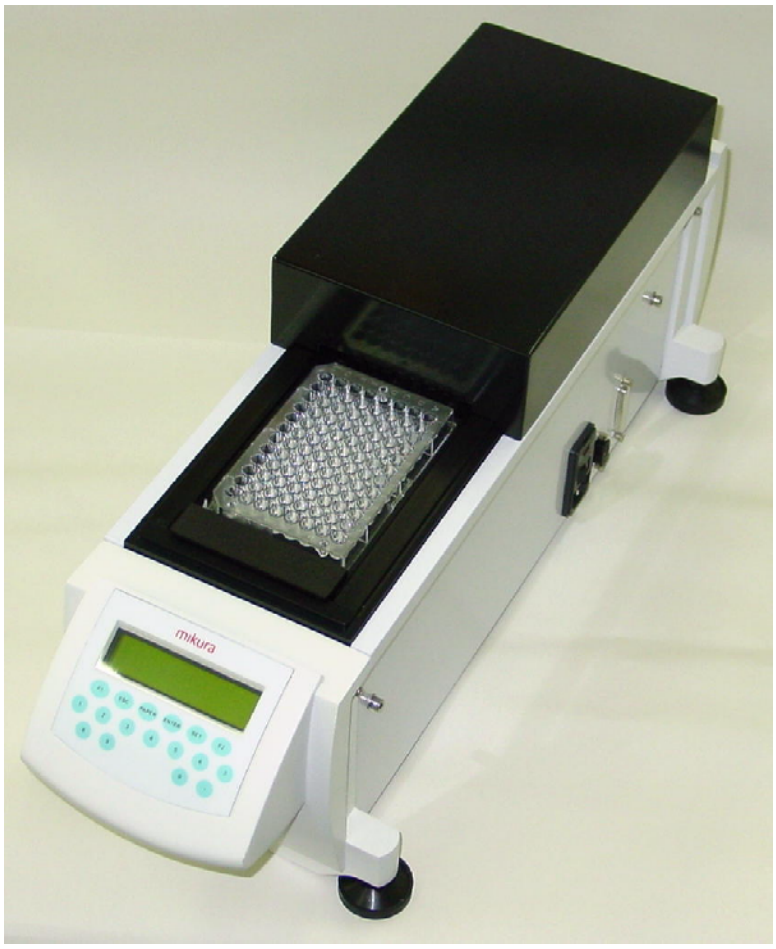
mikura
Optica

# Plate Reader

## Microplate reader




## USER'S MANUAL



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| Type | Date | Modifications |
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# CONTENS

# INTRODUCTION

## 0.1. DESCRIPTION

This manual provides the operator with all the necessary instructions and maintenance recommendations for a safe and suitable use of the instrument.

Manual content:

- **introduction** - warranty information, Technical Service and the CE conformity declaration
- **section 1** - general safety-warnings
- **section 2** - general information
- **section 3** - instrument performance and technical data
- **section 4** - installation and start up
- **section 5** - operating instructions
- **section 6** - periodic maintenance
- **section 7 -** how to put the instrument out of service, packaging, transport and storage
- **section 8** - appendices including instrument decontamination and spare parts list

This manual is considered as a part of the instrument; it has to be at the operator, user ,and maintenance technician's hand at any time. For accurate installation, use and maintenance please read the following instructions carefully.

In particular carefully read Section 1 "GENERAL SAFETY WARNINGS", describing the suitable operating procedures in order to avoid damages to the instrument and people.

In case of breakdowns or any troubles with the instrument, refer to the local Technical Service.

## 0.2. WARRANTY

Each provided instrument is completely tested, and guaranteed for twelve months from delivery.

The warranty is for all mechanical and electrical parts. It is granted only for a proper installation, use and maintenance in compliance to the given instructions contained in this manual.

The warranty does not include any responsibility for direct or indirect to people and material damages, caused by improper use and maintenance of the instrument.

All parts that are subject to deterioration, because of their specific use, are excluded from the warranty.

Due to a misuse of the instrument the warranty does not include (if requested) the travel and labor-hour expenses as well as all the accommodation expenses.

### 0.2.1 Asking for service

When asking for service, refer to this manual indicating also the data reported on the identification label of the instrument.

Only qualified Technicians with suitable instrumentation and original spare parts are entitled to fix the instrument; ordinary maintenance should be carried out by the user, as described in this manual.

### 0.2.2 Ordering spare parts

Parts that are subject to deterioration or that are defective and need to be replaced have to be requested as shown below.

When ordering spare parts, the following details are to be mentioned:

- customer's purchase order
- name and version of the instrument
- instrument code number
- part code number
- part description
- requested quantity
- name and company address to deliver the ordered goods

Replacing the parts with ORIGINAL SPARE PARTS guarantees effective and lasting instrument life

## 0.3. CE CONFORMITY

CE

*DECLARATION OF CONFORMITY*

The manufacturer:

# Mikura Ltd

***SCIENTIFIC INSTRUMENTS***

Unit 30 Huffwood Trading Estate, Partridge Green W Sx, RH13 8AU.
Tel: +44 (0) 1403 710298, Fax: +44 (0) 1403 711810

## *PLATE READER*

***model: Optica***

conforms to the following EC Directives, including the last modifications:

73/23/EC regarding low voltage
89/336/EC regarding Electromagnetic Compatibility

and that the below harmonized standard specifications have been applied:

Safety:

EN 61010 -1 (1997) "Electrical equipment safety requirements for measurement, control and laboratory use – Part 1: General requirements"

Electromagnetic Compatibility:

EN 61326 -1 (1998) "Electrical equipment for measurement, control and laboratory use – EMC requirements – Part 1: General requirements"

The Managing Director

# SECTION 1 - GENERAL SAFETY WARNINGS

## 1.1. GENERAL SAFETY WARNINGS

In this manual the following symbols stand for danger or warnings:

General DANGER symbol. Indicates that not following relative instructions and warnings is a serious safety risk.

Indicates ELECTRICAL VOLTAGE, which could cause death upon contact. Covers with this symbol can be removed and replaced by qualified people and only after electrical power disconnection.

Indicates that the instrument uses reagents and other DANGEROUS CHEMICAL SUBSTANCES, corrosive, irritating or noxious, which could cause health damages.

Indicates that the instrument handles potentially infectious samples (e.g. body fluids such as urine) which could cause INFECTION/CONTAMINATION. Always observe the general safety standard rules for the presence of these biological substances. Wear protective goggles, gloves and clothing.

Indicates that not following the correct instructions could cause damage to the instrument and/or its proper functioning.

Indicates important information concerning the instrument or a section of the document that is important to read with particular attention.

## 1.2. INSTRUMENT WORKING CONDITIONS

The instrument is an in vitro diagnostic medical device (IVD) intended to be used in the following working conditions:

- optical density readings as specified in the technical data
- use of the chemical reagents and accessories supplied and/or declared to be compatible with the instrument
- working at a specific temperature and humidity level according to the details given in this manual
- do not power the instrument in a potentially explosive or fire hazardous environment

The instrument has to be used as described in this manual. Any other use has to be regarded as improper

## 1.3. INTENDED USE OF THE INSTRUMENT

The instrument has to be used for the expected purpose and in perfect technical conditions, by qualified personnel, in working conditions and following maintenance operations described in this manual.

This manual contains instructions for qualified operators.

- **Qualified Users** have to make sure that the environment conditions are suitable, the installation is correct, the use and maintenance are proper, according to the general safety rules as well as to particular precautions described in the manual (although he is not entitled to repair the instrument).
- **Qualified Technicians** are entitled to service and fix the instrument with original spare parts, according to the received instructions.

**Modifications of the instrument are not allowed. The user is liable for any improper modifications and for the consequences deriving from them.**

For extraordinary maintenance, ask for licensed service centers. The maintenance will be carried out by Specialized Technicians that will be able to fix the instrument using original spare parts.

# SECTION 2 - GENERAL INFORMATION

## 2.1. INSTRUMENT DESCRIPTION: PURPOSE AND FEATURES

The PLATE-READER has been designed to automatically process the optical density reading of a micro titer plate with 96 wells. The plate has to be separately prepared before the reading process.

## 2.2. FEATURES

| | |
|---|---|
| ***Purpose*** | 96 well microplate reading |
| ***Kind of instrument*** | Stand alone instrument with its own software, display – keypad, and printer |
| ***Intended use*** | Photometer reading for ELISA/EIA methods |
| ***Software for PC*** | For the use of patient data management (optional) |

## 2.3 TECHNICAL SPECIFICATIONS

| | |
|---|---|
| ***Light source*** | tungsten lamps, automatically under-powered when in stand-by position |
| ***Optical filters*** | 2 filters (450, 630 nm); 2 more on request (max 4 filters) |
| ***Detectors*** | 8 silicon photodiodes |
| ***Reading system*** | 8 independent channels, mono or bichromatic reading |
| ***Accuracy*** | ± 1% from 0.000 to 1.500 OD<br>± 2% from 1.500 to 3.000 OD |
| ***Reading time*** | 16s to perform a monochromatic reading on a full plate; 31s for bichromatic reading |
| ***Cuvettes*** | 96 well plate or 8x12 or 12x8 well strips |
| ***Plate shaking*** | programmable by keyboard |
| ***LCD-Display*** | 2 lines with 16 columns |
| ***Printer*** | External Epson type |
| ***Keypad*** | 17 buttons |
| ***Interface*** | RS232 serial port |
| ***Curves*** | curve direct plotting: point to point, linear regression and 4 parameters (log-logit) |
| ***Results*** | by strip of 8 or 12 wells (X or Y) |
| ***Calculation Mode*** | OD, direct Cut-Off or calculated, single calibrator, programmable curves from 2 to 12 points |
| ***Memory capacity*** | 170 tests |
| ***Calendar/Timer*** | associates time with the results; timer function |
| ***Power requirements*** | 230/115 VAC, 50-60 Hz, 110 W |
| ***Measurements*** | cm 58 x 24 x 23 |
| ***Weight*** | 8.4 Kg |
| **Items supplied with the instrument:** | • A.C. power Cable.<br>• user's manual |
| **Additional accessories (optional)** | • PC cable connection<br>• PC communication software |

# SECTION 3 – INSTALLATION AND START UP

When installing and setting up the instrument, follow the safety warnings and general rules described in Section 1.

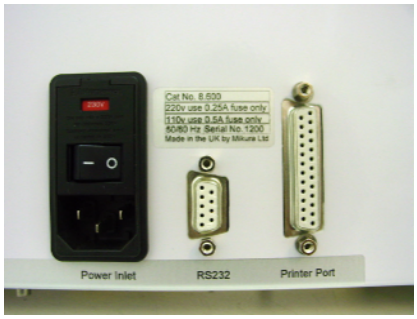
## 3.1 PLACING INSTRUMENT

### 3.1.1. Positioning the instrument

The instrument has to be placed on a leveled bench, assuring enough free space around the instrument to allow maintenance operations. The instrument has to be kept in a room where temperature has to be between 15 and 35 $^{o}$C with relative humidity below 80%, and protected from direct sun light.

### 3.1.2. Power connection

Once the instrument has been placed in the desired position proceed with plugging it into the right power source 230VAC or 115VAC (see label) using the proper cable.




