Instruction & Operation Manual

Leak Test Apparatus
Model: μLTCal$_{10}$

Version Number : _____

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1. Introduction

The μLTCal10 is an advance Leak test apparatus, offers fast and accurate leakage testing of food, drug and other industrial chemical products. It has been design and develops as per pharmacopeia requirements to test the quality of packing processes in strips, blisters and sachets containing tablets, granulates and liquid. It is also used to confirm /check that seals enclosing the product are perfectly intact.

The instrument is microcontroller based with Large LCD display having soft touch keys.

2. Environmental Condition

The Instrument can operate within temperature and relative humidity conditions of 0°C to 55°C and 5 to 95 % respectively. However, an environment comfortable for human habitation (reasonable constant temperature and humidity conditions) is recommended for optimum performance and instrument lifetime.

Exposure to corrosive substances (weather gas, liquid or solid) may affect materials and components used in instruments and should avoid.

3. Installation Prerequisites

3.1. Power Supply Requirements:

1) Stabilized Power supply 230 VAC ± 10 %, 50Hz.
   (Earth voltage should be **less than 3V AC** – between Earth & Neutral)

3.2. Chemicals and Accessories Required:

1) Purified Water - 1 liter.
2) 0.5% Crystal Violet solution
3) Tissue Paper Roll

3.3. Location

The μLTCal10 requires a conventional laboratory bench 60 cm. Long, 60 cm. Deep.

4. Packing List

Sr. No.	Description	Qty	Packed √ | X
01	Leak Test Apparatus- Basic Unit with inbuilt vacuum pump - μLTCal10	01	
02	Desiccators ID – (As per order)	01	
03	Silicon Tube (Meter)	01	
04	Power Supply Cable	01	
05	Operational & Instruction Manual	01	
06	Manufacturer test certificate	01	
07	Warranty Card	01	
Optional Items (If ordered)			
08	Keypad Screen Guard	01	
09	IQ/OQ/PQ/DQ Documents	01 Set	

Serial No.: _____ Packed By: _____

Unpacking Procedure

a. Open the box to an indication arrow.

b. Take out the bonded Accessories carefully.

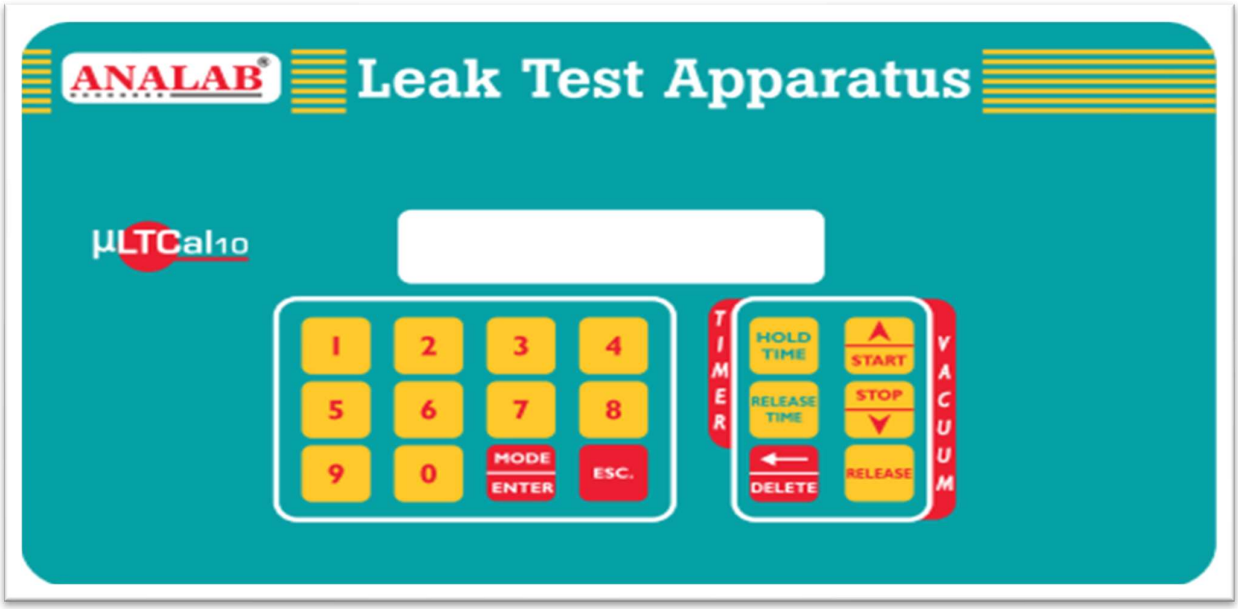
c. Install the unit according to procedure of installation.

