned with selected channel (point 1).
3. "Filter" to select the actual reading filter (340 nm, 405 nm, 492 nm, 505 nm, 546 nm, 578 nm, 630 nm, 700 nm).
4. Select "Tension" button to display reading results in voltage levels (mV) or "Abs" button to display absorbance reading results
5. Press "Reading" (toggle mode) button to run reading operation and start monitoring.
6. Press "Stop" to end reading operation.

If you select "Channel N" = 1 and "Cuvette N." = 1, after press "Reading" button ("Reading" toggle → "Stop"), reaction tray position will be as in Figure 29. For a coherent reading operation cuvettes must be filled with water. Photometer unit reads 4 cuvettes at the same time, this means that you have to fill cuvette numbers 1, 60, 59, 58, see Figure 29.

During reading operation channels results will display in "Read" sub menu edit boxes.

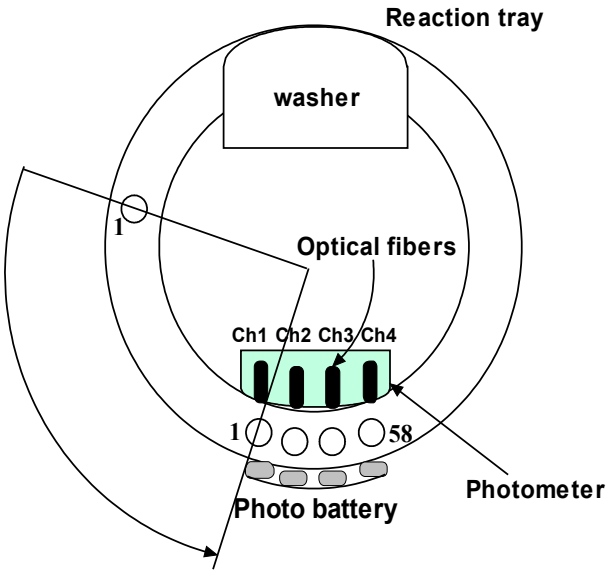


Figure 29 reading position alignment

If you select "Abs" button, software will display absorbance reading results. Selecting "Abs" mode, if you press "Zero" button and then "Graphic", software will open a graphical display to control photometer channels reading rate, Figure 30.