Warning: make sure that the electrical power is the one as requested and indicated on the identification label of the instrument !

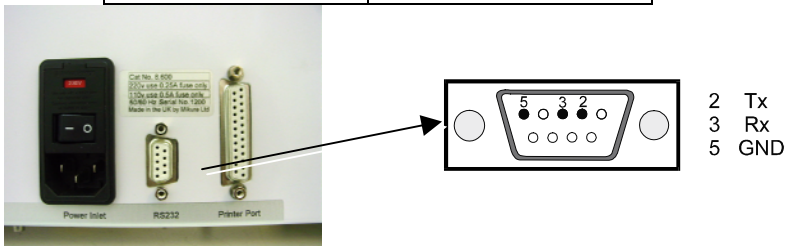
Warning: make sure that the fuses correspond to the ones indicated on the identification label of the instrument and in the manual!

| | | |
|---|---|---|
| 230 Vac | n° 2 | quick fuses 0.25 A |
| 115 Vac | n° 2 | quick fuses 0.5 A |

## 3.2. PLATE READER – COMPUTER CONNECTION

The instrument is equipped with an RS232 serial port for PC connection.
A cable and software are optionally available to link the instrument to PC (IBM or compatible in order to print, transfer and record the acquired data.
Connection to the PC must be made through the serial port COM2. Generally there are two serial ports to choose from, located on the rear of the PC: COM1 with a 9 pin male connector (for mouse connection) and COM2 with a 25 pin male connector.

| | |
|---|---|
| • 8 bit | • 600 baud rate |
| • no parity | • stop bit |



## 3.3. SET THE INSTRUMENT IN WORKING CONDITION

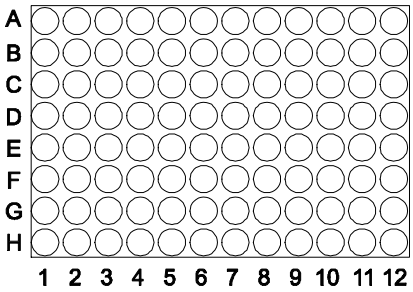
### 4.2.1. Connect the serial printer lead to the printer port on Optica and to the printer

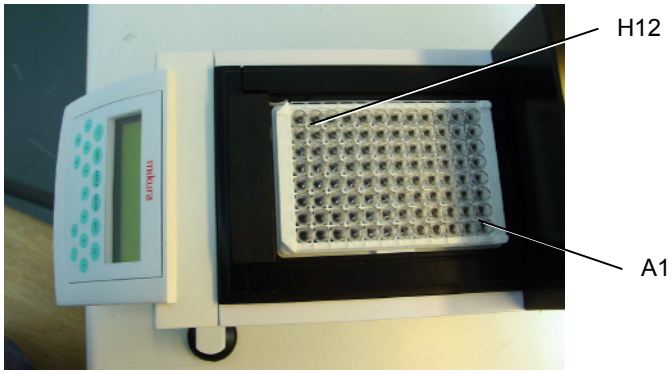
We recommend that you use tractor fed paper as this allow uninterrupted printing

Note: For a good printing, the use of original paper is recommended

### 4.2.2. Micro titer plate positioning

The micro titer plate should be placed onto the carriage, making sure that it is properly oriented.



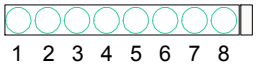




### 4.2.3. Strip positioning

Instrument reading system :

- 8 wells strip format
- 12 wells strip format

**strip with 8 wells:**

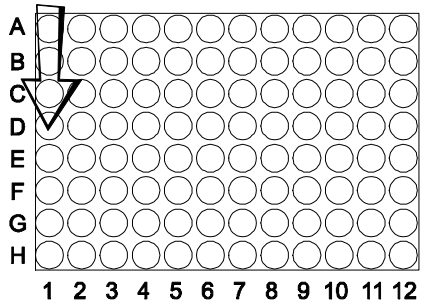



strip 1 1A, 1B, 1C, ⇒ 1H

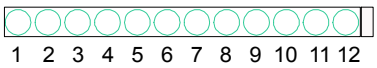
strip 2 2A, 2B, 2C, ⇒ 2H

⇓

strip 12 12A, 12B, 12C, ⇒ 12H




**Strip with 12 wells:**

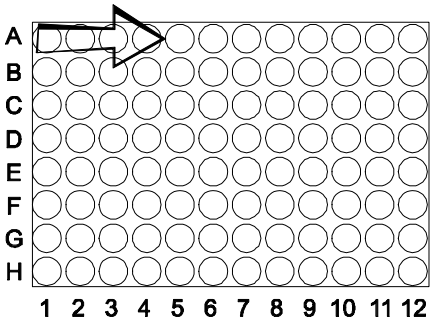



strip 1 1A, 2A, 3A, ⇒ 12A

strip 2 1B, 2B, 3B, ⇒ 12B

⇓

strip 8 1H, 2H, 3H, ⇒ 12H

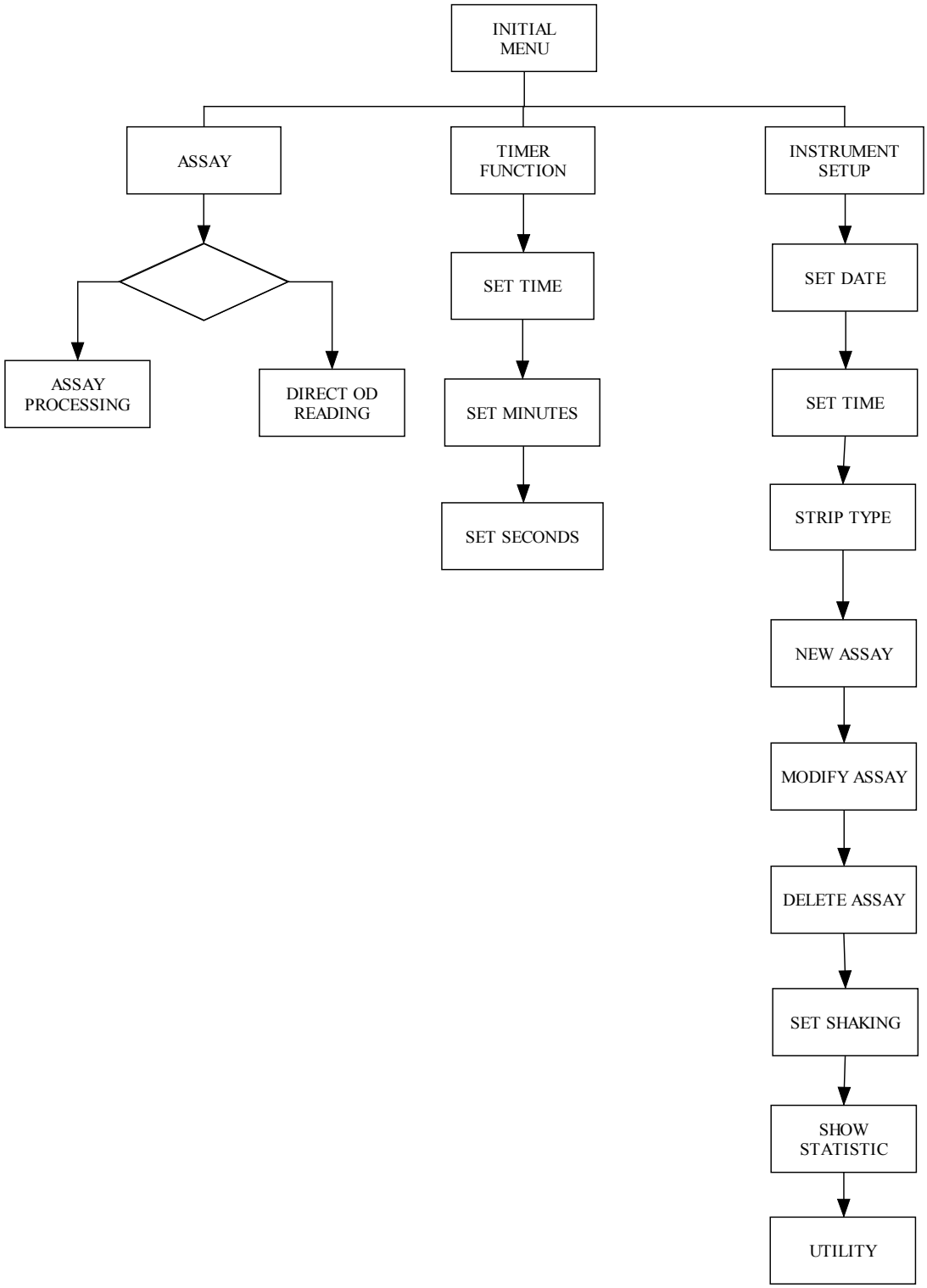


# SECTION 4 - HOW TO USE PLATE READER

## 4.1. INTRODUCTION

The flow diagram below indicates how the instrument is used. Detailed information for each step can be found in the indicated paragraph.

Table 5.1 - General flow diagram



## 4.2. SWITCHING THE INSTRUMENT ON

**The safety warning and general rules described in Section 1 have to be observed when using the instrument**

When switched on, the instrument automatically checks the functionality of its main parts; it prints the heading containing the instrument name, the software revision, the actual date and time, it checks the plate carriage home position.

Then the initial menu is shown as in fig. 1

Select one of the two options as shown on the display lower line (ASSAY or TIMER) by pressing the function keys **F1** or **F2**


fig. 5.1 Initial menu

When this initial menu is displayed the **SET** and **PAPER** buttons assume specific functions:

- **SET** button is to modify some parameters (for example date and hour, as specified in the SET menu chapter);
- **PAPER** does not function on this model
- When in this menu, **ENTER** button (usually it allows to enter data when required on the specific menu) is not enabled.
- **ESC** usually allows to go back to the previous menu

NOTE: SET, PAPER and ENTER, in particular menus can change their function as after explained.

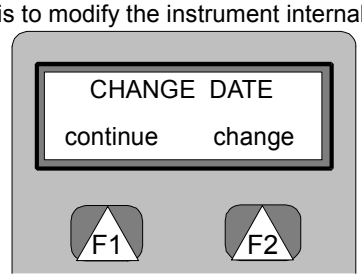
## 4.3. INSTRUMENT SET UP

### 4.3.1. General

By pressing **SET** button when in the initial menu (fig. 1), some instrument parameters can be modified. In the succeeding phases use **ESCAPE** to go back to the initial menu, use **SET** to go to the next menu.

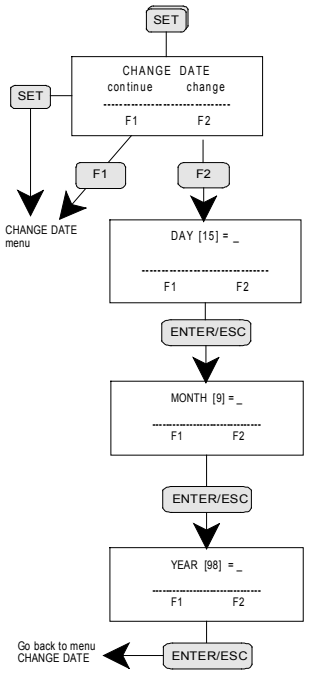
### 4.3.2. How to set the date

This menu is to modify the instrument internal date.