5. Technical Specifications

- Vacuum Controller : Microcontroller Based
- **Material of Construction : Stainless Steel**
- Maximum Vacuum Level **:** Better than 500 mm of Hg
- **Vacuum Setting : Vacuum can stabilize for a set value from:**
  Less than 400 mmHg : ± 10 mmHg within 30 seconds
  Above 400 mmHg : ± 5 mmHg within 30 seconds
- Vacuum Hold Timer **:** Variable from 1 sec. to 99 min
- Vacuum Release Timer **:** Variable from 1 sec. to 5 min
- Time **:** Real time clock
- Display **:**16 x 2 Line Alphanumeric Backlit LCD
- Keypad : Membrane waterproof polycarbonate soft touch keypad compliance with UL/ROHS
- Vacuum Gauge **:** Digital display by user friendly touch pad
- Auto Release of Vacuum : After completion of Vacuum Hold Time
- Analysis Data Storage : More than 500 analysis data which can be viewed & Print, company name, analysis date & time, record number, *Username, *Sample Name, *Bath Number/ID, Number of Sample, Set Vacuum, Vacuum Hold Time, Vacuum Calibration Date, instrument serial number, Instrument Make & Model & *Signature etc. Secondly, analysis data can be printed online without saving analysis data in Instrument.
  (*: Not possible to enter data by instrument keypad but it will be handwritten)
- Searching of data : With record number by scrolling.
- **Report Formation : As per Non-GLP Compliance**
- Printer Interface : Centronics Parallel Port / Serial (RS-232 C) Port
- Printer : 40 / 80 Column Dot Matrix Printer
- Power Supply **:** 230VAC ± 10%, 50Hz

6. Description of Keypad

µLTCal10 has EIGHTEEN keys with 16 x 2 LCD displays.



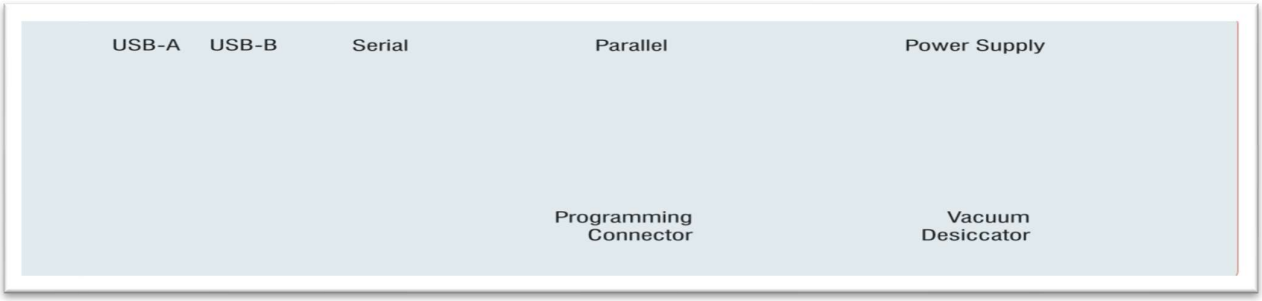
Vacuum Section

START	:	To start a Vacuum Pump
STOP	:	To stop Vacuum Pump
RELEASE	:	To release Vacuum from dedicators

Timer Section

HOLD TIME	:	To set Vacuum hold time.
RELEASE TIME	:	To Set Vacuum release time after completion
DELETE	:	To Delete a wrongly entered character
ENTER	:	To confirm entered value
ESCAPE	:	To come out from the last screen
NUMERICAL KEYS	:	To enter values
MODE	:	To enter in different modes.
▲/▼	:	To scroll the values up or downside

7. Description of Rear Panel



AC Power Supply : To connect AC Power Cable
Vacuum Outlet : To connect Vacuum tube for Desiccators
Programming Connector: To Update software

8. Installation

Install the unit in dust and water vapors free area.

Connect silicone tube between Desiccators and at rear side of instruments

Connect power cable and check mains supply 230 VAC±10%, 50Hz supply. Check the proper earth voltage between Neutral and Earth pin should be less than 3 VAC.

