ELISA PLATE SHAKER – INCUBATOR

DIA4000

Version – 5.0

DIAsource ImmunoAssays S.A.
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IVDInstrumentation.support@diasource.be.

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1. GENERAL INFORMATION

1.1. Warranty Information:

Each Instrument is completely tested and guaranteed for twelve months from delivery. The warranty applies to all the mechanical and electrical parts. It is valid only for proper installation, use, and maintenance in compliance with the instructions given in this manual.

DIAsource ImmunoAssays S.A. will at its discretion repair or replace parts, which may be found defective in the warranty period. The warranty does not include any responsibility for direct or indirect personal and/or material damages, caused by improper use or maintenance of the instrument.

Parts that are inherently subject to deterioration are excluded from the warranty. In case of defects due to misuse of the instrument, any incidental expenses like travel and man-hour service charges will be charged extra.

1.2. Technical Service:

DIAsource ImmunoAssays S.A. is always accessible to the customers for any kind of information about installation, use, maintenance, etc. While asking for service, please refer to this manual, and report the printed serial no. on the identification label.

Only qualified technicians are entitled to fix the instrument; the user, as described in this manual, should carry out ordinary maintenance.

1.3. Disposal instruction:

In case of removal or disposal of instrument, following instructions need to be followed

- Do not dispose in municipal waste; follow local regulations for instrument disposal.
- Plastic parts, Electronic PCBs and components can be recycled, so return back the instrument to manufacturer.

1.4. Contacts:

DIAsource ImmunoAssays S.A.
Rue du Bosquet 2
BE-1348 Louvain-La-Neuve
BELGIUM

IVD Instrumentation Support Service
Hotline phones availabilities : Monday to Friday; 08 :30 to 17:00 (Belgium time)
Please contact first Hotline 1. In case of no response please contact Hotline 2.
Hotline 1 phone number : 0032 (0)10 849932
Hotline 2 phone number : 0032 (0)10 849976
Fax : 0032 (0)10 849990
Email : IVDInstrumentation.support@diasource.be

2. GENERAL SAFETY WARNINGS

2.1. Danger – warnings symbols:

The following symbols are used to inform the user of the safety rules.

This symbol indicates generic danger. It means that, serious damage can occur to the operator if described precautions are not observed.

This symbol indicates HIGH ELECTRIC VOLTAGE. It is dangerous to touch any part having this label. Only qualified operators can access these components, after unplugging the instrument from the Supply.

This symbol indicates that the instrument involves the handling of samples, which can be infected (urine or human serum). In this condition, infection or contamination might occur. Pay attention to the general safety warnings when in presence of such biological substances. Use Protective clothes, gloves and glasses.

This symbol in the user manual indicates that damages to the instrument or erroneous results could occur if the given warnings are not followed.

This symbol indicates a portion, which is particularly important, and should be studied carefully.

This symbol indicates a Protective Earth or Ground terminal.

General Symbols

Symbol for “Manufacturer”

2.2. Use of the Instrument:

The instrument has to be used for the designed purposes under specified conditions, following proper procedures and safety rules, by qualified personnel.

THIS MANUAL CONTAINS INSTRUCTIONS FOR OPERATION BY QUALIFIED PERSONNEL ONLY.

- A qualified user has to make sure that the environmental condition is suitable, the installation is correct, the use and maintenance are proper, according to the general safety rules as well as to the particular precautions described in the manual (However, the user is not entitled to repair the instrument).

- A qualified technician is entitled to maintain and fix the instrument, according to the instructions given, using the original spare parts.

- Maintain room temperature and humidity as specified in the manual.

- The instrument must be used as described in this manual only. Usage in any other way will be regarded as improper.

- Alterations to the instrument are strictly prohibited. The user is liable and solely responsible for any improper modification to the instrument, and for the consequences derived as a result.

3. INTRODUCTION

3.1. Special Features:

- Simultaneous shaking & incubation operation.
- Buzzer indication on completion of incubation
- Indication of Remaining time
- Current temperature of incubation on display, on pressing TEMP Key.
- Separate Timer ON indication on Keypad.

3.2. Specifications:

Operating Modes	Shaker
	Incubator
	Shaking & Incubator
Temperature Control	
Temperature Range Resolution	37^0 C to 42^0 C 1^0 C
Incubation Time	1 to 999 min
Shaker	
Frequency Amplitude	400 to 700 RPM 2 mm
Operating Position	On horizontal flat, rigid and vibration free surface
Operating Conditions	
Temperature Relative Humidity	From + 18^0 C to 32^0 C Up to 80%
Storage Conditions	
Temperature Relative Humidity	From -10^0 C to 35^0 C Up to 80%
Enclosure	ABS Fire retardant
Size (cm)	28 X 25 X 16 (l X b X h)
Weight	3 Kgs (Approx)

4. PACKING, TRANSPORT AND STORAGE

4.1. General warnings:

Instrument has to be decontaminated before packing for transportation.

4.2. Packing:

Packaging is needed whenever it is to be transported or shipped by courier or other means.

To pack the instrument follow the instructions as below described:

- Decontaminate the instrument as explained in chapter No. 13 (Decontamination) of this manual.
- Place the instrument into the original packaging box; Instrument has to be properly protected by plastic protective material. Put copy of safety clearance certificate (copy of Safety Clearance certificate is attached at the end of this manual)
- Mark the package with address, instrument identification and **warning Labels.**

4.3. Instrument Transportation:

The transportation of the instrument in unpacked condition must be limited within the room where it is used, to avoid damage.