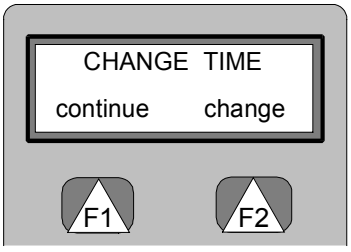

By pressing **SET** or **F1** the next menu is displayed, otherwise press **F2** to change the date.

The display shows in brackets the memorized day, month and year; modify the values if necessary and press **ENTER**, if no modification is required press **ESCAPE**.



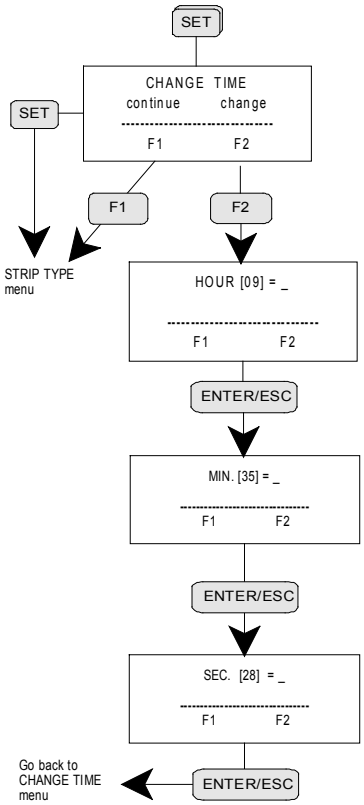

### 4.3.3. How to set the time

This menu is to modify the instrument internal time.




By pressing **SET** or **F1** the next menu is displayed, otherwise press **F2** to CHANGE the time.

The display shows in brackets the memorized hour, minutes and seconds; modify the values if necessary and press **ENTER**, if no modification is required press **ESCAPE**.

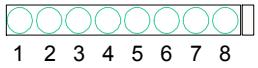


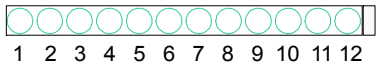
### 4.3.4. How to set the Strip type

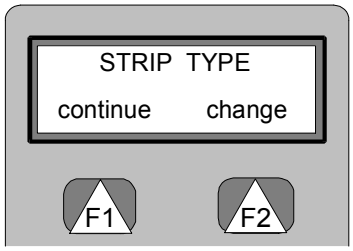
This menu is to set the strip type configuration on the micro titer plate:

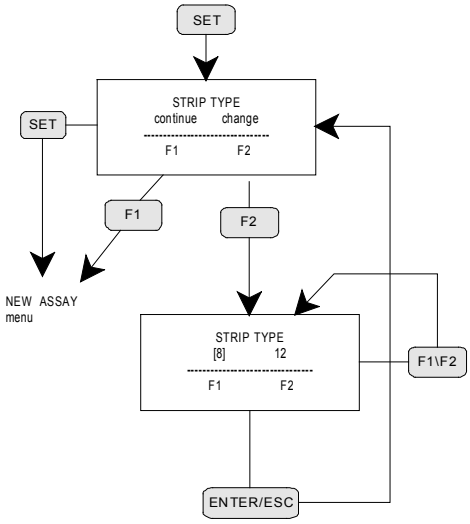
**#12 strips with 8 wells**

**#8 strips with 12 wells**



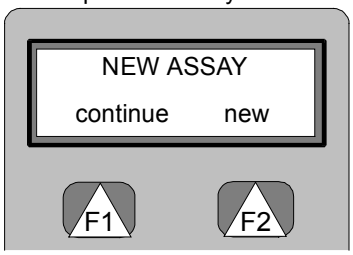



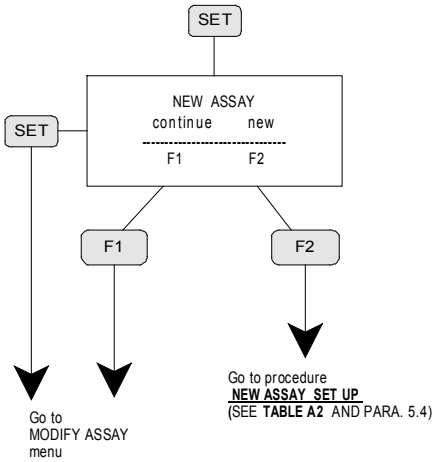

By pressing **SET** or **F1** the next menu is displayed, otherwise press **F2** to change the strip type.

The display shows in brackets the memorized Strip type, (8 or 12).
Select [8] or [12] by pressing **F1** or **F2** and press **ENTER**; if no modification is required press **ESCAPE**.

### 4.3.5. How to set up a new assay

This menu is to set up a new assay.



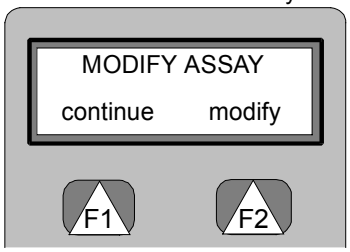



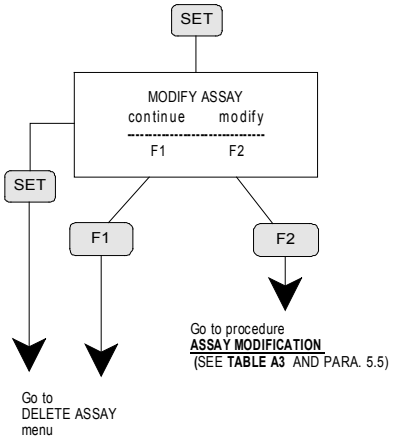

Press F1 to display the next menu or press F2 to run the procedure to set a new assay.

This procedure is described in details in para. 5.4 - New assay set up.

### 4.3.6. How to modify an assay

The MODIFY ASSAY menu is to modify filed assays.



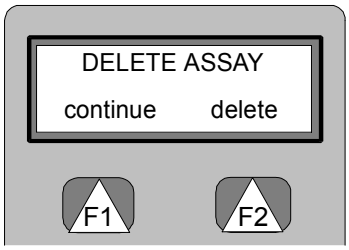




Press F1 to display the next menu or press F2 to start the modification procedure .

This procedure is described in details in par. 5.5 - Assay modification.

### 4.3.7. How to delete assay

DELETE ASSAY menu allows to delete filed assays.

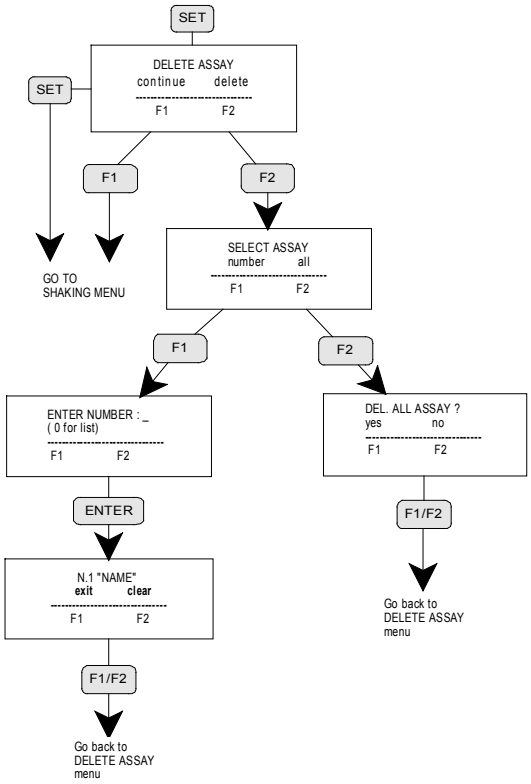



By pressing F1 the next menu is displayed, by pressing F2 it is possible to delete some or all the filed assays.

When F2 key is pressed, in order to avoid fortuitous mistakes, a further confirmation, before deleting all the filed assays, is required.

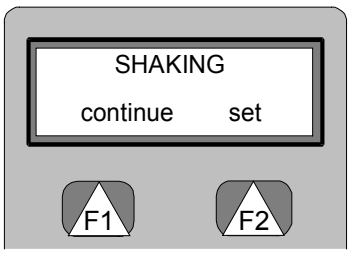
If F1 is pressed, the identification number of the assay to be deleted is required, then press ENTER.

Before deleting the selected assay a confirmation is required. Then the menu DELETE ASSAY is displayed again.



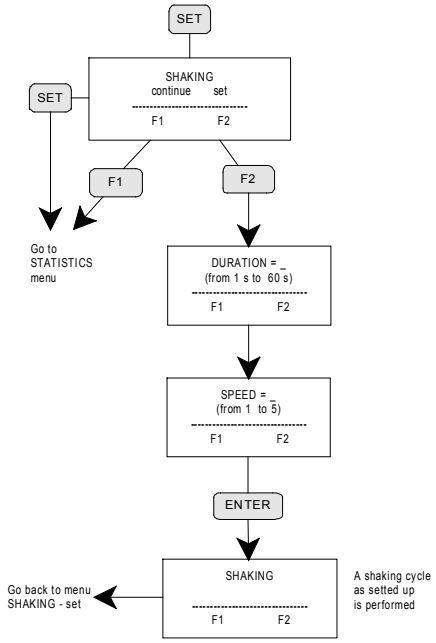

### 4.3.8. Shaking activation

The SHAKE menu allows to activate the plate SHAKING, this function has to be activated before the reading process.



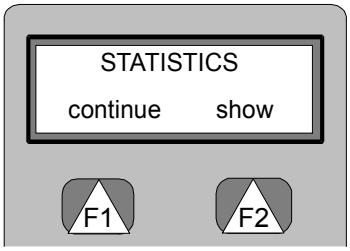

By pressing **F1**, the next menu is accessed.

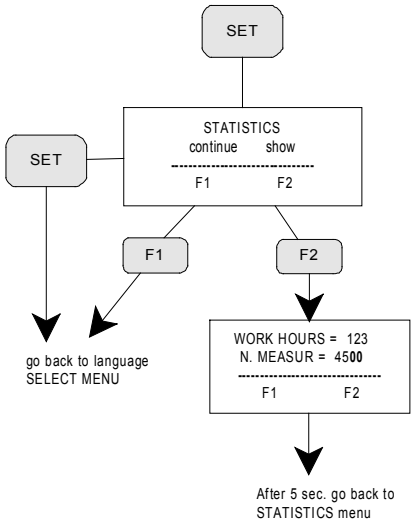
**F2** key is to set the plate shaking duration, as well as the shaking speed.



### 4.3.9. Statistical information

The STATISTICS menu is to list working data information.

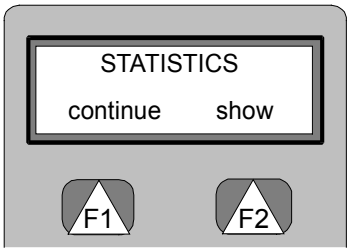


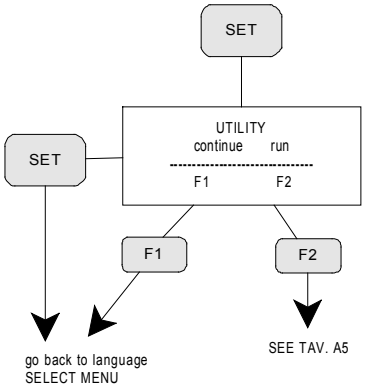




Press F2 to check the number of hours the instrument has been working as well as the number of performed reading.
After 5 seconds, the STATISTICS menu is displayed again.