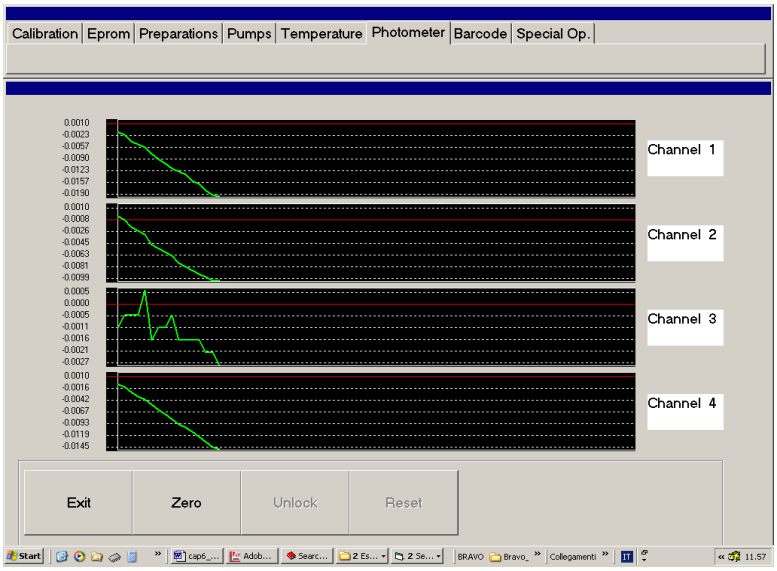


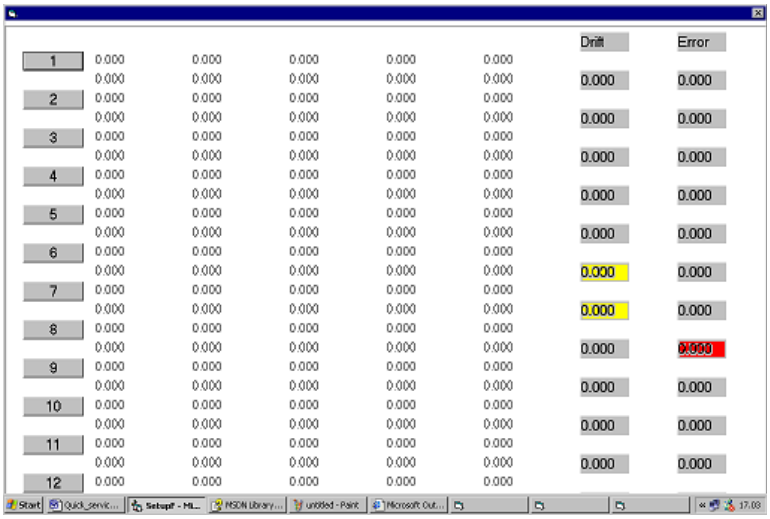
Figure 30 reading graphical display

2.3.1 Replacement function

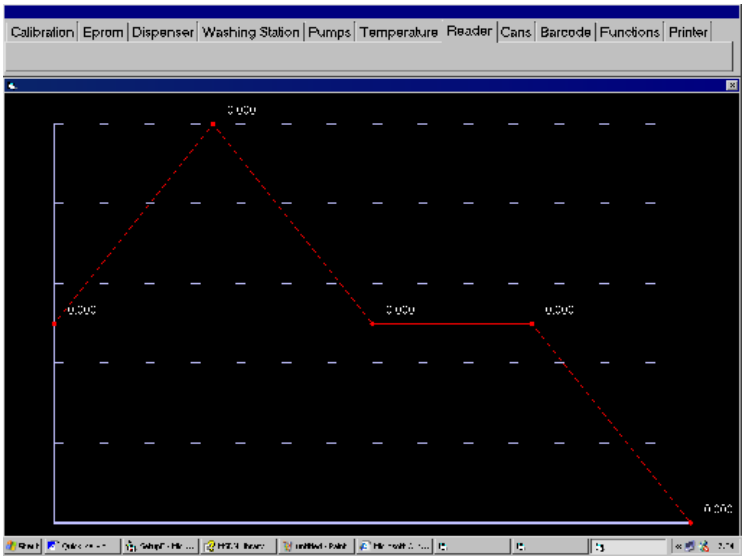
In order to test replacement error effect on photometer performance , an automatic procedure can be performed.
This procedure needs diluted 1/100 potassium bichromate K2Cr2O7 (ABS around 1.700)

- Fill bottle on reagent tray position 1 with diluted 1/100 potassium bichromate
- Start procedure with "Replacement" command
- Wait for end procedure

At the end of procedure results are shown in a form :



By pressing buttons 1, 2, 3... and so on a graphic of reading can be shown:



Each of 12 cuvette are filled with solution and they are read 5 times after moving reaction tray.

The procedure can estimate:

- **Replacement reading error** between each reading of a cuvette: if some cuvette reading are too different **the label under Error column becomes red**
- **Accuracy error** between each channel of photometer : if then mean reading of each channel is too different in comparison with the other **the results labels becomes red**
- **Drift rate** between each reading of a cuvette : if cuvette reading drift is too high **the label under Drift column becomes yellow**

Moreover form can be saved on file".bmp" by pressing F1 on keyboard (optional: user will be able to input a note in the file name), all files will be saved in "C:\EosBF\File" folder.

2.3.2 Photometer adjustment

In order to realize a photometer adjustment it is necessary that the photometric calibration has been executed first as described before.

Photometer check is as follows:

1. Ensure that photometric calibration is OK, then read the voltage level;

8. At 340 nm wavelength the average voltage level must be in the range of [400 ÷ 1000] mV;

9. Maximum variance for each channel from average energy level must be ± 20%;

10. For all the other filters, maximum energy level must be under 4100 mV, consider that 5000 mV energy level is the photometer saturation;

To change channel energy levels :

- Open instrument on lateral side, below photometer unit there are 4 screw for gain trimming, Figure 32 .

- Select the channel out of range and turn the screw to adjust the gain so that channel voltage level will be in the optimal range (for this operation you have to run photometer reading with filled cuvette and control channels monitor), Figure 31.

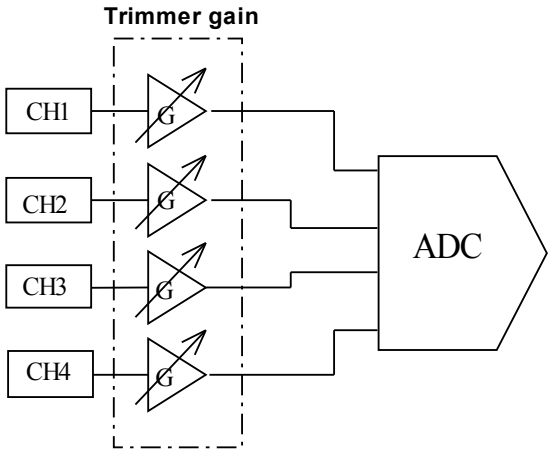
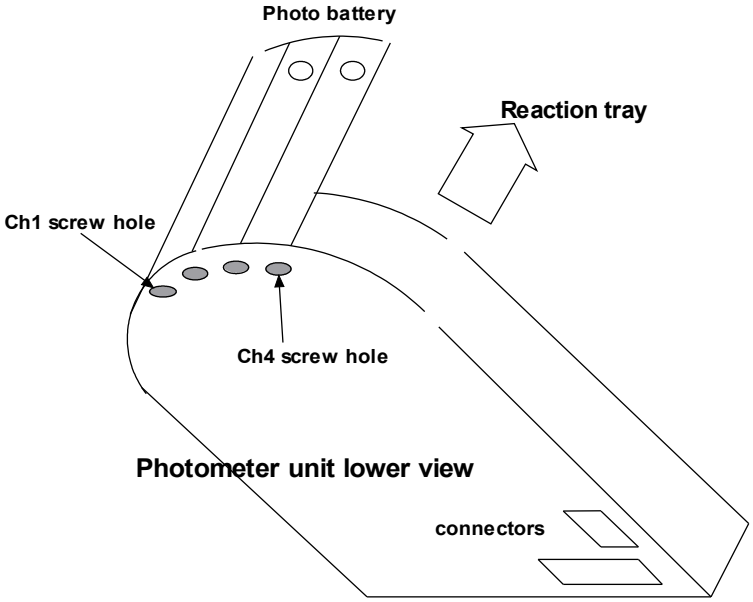