4.4. Storage of the Instrument:

Before storing the instrument for a long period, pack it carefully as described above and store indoors.

Relative humidity can be up to 80%, and temperature between -10°c and 35°c.

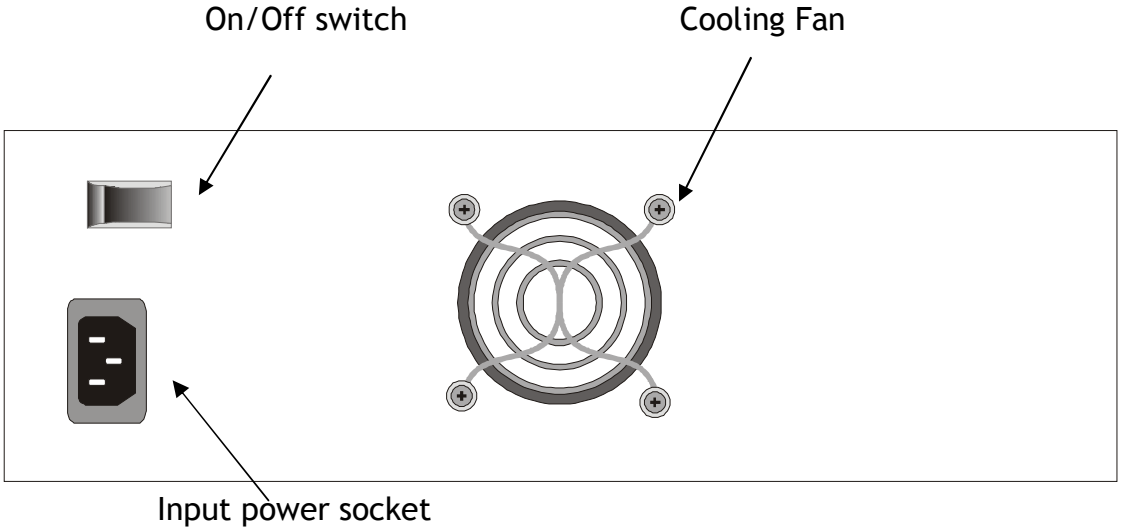
5. INSTRUMENT DESCRIPTION

Components of different views of the below pictured instrument:

5.1. Perspective View:

(A) Front View

(B) Rear View



6. Installation procedure and verification criteria

6.1. Unpacking instructions:

Check accessories as per packing list.

Kindly store all packing materials so as to use it to repack and ship for maintenance or servicing.

6.2. Placing the instrument:

-The instrument has to be placed on a level bench.
-**Room temperature has to be between 10 and** 35ºC with a relative humidity below 85%.
Protect it from direct sunshine

6.3. Power supply requirements:

Once the instrument has been placed, plug it into a power source by the locally available approved plug-in cable. Power cord should be CE, CSA, and UL marked.

115 - 230 Volts ± 10V, 60-50 Hz

6.4. Protective Grounding:

Warning : Please make sure that electrical power source is properly grounded.

6.5. Start up Instructions:

- Switch on the instrument. The instrument will display the company name
- The instrument initializes all the parameters internally, and carries out a power on self-test. It then displays “company name”. The temperature control of the plate starts. The temperature of the plate will maintain at 37 ºC ± 0.5
- The instrument is now in IDLE mode, and ready for use.

7. PRECAUTIONS

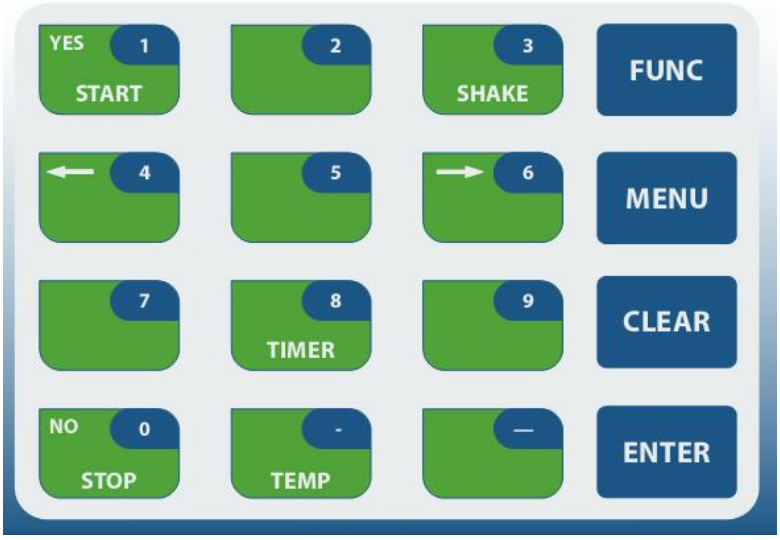
Precautions:

- Keep the place dry and clean.

- Check all the grounding wires properly.
- Use original packaging for transportation.

8. GENERAL KEY AND OPERATION

8.1. KEYPAD:



8.1.1. START / YES KEY

This option helps the user to **START** the process of Shaking.
Similarly, "YES" key is used when the instrument asks certain questions as follows –

For eg:

CREATE TEST Y / N ?

OR

START SHAKE Y / N ?

8.1.2. STOP / NO KEY

This option helps the user to **STOP** the process of Shaking.
Whereas, "NO" key is used to answer certain questions such as –

For eg:

CREATE TEST Y / N ?