### 4.3.10. Utility

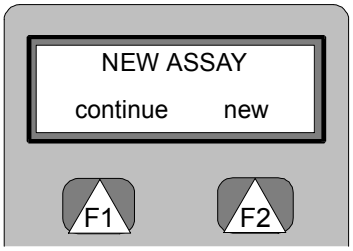
The UTILITY The "SERVICE" menu is to check the instrument functionality.



## 4.4. ASSAY set up

### 4.4.1. New Assay set up




From NEW ASSAY menu press F2 to automatically search a free position to store the new assay .

Press F1 or F2 to search for other free locations.
If not available, the message "FULL MEMORY" will be displayed.

By pressing ENTER, the following display will appear .

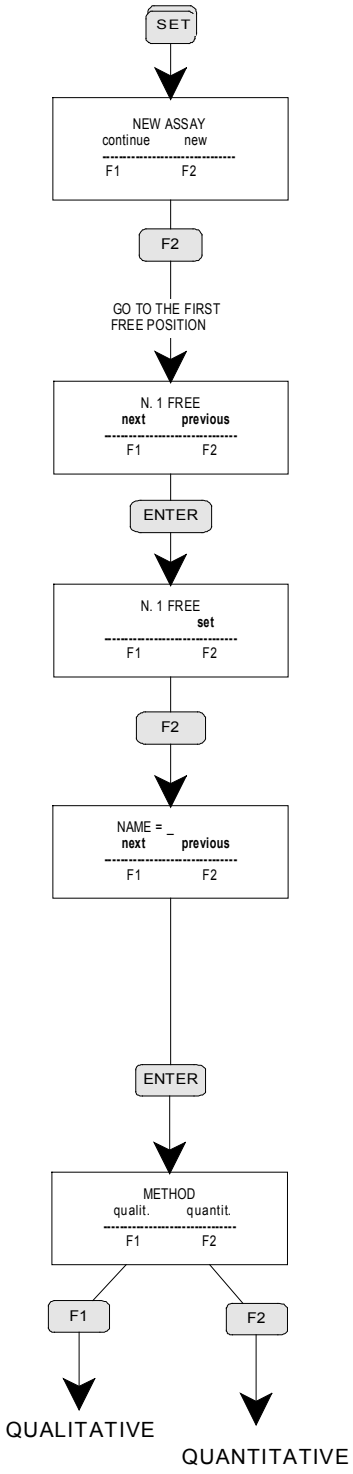
By pressing F2 a new assay can be set up by its parameters.

First of all, the name of the new assay has to be entered.
To enter the name (max 6 characters) use F1 and F2, to choose the desired letter or number.
Press SET to accept a letter and to shift to the next one.

Once the assay name has been typed, press ENTER.

Then the display will appear to choose for the assay method to carry out.

The assay is selected by pressing: F1 or F2 to select a Qualitative or a Quantitative method.



### 4.4.2. Qualitative Assay Set up

**Blank repetitions**
After the type of assay to set up has been selected, the number of blank to be repeated (to choose from 1 to 12) has to be entered: if no blank is required, enter "0".
The average of the measured absorbance values regarding the blank dispensed in the processed strip, will be automatically calculated.
By pressing ENTER, the selected option is confirmed and the next menu is displayed. In case of wrong typing press ESCAPE then repeat the input.
If more than 12 blank repetitions have been selected, is displayed a message to set again the right number of blank repetition to carry out.

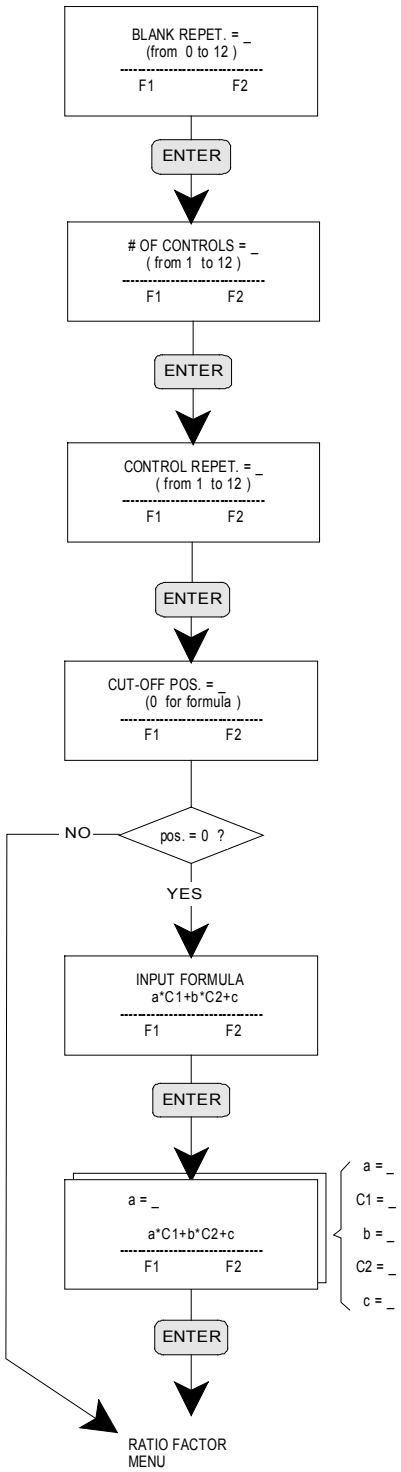
**Number of controls**
This menu is to set the number of controls as required by the method (maximum 12 controls).

**Number of control repetitions**
This menu is to set the number of controls repetitions up to 12 maximum; the average of the measured controls absorbances will be calculated, taking in account of all the processed controls of that strip.

**Cut-off set up**
When allowed by the method, simply enter the position number of the strip for the cut-off value, press ENTER to display the next menu.

Set "0" to enter the coefficients of the formula to calculate the cut-off according to the specific method requirements, then the structure of the formula to be used for the cut-off calculation will be displayed.

Press any key to set the value for the coefficient "a",
enter the well number of the strip (C1) to be used for the control, then set the the value for the coefficient "b" and the well number for the control position (C2) and the coefficient "c" required by the formula.



***Examples***

Some typical cases are afterwards analyzed to indicate the way to set the parameters for the cut-off calculation as required by the specific method.

*Example 1*

Having 3 controls (NC, PC, HC), supposing to calculate the cut off according to the Absorbance values average of the negative and positive controls [O.D. (NC) = NC, O.D. (HC) = HC]:

**cut-off** = (NC + HC) / 2 (1)

Considering that the (1) formula can be written as following:

**cut-off** = NC / 2 + HC / 2

comparing this formula with the one provided by the instrument sa described:

**cut-off** = a × C1 + b × C2 + c (2)

it is possible to calculate the cut-off value as required by the method, assigning to the coefficients "a", "b" and "c" the following values (2):

**a** = 0, 5 **b** = 0, 5 **c** = 0;

As the (1) involves the first and third control, has to be set for the C1 and C2 coefficients for the (2) :

**C1** = 1 **C2** = 3 ;

Using the acquired data set by the the operator and after having carried out the reading of the strip (controls included), the instrument automatically calculates the cut-off value according to the method requirements.

*Example 2*

**cut-off** = NC + K × PC ( K = Factor)

In this case the instrument calculates the cut-off as indicated by the method, using the (2) and by choosing the following values for the coefficients:

**a** = 1 **b** = K **c** = 0;

as the cut-off implies the first and the second control the following values are to be considered:

**C1** = 1 **C2** = 2;

*Example 3*

**cut-off** = PC × K ( K = Factor )

In this case the instrument calculates the cut-off according to the method requirements using the (2) and by choosing the following values for the coefficients:

**a** = K **b** = 0 **c** = 0;
**C1** = 2

*Example 4*

**cut-off** = K ( K = constant )

In this case the instrument calculate the cut-off according to the method requirements, using the (2) and by choosing the following values for the coefficients:

**a** = 0 **b** = 0 **c** = K.

***Ratio factor***

The "RATIO FACTOR menu" is to set the factor value.
To set the value press F1 button otherwise the menu goes to the next step (Positivity).

*note : Ratio has to be intended as
OD sample / OD cut-off

***Positivity***
This menu is to establish the positivity criterium; by pressing F1 (high positivity), the processed sample is considered positive if the absorbance value is higher than the cut-off value; by pressing F2 (low positivity) the processed sample is considered positive if the absorbance value is lower than the cut-off value.

The equivocal zone around the cut-off, that gives uncertainty is determined by the instrument.

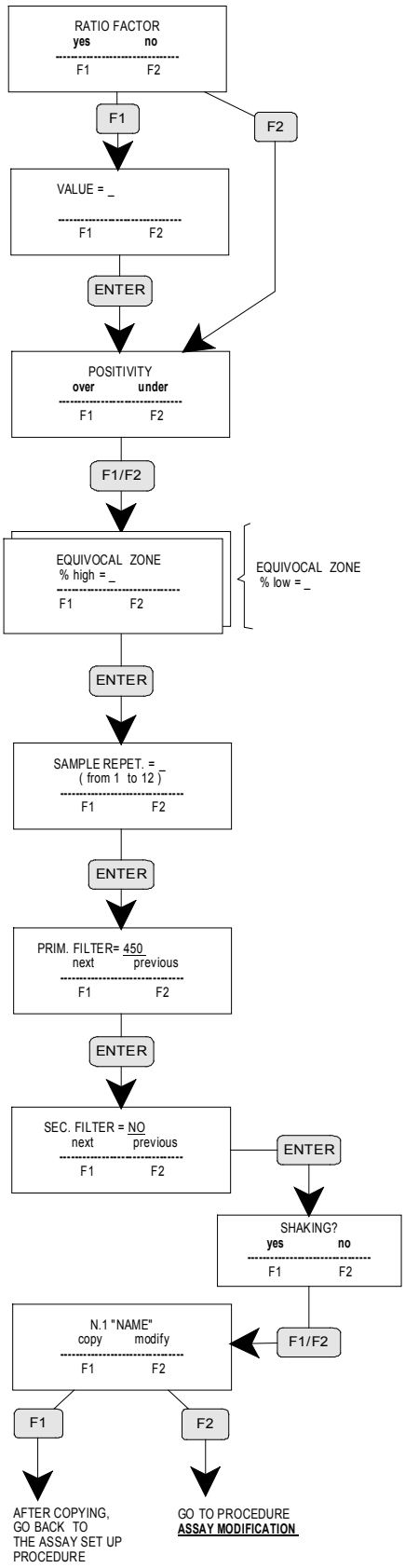
The instrument displays the menus to set the over and under cut-off values to determine the equivocal zone.

***Number of sample repetitions***
Set the number of samples repetition (max 4); the instrument calculates the absorbance average of the samples of the processed strip. When the required number of samples are set press ENTER to go to the next menu.

***Filters selection***
Set up the optical filters to be used for the test.
Select the primary filter; by pressing F1 or F2 the value of each existing filters to be set are displayed.
Once the primary filter has been selected press ENTER, then selct the secondary filter and press ENTER again.
To work with the absorbance monochromatic mode, press ENTER when the message "FILT. SEC. = NO" is displayed.