Figure 31 trimming



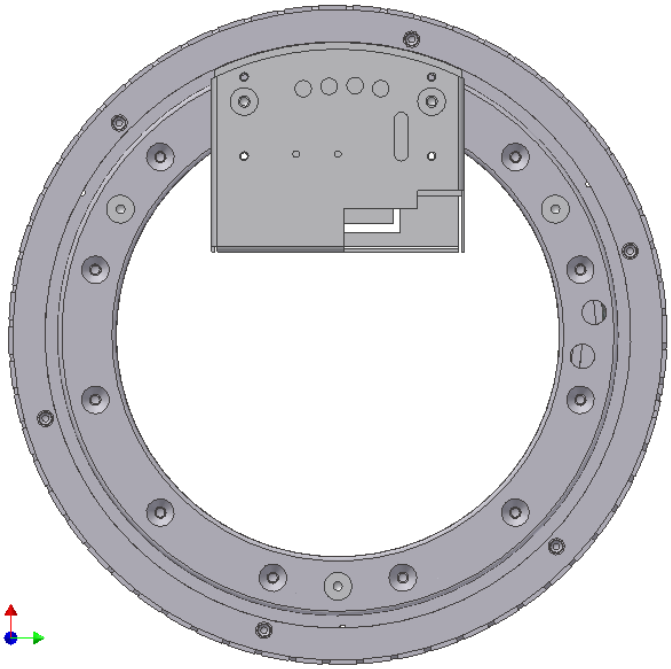


Figure 32: photometer below layer

2.4 Barcode

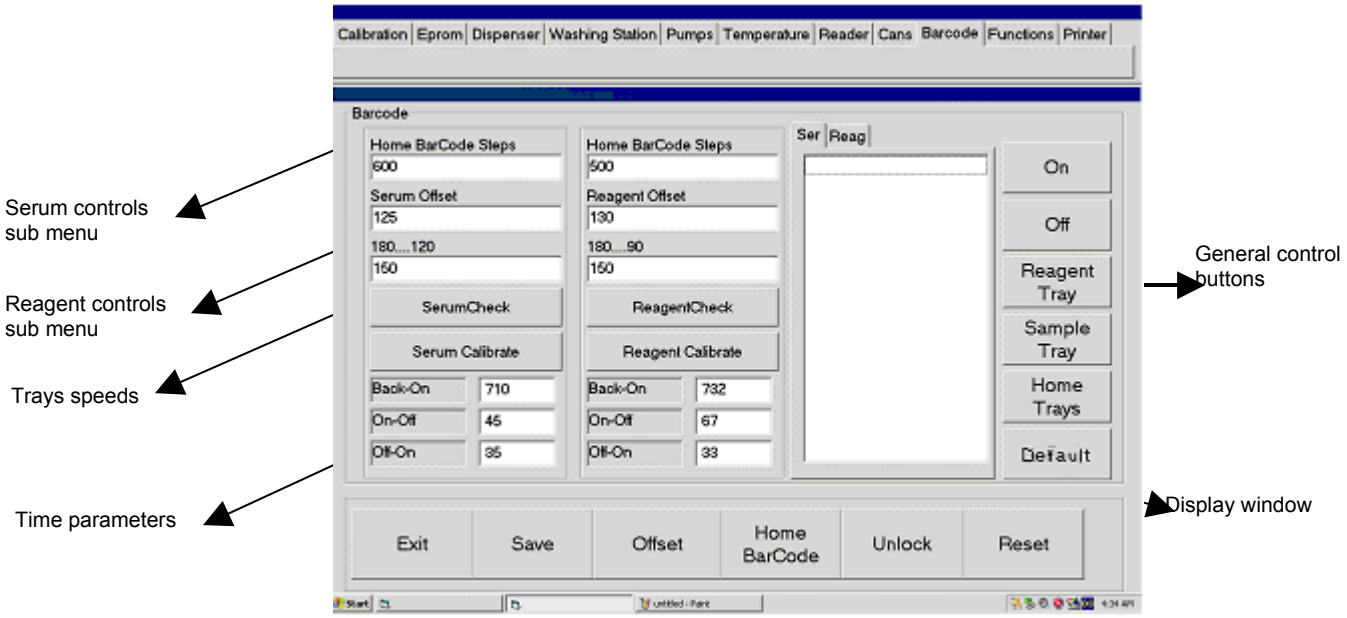


Figure 33 barcode menu

Figure 33 shows Barcode calibration menu. In right side, you have some general buttons:

1. "On" button to start barcode reading.
2. "Off" button to stop barcode reading.
3. "Reagent Tray" button to move one position in reagent tray.
4. "Serum Tray" button to move one position in serum tray.
5. "Home Tray" button to recover reagent and serum tray home positions.