Switch ON the mains switch.

ANALAB Leak Test App.	Instrument will Display: Manufacturer Name
Model : µLTCAL10	Model Number
Version 2409/03-02/01.00	Version Number
Serial Number ABCD1234	Serial Number
Instrument ID ANALAB/1234	Instrument ID
ANALAB VADODARA Vacuum : 000 mmHg	Standby (Home) Screen Actual Vacuum

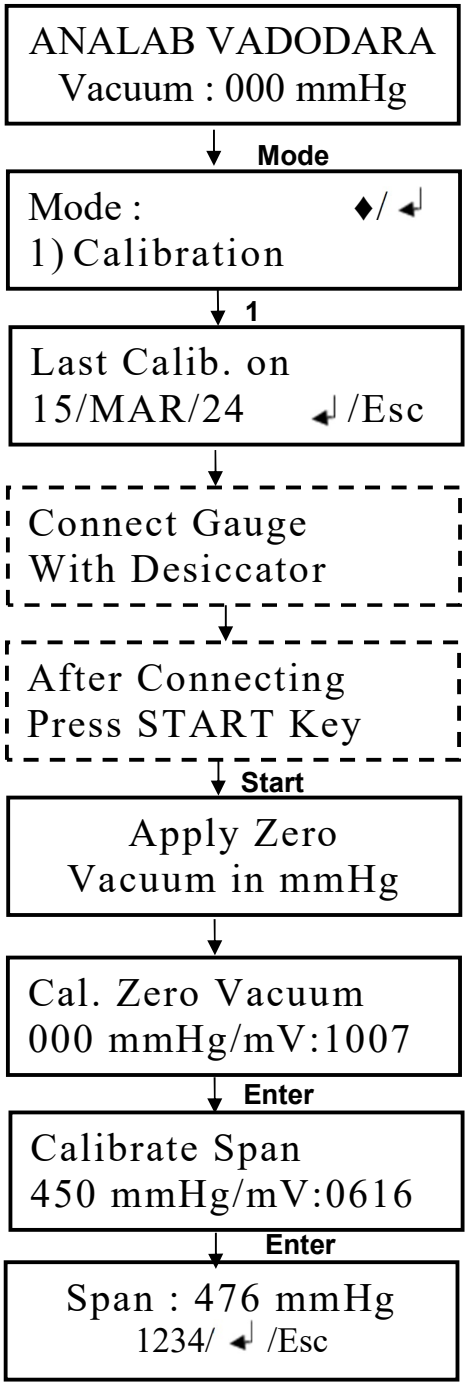
9. Operation Procedure

µLTCAL10 operation is distributed in Five (5) different modes i.e. Calibration, Analysis Data, Calibration Data, Utilities & Service for ease in operation.

9.1. Mode 1: Calibration

Calibration mode is useful to calibrate instruments with calibrated Vacuum Gauge. Connect Calibrated Gauge in series with instrument and desiccator.

NOTE: Instrument is pre-calibrated with Calibrated Vacuum gauge. Without calibration gauge it is not recommended to calibrate the instrument, it may lead to wrong reading.



Standby (Home) Screen

Press **MODE** & **ENTER** Key to select **Calibration mode**

Display will show the last calibration Date.
Press Enter to recalibrate

Connect Calibrated Vacuum Gauge in series with Desiccator

Press START key to calibrate instrument.

