DS 8000 / DS 14000

Dissolution Apparatus

with External Bath Circulator
(SC/TR)

Operator's Instruction Manual

LABINDIA
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Inst.Op_DS8000_DS14000_Peri_Pump_BC_Auto_V5.9

Chapter 1

Safety

Safety Practices and Hazards

Labindia Tablet dissolution Tester DS14000/8000 with External Bath Circulator System has been carefully designed in accordance with the safety standards. It is in the interest of the purchaser that he is aware of the resultant dangers of misuse and or incorrect handling of these products.

Information on safety practices is provided with your instrument and operation manuals. Before using your instrument & accessories, you must thoroughly read these safety practices.

The following general safety precaution must be observed during all phases of operation, service and repair of this instrument. Failure to comply with these precautions or with specific WARNINGS elsewhere in this manual may impair the protection provided by the equipment. In addition it violates safety standards of design, manufacture, and intended use of the instrument.

- The instrument is designed for Indoor use only.
- The instrument must always be used with the protective earth lead of the power cord correctly grounded to earth at the mains outlet.
- To permit sufficient cooling, ensure that proper space is available on the table.
- Do not operate the instrument in extreme humidity (above 95%).
- Do not operate the instrument in direct sunlight.
- Any equipment connected to the instrument should meet the requirement of the EN61010-1 or International safety standards.
- Detach the control unit from the main machine for relocation or movement.

Electrical Hazards:-

Labindia Tablet Dissolution Apparatus DS14000/DS8000 with External Bath Circulator contains electrical circuit, devices and components operating at high AC voltages. Contact with the high voltage part can cause a death, serious injury or painful electrical shock.

Enclosure covers that are retain by fasteners, which requires the use of the tool for removal and may be opened by Labindia trained or Labindia qualified or Labindia authorized service engineers. Personnel without such training or persons currently undergoing a course of training require through instructions. This operator's manual should form the basis of these instructions.
Application of the wrong supply voltage connection of the instrument to an incorrectly wired supply outlet or improper electrical grounding can create a fired hazards or a potentially serious shock hazard and could seriously damage the instrument and any attached accessory.

- Power cord – The Instrument uses detachable ac power cords between External Bath Circulator and Main Unit and un-detachable power cord for External Bath Circulator with earth connection. Failure to ensure adequate earth grounding by not using this cord may cause instrument damage. If the power cord becomes damaged, replace immediately.
- Fuse – Fuse ratings are clearly indicated on all fuse panels adjacent to the fuse holder. If and when replacement is necessary, the correct fuse rating must be adhered to.

Symbols:-

Warning symbols:

- Warning – Information about hazards which can be harmful to your health or lead to instrument damage.

Warning!
This equipment contains potentially hazardous voltage. Risk of electrical shock.

The product is marked with this symbol when it is necessary for the user to refer to the instrument manual.

Warning!
No serviceable parts inside. Do not open cover, service and maintenance should be performed by qualified personnel.

Caution Symbol:

A ‘caution’ message appears in the manual when failure to observe instructions could result in damage to instrument or cause serious or potentially fatal injury.

A ‘Note’ appears in the manual to give advice or information about technical requirement or error condition or warnings to the user.

Information Symbols

I	Switches Main Power ON
O	Switches Main Power OFF
~	Indicates Single-Phase alternating current

Use Of Instrument:-

Be sure the supply voltage is within the specified range as specified in the rear side of the instrument control unit.

The instrument is designed for use in laboratories. Use appropriate safety as per standards for handling of chemicals during measurement.

Any use that does not confirm with technical data of the instrument is being to be a case of misuse. The customer shall bear sole responsibility of any damage due to such misuse.

General Hazards:

General Hazards arise from:-

- Samples mixtures, Unknown chemical composition.

- Proper lifting arrangement is necessary for uploading & downloading the instrument. User should arrange 2-3 persons or use “Forthlift” for lifting the instrument.

- Only Labindia Authorised, Labindia Trained personnel is allowed to service the instrument.
- Do not use this instrument if it has unauthorised modifications. Unauthorised modification may result in fire, electric shock or other hazards.

Chapter 2

Introduction

Introduction to Dissolution

Scientific evidences have shown that in-vitro dissolution testing provides the means to evaluate critical parameters such as adequate bio-availability and provides information necessary to the formulator in development of more efficacious and therapeutically optimal dosage forms. Knowledge of critical operating variables for dissolution testing device is important to the pharmaceutical scientist interested in product development, quality control and research

Dissolution of a pure substance follows the Noyes Whitney Equation. $dc/dt = kS (Cs- Ct)$ where dc/dt is the rate of dissolution, k is the dissolution rate constant, S is the surface area of the dissolving solid, Cs is the saturation concentration of drug in the diffusion layer and Ct is the concentration of drug in dissolution media (or the bulk).

Dissolution testing serves as an important tool for characterization of the biopharmaceutical quality of product. It helps in choosing between different alternative formulation candidate at the formulation development stage. Today such in – vitro dissolution tests are seen to be the most sensitive and reliable predictors of in – vivo availability. The dissolution test has high relevance in quality control and quality assurance. The data will have great importance when assessing changes in manufacturing process or formulation and assist in decision concerning the need for bio-availability study.

All the above parameters can be fulfilled by a dissolution system with sufficient reliability i. e. the system being experimentally sound and gives accurate, precise and reliable results.
Keeping all these points in mind, Labindia Analytical Instrument Company with their sound knowledge and vast experience in manufacturing variety of instruments and excellent manufacturing facilities has designed Tablet Dissolution Test apparatus.

FEATURES:

1. DS8000 / DS14000 is used for dissolution rate analysis as per USP / BP / IP methods at specified temperature and shaft speed.
2. Advanced Micro-controller based user-friendly state-of-the-art product design.
3. Alphanumeric splash waterproof polyester soft keys for keyboard.
4. User interactive software in dialog mode for ease of operation with protection against invalid entries.
5. Clear Acrylic Water Bath for good visibility with Fill Level mark to ensure the correct amount of water.
6. Drain Tap for quick & easy cleaning.
7. Two Tier Password Protection – Admin and User with Alphanumeric entries of Sample Name, 10 User Password.
8. Sample Number, Identification Number for authentication. Daily Auto Incremented Run no., Date & Time, selected USP apparatus and Factory entered CUSTOMER NAME with Instrument Sr. No. on report Printouts makes the system foolproof and GLP compliant.
9. Selectable Report Format, complying with GLP requirements:
   a) RUN Report giving Run No., Set parameters and actual parameters (paddle/basket shaft speed at every sampling interval during the dissolution process for validation).
   b) Report of program parameters for 15 programs, with printout of empty programs.
   c) Printout of each bowl temperature (Optional).
10. Non-volatile memory storage of 15 methods with parameters and last dissolution run data. Reports can be printed even after resetting / power off / power failure conditions.
11. Built-in Real Time Clock (RTC) for date and time display and on printout.
12. BEEP indication for Bath Readiness and over temperature limit during RUN.
13. Error indication to help user trace the problem.
14. Dissolution RUN can be started with last run parameters.
15. Precise temperature control and speed control for repeatable results.
16. Automatic Depth adjustment for 25 mm depth setting.
17. Facility to View Set Process Parameters during Dissolution RUN.
18. Intelligent Facility to continue the dissolution analysis in case of short power interruption (Especially useful for long duration analysis of sustained release drug tablets).
19. Stirrer Hood up-down movement control through keyboard operation and depth position indicated on display.
20. Audible low water level alarm with indication on display for safety.

21. Facility to monitor Bowl temp with an external RTD Temperature Sensor (Pt100) or optional - temperature monitoring and data logging of 6 bowls when sampling assembly installed.
22. Availability of specially molded chemical resistant Polycarbonate / Glass Bowls with lids complying to USP/BP/IP. Clear as well as Amber colour.
23. Specially designed Bowl Lids for Evaporation Recovery when supplied with Tablet dispenser (Optional).
24. Tablet Drop Mechanism for instantaneous dropping of all 6 tablets in the respective bowls with bowl centering lid attachment.
25. Wakeup alarm for automatic bath heater control startup as per desired date & time.
26. Buffer change facility during run without discontinuation.
27. Recovery test with programmable RPM & Time.
28. Accessories available, Sinkers, USP5 Transdermal disk, USP6 - Transdermal rotating cylinder, Intrinsic apparatus (rotating and stationary). Stationary Basket for Felodipine Tablet, Sampling Cannula, Teflon coated paddles or gold plated baskets for demanding applications (Optional).
29. Rinsing facility for Sample carrier tubing during offline Sample Collection to reduce the carry over effect.
30. Specially designed Sampling attachment with intelligent interface for automatic positioning of sample collection depth complying to USP/BP/IP requirements which eliminates long duration interference of sampling tubes in the bowl during dissolution process.
31. Sample collection option – i) Standard start at Programmed interval or ii) Special USP complying with Spilt sampling time with respect to Interval.
32. Sample collector 10x6 (60vials), 16x6 (96 vials- test tubes with rinsing facility. Wide mouth Vials also available. For more sampling 18x6 (108 vials), 24x6 (144 vials – test tubes) also available.
33. User programmable Cleaning cycle for Sample tubing Path - consisting of filter, Sampling tubes, Replenishing tubes, Teflon (PTFE) Carrier tubing and Peristaltic pump tubing with ease of operation.
34. Validation Function for System parameters - RPM, Temperature, Sampling Volume & Replenishing Volume with GLP reporting.
35. Evaluation of % dissolved and Dissolution Profile for one buffer or two buffers, simply by entering sequential UV readings and report printing in GLP format with graph. No need of Personal Computer to evaluate final results. (Optional feature)
36. Choice of Dot matrix or Desk jet Printer connectivity. Desk jet printer with monochrome or colour selectivity. Coloured printout for easy distinguishing of the bowl 1 to bowl 6. Various Sampling Vials available, including for HPLC vials for HP/Agilent, Dionex and Shimadzu.

SPECIFICATIONS:

Control	: Micro-controller based.
Bath Circulation	: By external circulation pump unit BC0612 with safety Thermostat
Temperature range	: 20°C – 55°C, ± 0.1°C resolution
Temperature control accuracy	: upto 45°C ±0.1°C, >45°C to 55°C ±0.2°C
Temperature stabilization time	: Typical 35 – 40 minutes.
Temperature sensor	: Digital Temperature Sensor
Paddle/Basket Shaft Speed	: (a) Control : Stepper motor driven with feedback. (b) Range : 20 to 350 RPM ± 1RPM. (c) Setting : In steps of 1 RPM.
Sampling time selectivity	: Fixed / Programmable (varying) intervals.
Time interval selectivity	: In steps of 1 minute
Max No. of Intervals	: 30
Dissolution Process Time	: 1 minute - 720 hours
Method Storage	: 15 Programs with parameters.
Data Storage	: Non-volatile memory
Password Protection	: Two Tier - Admin and User (10 Users)
Keyboard	: Alphanumeric splash water-proof polyester with soft keys.
Display	: 40 x 2 line back lighted Liquid Crystal Display (LCD).
Report format	: a) GLP compliant - Process Report consists of: Customer name, Sample name, Identification no., Instrument Sr. No., Date, Time, Wavelength, Type of USP Apparatus, Stirrer Depth, Buffer Volume and Run number for authentication along with Set & Actual process parameters (Temp, Rpm, Interval number & Total Elapsed TIME), 6 bowls temperature (Optional). b) Program parameter Report.
Printer output : **Parallel Printer**	: Dot-matrix 80 column / Deskjet
Serial Printer	: 48 column Thermal Printer
Automatic Depth Adjustment	: 25mm setting.
Water Bath	: For DS8000 : 17 liters capacity with built-in safety Thermostat & Water Level Sensor For DS14000 : 29 liters capacity with built-in safety Thermostat & Water Level Sensor
Dissolution vessel	: Polycarbonate/Glass Bowls as per USP/BP/IP

<u>Optional</u>

Automatic Sample Collector	: Micro-controller Based Sample Collector with 60 position sample collector tray, Carrier Teflon tubing and 12 Channel Peristaltic Pump with Tygon Tubings.
Bowl Temperature Monitoring	: For 6 bowls. (12 bowls for DS14000)
Tablet Dispenser with bowl Centering	
PC Interface via RS232C	: RS232 for Data Downloading Centronics parallel port.
Environmental Operating Conditions	: a) Operation : Indoor b) Temperature : Ambient to 45°C c) Relative Humidity : 5-90% non condensing

Power Requirements	: a) DS8000	:	110/115VAC, 50/60Hz, ±10%, 1500Watts
	b) DS8000	:	220/230VAC, 50/60Hz, ±10%, 1500Watts
	c) DS14000	:	110/115VAC, 50/60Hz, ±10%, 1500Watts
	d) DS14000	:	220/230VAC, 50/60Hz, ±10%, 1500 Watts
Dimensions	: DS8000	:	110 x 60 x 110 cm.(L X W X H)
	DS14000	:	150 x 60 x 110 cm.(L X W X H)
Shipping Weight	: DS8000	:	Approx. 120 Kg
	DS14000	:	Approx. 200 Kg

Instrument Configuration / Models :-

Models

No	Model
1	DS-8000 with BC0612 - 1 LITRE
3	DS-14000 with BC0612 - 1 LITRE

Each model is available in following configuration

1) STD - Standard operation
2) STD + AS - Standard with Auto Sampler
3) STD + AS + TR - Standard with Auto Sampler + Temperature Reader

Standard Accessories

1) Sample Collector - SASC Labindia make with following options.