Reference label is on reagent tray, before barcode reader. With empty reagent tray, if you press "On" button barcode reads reference label and a message with the read value should appears (reference label value is "0000"). If the message doesn't appear, it means that barcode has some reading problems and you have to adjust its physical position, see Figure 34:

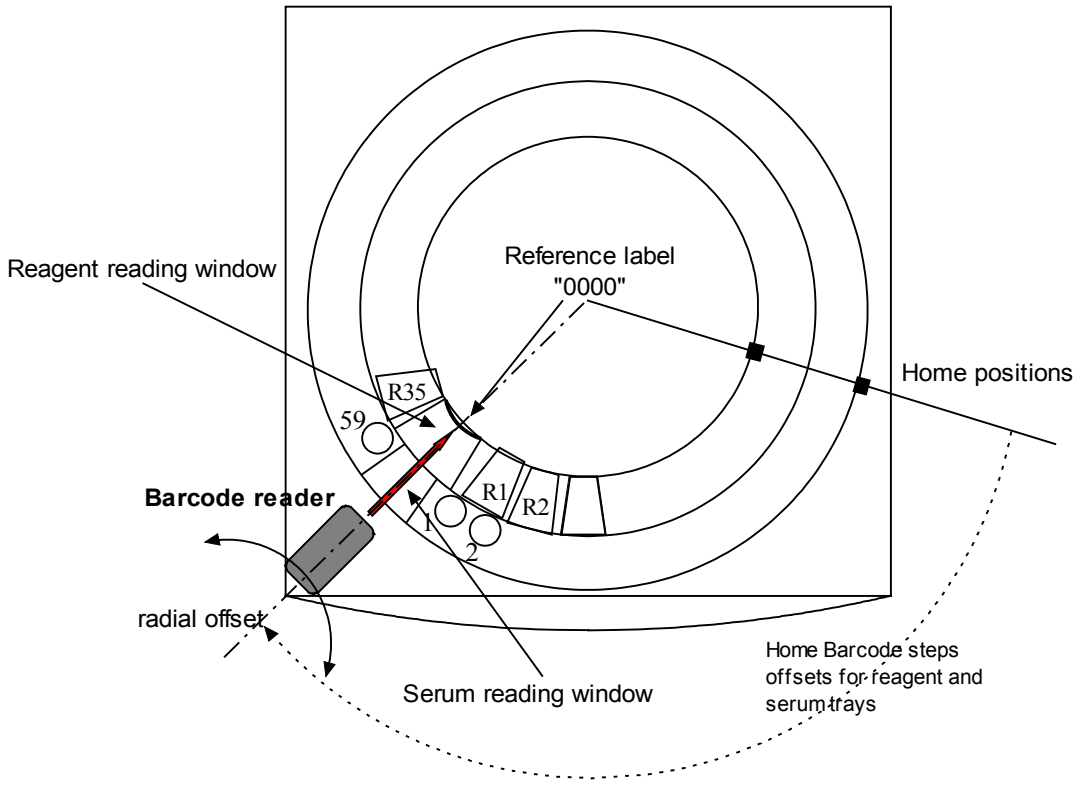


Figure 34 barcode reader

To calibrate barcode, open lateral and front cover.

Barcode calibration procedure:

1. Insert offsets values (steps) in “Home Barcode Steps” edit boxes (Figure 33) to have windows reading position aligned with barcode reader, see Figure 34. Then, press “Home Barcode” button to test the new offsets: reagent and serum trays will move them self to bring reading windows in front of barcode. Repeat this operation to find the best offsets, thus press “Save” button.
2. “Serum Offset” and “Reagent Offset” are steps distances to have sample and reagent first positions in front of barcode reader, see Figure 35. To test offsets, first insert tube and bottle in their relevant position with barcode label, then press “Offsets” button: reagent tray will bring the bottle in reading position. If you have chosen a good offset a message will appear to display the read code, then press “OK” message button. The same operation is for serum tray. Repeat this operation to find the best offsets, thus press “Save” button.