Open desiccator led to apply Zero Vacuum and press **Enter**

Display shows mmHg/mV signal. Press ENTER to calibrate Span

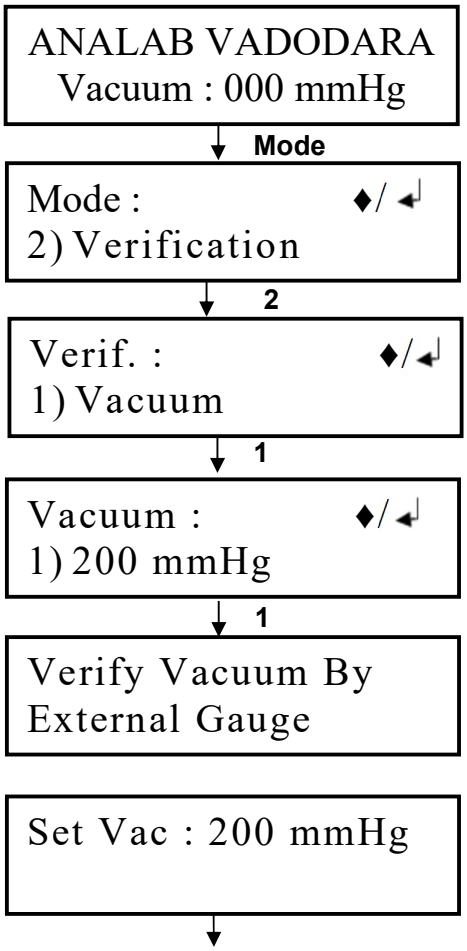
Observe Vacuum in gauge. Once it reaches between 450 – 500 mmHg Vacuum, press Enter.

Enter Vacuum Value Displayed on Calibrated Vacuum Gauge. Calibration will update.

9.2. Mode 2: Verification

This mode is useful to verify Vacuum after performing Vacuum calibration and to verify timer with external calibrated timer.

9.2.1. Vacuum Verification



Standby (Home) Screen

Press **MODE** & ▼ key to select Verification

Press 1 for Vacuum verification.

Select Vacuum to verify between 200 / 400 or user define vacuum

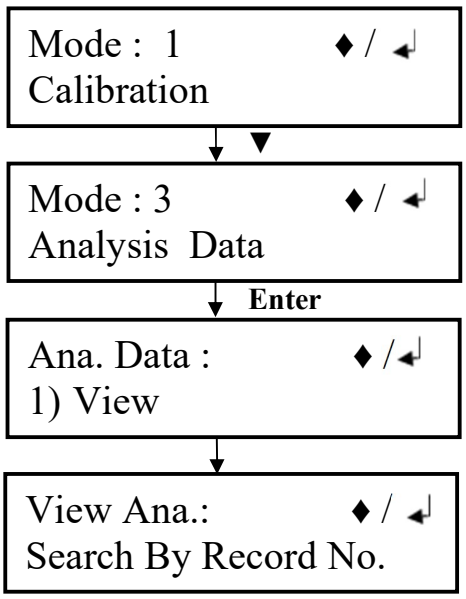
Connect External Gauge with desiccator,

Vacuum pump will start, and vacuum will reach up to set vacuum. Check and confirm vacuum with external gauge, if not match, recalibrate instrument.

9.3. Mode: 3 Analysis Data

µLTCal10 has facility to save more than 500 analysis data. These saved data can view, delete or print from this mode.

9.3.1. View Analysis Data



Press ▼ to select Mode 3 i.e. Analysis Mode

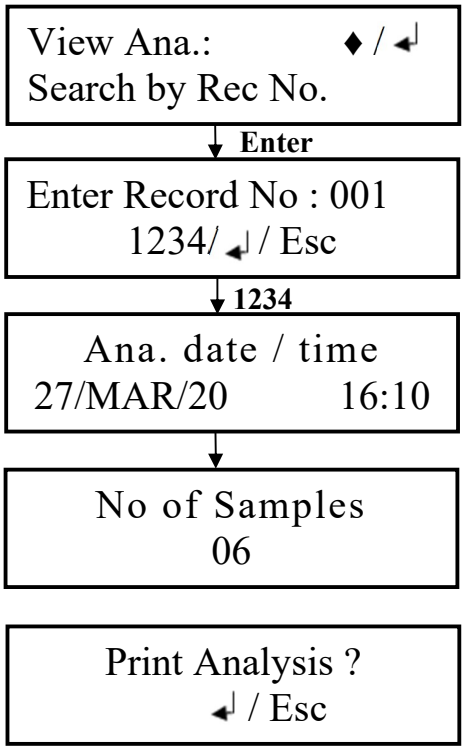
Press **Enter** to view or delete saved Analysis data

Press **Enter** to view analysis data.

Search analysis by record no.

9.3.1.1. Data Search with Record No.

Saved analysis data can be searched by Record number or by scrolling



Press **Enter** to search analysis data with corresponding record number.