Single Head (DS8000)	Dual Head (DS14000)
10 X 6	5 x 2 x6 – Bottle
16 X 6	8 X 2 X 6 – Bottle & Test Tube
24 X 6	12 X 2 X 6 – Test Tube

2) Peristaltic Pump - Ismatec make (12 Channel) for DS8000

3) Peristaltic Pump - Ismatec make (24 Channel) for DS14000

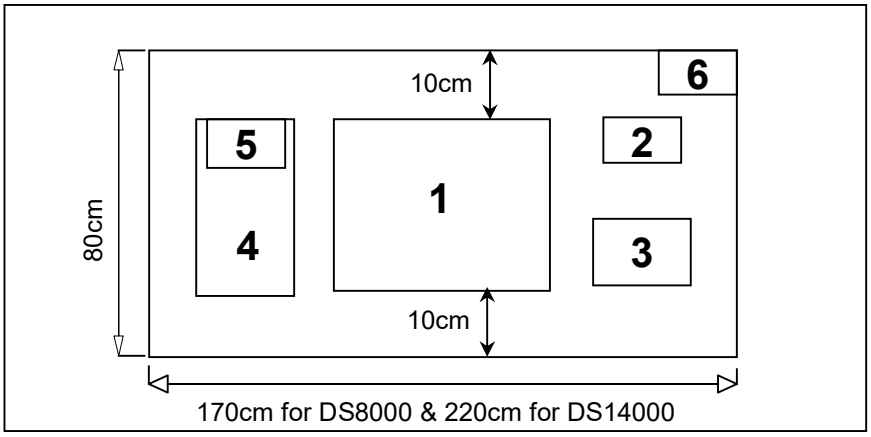
Chapter 3

Setting Up

Pre Installation Requisites

Lab Space Requirements:

The bench top where the instrument is to be installed should be large enough to accommodate the instrument and all accessories. The table should have following dimensions.
150cm x 60cm x 110cm (LxWxH) and should support approx.95kg of instrument weight. (DS8000)
200cm x 60cm x 110cm (LxWxH) and should support approx.190kg of instrument weight. (DS14000)



1 – Instrument	2 – BC0612 Unit
3 – Printer	4 – Sample Collector
5 – Peristaltic Pump	6 – Power Switch Board

The instrument should not be placed permanently against the wall because it must be accessible from back for servicing. An accessible space at least 40cm should be available behind the table. If it is not possible, the table on which the instrument is mounted should be on wheels so that it can be easily removed.

Power Requirements:

Model	Socket 1
DS8000 – 110/115VAC	125V / 15A
DS8000 – 220/230VAC	250V / 15A
DS14000 – 110/115VAC	125V / 15A
DS14000 – 220/230VAC	250V / 15A

Environmental Requirements:

The instrument is designed for indoor operation and therefore lab environment should be :-

- Relatively free from dust this is especially important when working with ultra-trace technique such as graphite furnace sampling.
- Free from flammable explosive, toxic, corrosive, vapors, or gases.
- Area should be free from vibrations, air drafts, direct sunlight's or direct bright light.
- Room temperature - atleast 3.0°C below the set bath temperature.
  e.g. For bath temperature = 25.0°C, room temperature should be below 22.0°C.
- Relative humidity - ≤ 80°
- Around the instrument there should be no equipment with strong power supply and no strong shaking machines.

INSTALLATION

☞ **NOTE : The installation procedure is described for 220VAC / 230VAC input operation. User should consider 110/115VAC and recommended fuse value if the installation is on 110-120VAC INPUT.**

1. REQUISITES

- Leveled Platform/Table with nearby 230Vac/ 15 Amp, 50Hz. power socket as per Input Power mentioned on the Controller Unit. (Ensure the Input Power supply is within ±10% tolerance).
- Make arrangements for liberal amount of fresh De-gassed D.M. / Distilled water.
- USP-Calibrator tablets a) Prednisone (Disintegrating) and Reference standards for calibration.
- Laboratory Glass ware - Clean & dry vials/test tubes/beakers for all sample collection, (10mL-Pipette)
- Suitable filter paper for sample filtering.
- Tissue paper roll and suitable container for Waste disposal.

2. SETTING UP THE INSTRUMENT WITH PERISTALTIC PUMP

- Carefully remove the instrument EP wrapping and the accessories from the packaging.
- Place the DS8000/DS14000 main unit, external bath circulator unit (BC0612) and accessories on the leveled table where it will be installed for dissolution analysis purpose.
- Now remove the stripes fixed to the Water Bath and remove the front supporting bar by unscrewing the Allen screws fixed on the DS8000/DS14000 top Hood and the Base.
- Check the electrical connection cables required for main unit and from external bath circulator unit (BC0612).
- Connect the external digital temperature sensor at the 3 pin shell connector on the rear side of the main unit, and other (Optional) accessories.
- Place the Sample collector on the left side of the main unit.
- Place the Peristaltic stand on the top surface of the Sample collector.
- Now connect the interconnection cable from main unit to Sample collector & Peristaltic Pump.
- Connect the Power cord/cables to them.

3. SETTING UP THE INSTRUMENT WITH EXTERNAL CIRCULATION (BC0612)

- Carefully remove the BC12 unit EP wrapping and the accessories from the packaging.
- Place BC0612 unit behind the tank or right hand side of the DS8000/Ds14000 main unit on tank base.
- Connect tank outlet tubing to BC0612 & tight with the cable tie.
- Connect tank inlet tubing to BC0612 & tight with the cable tie.
- Connect float switch connector, 2 pin shell female to the BC0612 unit.
- Connect 7 pin female – female shell connector assembly to BC0612 & other end to DS8000/DS14000 main unit.
- Connect 4 pin (24V out) female to female shell connector on the rear side of the DS8000/DS14000 main unit and other end to BC0612 unit.
- Fill the tank with distilled water till the level indicator.
- Do not switch on BC0612 unit with empty tank.

4. PRINTER INTERFACE CONNECTIONS

- Place the printer on the suitable side of the instrument.
- Connect the printer data cable to the 25 pin D-shell connector provided on the back panel.
- Adjust the printer dip switch settings as shown in. Refer Appendix – A.
- Ensure that printer is loaded with paper.

5. PERISTALTIC PUMP & SAMPLE COLLECTOR CONNECTIONS – (optional)

- Place the Sample collector on the Left side of the main unit.
- Place the P/Pump on the top surface of the Sample collector.
- Now connect the interconnection cable from Main unit to Sample collector and Peristaltic Pump.
- Connect the Power cord/cables to them and insert the respective plugs in mains socket.

6. SIX / TWELVE BOWL TEMPERATURE SENSOR CONNECTIONS FOR TEMPERATURE MONITORING – (optional)

Please note :- The 6 / 12 Sensors are factory installed along with the sampling assembly .

- Connect the 3pin power lock connectors (DS Sensors) from Sampling Assembly to Main unit.
- Connect the 4pin power lock connector (DISA Opto) from Sampling Assembly to Main Unit.
- Ensure the sensors are not touching to the sampling/replenishing tubes/filter.

7. FILLING THE WATER BATH

- Remove the corner side bowls by unlocking it.
- Wipe the inside of water bath with damp cloth to remove any debris that might lodge inside and damage pump.
- Make sure the pipe is connected to drain valve & drain valve is in open position.
- Fill bath upto the water level mark indicated.
- Close the drain valve & remove the pipe.
- Switch ‘ON’ the BC0612 and Main Unit, after initialization is over.

8. POSITIONING THE BOWLS (To install bowls on the tank cover)

- Raise the hood up using ‘UP’ arrow key.
- Insert a bowl in each position on the plate.
- Lock the bowls.
- Make sure that marking should be on the front side.

9. PADDLE AND BASKET INSTALLATION

- **Paddle Blade Installation**
  Carefully screw a paddle blade onto bottom of each shaft. Assemble finger-tight.

- **Basket Installation**
  1. Carefully screw a basket holder onto the bottom of each shaft. Assemble finger-tight.
  2. Place the basket, open end up, in palm with thumb and fingers grasping knurled grip.
  3. Press fit the basket into the basket holder.
  4. When removing the basket, pull-out the basket from bottom ring in downword direction.

- **Checking Paddles, Baskets and Shafts for Straightness**
  Verify straightness of stirring shafts, blades and baskets. Check shaft wobble near bottom end of shaft. Check basket wobble at bottom rim of basket. Record values at 20 and 350 RPM.

- **Paddle and Basket Height Adjustment**
  The paddle and basket height is factory set to 25mm and need not have to be changed unless the height is out of calibration. The following procedure describes how to properly adjust the height setting. This procedure should only be used to set the initial height.

- **Initial Height Setting For Paddles And Baskets**
  1. Attach the shaft into the shaft position at approximate distance.
  2. Put the 25mm diameter balls into the each bowl. BL1-6 / BL1-12
  3. Move the hood assembly down.
  4. For 25mm height setting, unscrew the shaft & rest on the balls.
  5. Tight all the shaft at this 25mm adjustment.

⚠	Install paddle blades on all shafts, even if baskets will be used for testing. Paddle blades must be used to set shaft collars.

10. INSTALLING THE EXTERNAL SENSOR

- This part is supplied with standard DS8000/DS14000 instrument. Using this probe user can measure bath and bowl temperature during run.
  1. Connect the 3 pin female shell connector at the rear side of the Main unit.
  2. Insert the probe at its position.
  3. Two positions are provided for temperature measurement.

11. SWITCHING 'ON' THE DS8000 / DS14000 DISSOLUTION APPARATUS

- Connect the power cord of BC0612 unit suitable 230 VAC, 50Hz stabilized power supply with proper earth connection.
- Connect power cord from BC0612 unit to Main unit.
- Switch 'ON' the instrument. The BEEPER will generate beep and the 40 character, 2 line LCD display will read,

LABINDIA DISSOLUTION TEST APPARATUS # V a_bc.d.e

☞ ***Note : Version will be display as per selection of model.***

- Use 'UP' key to move the Stirrer hood in upward direction.
- Fill water bath with clean/distilled water till the level mark (w/o Bowls, max. volume - 17ltrs for DS8000, 29ltrs for DS14000) and check for the drain tap leakage.
- Place bowls (8nos / 14 nos) in water bath filled with required dissolution media.
- Now attach the cleaned Paddles to the eight stirrers housing and lock its position.
- Use 'DOWN' key to move the stirrer hood down.

12. SWITCHING 'ON' THE PERISTALTIC PUMP (P/P) - Also refer the Mfgs. Manual.

- Connect the power cord from BC0612 unit to Peristaltic Pump with proper earth connection.
- Insert the P/P tubing in the cassette and load them on the P/P roller assembly 6 / 12 nos in left and 6 / 12 nos in right direction.
- Connect the teflon Sampling S1-S6 / S1-S12 and replenishing RP1-RP6 & R1-R6 / RP1-RP12 & R1-R12 tubing to the Peristaltic Pump as per the numbers marked.
- Switch 'ON' the Pumps. The LED display shows the pump % Speed (RPM) and the REMOTE LED ON indicating the connectivity is okay. Now Set the speed to 25% (Do not use speed more than 25 % for sampling)

13. SWITCHING 'ON' THE SAMPLE COLLECTOR (SC)

- Connect the power cord from BC0612 unit to Sample Collector with proper earth connection.
- Load the bottle tray in the Sample collector till the end.
- Connect the sample collectors teflon tubings to the P/Pump cassettes where S1-S6 / S1-S12 tubings are connected.
- Switch 'ON' the instruments. The BEEPER will generate beep and the sampler arm will move to the rinse position. The front panel has LED indication for AUTO, MANUAL and READY. The MANUAL LED glows on by default and the AUTO LED glows when the Auto command is sent by the DS8000 / DS14000 controller during RUN.
- It also has Sampling Arm forward and back movement keys. These key are active only in manual mode, in auto mode they are inactive.
- Ensure the sample vial/ Bottle tray is sensed by slightly pulling it out (indicated by beep)

14. PRINTER INTERFACE CONNECTIONS

A) Parallel Printer

- Place the printer on the suitable side of the instrument.
- Connect the printer data cable to the 25 pin D-shell connector provided on the back panel.
- Adjust the printer dip switch settings as shown in. Appendix - A.
- Ensure that printer is loaded with paper.

B) Serial Printer / PC Interface

- Place the printer on the suitable side of the instrument.
- Connect the printer serial data cable to the RS232-2 port in 9 pin D-shell connector provided on the back panel.
- Ensure that printer is loaded with paper.
- Kindly use Hyper terminal program for PC interface.

15. CONNECTIVITY TO PERSONAL COMPUTER

- Connect serial cable from PC serial Port to RS232-2 of DS8000/DS14000 main unit.

Note : RS232-2 is available for Serial printer / PC interface.

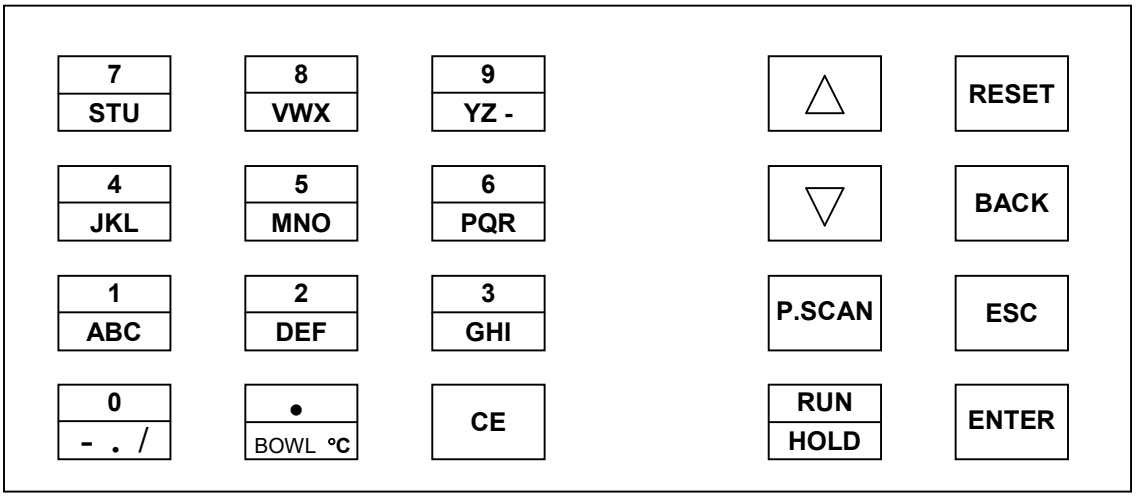
Congratulations YOU have done it this far.

PANEL DETAILS

Dissolution Apparatus Controller has two functional Panels, for which user has to get familiar with.

- Front Panel - Consisting of Front Splash waterproof polyester sticker with 40 character X 2 line back lighted LCD display and keyboard (20 keys).
- Back Panel - Consisting of
  a) 7-pin/M – shell connector for bath DTS Temperature sensor & Float Switch,
  b) 3-pin/M – shell connector for external bowl DTS Temperature sensor,
  c) 4-pin/M – shell connector for +24V supply to Bath Controller Unit
  d) 25-pin/F – D type connector for Parallel port Printer (Centronics).
  e) 9-pin/F – D type connector for Sample Collector & Peristaltic Pump
  f) RS232C -1 – Not Applicable
  g) RS232C -2 – 9 pin D connector for PC Conenctivity or serial interface.
  h) Mains input power connector from Bath Controller

1. Front Panel – Keyboard.



A) Dissolution Apparatus (DS8000/DS14000) :

Key functions:

L.H.S. Keys: Alphanumeric Dual Function (A~Z , 1~9), Zero (0) with Dash (-), Dot (.), Slash(/), decimal point (.) and Clear Entry(CE) Key.