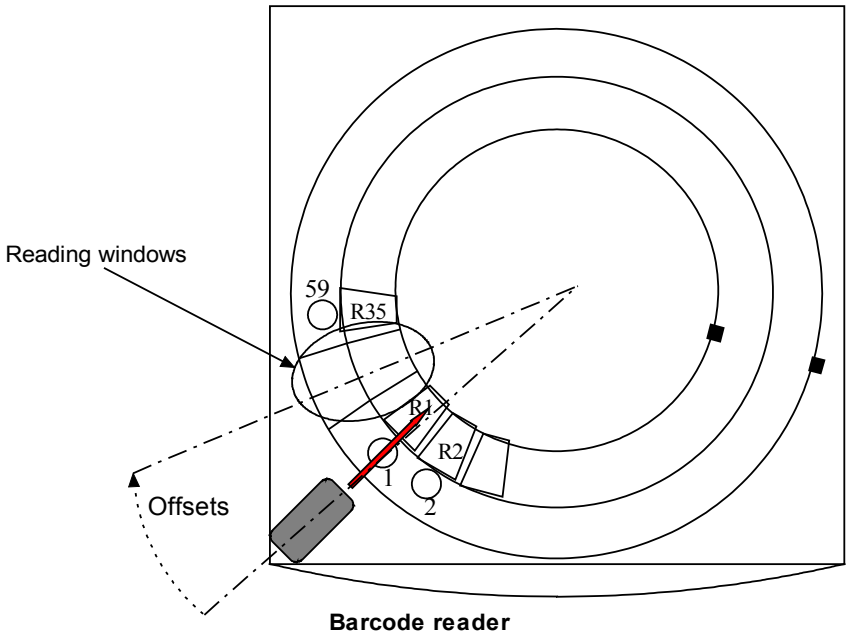
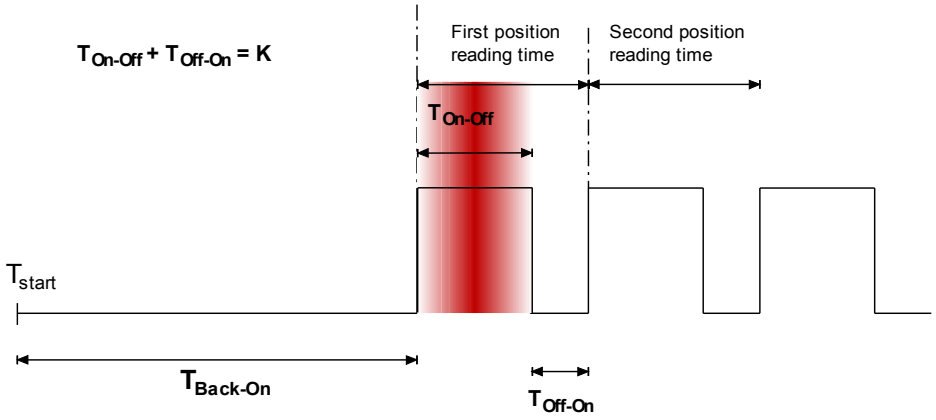


Figure 35 offsets calibration

3. Tray speed edit box: you can select tray speed in the range [190 – 90] rpm, the default values is 150 rpm, see Figure 33.
4. Time parameters: "Back-On", "On-Off" and "Off-On" values, to calculate them press "Reagent Calibrate" button for reagent tray and "Serum Calibrate" for serum tray.
   A fully automatic procedure will start to compute time parameters. It's necessary to have serum tube and reagent bottle with calibration code. Calibration code is defined in Main program: press "Functions" button, then open "Barcode" menu, here you can edit or modify calibration code. Physical meaning of time parameters:



TBack-On: time to wait first label in reading position from starting point
TOn-Off: time to read one label
TOff-On: delay for the next reading
If you change some computed values, remember that TOn-Off and TOff-On sum must be a constant

5. Insert some labelled bottles in reagent tray, then press "ReagentCheck" button for a complete barcode scan. In Display window "Reag" will appear scan results, thus control them with physical dispositions. If the test is not OK, repeated reagent calibration as previous point 4 or modify time parameters. Otherwise press "Save" button.
6. Insert some labelled tubes in serum tray, then press "SerumCheck" button for a complete barcode scan. In Display window "Ser" will appear scan results, thus control them with physical dispositions. If the test is not OK, repeated serum calibration at previous point 4 or modify time parameters. Otherwise press "Save" button.