The plate shaking before reading has to be selected, if necessary.

At the end of the set up phase a new assay is memorized and displayed.



### 4.4.3. Quantitative assay set up

***Number of the blank replicates***

Select the assay to be processed and enter the number of blank repetitions. The instrument automatically calculates the absorbance average of the blank samples of the strip under process. Press 0 to jump the blank processing.

Press ENTER to confirm the displayed option then the next menu is displayed.

***Number of standards***

A new calibration (increasing or decreasing) curve can be set using up to 12 standards. The instrument curve is a point-to point type on the optical density-concentration relation.

To set the number of standards for the instrument calibration, enter the wanted number and press ENTER.

***Number of standard repetitions***

A calibration with a single or up to maximum 12 standard repetitions can be carried out; for the dispensed standard the instrument automatically calculates the optical densities average.

Once the number of standards repetitions is entered, set the concentrations value of each calibrator. During this phase a control on the calibration curve is carried out.

For a correct assay set up it is requested to set the calibrator concentration values in growing order, if not a message of error is displayed and a new concentration value has to be entered.

***Type of curve***

This menu allows to select the type of curve used to compute concentration:

- point to point.
- 4 parameters (Log logit) *.
- Linear regression.

** Note: at least 4 calibrator has to be choosen to take advantage of this selection*

***Measure unit***

This menu allows to choose measure unit for concentration.

***Number of sample repetitions***

Set the number of sample repetitions, maximum 12; the instrument automatically calculates the average of the read optical densities of each sample dispensed in the plate.

Set the required samples and press ENTER to display the next menu.

***Filter selection***

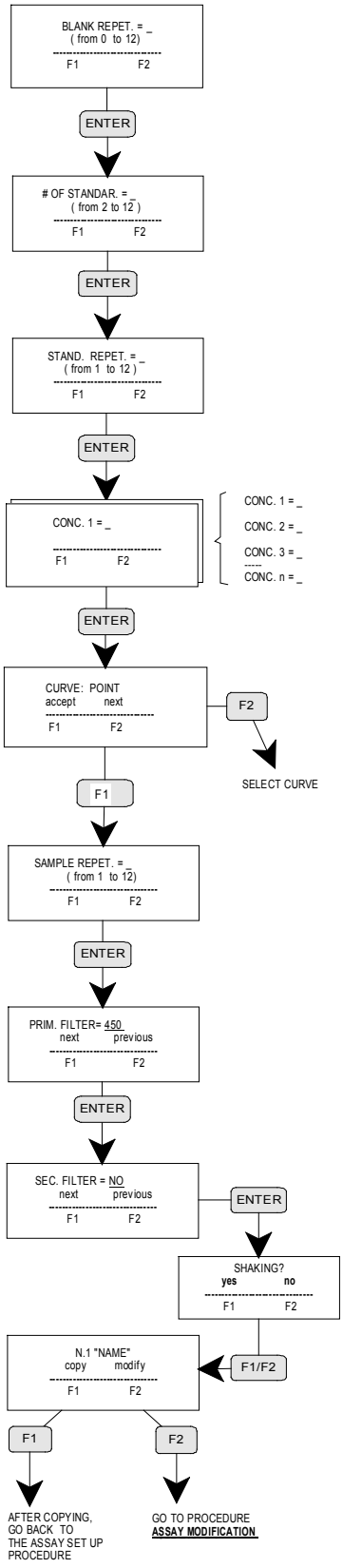
This menu allows to select and set the filters; by pressing F1 and F2 the value of each available filter is displayed.

Once selected the primary filter press ENTER it then the next menu to select and set the secondary filter is displayed.

To set the absorbance monochromatic mode press ENTER when the message "Filt. sec. = no" is displayed

The plate shaking before reading has to be selected, if necessary.

At the end of the set up phase of a new assay it is memorized and displayed.



## 4.5. ASSAY MODIFICATION

The MODIFY ASSAY menu is to modify filed assays.
Press F2 to display the selection menu.

By pressing F1 the assay to be modified has to be chosen. Enter the identification number or scroll the list of the already filed assays, by pressing F2 .

Press ENTER when the selected assay is displayed.

In both cases the selected assay name is displayed.

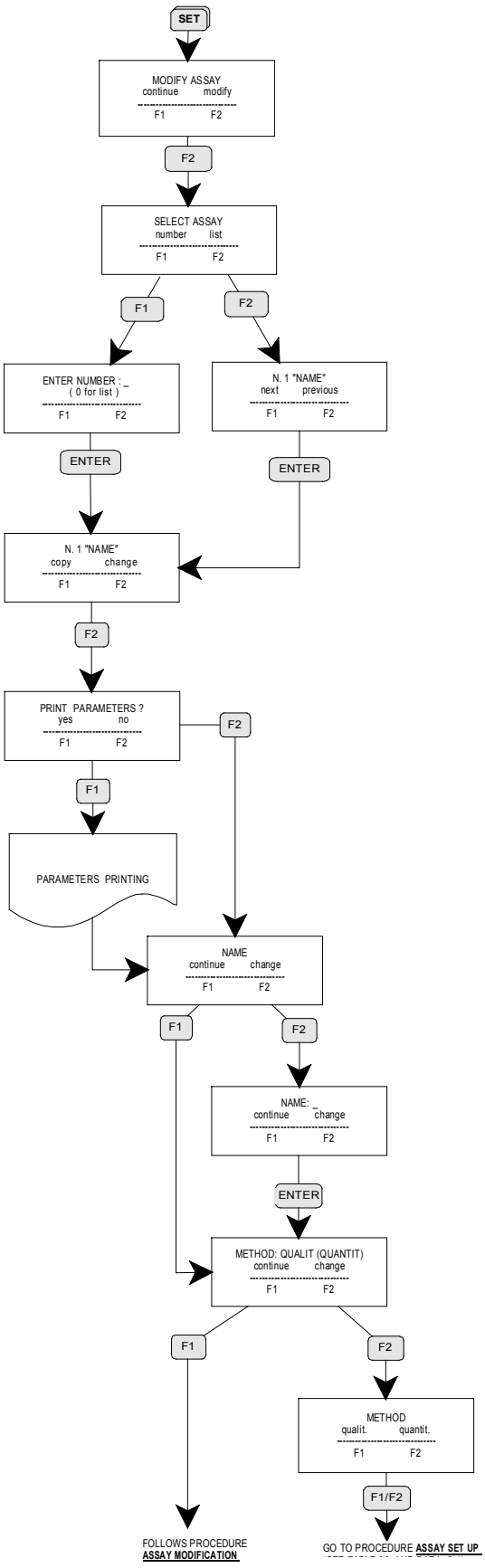
By pressing F1 the selected assay can be saved in the next free location.
The parameters of the filed assay can be modified by pressing F2.

Press F1 to print the selected assay parameters then the next menu is displayed, press F2 to go straight to Modify Menu.

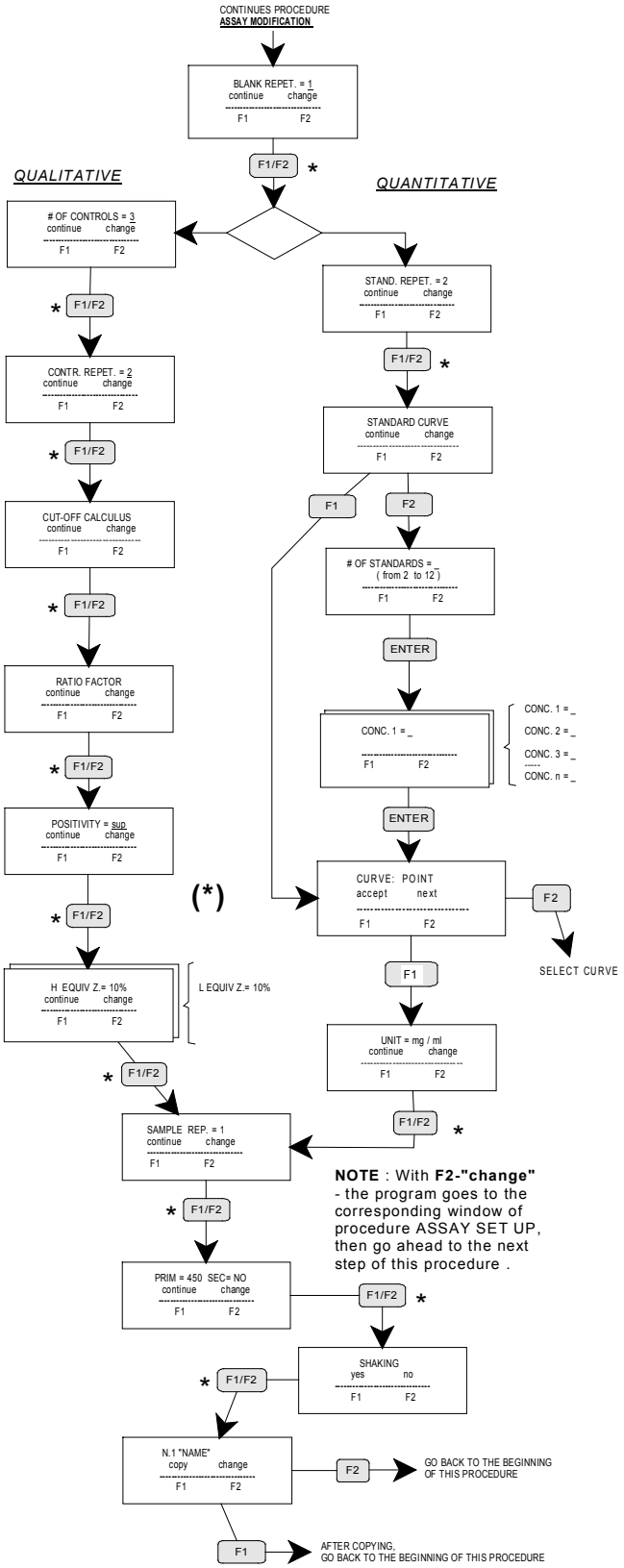
The name of the selected assay is displayed to be modified (by pressing F2) or confirmed (by pressing F1).

When F2 is pressed the next menu is displayed and a new assay name can be entered by simply repeating the same procedure as the one described in section " Assay Set up".

Now the selected assay mode is displayed (Qualitative or Quantitative), allowing the operator to modify it (by pressing F2), or confirm it (by pressing F1).



The parameters of the selected assay are sequentially displayed one by one.




Qualitative assay parameters:

- Number of blank repetitions,
- Number of controls,
- Number of control repetitions,
- Cut-off value,
- RATIO Factor,
- Positivity, lower and higher value of the equivocal zone,
- Number of sample repetitions,
- Primary and secondary filter
- Shaking

Quantitative assays:

- Number of blank repetitions,
- Number of standard repetitions
- Curve point
- Standard concentrations
- Curve type
- Measure unit
- Number of samples repetitions,
- Primary and secondary filter
- Shaking

Each parameter can be modified or confirmed.