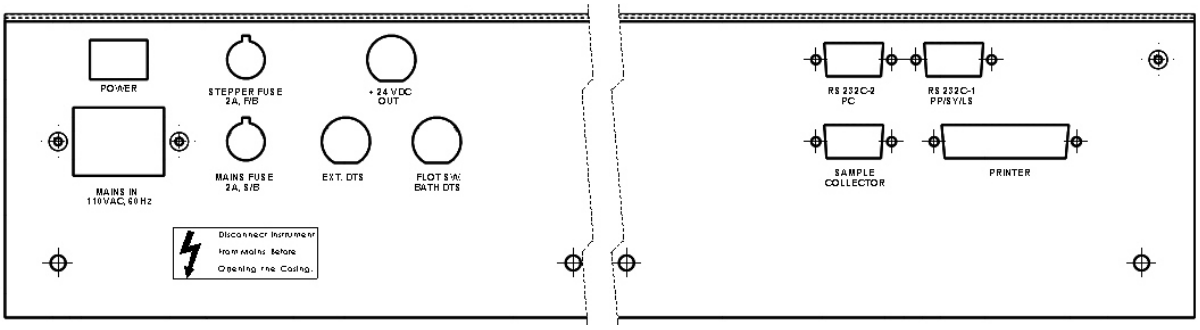
R.H.S. Keys: Functional Keys and RESET key.

Description of Functional Keys:

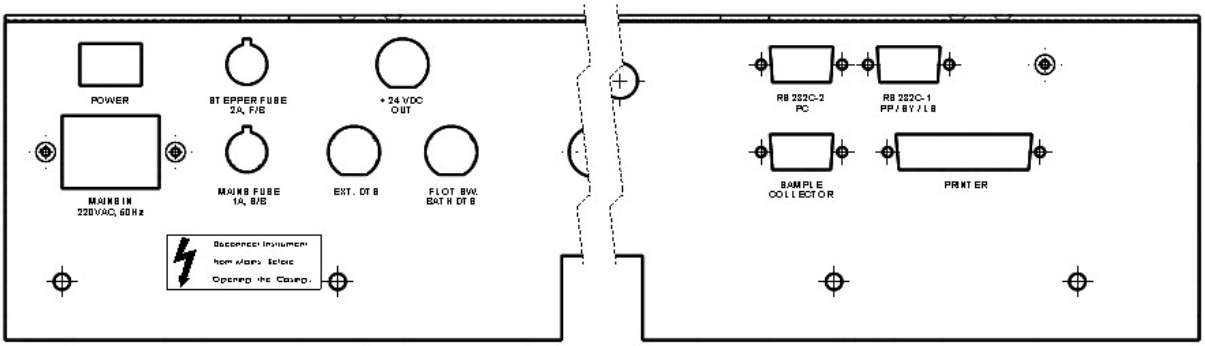
RESET	: To Reset the dissolution test apparatus.
BACK	: To go back to the previous menu.
ESC	: To Skip the next menu and go back to main menu.
ENTER	: To acknowledge the entered value.
△	: To lift up the stirrer hood manually.
▽	: To bring down the stirrer hood manually.
P.SCAN	: To SCAN the program parameters during run.
RUN / **HOLD**	: To stop the bowl stirrer shaft for tablet insertion before dissolution process / To start process after tablet insertion.
CE	: To clear the wrong entry.
• / BOWL °C	: To display 6 / 14 bowls temperature plus one external sensors / to enter numerical decimal point.

Back Panel – details for SC/TR option.

a) For 110VAC



b) For 220VAC

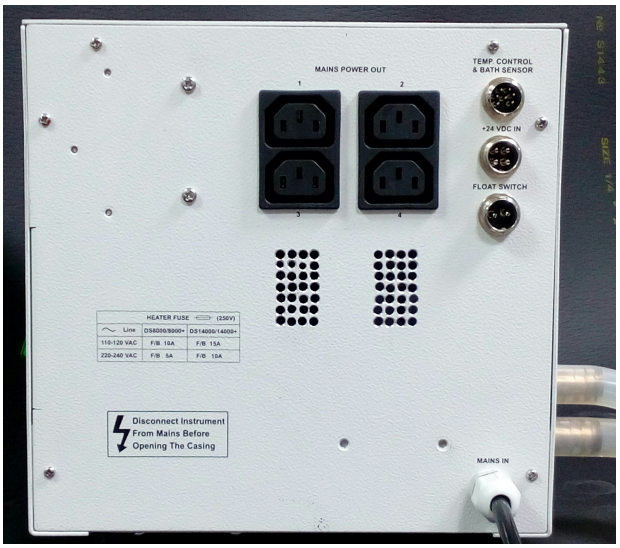


B) Bath Controller Unit (BC0612) :

BC0612 Unit has two functional Panels, for which user has to get familiar with.

- Front Panel - Consisting of Red & Green LED indications for
  Red LED : Heater Power ON
  Green LED : Circulation Pump ON

- Back Panel - Consisting of
  a) Non detachable Mains Power Input cable.
  b) IEC Outlet sockets / Mains Power out - 4 Nos. for Main Unit, SC06, Printer & PP08
  c) 7-pin/M – shell connector for bath DTS Temperature sensor & Float Switch,
  d) 2-pin/M – shell connector for water level float switch,
  e) 4-pin/F – shell connector cable for +24V supply from DS8000+ Main Unit



- Right Side Panel - Consisting of
  a) Heater power ON/OFF switch with illumination
  b) Heater fuse socket

- Left Side Panel - Consisting of
  a) Circulation outlet connection to connect PVC tubing with tank inlet
  b) Circulation inlet connection to connect PVC tubing from tank outlet

Labindia reserves the right to change specification without notice as part of its continuous program of product development

Chapter 4

Using the Instrument & Functional Mode

USING THE INSTRUMENT :

Dissolution Test Apparatus :- System Initialisation,

- RESET key is used to initialize the dissolution apparatus. By pressing the RESET key beeper gives a Beep and Display reads,

```
LABINDIA  DISSOLUTION TEST APPARATUS
                                V a_b c.d.e
```

A →

```
1>Prg  2>Run  3>Prn  4>Func.                    : _
 Bath   T ° C:   28.0       09:30   Position : 25 mm      * W
```

Main Display Details

Optional : Sampling Mode Status, AS - Auto MS - manual

```
1) Prg  2>Run  3>Prn  4>Func.   :_                    XX
 Bath T°C: 28.0          09:30  Position :25mm      *S*W
```

Bath Temperature sensor Status

Real Time Clock

Stirrer Hood Position, 25/Mid

*S - No Sample Collector

* W - Low Water level

Functions of Active Key :-

- **To move Stirrer Hood DOWN**

  Press

  ▽ → Stirrer Hood Moving Down !

  To stop the Stirrer Hood in-between,
  Press

  △ The Stirrer Hood will stop moving down, Display returns,
  Or automatically when it reaches the 25 mm position. → A

- **To move Stirrer Hood UP**

  Press

  △ → Stirrer Hood Moving Up !

  To stop the Stirrer Hood in-between,
  Press

  ▽ The Stirrer Hood will stop moving up, Display returns,
  Or automatically when it reaches the TOP position. → A

- **To read BOWL/S TEMPERATURE °C**

  Insert the bowl temperature sensor in the bowl whose temperature is to be measured.
  Press Dot key, the bowl temperature will be displayed for a few seconds :

  1>Prg 2>Run 3>Prn 4>Func. 5> Data Eval. : _
  Bowl T °C : 37.0 09:30 Position : 25 mm

  • BOWL °C → Buffer Volume <500
  1) Y 2) N

If Volume is less than 500ml

Press 1 ABC → Press ENTER → Display Not Applicable

OR, If Volume is more than or equal to 500ml

Press 2 DEF → Press ENTER → Display Wait! Sampling Assembly Moving Down

With Bowl Temperature Reader (Optional) installed, the Sampling Accessory is lowered down so as to immerse the temp. sensor tips in the bowl intelligently depending on the SET Buffer volume in the program, then system waits for stabilsation and Display reads the Actual respective Bowl Temperatures,

(For 12+2 model the display shows temperature of Bl 7 to Bl 12 and Blx 2 bowls)

```
Wait !  Reading  Bowl  Temperature
```

```
BL-01    BL-02    BL-03   BL-04    BL-05    BL-06    BLX1
 36.9     37.0     37.0    37.0     36.9     37.0     37.0
```

```
Wait !  Sampling  Assembly   moving   up.
```

```
1>Prg  2>Run  3>Prn  4>Func.                    : _
 Bowl T °C : 37.0          09:30   Position : 25 mm
```

Note : For Paddle over disk (watchglass) & intrinsic stationary, it is not possible to check bowl temperature in Main Menu.

FUNCTIONAL MODES:-

The Function can be selected by selecting option 1-4

Display Main Menu-

```
1>Prg  2>Run  3>Prn  4>Func.                    : _
Bath   T ° C: 37.5            09:30   Position : 25 mm
```

- 1 ABC → Refer page no. 30.
- 2 DEF → Refer page no. 44
- 3 GHI → Refer page no. 50
- 4 JKL → Refer page no. 52

After desired Functional Mode is selected, the screen changes accordingly.

1. Entering Program Parameters

A. ADD Program:-

a) Add / Edit a program for FIXED interval :-

Press: 1 ABC

Display:

```
1>Prg  2>Run  3>Prn  4>Func.                    : 1
Bath   T ° C: 37.5        09:30    Position : 25 mm
```

```
Programs : _
1>Add  2>View  3>Copy  4>Delete
```

Press: 1 ABC

Display:

```
Programs : 1
 1>Add  2>View  3>Copy  4>Delete
```

Press: ENTER

Display:

```
Enter Password: ***
```

Enter the Admin or User password

If Password entry is correct -

Press: ENTER

Display:

```
Prog. No (1-15)  :
ADD / EDIT Mode
```

DS8000 / DS14000 has storage memory for 15 Programs/methods.

Enter the program number whose parameters are to be entered and stored.
If the program already exists,

The previously entered/stored parameters are displayed, so that they may/may not be Edited,

To Edit/Create Program (Say program no 1),

Press	Press	Display
1 ABC	ENTER	SAMPLE NAME (Maximum 20 characters) : _

Enter **Sample Name** using Alphanumeric Keys. Refer Appendix B.

Selection of Apparatus

Press	Display
ENTER	USP App : 1) USP1 2) USP2 3) USP5 4) USP6 5) USP(1087) 6) Others : _

Select The **Apparatus type**, for USP –1 Basket – press 1,

Press	Display
1 ABC	USP App : 1) USP1 2) USP2 3) USP5 4) USP6 5) USP(1087) 6) Others : 1

OR

Select The **Apparatus type**, for USP –2 Paddle – press 2,

Press	Display
2 DEF	USP App : 1) USP1 2) USP2 3) USP5 4) USP6 5) USP(1087) 6) Others : 2

Press	Display
ENTER	Tablet – 1) Std. Vessel 2) Peak Vessel Granules – 3) Std. Vessel 4) Peak Vessel

OR

Select The **Apparatus type**, for USP – 5 – press 3,

Press	Display
3 GHI	USP App : 1) USP1 2) USP2 3) USP5 4) USP6 5) USP(1087) 6) Others : 3

Press	Display
ENTER	1) Paddle over disk (watchglass) 2) Paddle over disk (SS-316) : _

OR

Select The **Apparatus type**, for USP – 6 – press 4,

Press Display

4 JKL → USP App : 1) USP1 2) USP2 3) USP5 4) USP6
5) USP(1087) 6) Others : 4

Press Display

ENTER → 1) Rotating Cylinder (Standard)
2) Rotating Cylinder (Large) : _

OR

Select the **Apparatus type**, for USP 1087 – press 5

Press Display

5 MNO → USP App : 1) USP1 2) USP2 3) USP5 4) USP6
5) USP(1087) 6) Others : 5

OR

For **Other Apparatus** – press 6

Press Display

6 PQR → USP App : 1) USP1 2) USP2 3) USP5 4) USP6
5) USP(1087) 6) Others : 6

Press Display

ENTER → 1) Intrinsic Stationary 2) Felodipine
3) 250ml (RB) 4) 150ml (RB) 5) Enhancer cell

- For intrinsic Stationary,

Press **1 ABC** → Press **ENTER** → Display: Buffer Volume (100 – 1000ml) :

- For Felodipine,

Press **2 DEF** → Press **ENTER** → Display: Buffer Volume (100 – 1000ml) :

- For 250ml (RB) flask,

Press **3 GHI** → Press **ENTER** → Display: Buffer Volume (100 – 250ml) :

- For 150ml round bottom flask

Press **4 JKL** → Press **ENTER** → Display: Buffer Volume (100 – 150ml) :

- For Enhancer cell

Press **5 MNO** → Press **ENTER** → Display: Buffer Volume (100 – 150ml) :

After selection of USP Apparatus, select required option.

☞ **Note :** Auto Sampling is possible depending on the type of USP Apparatus & minimum Buffer Volume.

e.g. for USP Apparatus – 2,

Press → Display

Press	Display
2 / DEF	USP App : 1) USP1 2) USP2 3) USP5 4) USP6 5) USP(1087) 6) Others : 2

Press → Display

Press	Display
ENTER	Tablet – 1) Std. Vessel 2) Peak Vessel Granules – 3) Std. Vessel 4) Peak Vessel

Press → Display

Press	Display
1 / ABC	Tablet – 1) Std. Vessel 2) Peak Vessel Granules – 3) Std. Vessel 4) Peak Vessel : 1

Press	Press	Display
1 / ABC	ENTER	Buffer Volume (100 – 1000ml) :

Enter **Buffer Volume** required for the dissolution study (say 500 ml) using Numeric Keys.

Buffer Volume (100 - 1000 ml) : 500

Press	Display
ENTER	Buffer Volume (100 - 1000 ml) : 500 Bowl Temperature (20 - 55 °C) : _

Enter **Bowl (Dissolution Media) Temperature** - 37.0 °C using Numeric Keys.
The entered value is for USP Limit check and reporting purpose.

Press	Press	Display
3 / GHI	7 / STU	Buffer Volume (100 - 1000 ml) : 500 Bowl Temperature (20 - 55 °C) : 37_

Press	Display
ENTER	Set Bath Temperature (37 - 55 °C) : _

Enter **Bath Temperature** (≈37.5°C for Poly-carbonate Bowls/37.3°C for glass bowls) using Numeric Keys,

Press	Display
ENTER	Set Bath Temperature (37 - 55 °C) : 37.5 Set RPM (20 – 350) :

Enter **RPM** for the stirrer shafts (50 rpm) using Numeric Keys.