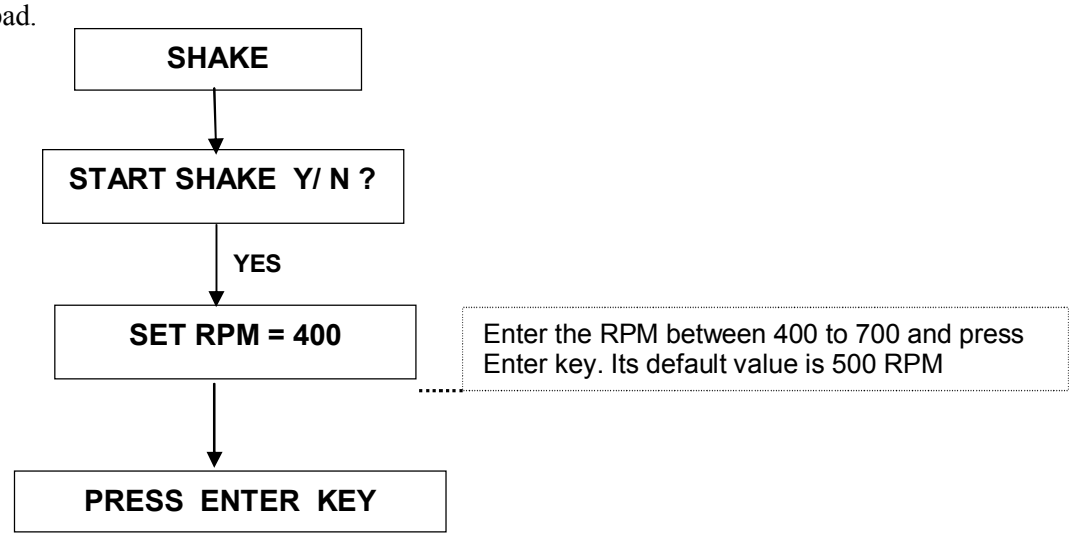
OR

START SHAKE Y / N ?

In such a case, user must select either "YES" or "NO" options to proceed further.

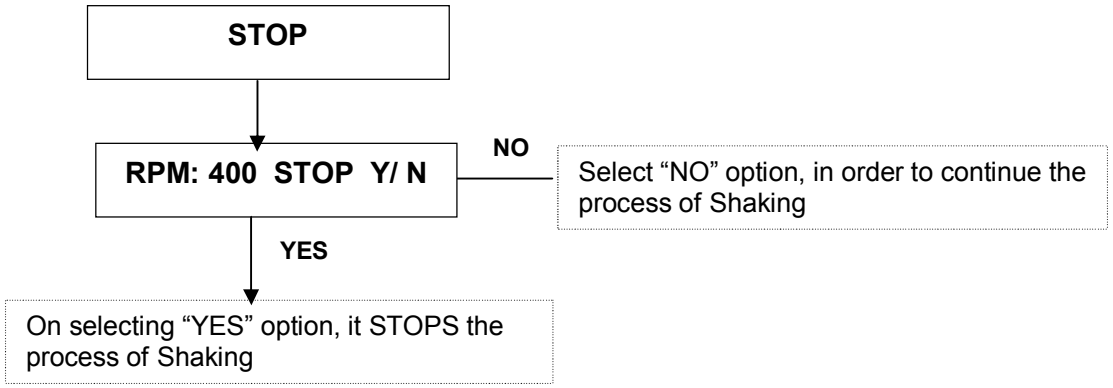
8.1.3. SHAKE KEY

User can directly start the process of Shaking just by selecting "SHAKE" key present on the keypad.