## 4.6. ASSAY PROCESSING

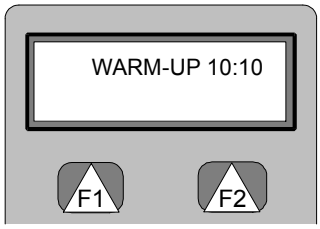
The instrument software is able to process up to 170 programmable tests in two different ways:

- **Qualitative assay**
- **Quantitative assay**

An identification number is associated to each test. By the identification number the test can be found in order to carry out the measure, the modification or the printing of its preset parameters.
Each test and its parameters are automatically memorized in order to avoid recalibration each time the instrument is switched on.

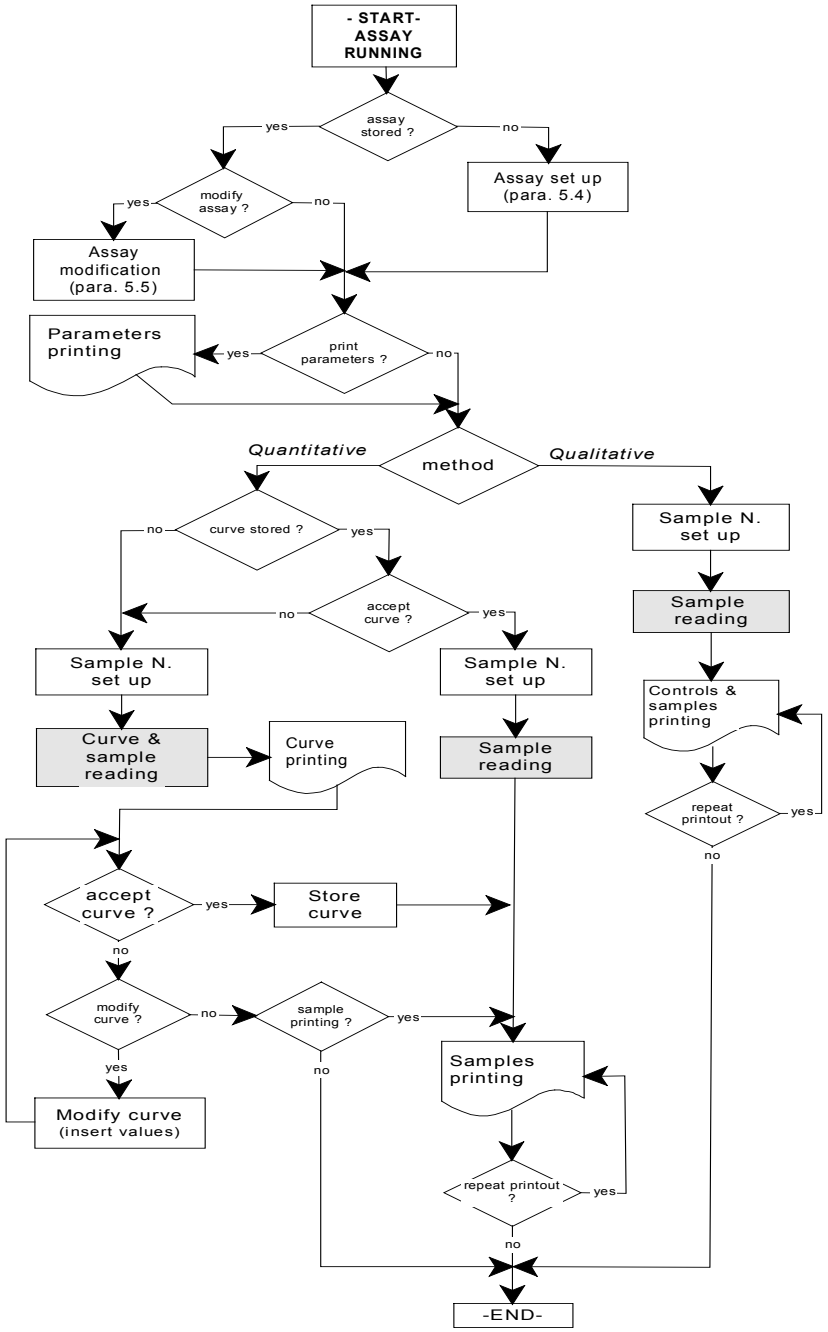
**Warm up**

By pressing F1 from the initial menu, the WARM - UP XX:XX message is displayed indicating the remaining time.




The WARM-UP phase can be avoided by pressing ESCAPE, the remaining time will be printed. In this case the samples reading could be less accurate than the one indicated in the technical specifications.

**Table 4.2 ASSAY PROCESSING**



### 4.6.1. Assay start up

By pressing F2 the auxiliary function TIMER is accessed (see par. 5.8). Press F1 to display the menu "Selection".

By pressing F2 from the menu Select, the optical density of the samples can be read; further details on this working mode can be found in the next paragraph, 5.7 DIRECT OD READING.

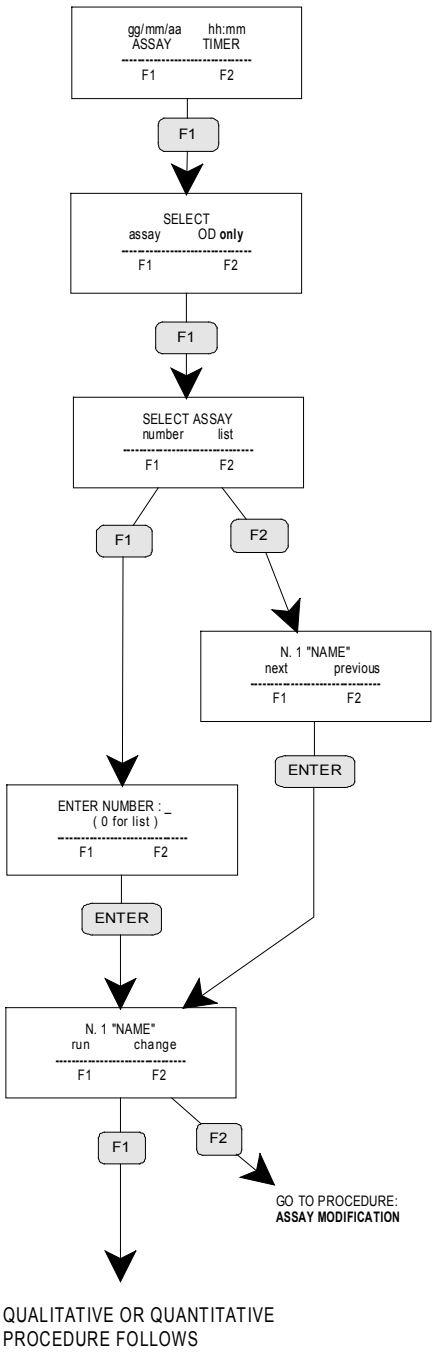
By pressing F1 from the menu Select the Select Assay menu is displayed.
Select the assay to process by scrolling the stored ones or type its number.

***List***
By pressing F2, the memorized assay list is displayed starting from the identification number "1".
By F1 and F2 it is possible to scroll the list to and from.
Press ENTER to accept the displayed selected assay.

***Number***
By pressing F1 from the menu shown in fig. 5.9 the assay identification number, if known, can be directly entered; then press ENTER to display the selected assay name.
To print the list of assays, enter "0".
To display the selected assay name type its identification number and press ENTER.

By pressing F2 the SET UP menu (par. 5.4) or MODIFY menu ( par. 5.5) is accessed.
By pressing F1 the instrument gets ready for the assay process.

**NOTE: The procedure is different for a qualitative assay or for a quantitative assay.**



### 4.6.2. How to carry out a qualitative assay

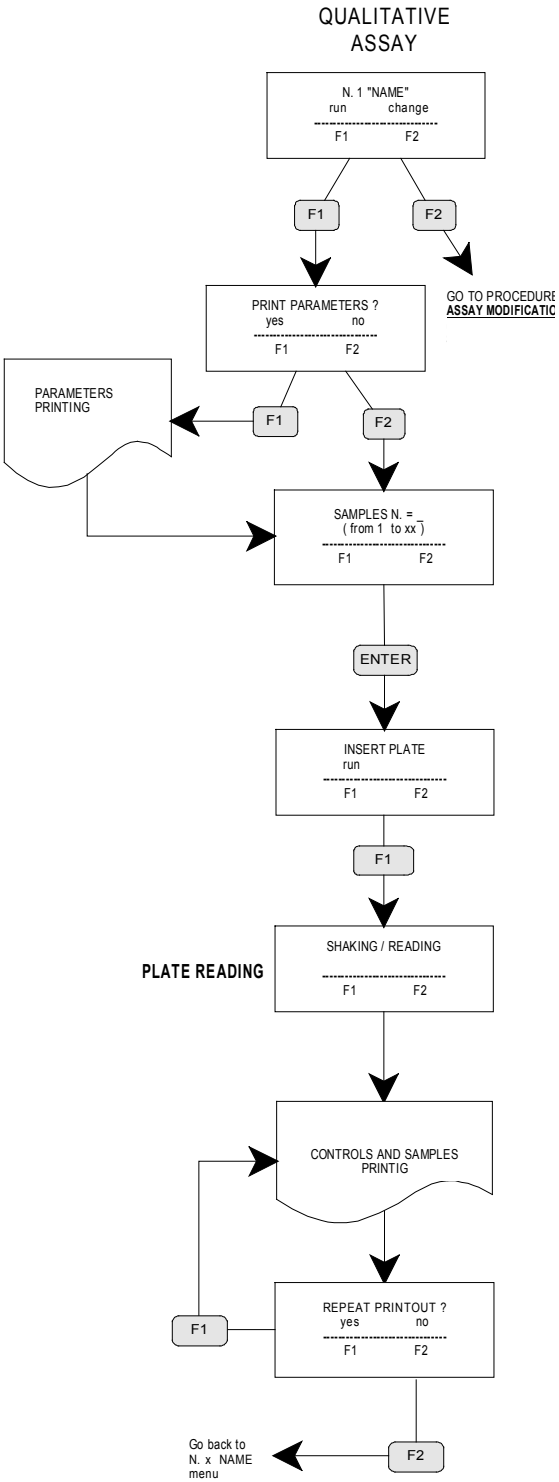
For a qualitative analysis, the procedure to follow will be as indicated.

Enter the number of samples to be analyzed.

In order to start the reading, locate the plate as required and displayed.

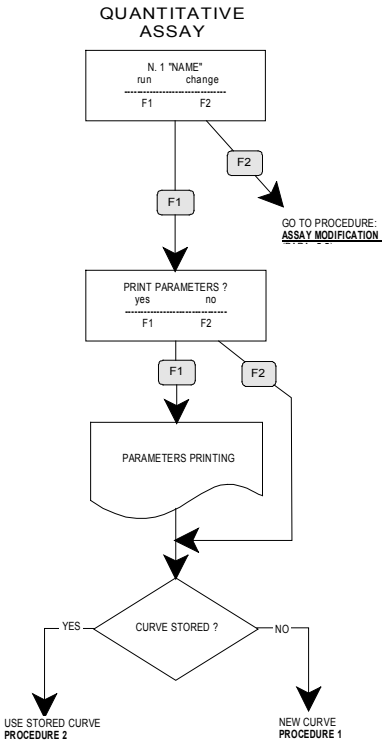
Press F1 to start the reading.

At the end of the process the results are printed and a menu by which the printing can be repeated is displayed.



### 4.6.3. How to carry out a quantitative assay

For a quantitative analysis, the procedure to follow will be as indicated:




Press F1 to run the selected assay.