Press	Display
ENTER	Set Bath Temperature (37 - 55 °C) : 37.5 Set RPM (20 – 350) : 50

Press	Display
ENTER	Sampling Mode 1> Auto 2>Manual: _

Select the Mode of Sampling

☞ **Note : Depending on selection of USP apparatus and buffer volume entered, instrument will automatically decides the sampling mode (Auto / Manual)**

Say 1 for “Auto”

Press 1 ABC → Press ENTER → Display: Sampling Volume (1.0 – 25.5 mL) : _

Enter **Sampling Volume** (10mL), using numeric keys,

Sampling Volume (1.0 – 25.5 mL) : 10

Press ENTER → Display:
Sampling Volume (1.0 – 25.5 mL) : 10
Rinsing Volume (0.0 – 9.0ml) :

Say 3ml

Press 3 GHI → Press ENTER → Display: Sampling – Start? 1>Intv. Time 2> Split : 1

Press 1 ABC → Press ENTER → Display:
Sampling – Start? 1) Intv.Time 2) Split : 1
Replenish? 1) Y 2) N :

Press 2 DEF → Press ENTER → Display:
Sampling – Start? 1) Intv.Time 2) Split : 1
Replenish? 1) Y 2) N : 2

Press ENTER → Display: Record T°C at 00:00 (HH : MM)? 1> Y 2> N : _

To read & store the initial zero time temperature, press ‘1’ &

Press ENTER → Display:
Record T° C at 00:00 (HH : MM)? 1> Y 2> N : 1
Samplings 1> Fixed 2> Prog : 1

Select (1) for Fixed intervals,

Press ENTER → Display: Total No. of Intervals (1-30): 1

Enter **No. of Intervals** using Numeric Key.

For 2) **Manual** sampling,

Press 2 DEF → Display: Sampling Mode 1> Auto 2>Manual: **2**

Press ENTER → Display: Record T°C at 00:00 (HH : MM)? 1> Y 2> N : 1

To read & store the initial zero time temperature, press ‘1’ &

Press ENTER → Display:
Record T° C at 00:00 (HH : MM)? 1> Y 2> N : 1
Samplings 1> Fixed 2> Prog : 1

Select (1) for Fixed intervals,

Press [1 / ABC] → Press [ENTER] → Display: Total No. of Intervals (1 - 30) : _

Enter **No. of Intervals** using Numeric Key.

For Single interval,

Press [1 / ABC] → Press [ENTER] → Display:
Total No. of Intervals (1 - 30) : 1
Intv. (00 : 01 - 24 : 00) : _ : (Hr : Mn)

Here please note, interval can be programmed from minimum **1min. to 24.00Hrs**.
Enter required **Interval Time** using Numeric Key.
For 5 min, Interval

Press [0 / - . /] → Press [ENTER] → Display:
Total No. of Intervals (1 - 30) : 1
Intv. (00 : 01 - 24 : 00) : 000 : _ (Hr : Mn)

Press [5 / MNO] → Display:
Total No. of Intervals (1 - 30) : 2
Intv. (00 : 01 - 720 : 00) : 000 : 0**5** (Hr : Mn)

Press [ENTER] → Display:
Recovery Test 1> Y 2> N :

1) For Recovery Test 'Yes'

Press [1 / ABC] → Display:
Recovery Test 1> Y 2> N : 1
Set RPM (20–350) :

Enter required RPM say 250, Enter 250 using numeric Key.

Press [ENTER] → Display:
Enter Time (5–99min) :

Enter recovery time say 10 min. by using Numeric Key.

Display:
Enter Time (5–99min) : 10

Press [ENTER] → Display:
Programs: 1
1>Add 2>View 3>Copy 4>Delete

2) For Recovery Test 'No'

Press **2 DEF** → Display: Recovery Test 1> Y 2> N : 2

Press **ENTER** → Display:
Programs: 1
1>Add 2>View 3>Copy 4>Delete

☞ **Note :** If any existing Program with Manual sampling mode is Edited to Auto Mode then, Display reads,

Sampling Mode 1> Auto 2>Manual: **1**
Mode Change : Re-enter Intv. Time ! . . . .

Minimum Sampling **Interval Time** will be calculated on the basis of pump speed, i.e. time required to sample out the entered Sample Volume plus the tubing dead volume i.e. Peristaltic pump Forward on time + Reverse on time.

b) <u>Add / Edit a program for programmed interval :-</u>

Press **1 ABC** → Display:
1>Prg 2>Run 3>Prn 4>Func. : 1
Bath T ° C: 37.5 09:30 Position : 25 mm

↓

Programs :
1>Add 2>View 3>Copy 4>Delete

Refer a) part – page no. 30.

☞ **Note: The program Parameter entries up to RPM are same as for fixed sampling interval, but for programmable Sampling Interval time now select 2,**

Say (2) for Manual Sampling

Display: Sampling Mode 1> Auto 2>Manual: 2

↓

ENTER → Record T°C at 00:00 (HH:MM)? 1>Y 2>N :

↓

Press **2 DEF** → Press **ENTER** → Display:
Record T°C at 00:00 (HH:MM): 1>Y 2>N : 2
Sampling 1> Fixed 2> Prog : 2

↓

Press **2 DEF** → Press **ENTER** → Display:
Total No of Sampling (1 – 30) : 2

↓

Press **2 DEF** → Press **ENTER** → Display:
Total No. of Sampling (1 – 30) : 2
Buffer Change Required? 1> Y 2> N : 2

• For Buffer Change Required NO, Press '2' &

ENTER → Total No. of Samplings (1-30) : 2
Smpl.1(00:01 – 720:00) :000:00 (HH:MM)

• For Buffer Change Required YES after 1st Interval

Press [1 ABC] → Press [ENTER] → Display: Buffer Change after Smpl No. (1–1) :

Press [1 ABC] → Press [ENTER] → Display: Buffer Change after Smpl No. (1–1) : 1
Smpl. (00:01 – 720:00) : 000:00 (HH:MM)

Enter Time for 1st Sampling Interval using Numeric Key.
Say 30min,

Press [0 - . /] → Press [ENTER] → Display: Total No. of Samplings (1 - 30) : 2
Smpl. 1 (00 : 01 - 720 : 00) : 000 : _ (Hr : Mn)

[3 GHI] → [0 - . /] → [ENTER] → Total No. of Samplings (1 - 30) : 2
Smpl. 1 (00 : 01 - 720 : 00) : 000 : 30 (Hr : Mn)

Enter time for **2nd Sampling Interva**l (45) using Numeric Key.

No. of samplings decides (Smpl. 1, Smpl. 2). The next Sampling timings entered should be in ascending order, or else message will be displayed:

Enter time > 0 (hour) 32 (min)

Display: Total No. of Samplings(1-30): 2
Sampl.2(00:01-700:00): 000:00 (Hr:mn)

Say 45 min.,

Press [4 JKL] → Press [5 MNO] → [ENTER] → Display: Total No. of Samplings (1 - 30) : 2
Smpl. 2 (00 : 01 - 720 : 00) : 000 : 45 (Hr : Mn)

☞ **Note :** Here Process time is same as that of last sampling Interval time, since it is cumulative. The Process time is displayed automatically (for verification).

Press [ENTER] → Display: Recovery Test 1> Y 2> N :

1) For Recovery Test 'Yes'

Press [1 ABC] → Display: Recovery Test 1> Y 2> N : 1
Set RPM (20–350) :

Enter required RPM say 250, Enter 250 using numeric Key.

Press [ENTER] → Display: Enter Time (5–99min) :

Enter recovery time say 10 min. by using Numeric keys.

Press **ENTER** → Display

Programs: 1
1>Add 2>View 3>Copy 4>Delete

2) For Recovery Test ‘No’

Press **2 DEF** → Display

Recovery Test 1> Y 2> N : 2

Press **ENTER** → Display

Programs: 1
1>Add 2>View 3>Copy 4>Delete

B. Viewing Program Parameters

```
                                   1>Prg  2>Run  3>Prn  4>Func. 5> Data Eval.          :
                                   Bath   T ° C: 37.5       09:30     Position : 25 mm

Press [1 ABC]                  Display  Programs :
                                        1>Add  2>View  3>Copy  4>Delete :

Press [2 DEF]                  Display  Programs : 2
                                        1>Add  2>View  3>Copy  4>Delete

Press [ENTER]                           Prog. No (1-15)  : _
                                        View  Mode
```

Enter the Program No. who's parameters are to be viewed, Say Program No. 1.

```
Press [1 ABC]  Press [ENTER]  Display   SAMPLE NAME  (Maximum 20 characters) :
                                        ABC

Press [ENTER]                  Display  USP App : Paddle with Std. Vessel Tablet

Press [ENTER]                  Display  Buffer Volume (100 - 1000 ml ) : 500

Press [ENTER]                  Display  Buffer Volume (100 – 1000 ml) : 500
                                        Bowl Temperature (20 – 55 °C): 37.0

Press [ENTER]                  Display  Set Bath Temperature(37.0 - 55°C) : 37.5
                                        Set  RPM                (20–350)       : 150

Press [ENTER]                  Display  Sampling Mode 1> Auto  2>Manual: 1
                                        Sampling Volume ( 1.0 – 25.5 mL )      : 10

Press [ENTER]                  Display  Sampling – start ?  1) Intv. Time      2) Split : 1
                                        Replenish ?           1) Y                2) N : 2

Press [ENTER]                  Display  Record T°C at 00 : 00 (HH : MM) ?  1) Y    2)  N : 1
                                        Rinsing Volume (ml) : 1.0

Press [ENTER]                  Display  Samplings      1> Fixed  2> Prog    : 2
```

Press	Display
ENTER →	Total No of Samplings (1 – 30): 2 Buffer Change Required? 1> Y 2> N : 1
Press	Display
ENTER →	Buffer Change after smpl no (1 – 1): 1 Smpl. 1 (00 : 01 - 720 : 00) : 000 : 30 (Hr : Mn)
Press	Display
ENTER →	Buffer Change after smpl no (1– 1): 1 Smpl. 2 (00 : 01 - 720 : 00) : 000 : 45 (Hr : Mn)
Press	Display
ENTER →	Recovery Test : Yes RPM (Rec) : 250 Time (Rec) : 10min.
Press	Display
ENTER →	Program : 2 1>Add 2>View 3>Copy 4>Delete

☞ **Note :**

If program does not exist, an error message is displayed on screen :

Prog. No (1-15) : 6 Program does not exist ! …

C. Copying Program Parameters

```
1>Prg  2>Run  3>Prn  4>Func. 5>Data Eval.          :_
Bath   T ° C: 37.5      09:30     Position : 25 mm
```

Press **1 ABC** → Display

```
Programs :
1>Add  2>View  3>Copy  4>Delete :
```

Press **3 GHI** → Display

```
Programs : 3
1>Add  2>View  3>Copy  4>Delete :
```

Press **ENTER** → Display

```
Source Program to Copy from (1-15) : _
```

Say **Copy Program No. 1 parameters to New program no. 5**

Press **1 ABC** → Press **ENTER** → Display

```
Source Program to Copy from (1-15) : 1
Destn. Program to Copy to      (1-15) : _
```

Press **5 MNO** → Display

```
Source Program to Copy from (1-15) : 1
Destn. Program to Copy to      (1-15) : 5
```

Press **ENTER** → Display

```
Program copied successfully ! . . .
```

☞ **Note :** For existing destination program :

Display

```
Program exists !  OVERWRITE ? 1> Y  2> N :
```

Option (1)

Press **1 ABC** → Press **ENTER** → Display

```
Program copied successfully ! . . .
```

Option (2)

Press **2 DEF** → Press **ENTER** → Display

```
Destn Program to Copy to      (1-15) :
```

Enter the empty/free Program No. to complete the copying operation.

D. Deleting Program

```
1>Prg  2>Run  3>Prn  4>Func. 5>Data Eval.          :
Bath   T ° C: 37.5      09:30    Position : 25 mm
```

Press [1 / ABC] → Display

```
Programs :
1>Add  2>View  3>Copy  4>Delete :
```

Press [4 / JKL] → Press [ENTER] → Display

```
Login :
1>Admin    2>User
```

Enter Admin / User Password and

Press [ENTER] → Display

```
Delete   1) Select Prg   2) All Prg : _
```

☞ **Note :**
When there is/are no programs made/added, i.e. program memory is empty then, for any selection Display

```
All Programs are empty  !
```

After 3-4 seconds display returns to main menu
Display

```
1>Prg  2>Run  3>Prn  4>Func. 5>Data Eval.          : 1
Bath   T ° C: 37.5      09:30    Position : 25 mm
```

Delete Individual Program Option (1) : Select Prg.

Press [1 / ABC] → Press [ENTER] → Display

```
Delete Program (1-15) : _
Press ESC to Quit
```

Press [1 / ABC] → Display

```
Delete Program (1-15) : 1
Press ESC to Quit
```

Press [ENTER] → Display

```
Program no. 1 deleted successfully ! …
```

☞ **Note :**
If program does not exist in the memory,
Display

```
Program does not exist  ! ….
```

Delete All Programs Option (2) : All Prg.

Press **2 DEF** → Press **ENTER** → Display: Delete ALL Prg ? Confirm 1>Y 2>N :

If Option (2) ,
Press **2 DEF** → Press **ENTER** → Display: Delete 1) Select Prg 2) All Prg : _

If Program No. 1,2 and 5 exist then

Press **1 ABC** → Press **ENTER** → Display: Program 1 deleted Successfully ! …

After 3-4 seconds

Display: Program 2 deleted Successfully ! …

After 3-4 seconds

Display: Program 5 deleted Successfully ! …

After 3-4 seconds

Program Menu Display:
Programs : _
1>Add 2>View 3>Copy 4>Delete

2. RUN Program Parameters

I) Starting the New Dissolution process RUN :

☞ **Note :** Always dry the stirrer shaft thoroughly.