2.5 Functions

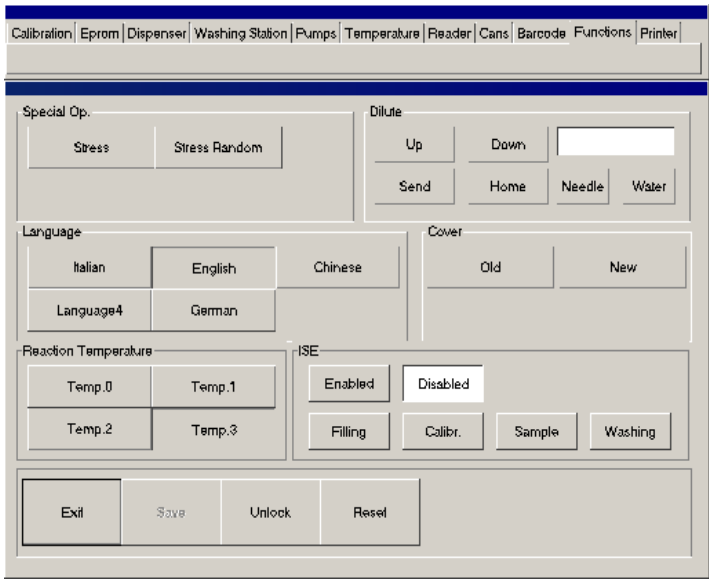


Figure 36 functions menu

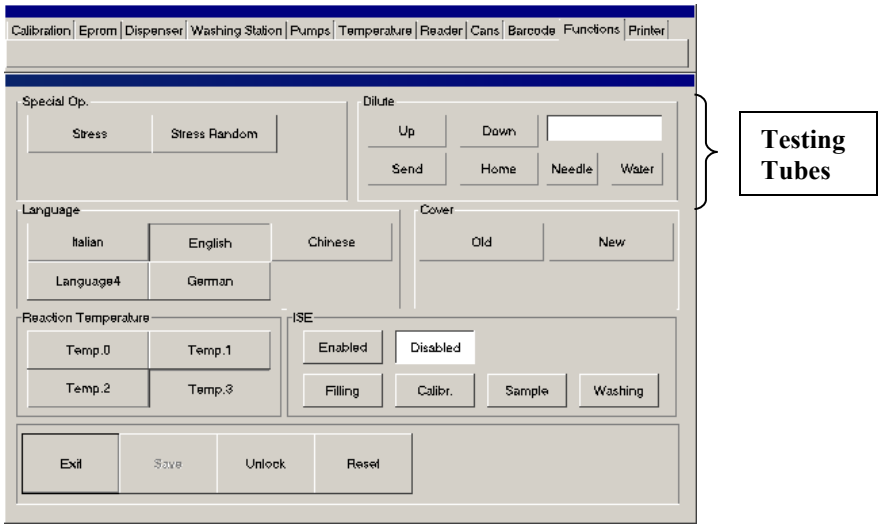
Use "Functions" menu

- To select interface language in "Language" sub menu.
- To pilot ISE module in "ISE" sub menu.
- To move dilutor in "Dilute" sub menu.
- To set start up temperature in "Reaction Temperature" sub menu

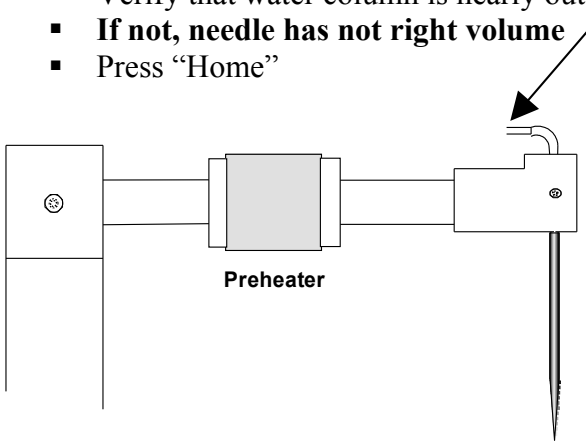
- To perform stress procedure in "Special Op." sub menu
- To set cover type of equipment in "Cover." sub menu

2.5.1 Testing Tubes with Dilutor

Using Dilute menu on "Functions" menu It's possible to test heater Teflon tubes and needle volumes.

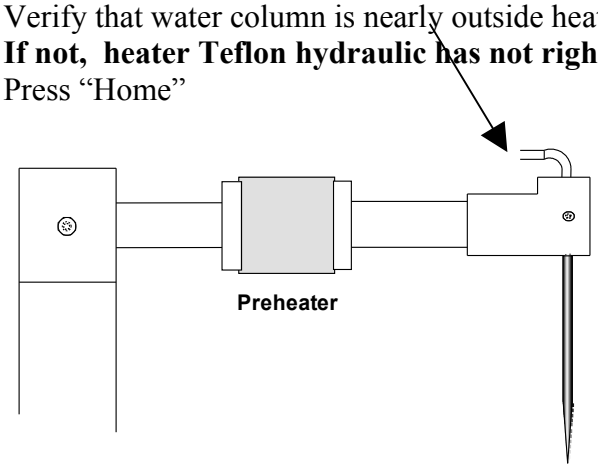


- **Needle Test**
  - Perform filling on "Washing Station" menu until hydraulic is completely filled
  - On submenu "Dilute" select "Down" and input **450** on text box , select "Needle" and press "Send"
  - Verify that water column is nearly outside needle.
  - **If not, needle has not right volume**
  - Press "Home"



- **Heater Teflon hydraulic Test**

- Perform filling on “Washing Station” menu until hydraulic is completely filled
- On submenu “Dilute” select “Down” and input **1900** on text box , select “Needle” and press “Send”
- Select “Water”, select “Up” and press ”Send”
- Select “Needle”, select “Down” and press ”Send”
- Selezionare NEEDLE, selezionare DOWN e premere SEND.
- Verify that water column is nearly outside heater.
- **If not, heater Teflon hydraulic has not right volume**
- Press “Home”



2.6 Printer

You can edit your printing format using Printer menu, see Figure 37. Before to enable printer option, install your printer on PC instrument. In default option, printer is not enabled.
After printer general enable, you can add logo to your format by "Image" selection and a printing header by "Header" function.
Common printing functions are available in Options area.
In patient data you can select different features.