Then the menu "Parameters?" is displayed; by pressing **F1**, all the selected assay parameters and the stored calibration curve (if any) are printed; by pressing F2 the only filters value will be printed along with the stored calibration curve (if any) .

There are now two possibility according to the presence of a stored curve or not, as in detail described in:

**PROCEDURE 1 – Reading a new curve** : a new curve is processed, samples are read, the results are then printed.

**PROCEDURE 2 – Using the stored curve** : a stored curve is used, samples are read, the results are then printed.

If the stored curve has to be modified or it is rejected, a third procedure apply:

**PROCEDURE 3 – Modify or reject the curve**: to modify / reject a stored curve.

**PROCEDURE 1 – Reading a new curve**

Enter the number of samples to be analyzed.

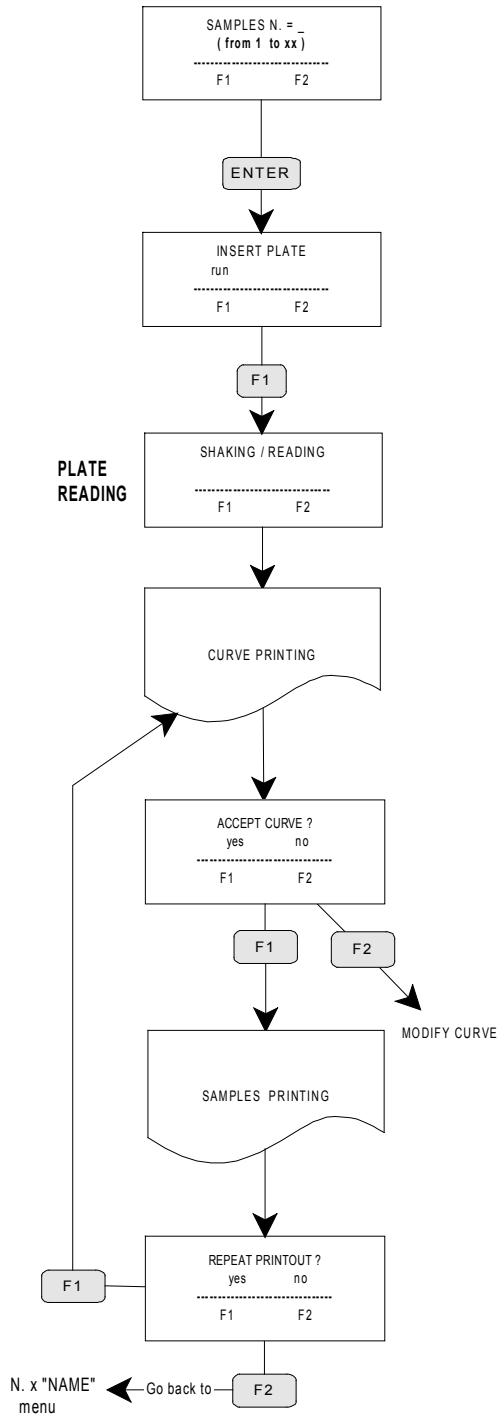
In order to start the reading, locate the plate as required and displayed.

Press F1 to start the reading.

At the end of the process the curve is printed.

If the results are not accepted it is possible to modify the curve (see Procedure 3)

If the results are accepted, the samples are printed and a printout can be repeated.



**PROCEDURE 2 – Using the stored curve**

Press F1 to plot the curve.

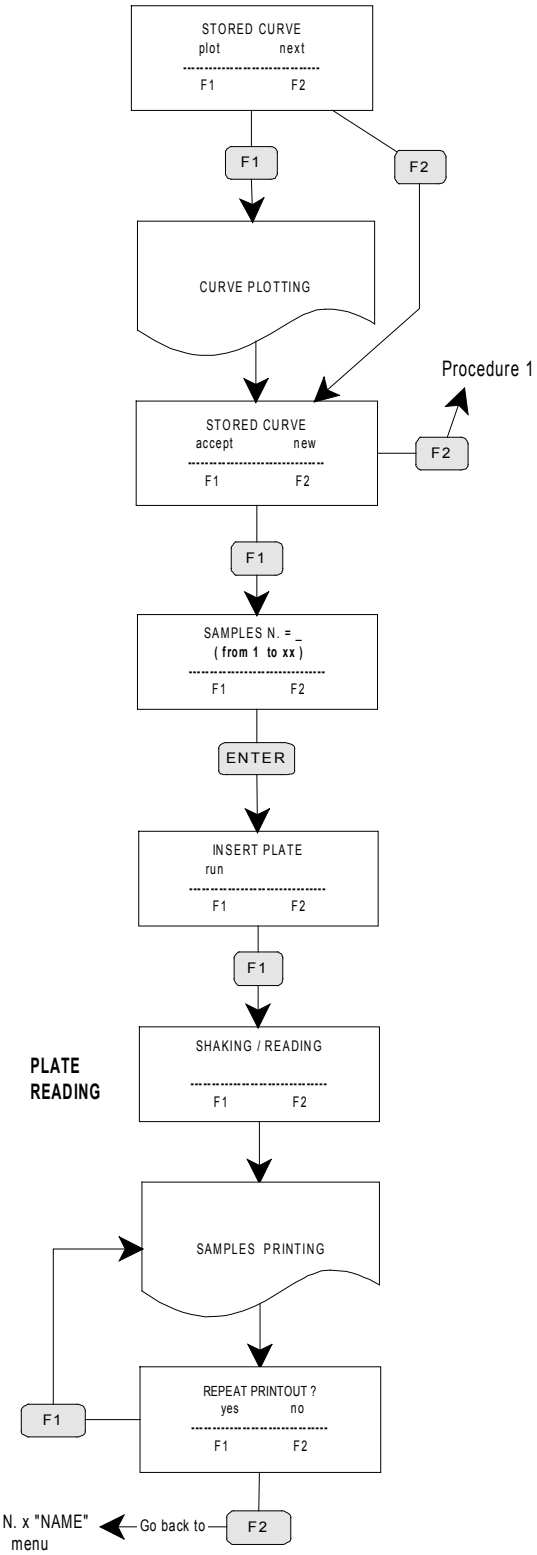
Press F1 to accept the stored calibration curve.
Press F2 to get a new calibration curve.

Set the number of the samples to be processed

The instrument is ready to read and a message to insert the plate is displayed.

Press F1 to start the reading.

After the reading, the curve will be printed.



**PROCEDURE 3 –Modify or reject the curve**

If the stored curve is not accepted from the Procedure 1 "Accept curve", pressing F2 the next menu "Modify curve" will be displayed.

Press F1 to modify the curve.

Entering the standard in ordinal number, the menu to insert the new optical density values, is activated. Enter the new standard OD values to modify the curve.

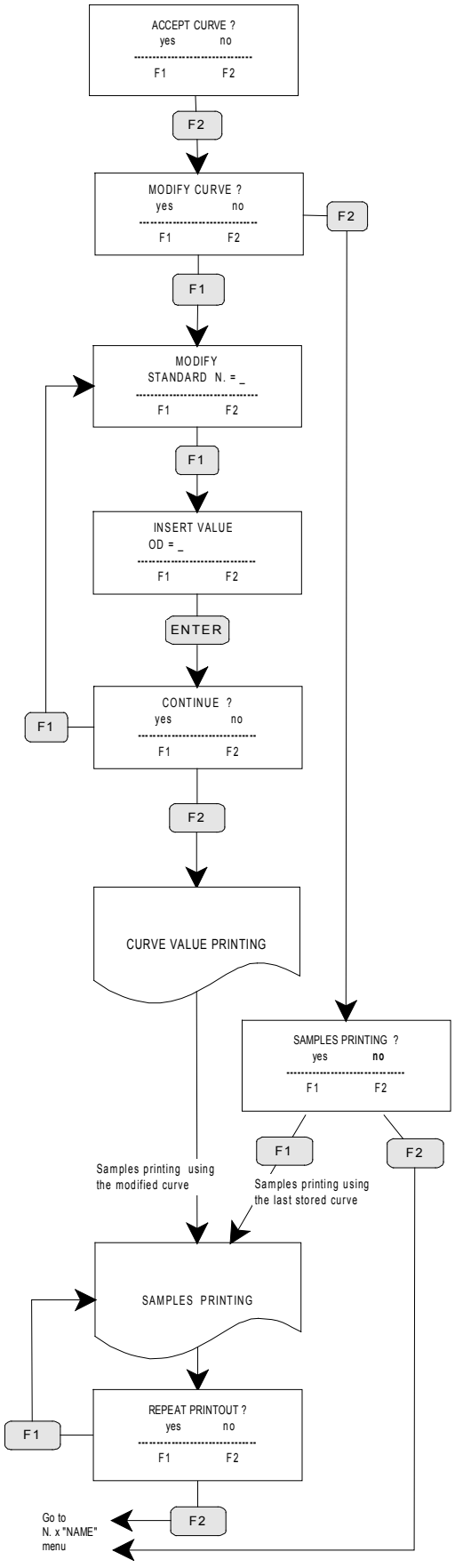
*NOTE:*
*A manual correction of the calibration curve can be operated by entering the correct values and avoiding to reprocess a new calibration when a mistake occurs (for example in case of a wrong standards positioning in the plate).*

Press F1 to continue so that more standards can be modified.

Press F2 to print the operated modifications of the calibration curve.

The instrument starts the reading process and prints the assay results by using the modified curve.

If the curve modification is rejected (F2 of "Modify curve?" menu), the instruments carries out the samples reading and prints the assay results by using the already stored curve, if any; otherwise it only prints the OD values.



## 4.7. DIRECT OD READING

By pressing F1 from the initial menu the Selection menu is displayed.

Press F2 for a direct reading of the optical densities of the samples on a micro titer plate.

The number of strips positioned on the plate has to be entered.

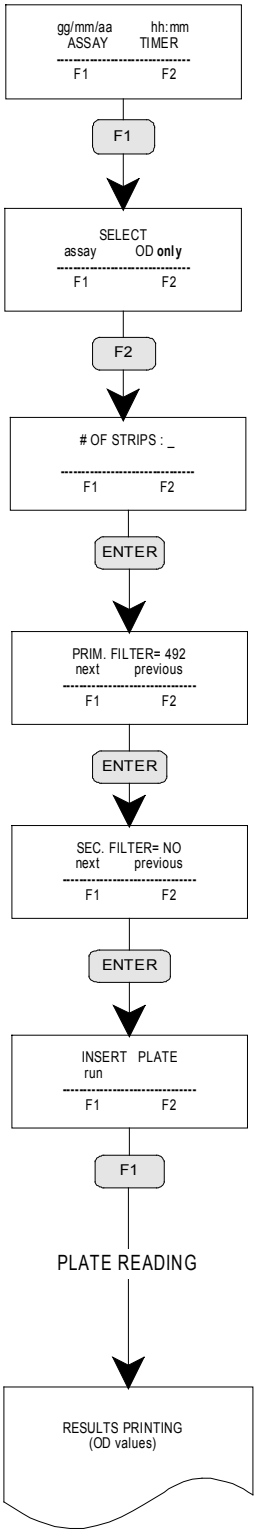
The filter selection menu is then displayed to select the primary filter. By pressing F1 and F2 buttons the value of the existing filters is displayed.