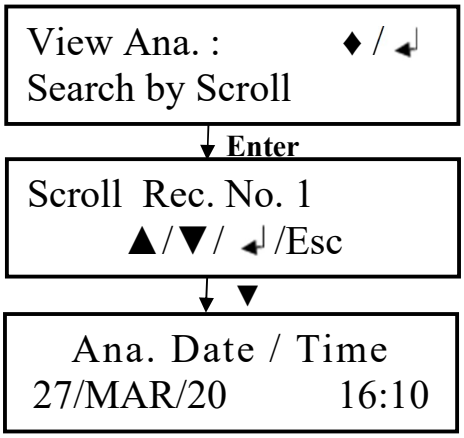
Enter record number and press **Enter**

Display : Analysis date and time

All Set parameters for analysis will be displayed.

Selected Analysis data can print with Enter command.

9.3.1.2. Data Search with scroll



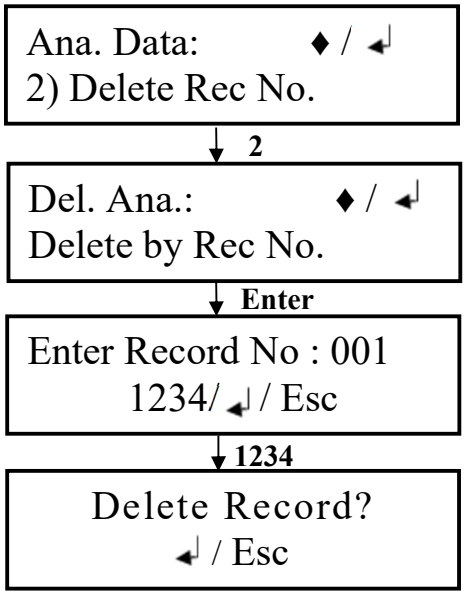
Press Enter to select “Serarch by Scroll”

Scroll record number with ▼/▲ and selecte analysis record to view and press **Enter**

All displays shown as per in mention in “ search by record no.”

9.3.1.3. Delete By Record No.

Saved analysis data can be deleted by Record number or by scrolling



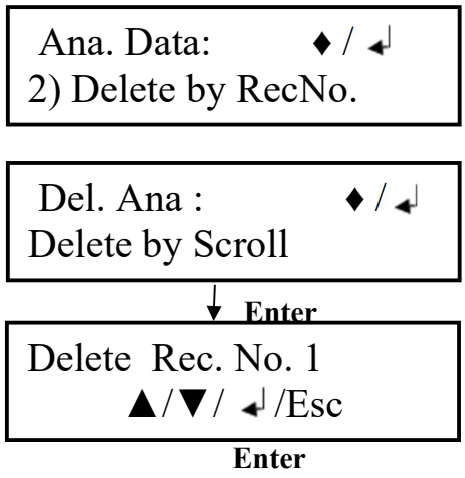
Press 2 in Analysis data mode to delete data

Press **Enter** to delete analysis data with corresponding record number.

Enter record number and press **Enter** to delete

The instrument will confirm about deleting of selected analysis data. Press Enter to delete or Esc to come out without deletion.

9.3.1.4. Data delete by scroll



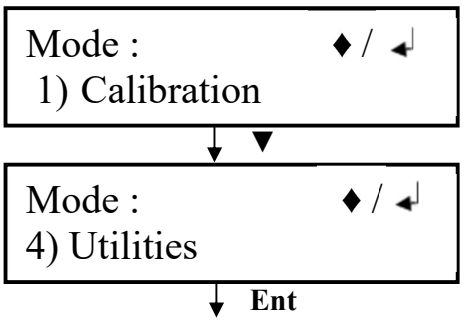
Press 2 in Analysis data mode to delete data

Press ▼Enter to select “Delete by Scroll”

Scroll record number with ▼/▲ and selecte analysis record to delete and press **Enter**

9.4. Mode: 4 Utilities

This mode is useful to set instrument parameters like date and time, Printer configuration, Company name set, Instrument ID set and for system update.