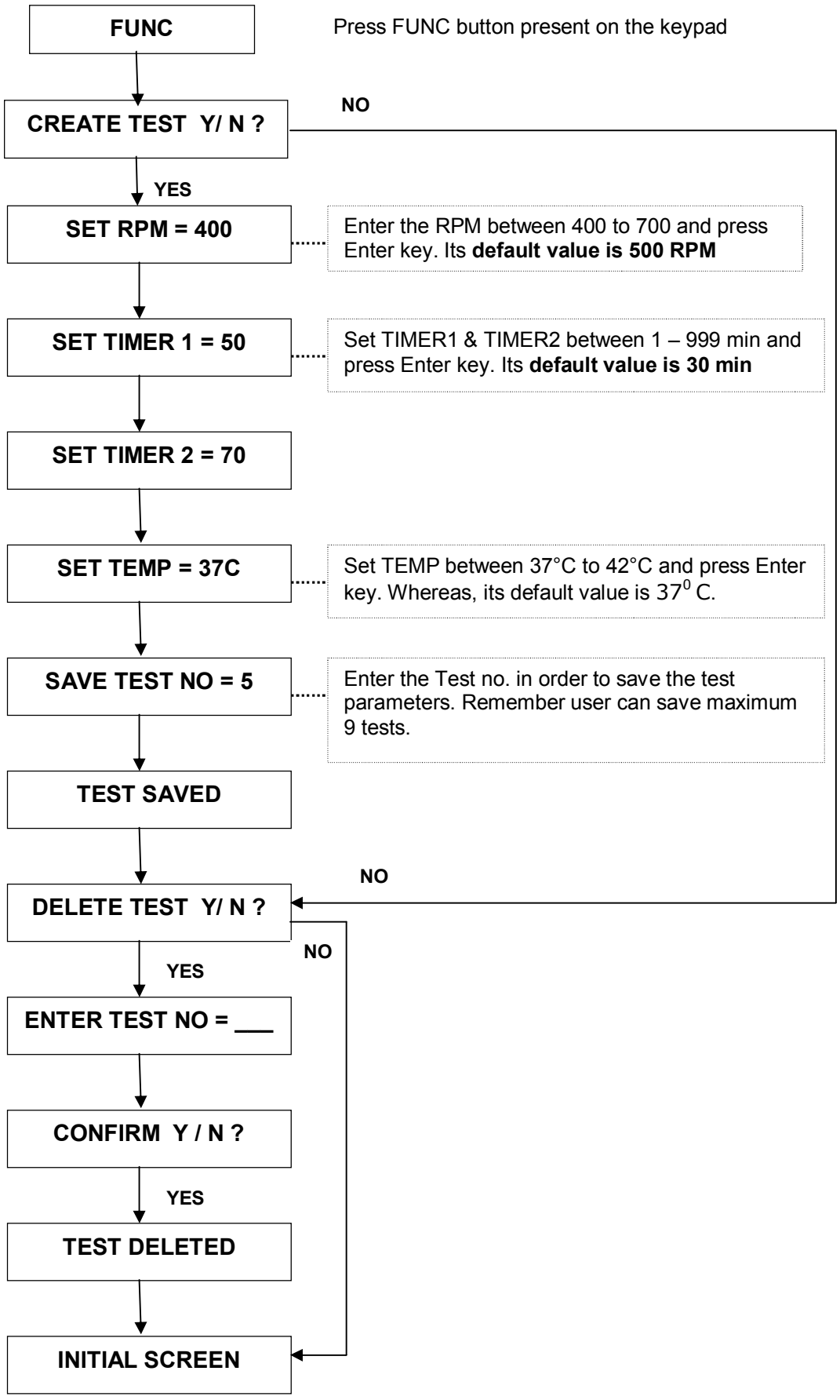


Finally Shaker starts at 400 RPM. This process continues until user selects STOP button
present on the keypad.

For Terminating the process, select STOP button.

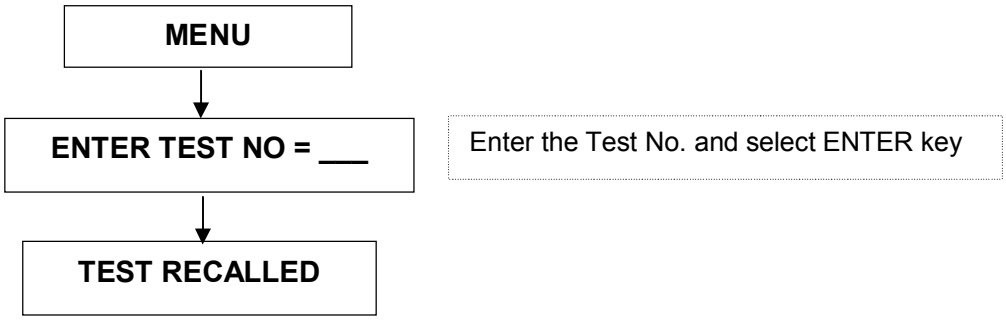


8.1.4. FUNC KEY:


FUNC
Press FUNC button present on the keypad
CREATE TEST Y/ N ?
NO
YES
SET RPM = 400
Enter the RPM between 400 to 700 and press Enter key. Its default value is 500 RPM
SET TIMER 1 = 50
Set TIMER1 & TIMER2 between 1 – 999 min and press Enter key. Its default value is 30 min
SET TIMER 2 = 70
SET TEMP = 37C
Set TEMP between 37°C to 42°C and press Enter key. Whereas, its default value is 37^0 C.
SAVE TEST NO = 5
Enter the Test no. in order to save the test parameters. Remember user can save maximum 9 tests.
TEST SAVED
NO
DELETE TEST Y/ N ?
NO
YES
ENTER TEST NO = ___
CONFIRM Y / N ?
YES
TEST DELETED
INITIAL SCREEN

8.1.5. MENU KEY:

This option helps the user to recall the saved test by entering its test no.