Once the wanted primary filter has been displayed, press ENTER.

The next menu, allows to select the secondary filter.
To set the optical density monochromatic mode, press ENTER when the message "Filt. sec. = no" is displayed

Insert the plate and press F1 to process the plate.

At the end of the process the OD reading results will be printed and the CV will be computed only the read strips



## 4.8. TIMER

The TIMER is to generate a sound alarm at the end of the time set.
The timer function is programmable for a time of 23 hours, 59 minutes and 59 seconds by steps of 1 second.
Enter the TIMER function from the initial menu by pressing F2 "TIMER"

Press F1 to set a new time.

If the shake is enabled press F2 to start the countdown and, at the same time, the plate shaking. The plate shaking will be performed during all timer countdown.

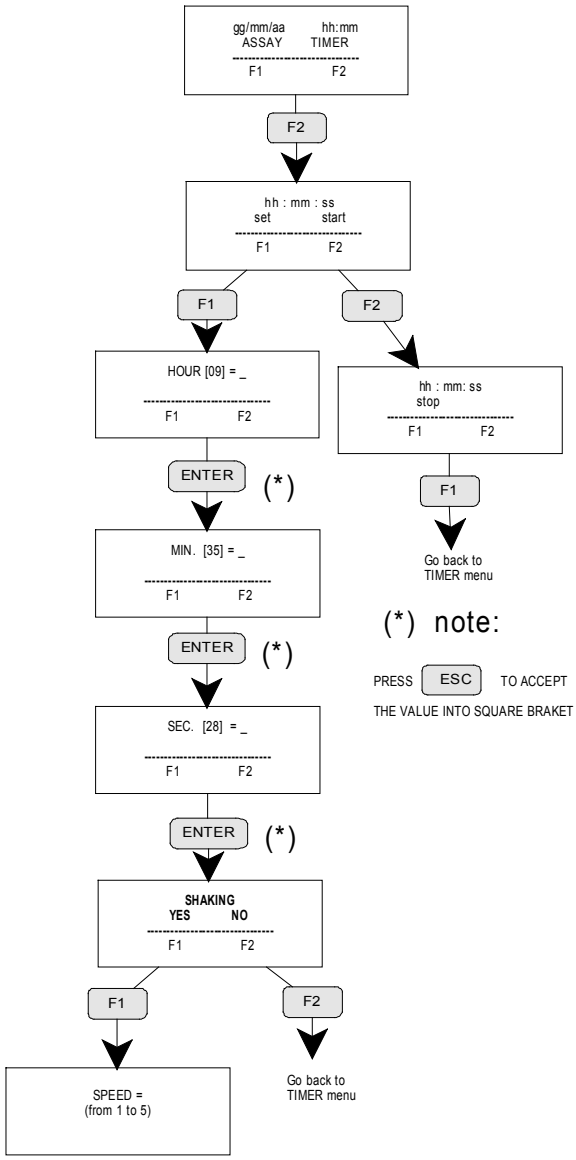
During the countdown, the remaining time is displayed.
To stop the countdown press F1 “stop”.
A sound indicates the end of the countdown.

To set a new time interval:

First, enter the hour, then the minutes and finally the seconds. The programmed time is displayed in brackets.

Press ENTER to accept, otherwise type the new value and press ENTER. . The new programmed time is displayed.

To shake the plate during timer countdown
To set plate shaking speed.
The programmed time will be saved until a new modification.
The initial menu is displayed by pressing ESCAPE.



# SECTION 5 - MAINTENANCE

Only qualified personnel is entitled to carry out maintenance (see Section 1 of this manual). Carrying out the maintenance operations, follow the general warnings as described in Section 1 of this manual as well as the below safety rules.

The operating instrument makes use of chemical reagents and other dangerous (corrosive, irritant and harmful) CHEMICAL SUBSTANCES which can cause material and personal damages. When this label is found, pay attention to the producer recommendations

The operating instrument handles samples which can be infected (urine and human serum). In this condition INFECTIONS or CONTAMINATION might occur. Pay attention to the general safety warnings when in presence of such biological substances. Use protective clothes, gloves and goggles.

## 5.1. MAINTENANCE AND CHECKS PREVENTIVE MEASURES

The suggested preventive measures are indicated in this chart :

| Operation | Period |
|---|---|
| Cleaning | Daily and/or at the end of each working session. |
| OD test<br><br>Linearity test | At interval of 3 months |
| General inspection and checks | At interval of 6 months |

Under normal use conditions of the instrument, it is recommended of carrying out scheduled servicing as above indicated, the same it is recommended also before using the instrument after a long period of no use.

### 5.1.1. Cleaning

Warning: when cleaning do not use alcohol or similar solutions !

While cleaning do not wet the electrical parts (connectors, ecc.) if by accident the electrical parts do get wet, before using the instrument accurately dry these parts.

After each work session it is recommended to clean well the instrument:

- follow the decontamination procedure described in Appendix A or other equivalent procedure
- for the instrument cleaning use a cloth damped with water and light detergent
- keep clear and clean all the involved work areas of the instrument, remove any dirt or cleaning substances

### 5.1.2. Instrument testing

After each 3 months period it is advisable:

- Checking the optical density (OD) utilizing standard OD values.
- Checking the optical linearity utilizing the standard value and diluting it more times to obtain different solutions at known values.

In case of not acceptable values, find out the probable cause of problem; in case of persistence, call for the Technical Assistance.

### 5.1.3. Inspection and controls

- It is advisable to check periodically all the instrument parts.
- Inspect the power cable, change it if damaged

**5.1.4. Troubleshooting (diagnosis)**

Some troubles that might occur during the instrument functioning as well as the specific remedy are shown in the following table.

| TROUBLE | PROBABLE CAUSE | REMEDY |
|---|---|---|
| The instrument doesn't go on | The power source is faulty | Check the power cord and power point<br><br>Check the fuses, if necessary replace them |
| Date and hour are not correct | The inside battery is flat | Call for technical assistance. |
| Incomprehensible messages are displayed | The start up has gone wrong | Switch off the instrument and after a while switch it on again. In case of failure repetition call for Technical Assistance. |
| PRINT ERROR H is displayed: | The printer doesn't work; the print-head doesn't go to its left position | Remove the paper that probably block the mechanism. If the problem continues, call for Technical Assistance. |
| MEMORY ERROR is displayed | It means that some memorized data are missing. | Call for Technical Assistance |
| LAMP ERROR is displayed | One or more channels of the reader are not properly working | Change the lamp block or call for Technical Assistance |
| LAMPS OFF is displayed | Lamps are exhausted | Change the lamp block or call for Technical Assistance |
| The instrument doesn't dialogue with the PC | Incorrect connection | Check the cable connection, be sure of the serial port<br><br>Check the program setting for the utilized serial port |
| The instrument sends to the PC wrong messages | The instrument transmission is different from the one of the communication program | Check the data transmission speed of the instrument and the one of the program are the same (9600 baud) |

NOTE:

In case of problems with the printer, it will be automatically ignored but the data will be presented on the LCD display and the instrument RS232 serial port.

## 5.2. MAINTENANCE

If any problem occurs while working with the machine, ask for a qualified technician for the servicing of the instrument.

**The service maintenance of the instrument (extraordinary maintenance), has to be carried out only (see Section 1 of this manual) by:**

**Qualified technicians**, that deeply know the instrument, knowledge acquired from a training course, and carefully follow the "service" instructions on the manual. Only original spare parts can guarantee the instrument performances.

Alterations or modifications of the instrument are not allowed. The user is liable for any instrument improper use or modification as well as for the deriving consequences.

# SECTION 6 - PACKING, TRANSPORTATION AND STORING

## 6.1. GENERALITY

For the packing, transportation and storing operations it is required to put the instrument "out of service". For this it is necessary to follow carefully the instructions contained in Sec. 8 of this manual.

**The instrument has been used with samples potentially infected (urine, human sera etc.) that could have been caused INFECTIOUS CONTAMINATIONS. General safety warnings about biological substances potentially infected have to be observed.**

**Before putting the instrument out of service, IT HAS TO BE DECONTAMINATED! (see APPENDIX A)**

**Before transportation or storage of the instrument, draw up the DECONTAMINATION DECLARATION dated and signed by a qualified person.**

## 6.2. PACKING THE INSTRUMENT

Packing of the instrument is required when transportation is involved .
To pack the instrument follow the instructions as below described:

- Position the instrument inside its original case or in a equivalent safe container. In this case protect the instrument with plastic sheets, fixed with packaging tape.
- Apply on the case proper stickers and safety indications:

| |
|---|
| "**OUT OF SERVICE MATERIAL**" |

| | |
|---|---|
|  | **Material with potentially infectious substances** |

## 6.3. TRANSPORTATION

The transportation of the instrument without its case should be limited to the work area.

During transportation the instrument has to be accompanied by the decontamination declaration.

## 6.4. STORING THE INSTRUMENT

For the instrument storage, put it in the original packaging and store it at 80% max of relative humidity and at temperature range of 10/ 60 $^{o}$C

The instrument has to be accompanied by the decontamination declaration (see section 8 of this manual) possibly stuck on the case.

The safety warnings and general rules have to be observed when moving or lifting the instrument.

# SECTION 7 – APPENDIX

## APPENDIX A

## A.1. INSTRUMENT DECONTAMINATION.

**The instrument involves the handling of samples which can be infected by urine and human sera.**
**In this condition INFECTIONS or CONTAMINATION might occur.**
**Every part and accessory of the instrument must be considered potentially infected.**

### A.1.1. Decontamination procedure

Use one of the following wide band disinfectant solutions (or equivalent):

- Aseptisol Manufacturer: Bode Chemie Amburg;
- Germocid Plus Manufacturer: Germo S.p.a. Milano;
- Lysetol Manufacturer: Schülke & Mayr Ges.m.b.H.

**Use the solution only for the instrument surface.**

1. Wear disposable gloves, protective glasses and suitable clothes
2. prepare an autoclave bag for the disposable items used for the decontamination and label the bag with an autoclave band mark
3. unplug the instrument in order to avoid explosions
4. remove all the accessories and disinfect the ones which have to be sent with the instrument
5. spray the disinfectant solution on the instrument surface or use a cloth or paper soaked in a disinfectant solution
6. leave the solution on the instrument for 10 minutes and repeat the treatment from the preceding point
7. leave the solution on the instrument for 5 hours, clean the instrument surface by a light detergent or water to eliminate any dirt or disinfectant solution
8. carefully dry the instrument
9. put the instrument and its accessories into their original box
10. wash and disinfect the hands by using a light detergent
11. Fill in a Decontamination Declaration and enclose it with the instrument

**A.1.2. Decontamination declaration**

The Decontamination declaration as shown below, has to be filled in and enclosed with the instrument before shipping it for maintenance service.
The declaration has to be stuck on the instrument package.

## DECONTAMINATION DECLARATION

**Instrument:**_____

**Model:** _____

**S/N :**_____

### We declare that :

☐ **the instrument and its accessories never came in touch with dangerous biological substances**

☐ **the instrument and its accessories have been decontaminated to eliminate every biological substance which could be dangerous for personnel.**

**User/Client name:**_____

**Address:** _____

**Country:** _____

**Responsible name:**_____

**Date** _____ *Signature and Stamp*