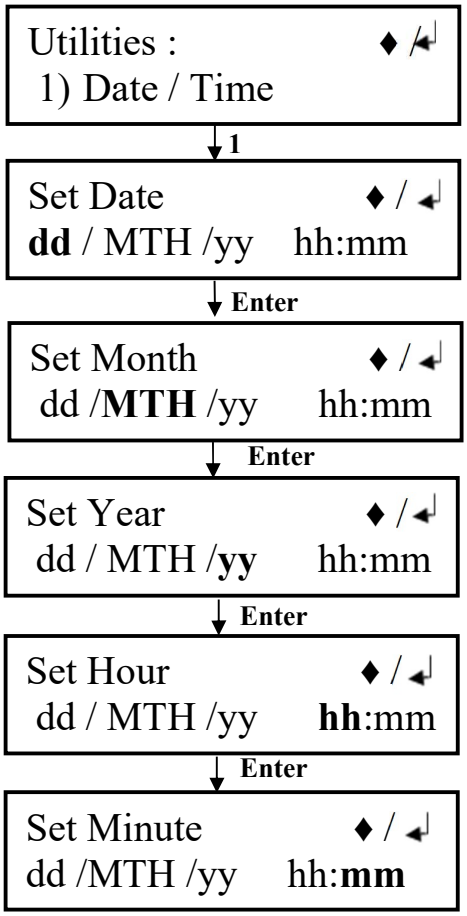


Press ▼ to select Mode **3** i.e. Utilities Mode.

Press **Enter** to proceed with different utilities.

9.4.1. Utility :1 Date & Time

µLTCal10 has in built clock which will updates with inbuilt battery. User Can Set Date and Time from this utility.



Press 1 to set date and time

Set DATE with ▲ / ▼ Key.

Press **Enter** to set Month

Set MONTH with ▲ / ▼ Key.

Press **Enter** to set year

Set YEAR with ▲ / ▼ Key.

Press **Enter** to set Hour

Set HOUR in 24 hrs. format with ▲ / ▼ Key.

Press **Enter** to set Minutes

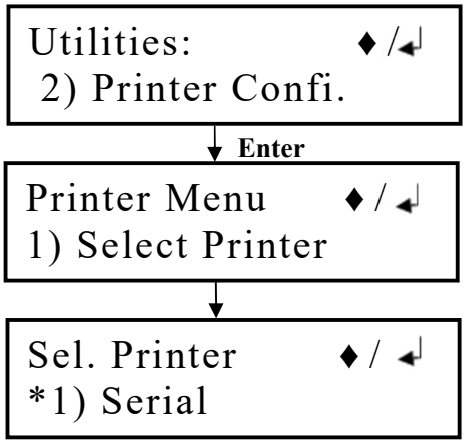
Set MINUT with ▲ / ▼ Key.

Press **Enter** to update values.

9.4.2. Utility :2 Printer Configuration

This utility is useful to select and test printer output of instrument. Users can connect 40 column serial or parallel dot Metrix printer with instrument.

9.4.2.1. Select Printer

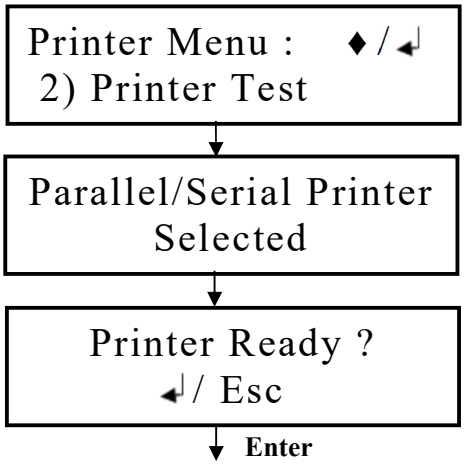


With this menu, users can select printer between Serial or Parallel

Printer Menu. Press 1 to select printer between Serial or parallel

Select printer * indicates selected printer. Use ▼ key to select parallel printer

9.4.2.2. Printer Test



This menu is used to check the working of connected printer

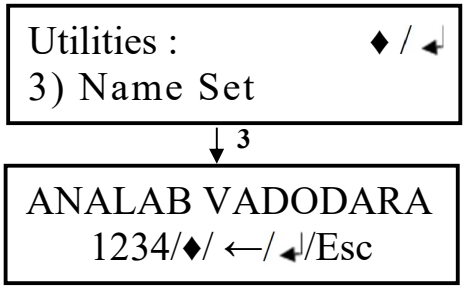
Will display connected printer type

Press **Enter** to print

Default company name will print.
If there is no printing on printer, then it indicates problem in instrument. Contact your nearer service center or manufacturer.

9.4.3. Utility : 3 Name Set

Set the name of company to display on the default screen of the instrument. Same name will view and print on report.