Enter the Valid Test No. or else it will display following string-

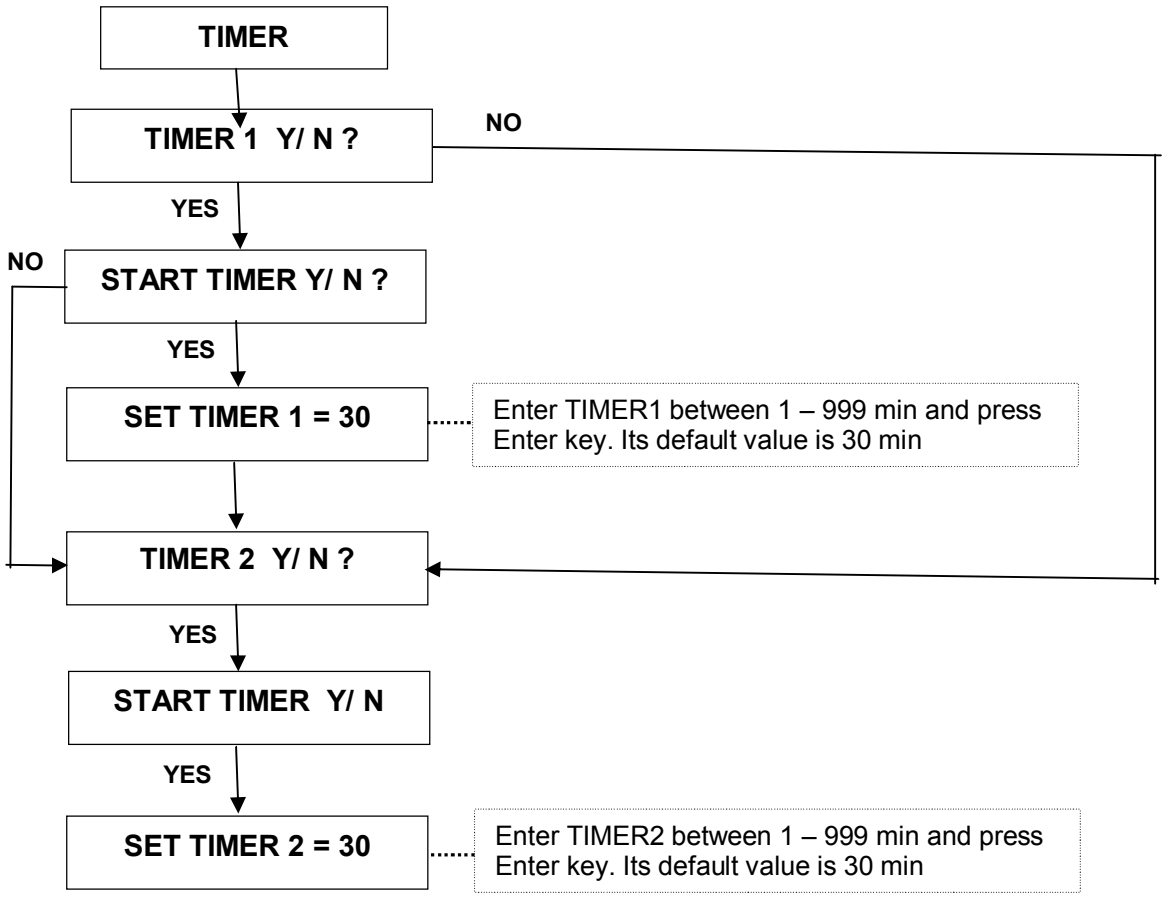
INVALID TEST NO

Since, user can save maximum 9 tests; one has to enter the test no. in between – 9 in order to recall the test.

If user enters the number which donot exist or in other words, the test is not saved with that particular number; then in such a case it will display following string-

TEST NOT EXIST

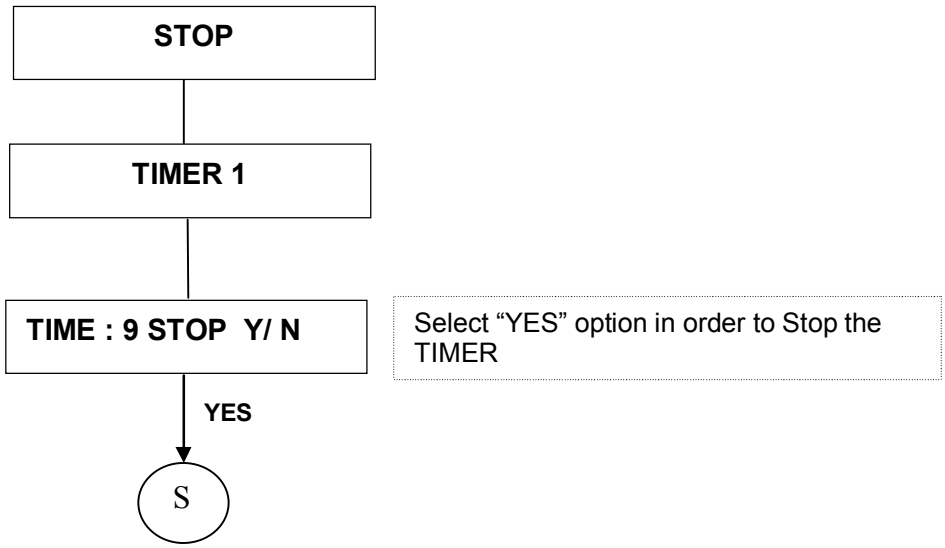
8.1.6. TIMER KEY: This option is used to set the timer for the respective plates

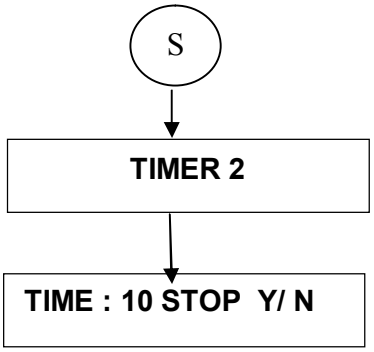


After selecting Timer1 and Timer2, LED glows of the respective Timer. On completion LED gets OFF and the buzzer beeps in order to indicate that the Timer has reached its set value. Now select Enter key to stop the buzzer.

The TIMER continues until user selects STOP button present on the keypad.