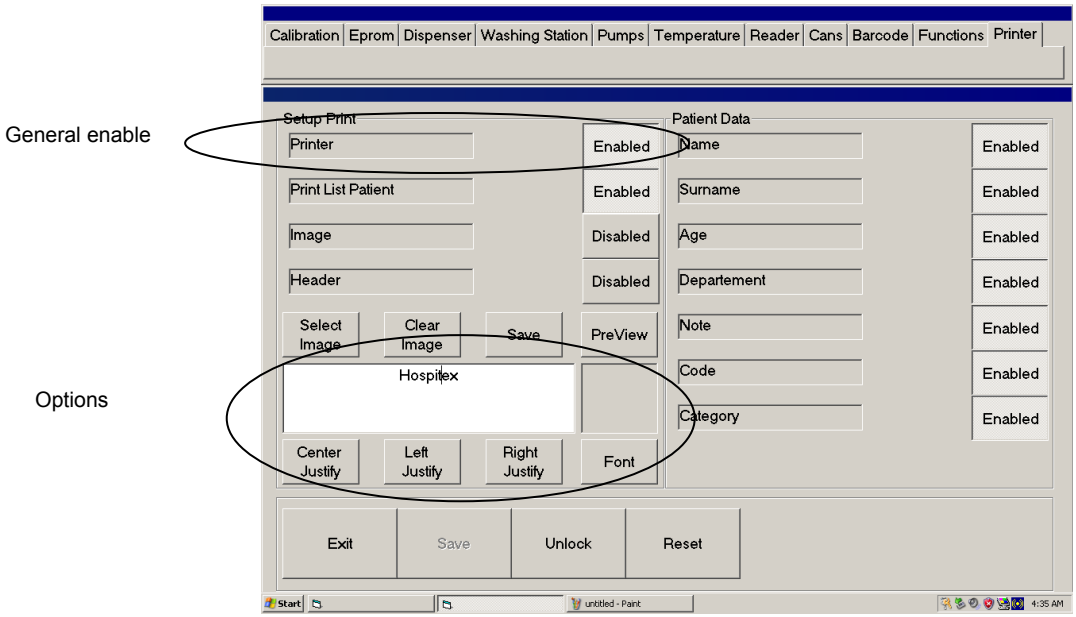


Figure 37 printer menu

3 PUMP SUBSTITUTION

To replace one of the peristaltic pumps on the side of instrument pull out the pump head and unscrew the two tubes, see the below figure:

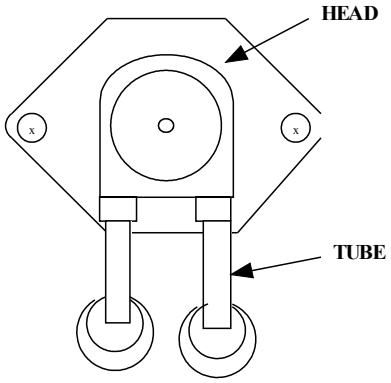


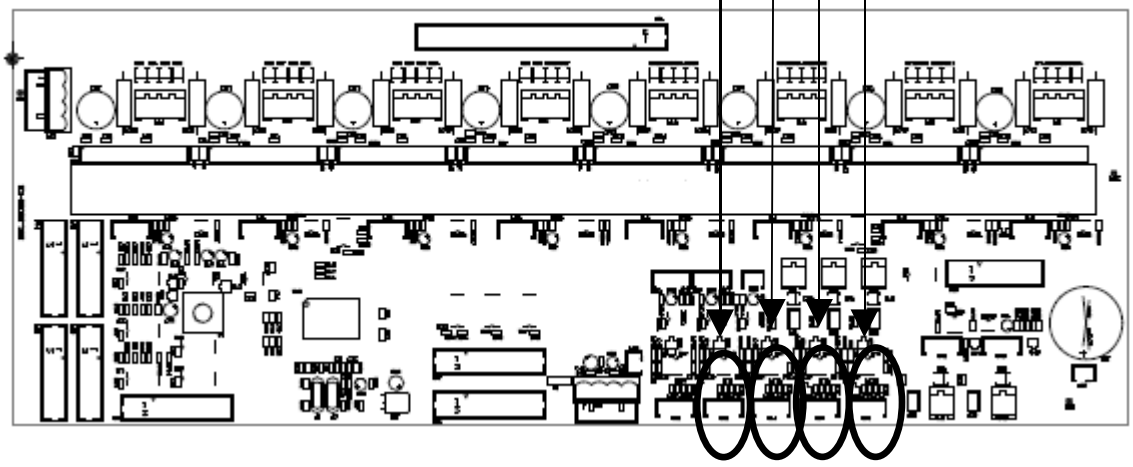
Figure 38: Peristaltic pump

Note: do not intertwine the lateral tubes when you reinsert the pump.