To Run the Dissolution, at least one program must exist and water bath should be filled up to the level mark, so as the display will not show the *W mark on the RHS and fill the bowls with required Media volume as per the media preparation guidelines given in pharmacopoeia.

```
1>Prg  2>Run  3>Prn  4>Func.                    : 2
Bath   T ° C: 37.5      09:30    Position : 25 mm
```

Press [2 / DEF] → Display

```
Login : ___
1>Admin   2>User
```

Enter Admin / User password

Display

```
Prog. No (1-15)  : _
(1, 2, 5)
```

Display also shows the existing programs on the 2nd line,

☞ **Note :**
If all programs are empty then,

Display

```
Prog. No (1-15)  :
All Programs are empty  !
```

After 3-4 seconds

Main Menu Display

```
1>Prg  2>Run  3>Prn  4>Func. 5>Data Eval.       : 1
Bath    T ° C: 37.5      09:30    Position : 25 mm
```

For e.g. Program no. 1 is to be selected for dissolution process,

Press [1 / ABC] → Press [ENTER] → Display

```
Prog. No (1-15) : 1
1)Run  2) View  : 1
```

a) To view program parameters of the program selected for RUN :

Press [2 / DEF] → Press [ENTER] → Display

```
SAMPLE NAME  (Maximum 20 characters) :
ABC
```

The view function is same as of mentioned in Prog. Mode. for further details.

b) To run the program :

Press [1 / ABC] → Press [ENTER] → Display

```
Identification No.  (Maximum 10 characters) :
_
```

Enter **Identification No**. using Alphanumeric Keys. (Batch no. or lot no.)

```
Wait ! Checking Sampling Assembly
```

Dissolution process RUN (contd.) :

Sampling Assembly Moving Down

BLX 1°C	RPM	BATH °C	DEPTH : 25mm
27.3	50.6	30.1	

System shows reminder Display
If Sample Collector is Not connected or Not Ready due to some reason,

Sample Collector Not Connected !.

System also shows reminder Display
If Sampling Assembly is Not working,

Sampling Assembly Not OK ! Continue? :_ 1> Y 2> N

Select Desired option,

Option (2), No - System returns the display to Main Menu (A)

Option (1), Yes - continue the Run. System starts the run with sampling mode as Manual since Sample Collector / Sampling Assembly not working. The Run report will have Note : Prog. For Auto, manual sampling done. Reason: Sampling assembly not working or Sample Collector not connected.

Now depending on the Status of bath water temperature system display reads,

If bath temperature is < Set temperature - 0.5 °C, Display reads

Bowl °C	RPM	Bath °C	Depth : 25 mm
28.5	150.3	30.0	Wait Bath Heating !

If bath temperature is > Set temperature + 0.5 °C, Display reads

Bowl °C	RPM	Bath °C	Depth : 25 mm
28.5	150.3	40.0	Wait Bath Cooling !

If bath temperature is within ± 0.5 °C of set temperature, Display reads
And the Ready condition Buzzer starts,

Bowl °C	RPM	Bath °C	Depth : 25 mm
36.9	150.3	37.5	

The keys active during the process are RESET, ESC, DOT, HOLD & PSCAN.

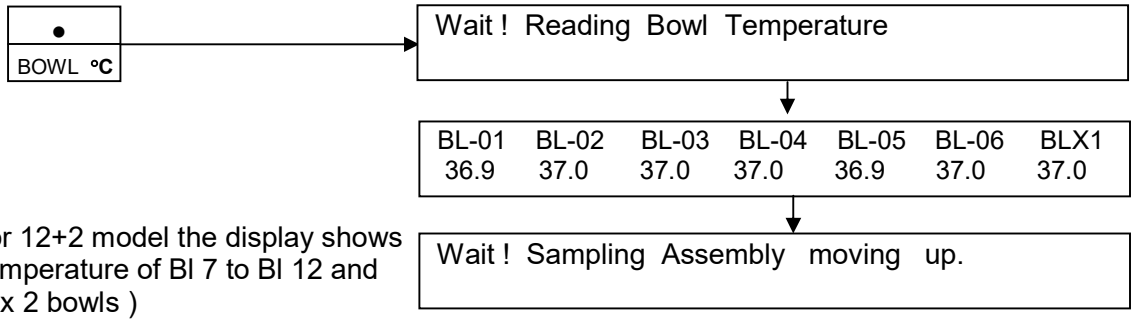
- **To abort the RUN process**

Press **ESC** , to abort the RUN. & display → A

- **To scan program parameters during RUN**

Press **PSCAN** , to view the program parameters during RUN.

- **To read Bowl Temperature during RUN**



(For 12+2 model the display shows temperature of Bl 7 to Bl 12 and Blx 2 bowls)

☞ **Note :** Depending on selection of apparatus and buffer volume, instrument will display all bowl temperatures or it will display only temperature of external RTD.

- **To Add/ drop the tablet/s in bowl/s during the RUN process**

When the bowl temperature reaches within ± 0.5 °C of the set temperature,

Press **HOLD / RUN** , to stop the bowl stirrer shafts, so that there is no vortex / turbulence in the Bowl. Now tablet can be dropped in the bowl/s.

When Tablet dispenser is Installed – Ensure the Tablet Drop lever is in released position (RHS) and the ports are Clean & Dry. Put the sample tablets in the tablet ports. To Drop the Tablets in the respective bowls move the Drop lever toward left side until the lever gets locked.

For PADDLE apparatus II, while dropping the tablet in the bowl, press **HOLD / RUN** key again to start the dissolution process.

For BASKET apparatus I, the bowl stirrer shafts stop rotating and the stirrer hood starts moving up for access to basket for putting the tablet/s in the Baskets.

Display

BLX1 °C	RPM	Bath °C	Wait Moving Up !
37.0	0	37.5	WAIT …

Stirrer Hood stops on reaching the UP position. Now remove the baskets carefully, blot dry the baskets mesh and the clamp and insert the tablet/s in the basket. Refit the baskets to their respective shafts. Ensure the tablets are sitting flat to the base of Basket.

Press **HOLD / RUN** To again start the RUN, the stirrer hood comes down adjusting to 25 mm position as program entry.

Display

BLX1 °C	RPM	Bath °C	Wait Moving Down !
37.0	0	37.5	WAIT …

After the Stirrer hood reaches to 25mm depth, Sample Collector initialises to Row Position No. 1

Dissolution process RUN (contd.) :

'AS' - Indicates SC & SA are OK.

Display reads :

STEP 1

BLX1 °C	RPM	Intv	#	Smpl Time	Time AS
37.0	150.3	01/02		00 : 30	00:00:10

Denotes the bowl temperature

Denotes Intv. No.

Stirrer shaft speed (RPM Measured by internal Tachometer)

Denotes the sampling interval time as from when the run has been started

Denotes total elapsed time since the run has been started

'AS' – in the RHS top corner of the display indicates – Auto Sampling Mode
'MS' – in the RHS top corner of the display indicates – Manual Sampling Mode

Note : The intervals are indicated by audible beeps. The **PSCAN** key is inactivated a few seconds before the interval time.

For Dissolution Test Run with Buffer Change option selected, the stirrer hood is automatically raised up after set interval for buffer change is completed with sampling & replenishing, Clean function is initiated.

Display

```
Do you wish to Clean?
1) Y   2) N
```

Here user can select to continue the test run with or without cleaning of the sampling path. If cleaning is not necessary for continuing with next buffer / media Press '2' (No) else to continue with cleaning Press '1' (Yes) refer Cleaning Process from Pg. No. 73.

When run ends at the time of sampling & replenishing

Display

BLX1°C	RPM	Intv.	#	Smpl Time	Time AS
37.0	100.5	–	#	–	000:30:20

After Process ends

Display

BLX1°C	RPM	Intv.	#	Recv Time	Time AS
37.0	250.0	–	#	000:05	000:00:10

After completion of Recovery Time

Display

```
BLX1°C                    Process Over…….
37.0
```

After some time

Display

```
Process End
```

Display

```
Do you wish to Clean?
1) Y    2) N
```

If Press ‘1’, refer Cleaning Process from Pg. No. 73

OR

If Press ‘2’, Display

For Manual Run –

```
1>Prg  2>Run  3>Prn  4>Func.                    : 2
Bath   T ° C: 37.5      09:30    Position : 25 mm
```

After completion of Run Display

```
BLX1°C    RPM    Intv.  #    Hold Time    Time       MS
37.0      100.5  –      #    –            000:30:20
```

Hold time is to collect sample manually.
After completion of hold time, Recovery time will start.

Display

```
BLX1°C    RPM    Intv.  #    Recv Time    Time       MS
37.0      249.5  –      #    00:05        000:00:20
```

After completion of Recovery time Display

```
BLX1°C                      Process Over…….
37.0
```

After some time Display

```
Process End
```

Note : Rotation of stirrer shaft will be automatically stopped after the sample is collected, replenished & all six bowl temperature is logged.

Display

```
Do you wish to Clean?
1) Y    2) N
```

If Press ‘1’, refer Cleaning Process from Pg. No. 73

OR

If Press ‘2’, Display

```
1>Prg  2>Run  3>Prn  4>Func.                    :
Bath   T ° C: 37.5      09:30    Position : 25 mm
```

II) To continue an Interrupted dissolution process :

This provision has been made to Continue the Dissolution process when MAINS Power fails / interruptions for a short duration or system is RESETed. (@ User discretion)

If a dissolution process is not completed due to power breakdowns, then it is possible to continue the dissolution run. If the power breakdown time is less than time entered in Auto Start function then refer pg. 59 & if the time is more than time entered in Auto Start function then Main Menu appears, Display

```
1>Prg  2>Run  3>Prn  4>Func.                    :_
Bath    T ° C: 37.5        10:45     Position : 25 mm
```

Press [2 / DEF] → Press [ENTER] → Display

```
Do you want to continue Process (Prg : 2)
from  000 : 17 (Hr:Mn)  1)Y  2)N : _
```

For option (2), Display return to main menu.

For option (1), the process (parameters as for say program no. 2) continues from 0:17 hrs (Time at which the Dissolution was interrupted due to power failure/Reset).

Before the process is started, the bath temperature is checked for limits i.e. within ± 0.5 °C of set temperature.
If bath temperature is not within limits,

```
Bath temperature not within Limits !
Do You Wish to Continue ?  1)Y 2)N : _
```

For option (1), the depth of bowl shaft is checked (25 / 40 mm as programmed). If the required depth setting is not found then the stirrer hood shaft will move up/down to match with 25 mm setting.

Press [1 / ABC] → Press [ENTER] → Display

Bowl °C	RPM	Intv	#	Smpl Time	Time
37.0	150.3	01/02		00 : 30	00:00:17

Now The DISSOLUTION Process restarts and continues as mentioned earlier. The dissolution run report will be marked a '$' sign to indicate that the run was interrupted.
e.g. $ 4 indicates that the run was interrupted before the 4th interval.

☞ **Note : The Dissolution Run cannot be continued if it has been interrupted during Sampling/Replenishing time.**

3. REPORT printing:-

a) Printing Run Report :- Connect the printer and ensure that it is ready.

Press **3 GHI** → Display:
1>Prg 2>Run 3>Prn 4>Func. 5>Data Eval. : 3
Bath T ° C: 37.5 09:30 Position : 25 mm

ENTER → 1>Run Report 2>Prg Parameters :
3>Validation Report 4>System Report

Press **1 ABC** → Press **ENTER** → Display: Wait ! Printing Data …

b) Printing Program Parameter :-

Press **3 GHI** → Display:
1>Prg 2>Run 3>Prn 4>Func. 5>Data Eval. : 3
Batch T ° C: 37.5 09:30 Position : 25 mm

ENTER → 1>Run Report 2>Prg Parameters :
3>Validation Report 4>System Report

Press **2 DEF** → Press **ENTER** → Display: PRINT : 1>Select Prg 2>All :

• To print selected prog.

Press **1 ABC** → Press **ENTER** → Display: Select Prg. No. :
(1,2,3)

Say Prg. No. 1

Press **1 ABC** → Press **ENTER** → Display: Wait Printing Data …..

Display:
1>Prg 2>Run 3>Prn 4>Func. 5>Data Eval. : 3
Batch T ° C: 37.5 09:30 Position : 25 mm

To print all programs

Press **2 DEF** → Press **ENTER** → Display: Wait Printing Data …..

Display:
1>Prg 2>Run 3>Prn 4>Func. 5>Data Eval. : 3
Batch T ° C: 37.5 09:30 Position : 25 mm

c) Printing Validation Report :-

Press **3 GHI** → Display:
1>Prg 2>Run 3>Prn 4>Func. 5>Data Eval. : 3
Bath T ° C: 37.5 09:30 Position : 25 mm

ENTER →
1>Run Report 2>Prg Parameters :
3>Validation Report 4>System Report

3 GHI → **ENTER** →
Print Validation Report:
1> Temp 2> RPM 3> Smpl Vol. 4> Replenish Vol.

For Temperature validation report, press 1
For RPM validation report, press 2
For Sampling volume validations report, press 3
For Replenishing Volume validation report, press 4

d) Printing System Report :-

Press **3 GHI** → Display:
1>Prg 2>Run 3>Prn 4>Func. 5>Data Eval. : 3
Bath T ° C: 37.5 09:30 Position : 25 mm

ENTER →
1>Run Report 2>Prg Parameters :
3>Validation Report 4>System Report

Press **4 JKL** → Press **ENTER** → Display:
Wait Printing Data …..

Display:
1>Prg 2>Run 3>Prn 4>Func. : 3
Batch T ° C: 37.5 09:30 Position : 25 mm

☞ **Note : Error message for printer**

Printer Not Ready ! …
1> Continue Printing. 2> Quit Printing.

If printer is not ready, due to
Power Off, Off-line or No paper

After making printer ready

Press **1 ABC** → Press **ENTER** → Display:
Wait ! Printing Data …

Or if don't want to print

Press **2 DEF** → Press **ENTER** → Display (After 1 Sec):
1>Prg 2>Run 3>Prn 4>Func.
Batch T ° C: 25.0 09:30 Position : 25 mm

For Data Transfer to PC with Windows HyperTerminal software (Please refer Data Downloading Software Setting Manual).

Press 3 to print the data – by transferring it to PC. As needed the user can Copy the data from the Hyperterminal Window and paste the same to any text processing software like – Notepad or Winword or Wordpad, etc.

4. FUNCTION :-

To enter in to function mode,

Press **4 JKL** → Display

```
1>Prg  2>Run  3>Prn  4>Func. 5>Data Eval.          : 4
Batch  T ° C: 25.0       09:30     Position : 25 mm
```

↓

```
1>Clk     2> Wake Up  3> Cfg    4> Validate  5> Beep
6> Pump 7>Sampler     8> Clean 9> System Check
```

1) CLOCK:

Setting Clock : To set date and time

Display

```
1>Clk     2> Wake Up  3> Cfg    4> Validate  5> Beep
6> Pump 7>Sampler     8> Clean 9> System Check
```

Press **1 ABC** → Display

```
Login :
1) Admin   2) User
```

Say 1 for Admin,

Press **1 ABC** → Display

```
Enter Admin Password :
```

Press **ENTER** → Display

```
01 / 01 / 13              09: 30
Press 'ENTER' to Edit
```

Press ‘ESCAPE’ key to return to main menu, if the DATE/TIME is not to be changed.