For Terminating the process, select STOP button

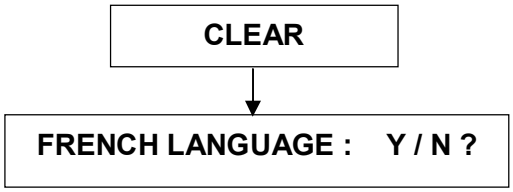




Select “NO” option, in order to continue the TIMER

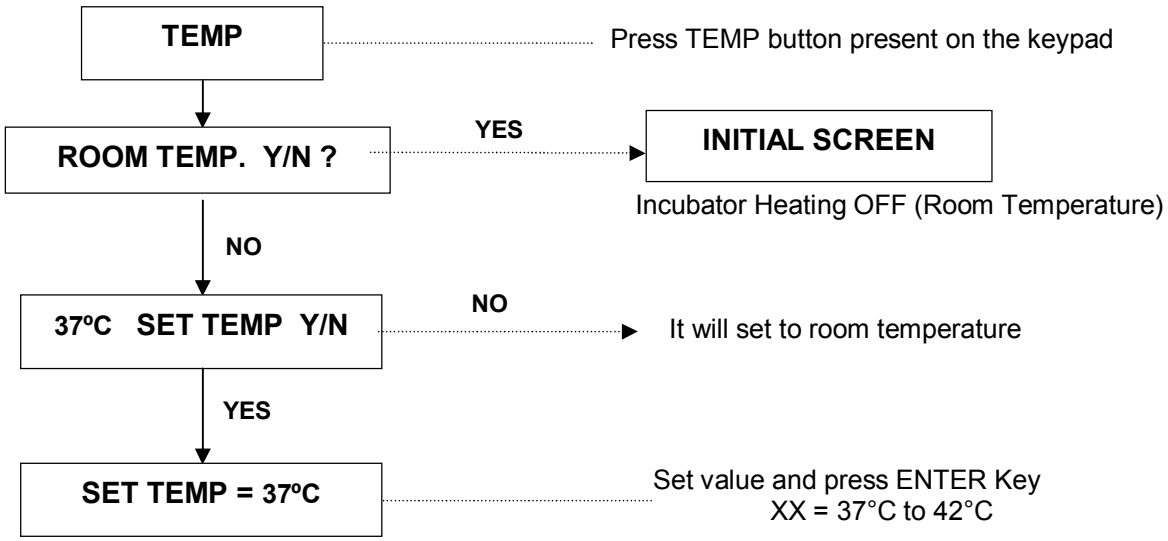
8.1.7. CLEAR KEY

This key is used to select the Language option and also to clear the test entry. In other words, user can abort the test by pressing CLEAR key.



Select “Yes” for French Language or otherwise “No” to continue in English.

8.1.8. TEMP KEY



NOTE: By Default condition incubator heating is off, Instrument will show Room Temperature

8.1.9. ENTER KEY

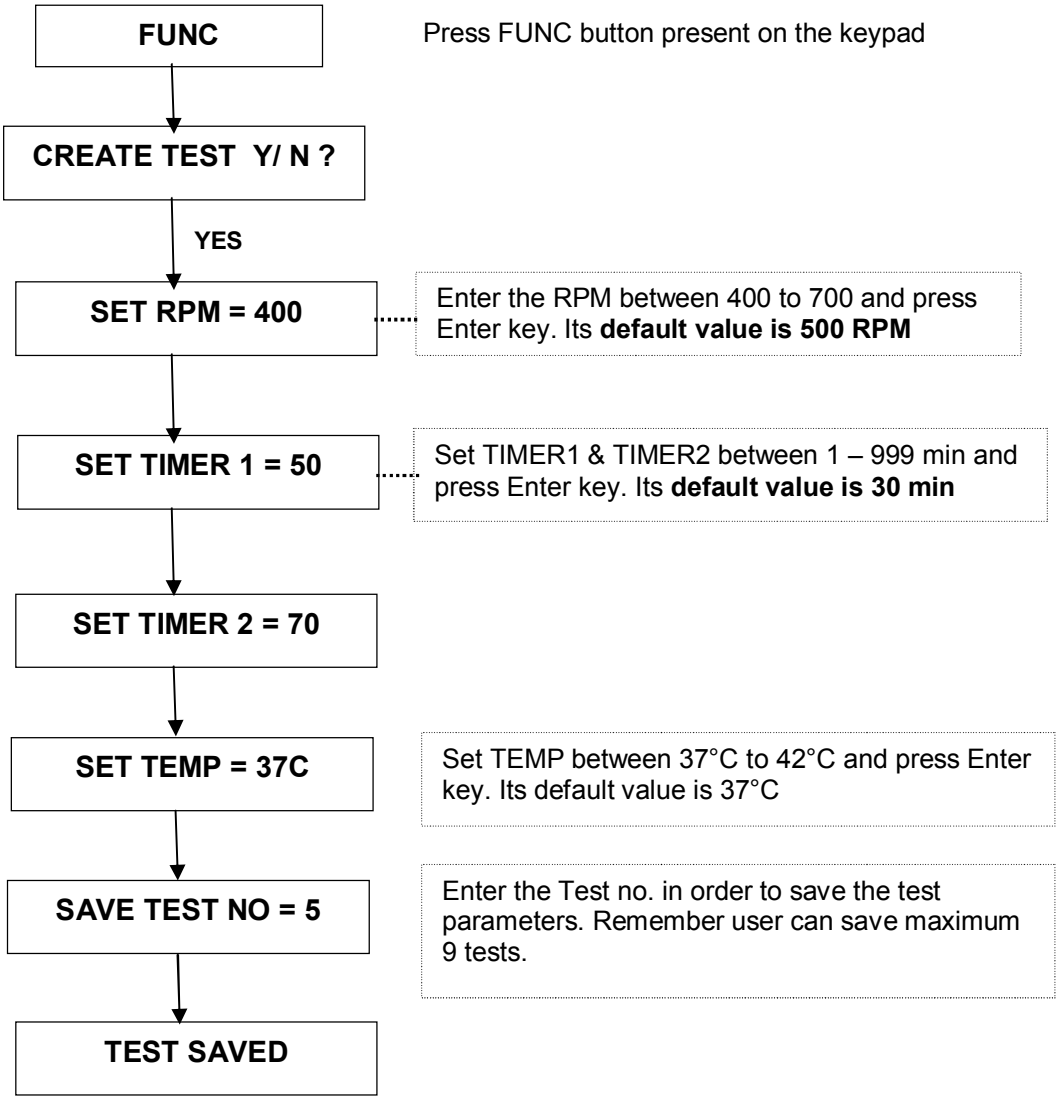
Enter button present on the keypad helps the user to set the value for the selected parameters
(ie. on completion of data entry)