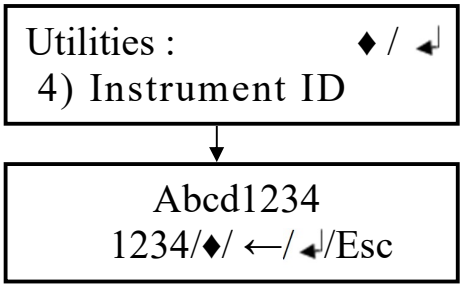


Press **Ente**r key to set the name of company.

Enter the name to set with help of ▲/▼ keys (Max. 16 character can set) and press **Enter** to update new name.

9.4.4. Utility : 6 Instrument ID

Users can set instrument ID. Instrument ID is different than serial number.

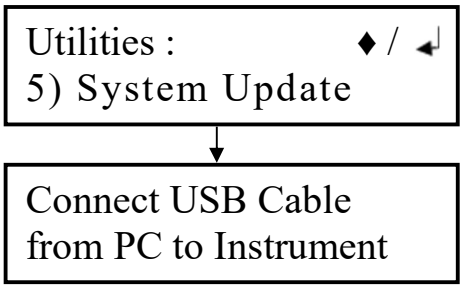


Enter to enter instrument ID

Enter instrument ID with ▲▼ keys and press Enter to confirm.
Press Esc to come out from utility.

9.4.5. Utility : 5 System Update

To update system software, this utility will be used. (Only authorized person will perform this update.)



Press 5 for system update.

The instrument will give instructions to update the system.

9.5. Mode: Services

Service mode is only available for service personnel and without master password, it can not open.

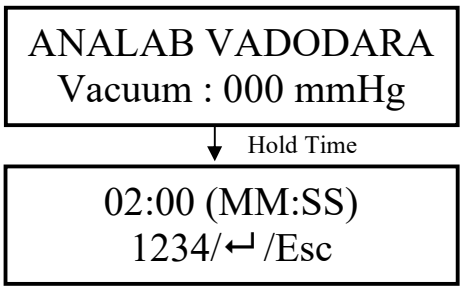
10. Analysis

µLTCal10 operation is very easy to operate. Separate keys are given for Vacuum pump start, stop and release the vacuum from dedicators and set timer for hold time and release time.

Fill desiccators with purified water up to the mark indicated and add 0.5 % crystal violet solution in water, insert SAMPLES required to test, place resting plate and place the lead top on dedicators.

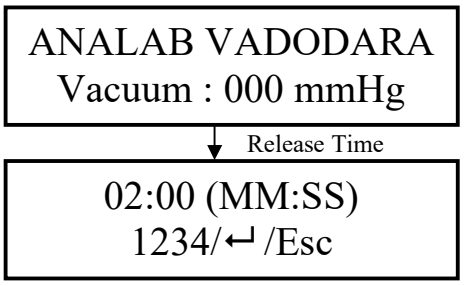
Before conducting test, set Vacuum, Vacuum time and Vacuum release time.

10.1. Vacuum Hold Time



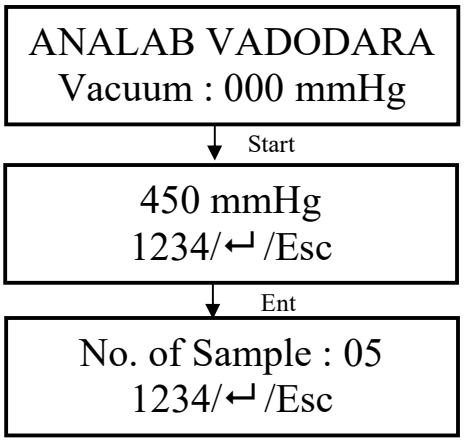
Set Vacuum Hold Time.