Press **ENTER** → Display

```
01 / 01 / 13              09:30
Edit Mode
```

Enter the desired date and time, Note the Cursor advances as the entries are made and accepted by pressing ENTER key till time hh:mm (say, 09:35) entry is over and

Display

```
1>Clk     2> Wake Up  3> Cfg    4> Validate  5> Beep
6> Pump 7>Sampler     8> Clean 9> System Check
```

☞ **Note : Data entries are checked for date, Month, & Year / Leap year and Time 24hr format.**

2) **Wake UP** :

To Set the Bath heater in standby mode (No heating - Power Save) and set the Wake up / activation time.

Display

```
1>Clk     2> Wake Up   3> Cfg     4> Validate  5> Beep
6> Pump 7>Sampler      8> Clean 9> System Check
```

Press **2 DEF** → Display

```
Set Wake up Alarm (dd/mm/yy   HH:MM)
02/01/13       07:30
```

The display shows the last Wake up alarm date & time

Enter the desired date and time, Note the Cursor advances as the entries are made and accepted by pressing ENTER key till time hh:mm,
After the Entry is acknowledged, the display returns to function menu with new time value.

```
Wake up alarm :  07: 30       02 / 01 / 13
1) Set Alarm  2) Enable wake up Mode. :
```

- **To Enable the Wake Up Mode.**

Press 2 and Enter.
The wakeup mode is enable and display reads

```
Wake Up  Mode                          07: 30      01 / 01 / 13
Wake up   alarm   set   time        :  07: 30      02 / 01 / 13
```

Heater will start at entered Date & Time.
Press **ESC** → Display

```
1>Prg  2>Run  3>Prn  4>Func. 5> Data Eval.                : 1
Bath    T ° C: 37.5        09:30     Position : 25 mm
```

If the Dissolution Test Apparatus Stirrer hood is not in the 25 mm depth level the system display prompts for Lowering the Hood, display

```
Stirrer  Hood  will  be  lowered   to   25 mm
position.   OK ?     1) Y   2) N :_
```

To continue,
Press 1 and Enter,

```
Stirrer  Hood  Moving Down !.
```

Once the Stirrer Hood is reached to the 25mm level the Display reads as (C)

To Discontinue,
Press 2 and Enter - The display returns to Main Menu, (A)

To quit the wakeup alarm function either BACK or ESCAPE key can be used so as to work again on the Dissolution Test Apparatus.

3) Configure : -

Here the user can configure the Password (Admin & User) and Printer type.

Display

```
1>Clk     2> Wake Up   3> Cfg     4> Validate  5> Beep
6> Pump 7>Sampler      8> Clean 9> System Check
```

Press | Display

3 / GHI → For DS8000 →

```
1) Password  2) Data Xfer  3) Auto Start :
4) Temp. Reader  5) SA
```

For DS14000 →

```
1) Password  2) Data Xfer  3) Auto Start :
4) Temp. Reader  5) 12 Bowl
```

☞ **Note :** Option no. 4 is only for Dissolution Test Apparatus with Temperature Reader
Option no. 6 is only for 14 Bowl Dissolution Test Apparatus

1) To Configure/SET Password.

i) To Change Password:-

Press | Display

1 / ABC → ENTER →

```
1>Change Password 2>Enable/Disable Pwd:
3>UAC Enable
```

a) To Change Password:-

Press | Display

1 / ABC → ENTER →

```
Change Password :
1>Admin   2>User
```

Press | Display

1 / ABC → ENTER →

```
Enter Admin Password:
```

First Enter Last stored Admin Password.
If old password entered is wrong, following message will be displayed.

```
Enter Admin Password:
Incorrect Password . . .
```

Display

```
1>Change Password 2>Enable/Disable Pwd:
3>UAC Enable
```

Press | Display

ENTER →

```
Set  Admin Password: _
```

Here, Enter new Admin Password. Password should be minimum 4 digits or maximum 8 digits.

☞ **Note:**

If password is less than 4 digits Message will be displayed as:

Set Admin Password: Min. Password Entry – 4 digits.

If password is more than 8 digits, Message will be displayed as:

Set Admin Password: Max. Password Entry – 8 digits.

To confirm the password, re-enter the Password.

Press	Display
ENTER →	Re-Enter Admin Password: _

☞ **Note:**

While re-entering the password, if it has been entered wrongly, following message will be displayed:

Error…Password not changed.

On successful completion of change of password, following message will be displayed:

Password changed Successfully!

Change Password : 1>Admin 2>User

<u>ii) To Set User Password:</u>

Press		Display
2 DEF →	**ENTER** →	Enter Admin Password: _

Enter Admin Password.

To Set/change User password as a part of security the Admin-authorisation is done by entering the Admin password.

☞ **Note:**

If admin password is wrong, following message will be displayed:

Enter Admin Password: Incorrect Password…!

Press | Display

ENTER → Enter User No. (1 – 10):

10 user Password can be entered.
Say no. 1

Press | Display

1 ABC → **ENTER** → Set User1 Password:
*****

Press | Display

ENTER → Re.Enter User Password:
*****

Password changed successfully → Enter User No. (1 – 10):

** Similarly Passwords for User 2 to 10 can be stored and assigned

Press | Display

ESC → 1>Prg 2>Run 3>Prn 4>Func. : **1**
Bath T ° C: 37.5 09:30 Position : 25 mm

Enter new User Password. Password should be minimum 4 digits or maximum 8 digits.

☞ **Note:**
If password is less than 4 digits Message will be displayed as:

Set User Password:
Min. Password Entry – 4 digits.

If password is more than 8 digits, Message will be displayed as:

Set User Password:
Max. Password Entry – 8 digits.

To confirm the password, re-enter it in below screen.

ENTER → Re-Enter User Password: _

☞ **Note:**
While re-entering the password, if it has been entered wrongly, following message will be displayed:

Error…Password not changed.

On successful completion of change of password, following message will be displayed:

Password changed Successfully!

b) To disable the password

Select configure menu — Display

3 GHI → 1) Password 2) Data Xfer 3) Auto Start
4) Temp. Reader 5) SA

Press — Display

1 ABC → ENTER → 1>Change Password 2>Enable/Disable Pwd:
3>UAC Enable

Press — Display

2 DEF → ENTER → Enter Admin Password:
*****

Press — Display

ENTER → 1>Enable PWD 2> Disable PWD:

Press — Display

2 DEF → ENTER → 1>Clk 2> Wake Up 3> Cfg 4> Validate 5> Beep
6> Pump 7>Sampler 8> Clean 9> System Check

c) To Enable UAC control : To enable or disable User (User 1 to User 10) access privileges to Program Parameters (Add/Edit, View, Copy & Delete) & Validation Function.

Select configure menu — Display

3 GHI → 1) Password 2) Data Xfer 3) Auto Start
4) Temp. Reader 5) SA

Press — Display

1 ABC → ENTER → 1>Change Password 2>Enable/Disable Pwd:
3>UAC Enable

Press — Display

3 GHI → ENTER → 1> Prg. Parameters 2> Validation 3> Both :
4> None

Select appropriate privilege for Users & Press 'ENTER' key.

Display

1>Clk 2> Wake Up 3> Cfg 4> Validate 5> Beep
6> Pump 7>Sampler 8> Clean 9> System Check

2) To Configure the Data Transfer destination:- Parallel or Serial

2.1) To select the data transfer to Printer : DS8000 / DS14000 has built in printer drivers for EPSON and PCL control language compatible Parallel port printers.

Display

1>Clk 2> Wake Up 3> Cfg 4> Validate 5> Beep
6> Pump 7>Sampler 8> Clean 9> System Check

Press → **3 GHI** → Display: 1) Password 2) Data Xfer 3) Auto Start
4) Temp. Reader 5) SA

Press → **2 DEF** → **ENTER** → Display: Select Port
1) Parallel 2) Serial

i) To select Printer Dot matrix / Inkjet

Press → **1 ABC** → **ENTER** → Display: Select Printer : 1
1>Dot Matrix / Inkjet 2>DeskJet

Press → **1 ABC** → **ENTER** → Display: 1>Online Print 2>Offline Print :

To get **Online** printout press “1” and for **Offline** printout press “2”

Press → **1 ABC** → **ENTER** → Display: Select Port
1) Parallel 2) Serial

☞ **Note :** Option no. 4 is only for Dissolution Test Apparatus with Temperature Reader
Option no. 5 is only for 14 Bowl Dissolution Test Apparatus

ii)To Select Deskjet printer (PCL command) – Online Printing Option is not available

Press → **2 DEF** → **ENTER** → Display: Select Printer:
1> Dot Matrix / Inkjet 2> Deskjet.

Press → **2 DEF** → **ENTER** → Display: Configure Printer (Deskjet):
1> Monochrome 2> Colour.

a)To Select Monochrome (Black and white):

Press

1 ABC → ENTER

or

b)To Select Colour Mode

Press

2 DEF → ENTER

Select Port
1) Parallel 2) Serial

2.2) To select Data Transfer to PC

Press

2 DEF →

Display

Select Port
1) Parallel 2) Serial

To transfer data to Parallel

Press

1 ABC →

Display

1) Password 2) Data Xfer 3) Auto Start
4) Temp. Reader

OR

To transfer data to Serial

Press

2 DEF →

Display

1) Password 2) Data Xfer 3) Auto Start
4) Temp. Reader 5) SA

☞ **Note :** Option no. 4 is only for Dissolution Test Apparatus with Temperature Reader
Option no. 5 is only for 14 Bowl Dissolution Test Apparatus

3) Auto Start Function :

After power interruption, for auto restarting the last program in specified entered time i.e. 2-10min.

Display

1>Clk 2> Wake Up 3> Cfg 4> Validate 5> Beep
6> Pump 7>Sampler 8> Clean 9> System Check

Press

3 GHI →

Display

1) Password 2) Data Xfer 3) Auto Start
4) Temp. Reader 5) SA

Press

3 GHI → ENTER →

Display

1) Enable 2) Disable

• To enable the function,

Press | Display

1 ABC → ENTER → Enter Time (2 – 10 minutes) :

Say 5 minutes,

Press | Display

5 MNO → ENTER → 1) Password 2) Data Xfer 3) Auto Start
4) Temp. Reader

• To disable the function,

Press | Display

2 DEF → ENTER → 1) Password 2) Data Xfer 3) Auto Start
4) Temp. Reader 5) SA

4) To enable or disable auto temp. reader for all 6 / 12bowls,

Display

1>Clk 2> Wake Up 3> Cfg 4> Validate 5> Beep
6> Pump 7>Sampler 8> Clean 9> System Check

Press | Display

3 GHI → 1) Password 2) Data Xfer 3) Auto Start
4) Temp. Reader 5) SA

Press | Display

4 JKL → ENTER → 1) Enable 2) Disable

To enable press “1” or for disable press “2” and “Enter”

Display

1) Password 2) Data Xfer 3) Auto Start
4) Temp. Reader 5) SA

5) SA Mode (Sampling Assembly) :

Select configure menu | Display

3 GHI → 1) Password 2) Data Xfer 3) Auto Start
4) Temp. Reader 5) SA

Press | Display

5 MNO → ENTER → 1) Static 2) Dynamic

Press 1 for Static OR Press 2 for Dynamic

Press | Display

ENTER → 1) Password 2) Data Xfer 3) Auto Start
4) Temp. Reader 5) SA

Static Mode : By selecting this mode sampling assembly will remain in lowered position continuously throughout the test run.

Dynamic Mode : By selecting this mode sampling assembly will be lowered down automatically prior to sampling interval time according to the type of USP apparatus & media volume selected in the method. After completion of sample collection process it will raised to home position.

6) To select Bowl configuration (Note : This option is only for DS14000 (12+2) Bowl Dissolution Test Apparatus.)

Display

```
1>Clk     2> Wake Up   3> Cfg     4> Validate  5> Beep
6> Pump 7>Sampler      8> Clean 9> System Check
```

Press → **3 GHI** → Display

```
1) Password  2) Data Xfer  3) Auto Start
4) Temp. Reader  5) SA
```

Press → **5 PQR** → **ENTER** → Display

```
Bowls to be used:
1>BL–01 to BL–06  2>BL–07 to BL–12  3>All
```

To select All

Press → **3 GHI** → **ENTER** → Display

```
1) Password  2) Data Xfer  3) Auto Start
4) Temp. Reader  5) SA
```

Press → **ESC** → Display

```
1>Prg  2>Run  3>Prn  4>Func.                    : 1
Bath   T ° C: 37.5      09:30     Position : 25 mm
```

4) Validate: -

DS8000 / DS14000 has built in software for validating the dissolution process parameters such as temperature, RPM, Sampling Volume & Replenishing Volume.

Display

```
1>Clk     2> Wake Up   3> Cfg     4> Validate  5> Beep
6> Pump 7>Sampler      8> Clean 9> System Check
```

Press → **4 JKL** → **ENTER** → Display

```
Login: _
1>Admin  2>User
```

To enter Admin Password select 1 or to enter User Password select 2. After password being entered, following screen will be displayed.

```
Validate:
1> Temp 2> RPM 3> Volume
```

1) MEDIA TEMPERATURE:

Validate Bowl Media temperature after stabilization with respect to bath temperature. Bath control temperature with in range 20°C to 55°C. The system stores the temperature reading as per programmed logging interval.

Press Display

1 ABC → ENTER → Set Bath Temperature (20-55°C): _

The most Required Bowl Media temperature is 37.0 ±0.5 °C as per Pharmacopeia,

For Poly-carbonate bowls the bathe temperature should be set 0.5~0.6 °C and for Glass bowls 0.2~0.3°C higher than the required Bowl Media temperature. E.g for 37.0 °C bowl media temperature the SET Bath Temperature should be 37.5/37.6°C for Poly-carbonate bowls.

Ensure the Bath has required level of water filled and all the bowls are filled with DM water to the desired Media level (900mL/1000mL)

Ensure Paddle stirrers are correctly locked in the stirrer housing.

Press Press Display

3 GHI → 7 STU → Set Bath Temperature (20-55°C): 37

Press Display

ENTER → Logging Time (2 – 60 min):

Enter Logging time interval at which temperature is to be logged. E.g. 5 minutes.

5 MNO → Logging Time (2 – 60 min): 5

Press Display

ENTER → No of Log Points (1 – 30):

Enter number of log points at which temperature is to be recorded. E.g. 5

5 MNO → No of Log Points (1 – 30):5

Press Display

ENTER → Buffer Volume <500ml :_
1) Y 2) N

If Volume is less than 500 ml, Display

Wait ! Sampling Assembly Moving Down

Display

Wait reading bowl Temperature

Press Press Display

1 ABC	→	ENTER	→	BLX1°C Bath°C 36.8 37.2 Press 'ENTER' to Log……..

It will store temperature of external RTD only.