8.2. DEFAULT SETTING (OPERATING MODE)

PARAMETERS	DEFAULT VALUES	RANGES
RPM	500 RPM	400 to 700 RPM
Temperature range	37^0 C	37^0 C to 42^0 C
Incubation Time Timer 1 Timer 2	 30 min 30 min	 1 to 999 min

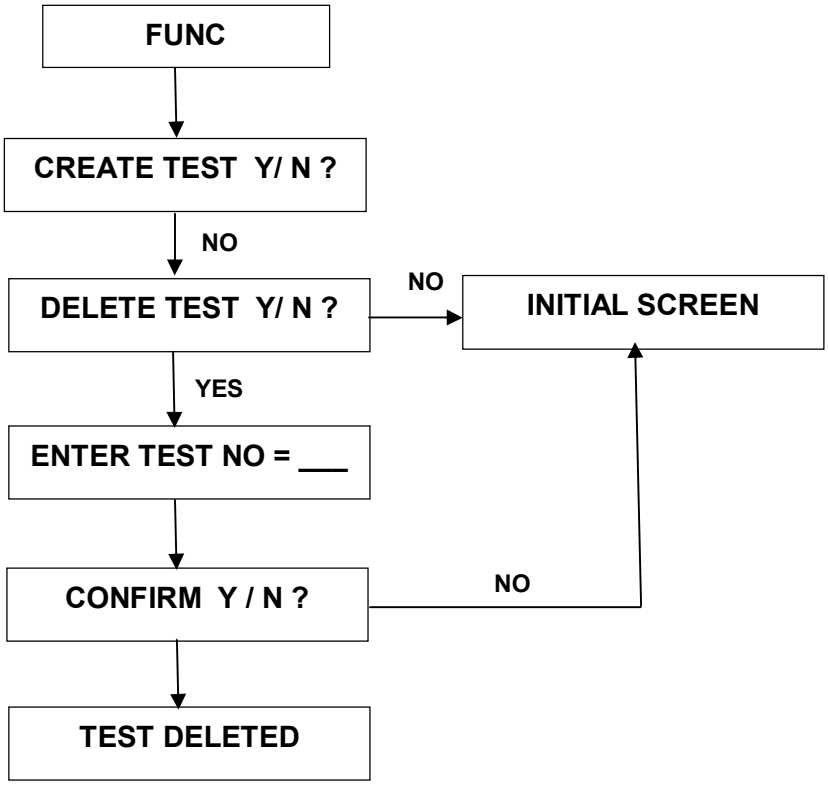
9. SAVING THE TEST

Saving the Test itself means creating new test with new parameters.