10.2. Vacuum Release Time



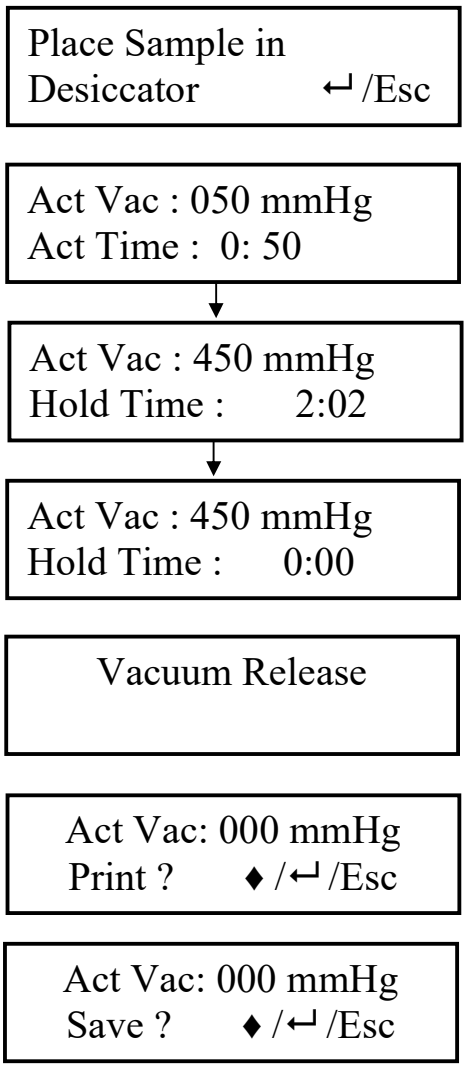
Set Vacuum Release time.

10.3. Vacuum Set



Set the Vacuum require for sample test

Enter number of samples kept for testing



Place samples in desiccator and close desiccator lid.

Vacuum pump will start and Vacuum will start increasing in desiccators

Once set vacuum achieves, hold time will start till set hold time.

Vacuum hold time achieves.

Vacuums will be released.

Press Enter to Online print report. Press ▼ key to save analysis data.

Press Enter to save analysis data in internal memory.

Remove samples clean with tissue paper and check for any leakage observed in sample.

11. Cleaning Procedure

11.1. Use purified water to clean desiccators

11.2. Clean outer and inner surface with help of clean, dry and soft cloth.

11.3. Keep the desiccator for half an hour dry.

11.4. Change the desiccator's water twice in a week.

12. Standard Operating Procedure (SOP)

12.1. Operation of leak test apparatus to determine leakage in strips/blister

12.1.1. Ensure that the leak test apparatus and Desiccator are clean and dry.
12.1.2. Open Desiccator lid and fill the Desiccator with pure water till strips get submerged in water.
12.1.3. Remove and clean O ring and groove of Desiccator with the help of soft dry cloth and remove any kind of dust particles and fix it again on the groove.
12.1.4. Insert the strip or blister to be tested for leak test and place the resting plate into the desiccator and close the lid tightly.
12.1.5. Ensure the vent valve is also tightly closed.
12.1.6. Set Hold time and release time as required for sample.
12.1.7. Press “Start” key, Set require Vacuum and sample number, and press Enter, pump will start, and vacuum starts increasing.
12.1.8. Once set Vacuum achieves it will hold up to set hold time.
12.1.9. After completing the hold time, vacuum will be released automatically.
12.1.10. Users can take print of analysis record or can save the record in internal memory.
12.1.11. When complete vacuum release and vacuum shows Zero, open the desiccator lid.
12.1.12. Remove strips/Blister
12.1.13. Wipe the strips/blister with tissue paper to remove water droplets.
12.1.14. Observe the strips/blisters for any water seepage inside. If seepage is observed, then it indicates failure of leak test.

13. Guarantee

This Leak Test apparatus is guaranteed for a period of 12 calendar months from the date of installation OR 18 calendar months from the date of delivery (whichever is earlier) against defects in material or workmanship other than valves, semiconductors, electrodes, batteries, PVC & Polycarbonate material etc. During the guarantee period, our liability is limited to the repair or replacement at our option of the instrument or parts thereof found to be defective.

14. Service After Sales

The most care is taken in the design, manufacture, and inspection of all ANALAB instruments to ensure trouble free service for long periods. However, in case of unsatisfactory performance of any of our instruments please contact our distributor for your area through whom the instrument was purchased under intimation to us.

Manufactured By:

Analab Scientific Instruments Pvt. Ltd.

Plot No. 361, Sayaji market,
N. H. No.: 8 By-Pass, At & Post: Sayajipura
Vadodara – 390019
Gujarat (INDIA)

+91-9714503393, +91-265-2514404
info@analab.co.in
www.analab.co.in
www.analabscientific.com

service@analab.co.in For Service Support
Enquiry@analab.co.in For Sales Enquiry