4 AD lines

Equipment main board has 4 AD lines :

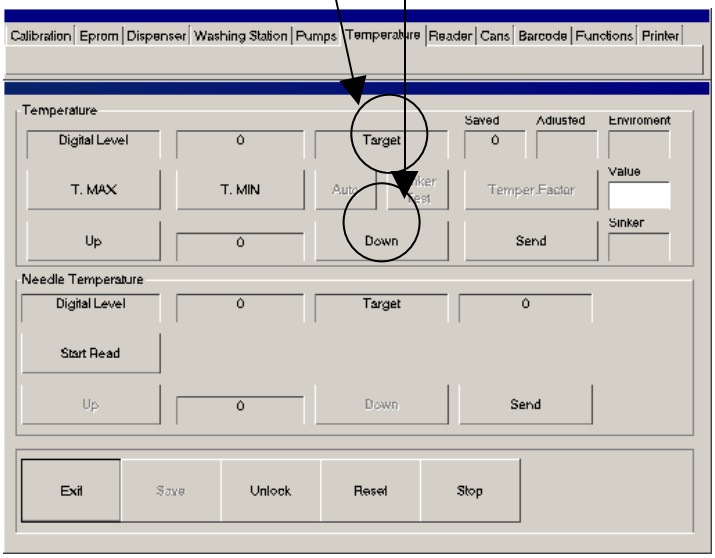
1. Reaction Tray temperature……P42
2. Needle Heater temperature……P43
3. Environment temperature……P44
4. Sinker temperature……P45



Lines 1 and 2 are used to control temperature , that's because they have a gain(around 10) that makes reading very accurate.

Lines 3 and 4 are used just to monitor temperature(environment and sinker) , so they have no gain. In order to have good reading on these lines it's necessary to calculate offset. Software uses an **automatic procedure to evaluate offset** on line 3 and 4

- Be sure that sensor is connected on P44
- Be sure that sensor is connected on P45
- Switch on equipment
- Use Service program on menu "Temperature"
- Push "TMAX"button
- Press F1 on keyboard (environment and sinker temperature will appear)
- Disconnect sensor on P44 and wait for environment temperature monitor becomes zero
- Connect sensor on P44 again and wait temperature monitor reaches real value starting from zero
- Disconnect sensor on P45 and wait for sinker temperature monitor becomes zero
- Connect sensor on P45 again and wait temperature monitor reaches real value starting from zero



Notes :

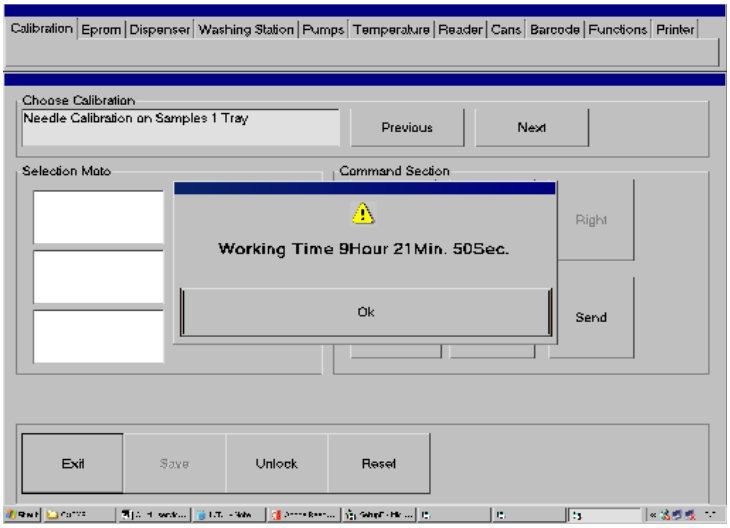
- Reaction tray temperature control according to environment temperature is disabled if this procedure is not properly performed .
- In order to clear current offsets use "Clear AD Offset" button on "Eprom" menu

4.1 Hidden Keys

- **ESC :** Reaction tray temperature auto calibration and sinker test can be suddenly stop , by pressing ESC key (see 1.3.7 section) . Note that during auto calibration current level and environment temperature will be saved.

- **F1 :** During reaction tray temperature auto calibration and manual calibration , environment and sinker test can be shown by pressing F1 key (see 1.3.7 section).

- **F11 :** Service software allows user to monitor equipment working time by pressing F11 key on each menu



- **F12 :** Service software allows user to "reset & start again program" time by pressing F12 key on each menu . This function is very important to unlock software any time it's necessary.