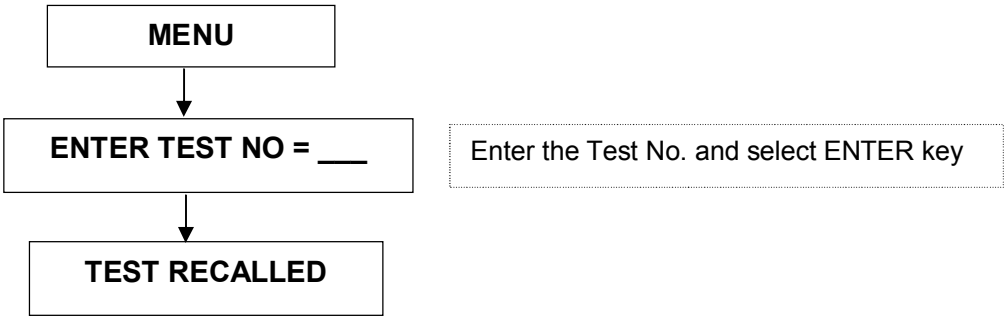


10. DELETING THE TEST

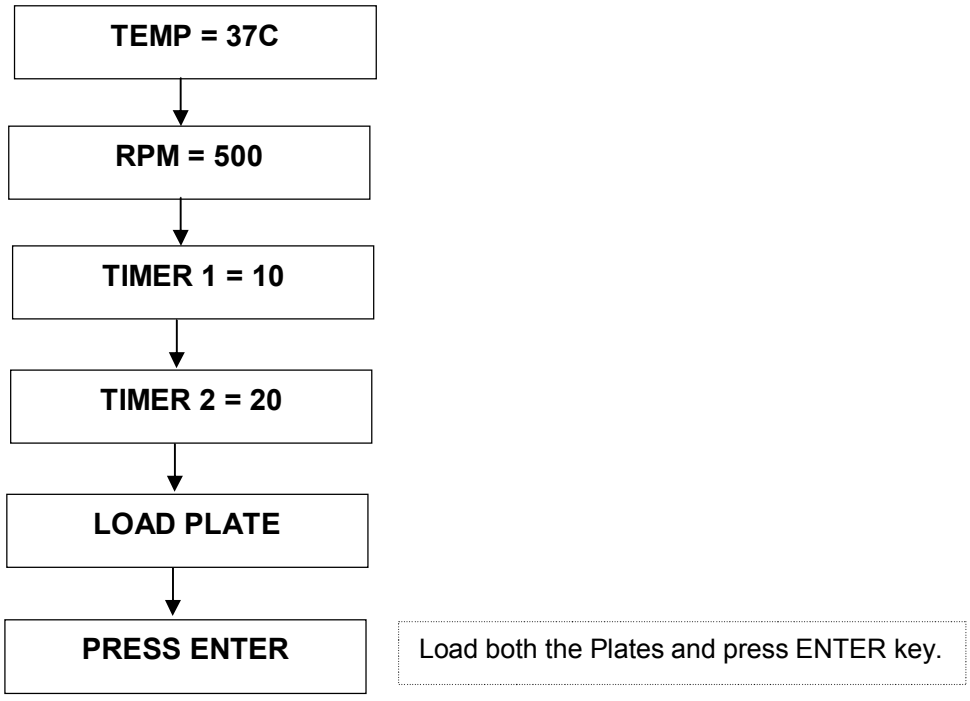
One can Delete the saved test by following the procedure mentioned below-



11. RECALLING THE TEST



After Recalling the test it will flash following Test parameters and finally ask the user to Load
the Plate and press Enter key.



Since the Timer is set it will beep twice after reaching its time set for both the corresponding plates.

(Note: Before loading the plate it will attain its set temperature)

12. ERROR MESSAGES

MESSAGES	CAUSE /CORRECTIVE ACTION
Test Not Exist	This message appears only when the test no. is recalled which does not exist.
Test Present	When test is already present.
Invalid RPM	This message appears when the entered RPM Value is out of the given range.
Invalid TM1 / TM2 Val	This message appears when the entered Timer Value is out of the given range.
Invalid Temp	This message appears when the entered Temperature Value is out of the given range.
Invalid Test No.	While deleting any test if user enters the test no. which does not exists then it will show the corresponding message.

13. DECONTAMINATION

Check whether all the tubing is properly connected. Switch on the instrument.

13.1. Decontamination Procedure:

If the instrument is to be shipped after being exposed to potentially hazardous material, it should be decontaminated. The following procedure outlines the method to decontaminate the instrument before packaging and shipment.

13.2. Purpose of Decontamination:

Decontamination minimizes the risk to all who come in contact with the instrument during shipping, handling, and servicing.

13.3. General Considerations:

- Any laboratory instrument that has been used for clinical analysis is considered a bio-hazard and should be decontaminated prior to handling. Intact skin is generally considered an effective barrier against infectious organisms; however, small abrasions and cuts may not be always visible. Prophylactic gloves must be worn when handling instruments that have not been decontaminated. Gloved hands should be considered contaminated and must be kept away from eyes mouth and nose at all times.

- Mucous membranes are considered as the prime entry routes for infectious agents. Wear eye protection and a surgical mask when there is a possibility of aerosols.

- Eating and/or drinking while decontaminating instruments is not advisable.

13.4. Decontamination Procedure:

- A solution of 0.5% Sodium Hypo Chlorite (NaOCL) solution (Bleach) is used. Commercial bleach is 5% NaOCL; household bleach is 3% NaOCL. When using commercial bleach, use a 10:1 mixture; if using household bleach, a 6:1 mixture is required. This is a caustic solution. It is important to wear gloves and eye protection when handling it.

- Wipe down the carrier and all exposed surfaces of the unit with the bleach solution. Remove the top shroud of the instrument and wipe down the top surface of the instrument base, as well as the inside of the top shroud.

- Reassemble the unit and discard the used gloves and towels.

14. SAFETY CLEARANCE CERTIFICATE:

Please complete all information requests on this form prior to returning the instrument to the manufacturer or your local distributor for servicing, repairs or return. Thank you for your co-operation.

Customer _____ Contact _____

Address _____ Position _____

_____ Dept _____

_____ Tel: _____

Country _____ Fax: _____

Post Code _____

Model No. _____ Serial No. _____

Accessories Returned _____

Date of Purchase (if known) _____

Complaint _____

_____

_____

_____

Has the equipment been exposed to any of the following: (*delete as applicable)

a) Blood, body fluids, pathological specimens *YES/NO

If YES, please specify _____

_____

b) Other Biohazard *YES/NO

If YES, Please specify _____

_____

15. SPARE PARTS

15.1. Ordering Spare Parts:

Parts subject to deterioration, or defectives which need to be replaced, have to be ordered by giving following details.

Ordering the spare parts, the following data are to be mentioned:

- Customer's purchase order No.
- Name and version of the instrument.
- Instrument code number.
- Part code number.
- Description of the part.
- Requested quantity.
- Name and company address for delivering the ordered goods.

While replacing the parts, the use of ORIGINAL SPARE PARTS guarantees the efficiency and a lasting instrument life.