Press Display

ENTER	→	Temp. logging started …

Display

BLX1°C	Bath°C	Log Pt.	Log min	Time
36.8	37.2	1/5	5	000:01:20

At log time it will store the temperature.

Display

BLX1°C	Bath°C
37.0	37.2

If Buffer Volume is equal to or grater than 500ml

Press Press Display

2 DEF	→	ENTER	→	Wait ! Sampling Assembly Moving Down

Display

Wait reading bowl Temperature

Now the instrument Temperature reader will read temperature at 10 reading points each with interval of 5 minutes. Total temperature validation time will be of 50 min.
Instrument will take the Start/initial temperature first.

For 6 channel temperature reader

BL-01	BL-02	BL-03	BL-04	BL-05	BL-06	BLX1
37.0	37.1	36.9	37.0	37.2	37.0	37.0

Bowl ° C	Bath ° C	
37.0	37.5	Press 'ENTER' to Log

Press Display

ENTER	→	Temp Logging Started. .

Bowl ° C	Bath ° C	Log Pt.	Log Min.	Time
37.0	37.5	1/10	5	000:00:40

After end of 5.00 min. interval temperature will be recorded and displayed on screen.

BL-01	BL-02	BL-03	BL-04	BL-05	BL-06	BLX1
37.0	37.1	36.9	37.0	37.2	37.0	37.0

Now simultaneously Verify the Media temperature in the bowl/s by Calibrated external thermometer.
Note the changes in the displayed values for Log pt., Log Min and Time.

Bowl ° C	Bath ° C	Log Pt.	Log Min.	Time
37.0	37.5	2/10	10	000:05:40

For last log point the display

Bowl ° C	Bath ° C	Log Pt.	Log Min.	Time
37.1	37.5	10/10	50	000:49:59

BL-01	BL-02	BL-03	BL-04	BL-05	BL-06	BLX1
37.1	37.2	37.0	37.1	37.2	37.0	37.1

After all the log points are recorded, displayed and stored.

Temperature Validation Over.

Now the Sampling assembly will be automatically moved to home position.

Wait! Sampling Assembly Moving Up.

After completing temperature validation it will return to Validate menu screen.

Validate:
1> Temp 2> RPM 3> Volume

☞ **Note:** To abort the validation in between process

Press → Display

ESC → 1>Prg 2>Run 3>Prn 4>Func. : **1**
Bath T ° C: 37.5 09:30 Position : 25 mm

Temperature validation report of stored log points can be printed from print option of Main Menu.

Temperature validation report is available in Print option of Main Menu.

2) RPM: Validate speed/rpm of stirrer shaft,

Press → Display

2 DEF → Validate: 2
1> Temp 2> RPM 3> Volume

Press → Display

ENTER → RPM Set Pts. (1 – 15): 2_

Select No. of RPM set points to which validation is to be done. E.g. 2 points (say 50rpm and 200rpm)

Press | Display

2 DEF → ENTER → Set RPM (1) (20-350): _

Enter 1st RPM value, say 50.

Press | Display

5 MNO → 0 - . / → Set RPM (1) (20-350): 50

Press | Display

ENTER → Set RPM (1) Measured RPM
50 50.1

Now measure the RPM with Calibrated external tachometer, (refer manufacturer's manual for correct use).

Press ENTER key to store the RPM measured by internal Tachometer for validation report.

Press | Display

ENTER → Set RPM (2) (20-350):

Enter 2nd RPM value, say 200.

2 DEF → 0 - . / → 0 - . / → Set RPM (2) (20-350): 200_

Press | Display

ENTER → Set RPM (1) Measured RPM
200 199.6

Now measure the RPM with Calibrated external tachometer, (refer manufacturer's manual for correct use).

Press ENTER key to store the RPM measured by internal Tachometer for validation report.

ENTER → Validate:
1> Temp 2> RPM 3> Volume

RPM Validation Report is available in Print option of Main Menu.

3) VOLUME : Validation of Sampling and Replenishing volume : For Automatic offline sampling dissolution system only.

To perform Sampling Volume and Replenishing Volume withdrawn by the Peristaltic pump from the Dissolution bowl, First Verify the Tubing Dead Volume and calibrate the pump flow rate. Refer the pump section in this manual.

☞ **Note :** Following things are required before starting the Volume validation.

1. Clean dry bottles/vails (supplied along with the sample collector) - 6 x 5 nos. and Centifuge tubes 15-20mL or similar for collecting replanished volume.
2. Cleaning tray with beaker filled with distilled water.- 8 nos.
3. Waste tray (supplied with Sample collector).
4. Semi-micro Balance (0.01mg) for weighing the bottles/vials.

First remove the Paddel/basket shaft from the stirrer housing.
Weigh the dry bottles and number them for easy identification.
Place the dry bottles in the sample tray and insert the tray correctly in the sample collector.
Ensure that the Peristaltic Pump and Sample collector are connected to the Controller and switched ON.
Ensure correct RPM setting on P.Pump for required Flow rate has been done as per Pump Parameter setting.

Press → **3 GHI** → Display: Validate: 3
1> Temp 2> RPM 3> Volume

Press → **ENTER** → Display: Validate:
1> Sampling Volume 2> Replenishing Volume

I) <u>Sampling volume</u>: To perform validation of sampling volume,

Press → **1 ABC** → Display: Validate: **1**
1> Sampling Volume 2> Replenishing Volume

Display: Wait! Checking Sampling Assembly

Press → **ENTER** → Display: Rinsing Volume (0 – 15.0 ml) :_

Say 3 ml
Press → **3 GHI** → **ENTER** → Display: Sampling Volume (4.0 – 25.5ml):

Enter the desired sampling volume value, e.g. 10.0mL and place first 2 rows of dry vials in sampling tray.

1 ABC → **0 - . /** → Sampling Volume (4.0 - 25.5 ml) : 10_

Press → **ENTER** → Display: Initializing Sample Collector

Press | Display - if the hood is not in top position.

ENTER → Wait! Stirrer hood moving up. . .

Place Beaker Tray properly under
Sampling Tube & Press 'ENTER'. . .

Place the Clean/Beaker Tray with D.M. water (250mL) filled beaker in location from 1 - 6. Do not keep beakers in location no. 7 & 8. Locate the tray centrally over to Bath top so as the Sampling tubes have proper clearance during immersion.

Press | Display

ENTER → Wait! Stirrer Hood moving Down.

Once the hood reaches clean position,
The sampling assembly is lowered.

Wait! Sampling Assembly moving Down.

After the sampling assembly is fully lowered down with sampling tubing immersed in the beakers, for some time the pump will rotate in reverse direction to ensure that tubings are dry. The reverse runtime is determined on the tubing dead volume and flow rate.

Smpl	PPml/Min	Dead Vol	PPTime	- Dir
1/1	10	2.0ml	00:59	- REV

After REV. cycle time (here PPTime=00:59) is over, the FWD sampling cycle will start for given volume (10mL) considering the flow rate and tubing dead volume.

Smpl	PPml/Min	Dead Vol	PPTime	- Dir
1/1	10	2.0ml	00:xx	- FWD.

After the FWD cycle is over the Sample Collector arm will automatically advanced to next location and P.Pump will rotate in reverse direction to empty the tubings

After completing Sampling, stirrer assembly will move up,

The Sampling validation run can be stopped by pressing the ESC key. To interrupt press' ESC' key.

Press | Display

ESC → Wait! Sampling Assembly Moving Up.

Display

Validate:
1> Sampling Volume 2> Replenishing Volume

Now Carefully remove the Cleaning tray from top of the bath.
Remove the Sample Collector Tray and weigh the filled bottles/vials Bowl 1.S1, bowl 2.S1, … bowl 6.S1, ….to Bowl 1.S2, bowl 2.S2, …..bowl 6.S2.

Determine the weight of the DM water volume collected by the sampling system and record.

- **If the volume error is noticed, check and adjust appropriately the Pump flow rate and also tubing dead volume. Also ensure that the Filters fitted on the sampling probes are cleaned and not clogged.**

- **Validation Report for Sampling Volume can be taken from Print option of Main Menu.**

II) **<u>Replenishing Volume</u>** : To validate replenishing volume,

Press → **2 DEF** → Display: Validate: 2
1> Sampling Volume 2> Replenishing Volume

Display: Wait ! Checking Sampling Assembly

Press → **ENTER** → Display: Replenishing Volume (1.0 – 25.5 ml):

Enter the desired Replenishing volume value, eg 10.0mL

1 ABC → **0 - . /** → Replenishing Volume (1.0 - 25.5 ml) : 10_

Press → **ENTER** → Display - if the hood is not in top position.
Wait! Stirrer hood moving up. . .

Else Display

Place empty & dry vials properly under Replenishing Tube & Press 'ENTER'. . .

Place the Clean Beaker Tray with D.M. water (250mL) filled beaker in location no. 7 & 8. Do not keep beakers in location from 1– 6. Locate the tray centrally over to Bath top so as the Replenishing tubes have proper clearance during immersion.

Press → **ENTER** → Display: Wait! Stirrer hood moving down.

Once the hood reaches clean position,
The sampling assembly is lowered. → Wait! Sampling Assembly Moving Down.

Now insert the 15mL x 6 nos. Centrifuge Test tubes/Vials over the replenishing return tubes and fix them with either sticker tape or by any other suitable method.

After the sampling assembly is fully lowered down with replenishing tubing immersed in the beakers 7 & 8, for some time the pump will rotate in FWD, forward direction to ensure that tubings

are dry. The forward runtime is determined on the tubing dead volume and flow rate (similar to Sampling.

Display

Repl	PPml/Min	Dead Vol	PPTime	- Dir
1/1	10	2.0ml	00:59	- FWD

After FWD cycle time (here PPTime=00:59) is over, the Reverse cycle will start for given Replenishing volume (10mL) considering the flow rate and tubing dead volume.

Smpl	PPml/Min	Dead Vol	PPTime	- Dir
1/1	10	2.0ml	00:xx	- REV

After the 10 mL replenishing volume has been transferred to Centrifuge tubes REV cycle gets over, remove the centrifuge tubes carefully,(without any spillage).

After completing cycle stirrer assembly will move up,

The Sampling validation run can be stopped by pressing the ESC key. To interrupt the sampling process press' ESC' key.

Press Display

ESC → Wait! Sampling Assembly Moving Up.

↓

1>Prg 2>Run 3>Prn 4>Func. 5>Data Eval. :
Bath T ° C: 37.5 11:30 Position : MID

Now Carefully remove the Cleaning tray from top of the bath.

Remove the vials/Centrifuge tubes and weigh the filled vials/Centrifuge tubes Bowl 1.R1, bowl 2.R1, … bowl 6.R1.
Determine the weight of the DM water volume collected by the sampling system.

- **If the volume error is noticed, check and adjust appropriately the Pump flow rate and also tubing dead volume.**
- **Validation Report for Sampling Volume can be taken from Print option of Main Menu.**

5) Beep :

Disso Main controller is incorporated with a small buzzer as audible indication for user. The buzzer gives BEEP's on following system temperature conditions :-

a) Beep for Bowl temperature Ready condition :-
After start of dissolution run in preheating stage, once the bowl temperature is attained within ±0.5°C of the Set Bowl T°C, the buzzer gives single beep periodically.

b) Beep for Bowl temperature out of limit error :-
While the dissolution test is in progress, if any one of the bowl temperature sensor read temperature out of ±0.5°C limit, the buzzer gives beep nine times periodically.

Display

1>Clk 2> Wake Up 3> Cfg 4> Validate 5> Beep
6> Pump 7>Sampler 8> Clean 9> System Check

Press | Display

5 / MNO	→	Beep for Bowl Temp. Ready & Error Cond : 1>On 2>Off

To enable or disable the buzzer Beep, select appropriate option.

To make Beep ON, press [1 / ABC] OR to make Beep OFF, press [2 / DEF]

6) P.PUMP : - To Operate the Peristaltic Pump for priming the Tubing.

Display

1>Clk 2> Wake Up 3> Cfg 4> Validate 5> Beep
6> Pump 7>Sampler 8> Clean 9> System Check

Press | Display

6 / PQR	→	Peristaltic Pump : 1) Pump Para. 2) Pump FWD 3) Pump REV

1) To Set the Peristaltic Pump Parameters,

Press 1 and Enter,

Parameters entries like the Flow rate (measured volume per minute), Sample carrier teflon tubing dead volume, etc can be entered for validation.

Tubing Dead Volume Measurement:-

Note :- Following things are required before starting the Dead Volume validation.

1. Clean dry bottles/vails (supplied along with the sample collector) - 6 x 5 nos. and Centifuge tubes 15-20mL or similar for collecting replanished volume.
2. Bowls filled with distilled water.- 6 nos.
3. Waste tray (supplied with Sample collector).
4. Semi-micro Balance (0.01mg) for weighing the bottles/vials.

First remove the Paddel/basket shaft from the stirrer housing.
Weigh the dry bottles and number them for easy identification.
Place the dry bottles in the sample tray and insert the tray correctly in the sample collector.
Ensure that the filters are clean and not clogged
Ensure that the Peristaltic Pump and Sample collector are connected to the Controller and switched ON.

Set the RPM according to the inner diameter (I.D.) of the Tygon tubings used. Refer the P/Pump manual.

Tubing ID. (Tygon LFL)	Approx. RPM
3.17 mm	13-14
2.79 mm	14-15
1.52 mm	38-40

Now from the Main Menu select the Function Menu.

4 / JKL	→	1>Prg 2>Run 3>Prn 4>Func. : 4 Bath T ° C: 37.5 11:30 Position : 25 mm

Press Display

ENTER → 1>Clk 2> Wake Up 3> Cfg 4> Validate 5> Beep
6> Pump 7>Sampler 8> Clean 9> System Check

The dead volume measurement is performed by using Sampler and Pump options in below given sequence.
First select the Sampler Option and take the sampler down by selecting option 2 , so as the sampling probes get immersed in the bowl media (DM Water).

7 STU → ENTER → Sampler : _
1) Sampler UP 2) Sampler DOWN

Press Display

2 DEF → ENTER → Wait! Sampling Assembly moving Down.

Now Keep the waste tray under the sample collector dispense tips.
Then press the **BACK** key to return to previous display screen**. (DO NOT press ESCAPE key as it will return the screen to Main Menu).**

BACK → 1>Clk 2> Wake Up 3> Cfg 4> Validate 5> Beep
6> Pump 7>Sampler 8> Clean 9> System Check

Select Pump menu and operate the pump in FWD direction

Press Display

6 PQR → ENTER → Peristaltic Pump :
1) Pump Para. 2) Pump FWD 3) Pump REV

Press Display

2 DEF → ENTER → P. Pump ON in FWD direction
Press 'ESC' to put off the P. Pump

Let the PUMP remain ON until the DM water comes out from the dispense tips of the Sample collector the Sampling tubes will get filled up.

Now Press ESC key to Stop the PUMP.

ESC → Peristaltic Pump :
1) Pump Para. 2) Pump FWD 3) Pump REV

Then press the BACK key to return to previous display screen**. (DO NOT press ESCAPE key again as it will return to Main Menu).**

Press Display

BACK → 1>Clk 2> Wake Up 3> Cfg 4> Validate 5> Beep
6> Pump 7>Sampler 8> Clean 9> System Check

Now select the Sampler Option and take the Sampling assembly up by selecting option 1 , so as the sampling probes are out from the bowl media (DM Water).

Press Display

7 STU → ENTER → Sampler : _
1) Sampler UP 2) Sampler DOWN

Press Display

1 ABC	→	ENTER	→	Wait! Sampling Assembly moving Up.

Now remove the waste tray from the sample collector dispense tips and keep the sample collector Bottle/vials tray with empty, clean dry bottles/vials..
Then press the BACK key to return to previous display screen**. (DO NOT press ESCAPE key as it will return to Main Menu).**

BACK	→	1>Clk 2> Wake Up 3> Cfg 4> Validate 5> Beep 6> Pump 7>Sampler 8> Clean 9> System Check

Select Pump menu and operate the pump in FWD direction

Press Display

6 PQR	→	ENTER	→	Peristaltic Pump : 1) Pump Para. 2) Pump FWD 3) Pump REV

Press Display

2 DEF	→	ENTER	→	P. Pump ON in FWD direction Press 'ESC' to put off the P. Pump

Let the PUMP remain ON until the entire DM water comes out from the dispense tips of the Sample collector the Sampling tubes which was filled up earlier.
Now Press ESC key to Stop the PUMP.

ESC	→	Peristaltic Pump : 1) Pump Para. 2) Pump FWD 3) Pump REV

Weigh the above DM water filled Bottles /vials and find the difference to determine the Dead volume of the entire sampling tubing path.
Verify the Volume by repeating the process and Enter the Dead Volume in the PUMP PARA option 1.

2) To start the Peristaltic Pump in Forward direction (Sampling),

Press 2 and Enter,
This function is helpful when the teflon tubes are to be primed (wetting) With the buffer used for dissolution analysis.

3) To start the Peristaltic Pump in Reverse direction (Replenishing),

Press 3 and Enter,
This function is helpful when the teflon tubes are to be primed (wetting) with the buffer used for dissolution analysis.

7) SAMPLER : - To Operate the sampling Assembly UP or DOWN . (Available if functionally Sampling Accessory drive is found okay during system check)

Display

1>Clk 2> Wake Up 3> Cfg 4> Validate 5> Beep 6> Pump 7>Sampler 8> Clean 9> System Check

This Function is basically an utility for checking the operation of the sampling assembly.

Press Display

7 STU	→	Wait ! Checking Sampling Assembly

Display

Sampler : _ 1) Sampler UP 2) Sampler DOWN

Choose the required mode by pressing the appropriate (1 or 2) key.
The System will prompt with relevant Display screen. ‘ESC’ and ‘BACK’ are active when sampler is in up position.

Press → **2 DEF** → **ENTER** → Display

Buffer Volume <500ml : _ 1) Y 2) N

If Volume is less than 500 ml

Press → **1 ABC** → Press → **ENTER** → Display

Not Applicable

Display

Sampler : _ 1) Sampler UP 2) Sampler DOWN

OR, If Volume is more than or equal to 500 ml

Press → **2 DEF** → Press → **ENTER** → Display

Wait! Sampling Assembly Moving Down

Display

Sampler : _ 1) Sampler UP 2) Sampler DOWN

8) CLEAN : - To CLEAN the sampling tubing.

This function is used to perform an unattended cleaning cycle for entire sampling path.
NOTE: Remove the Paddle Shafts and the Bath stirrer shafts from their respective housings.

Display

1>Clk 2> Wake Up 3> Cfg 4> Validate 5> Beep 6> Pump 7>Sampler 8> Clean 9> System Check

Press → **8 VWX** → Display

Wait ! Checking Sampling Assembly

for Sampling Assembly is functionally **not okay**,

Sampling Assembly Not OK!

→ A (Main Menu)

If the Sampling Assembly is **okay**,

Wait ! Stirrer Hood Moving Up . . .

As Hood reaches the UP position, Display

Place the Cleaning Tray & press ‘ENTER’

Now Place the Cleaning tray and the Beakers filled with the cleaning solvent / buffer over the bath top.
Ensure that the position is correct and does not obstruct the entry of sampling tubes.

Press Display

ENTER → Wait ! Stirrer Hood Moving Down . . .

As soon as the pre-defined hood position is reached the Sampler Assembly starts lowering down till the sampling tubes gets immersed in the solvent / buffer,

Display

Wait ! Sampling Assembly Moving Down . . .

After reaching the lower position

Display

Pump Fwd On Time (0 – 30 min) : _

Enter the desired Forward and Reverse cycle time in minutes.
e.g. 5min each direction,

Press Display

5 MNO → **ENTER** → Pump Fwd On Time (0 – 30 min) : 5
Pump Rev On Time (0 – 30 min) :

5 MNO → **ENTER** → Pump Fwd On Time (0 – 30 min) : 5
Pump Rev On Time (0 – 30 min) : 5

Do you wish to REPEAT clean? :
1> Y 2> N

To Repeat the Clean cycle for cleaning the sampling path with another dissolution media,
Press

1 ABC → **ENTER** → P. Pump On in FWD Direction . . .
00 : 05

For Time entered = 00:00 the FWD cycle is skipped.
After the FWD cycle time is over the REV cycle is started,

P. Pump On in REV Direction . . .
00 : 05

Here also if the time entered = 00:00 the REV cycle is skipped

After the REV cycle is over the samplings assembly is raised UP,
Display

For Option (1) Sampling assembly position: UP
Press 'ENTER' to continue clean…

For Option (2) OR If During the cleaning cycle "ESCAPE" key is pressed,

Wait ! Stirrer Hood Moving Up . . .

Wait ! Sampling Assembly Moving Up . . .

Now to remove the Cleaning media/solvent carry over from the tubing,
The P. Pump is again turned on in forward & reverse direction (dry run) for default time (2 min.)

Display

P. Pump On in FWD Direction . . .

↓

P. Pump On in REV Direction . . .

↓

Wait! Stirrer Hood Moving Up . . .

↓

A Main Menu

9) SYSTEM CHECK : To check proper functionality & connectivity of various parts like Bath Sensor, Bowl Temp. Sensor, RPM Motor, Sampling Assembly, Sample Collector, Piston Pump & Filter Changer.

Display

```
1>Clk     2> Wake Up   3> Cfg     4> Validate  5> Beep
6> Pump 7>Sampler      8> Clean 9> System Check
```

Press **9 / YZ -** → **ENTER** System then performs self test sequentially for

1) Bath temperature sensor (OK / NC / > 60°C/ OR),

```
System Checks :
BATH  T°C :   Bath sensor OK
```

If bath sensor is not connected display reads :

```
System Checks :
BATH T °C :   NC
```

If bath sensor reads temp, > 60 °C , display reads :

```
System Checks :
BATH  T°C :   OR
```

Note : NC : Not Connected
OR : Over Range

2) Stirrer Motor,

```
System Checks :
Stirrer Motor : Ok
```

3) Lift Mechanism,

```
System Checks :
Lift Mechanism : Ok
```

4) Sample Collector Connectivity,

When not Conn. or not ON

```
System Checks :
Sample Collector  Not  Ready.
```

5) Sampling Assembly Operation (OK / Not OK),

```
System Checks :
Sampling Assembly : Wait! Checking . . . .
```

If Operation okay,

```
System Checks :
Sampling Assembly : OK .
```

If operation fails/not okay,

```
System Checks :
Sampling Assembly : Not OK !
```

6) Bowl temperature sensor/s (OK / NC / OR) for Standard version only,

```
System Checks :
Bowl T °C :   Bowl sensor OK
```

☞ **Note :** If bowl sensor is not connected , display reads :

```
System Checks :
Bowl T°C :  NC
```

If bowl sensor temp. > 60 °C, display reads :

```
System Checks :
Bowl T°C :  OR
```

Optional - With Bowl Temperature Monitoring Option, Six Bowl temperature sensors are checked, (For 12 +2 bowl all 12 bowls sensors are checked)

```
System Checks :
Bowl Temp Sensor  : Wait! Checking . . . .
```

When sensors are okay,

BL-1	BL-2	BL-3	BL-4	BL-5	BL-6	BLX1
OK	OK	OK	OK	OK	OK	OK

When sensors not connected,
If temperature > 60°C,
"OR" will be displayed

BL-1	BL-2	BL-3	BL-4	BL-5	BL-6	BLX1
NC	NC	NC	NC	NC	NC	OK

When all the checks are finished, display reads,

```
1>Clk     2> Wake Up   3> Cfg    4> Validate  5> Beep
6> Pump 7>Sampler     8> Clean 9> System Check
```

---X---X---X---

Chapter 5

Maintenance And Troubleshooting

General Information

This chapter provides instructions for user maintenance and service operations, and a schedule for preventive maintenance. Contact LABINDIA service representative for more service information.

☞	Before cleaning the instrument unplug the power cord from the power source.

Introduction

Regular maintenance is important for safe and trouble-free operation of the Tablet Dissolution Apparatus. The user should keep the instrument clean. Preventive maintenance should be performed on a yearly basis by qualified service personnel.

Cleaning procedures

Cleaning the instrument regularly

For proper function, the Dissolution Apparatus should be kept clean and dry from outside.
Chemical stains and dust should be removed.

1. Disconnect the instrument from the ac mains.
2. Wipe the instrument cover with a soft damp tissue. If needed, use a mild detergent to remove stains.
3. Electronics require no customer attention. In the event of a malfunction, please call the Labindia service personnel before attempting any repairs.

Clean the tubing's periodically using distilled water.

Emptying the Water Bath:-

1. Move the hood assembly 'Up' by using 'UP' key.
2. Turn the instrument 'off'.
3. Remove paddle / basket from the bowls.
4. Attach drain tube to the drain valve.
5. Place the drain tube in a large bucket.
6. Open the valve.
7. When all the water is emptied, close the drain valve & remove the drain tube.
8. To remove the water left at the bottom of the tank, make use of sponge and finally wipe out the entire inner surface with a dry sponge. Care should be taken that there is no disturbance to the heater and circulation pump during the process. Antifungal agent can be used to prevent fungal growth.

Refilling the bath :-

1. The bath can be filled manually or connecting the drain valve directly by the hose pipe to demonized water supply if available in the laboratory up to the level mark.
2. Make sure the pipe is connected to drain valve & drain valve is in open position.
3. Fill bath to up to the water level mark indicated.
4. Close the drain valve & remove the pipe.
5. Switch 'ON' the instrument.

Fuse Replacement :-

1. DS8000/DS14000 fuse Replacement :
   110/115V : Slow Blow 5x20mm – 1A 250V
   220/230V : Slow Blow 5x20mm – 1A 250V

   Fuse Replacement (for Heater Box):
   110/115V : Slow Blow 6.35x31.8mm – 10A 250V
   220/230V : Slow Blow 6.35x31.8mm – 5A 250V

   Fuse Replacement for stepper motor
   Fast Blow 5 x 20mm – 2A 250V

⚠ For continued protection against risk of fire, replace with fuses of the same type and rating only.

⚠ For Peristaltic Pump & its tubing related maintenance – refer manufacturers operating manual.

Moving the instrument

Disconnect all interconnections & tubing's before moving / relocating the instrument.

The Dissolution Apparatus consist of main machine and controller unit. The instrument weighs appox. 60 kg. Two persons are required to lift the instrument.

To move the system to another room:

1. Switch off the instruments and disconnect mains cables of Dissolution main machine, other accessories from bath circulator unit.
2. Disconnect the interconnection cables from the main unit & bath circulator unit.
3. Detach the water bath by disconnecting tubing coupling of inlet & outlet from bath circulator unit.
4. Disconnect Sample collector & Piston Pump tubing's from Dissolution main machine.
5. Carefully move the machine to the new desired location. Note : Do not hold the top cover / hood assembly to lift the machine.
6. Maintain the same installation setup sequence. (Refer the "Installation - Pg. No. 20")

Mechanical maintenance: Contact LABINDIA service personnel for mechanical maintenance.

TROUBLESHOOTING

Before performing any procedure in this section, please disconnect AC power from the unit.

Improper servicing or adjustment practice can cause equipment failure or serious physical injury. This equipment must be adjusted and serviced by qualified electrical maintenance personnel who are familiar with the construction and operation of the equipment and the hazards involved. Take care during adjustment. All exposed points on the control circuit boards are electrically hot with respect to earth ground.

HIGH VOLTAGE IS EXPOSED WHEN MAINS INPUT IS OPENED ON THE SYSTEM. Dangerous voltages exist on the circuit boards when powered. Disconnect AC power from the unit while troubleshooting. Be alert. High voltage can cause serious or fatal injury.

Use the table below to solve minor installation or operation problems :

Symptom	Possible Cause	Solution
Paddle not moving	Check Motor fuse	Check motor fuse
SC not operates	Interface connector may not be connected	Check SC switched on & its interface to Main unit
Pump not operates	Interface connector may not be connected	Check pump is switched on & its serial interface to Main unit
* W – Water level is less	Water is below the level mark	Check float switch connections & water level
* S – SC is off – ON	Sample collector may be off	Check SC fuse, Power & cable
Temperature is not rising	Heater, SSR, Fuse, Float switch may not be working	Check BC0612 unit connectivity cables. Check LED status. Check heater ON/OFF switch, Fuse & Water Level Or call service engineer
Bath temperature is not stable	Voltage fluctuation or circulation pump is faulty	Check circulation Pump is ON / working
Bath temperature not showing on display	Connectivity problem	Check Bath controller connectivity with Main Unit
Temperature value shows +0.00	Particular sensor may be open OR Calibration is cleared	Check the sensor connectivity
Temperature value shows offset reading	Particular sensor may be open	Check the sensor connectivity
RPM not changing or showing on display	Internal Connection Problem	Reset the system or Call service engineer
No temperature display or erratic display.	Temperature sensor not plugged in.	Check all the temperature probes inserted in the vessel properly.
No display on LCD	Mains fuse may be blown.	Check ON/OFF switch & Mains fuse.
Peristaltic Pump not connected	Interface cable may not be connected or Peristaltic Pump may be switch off.	Check Interface cable Or Power ON the Peristaltic Pump.

☞ **Consult LABINDIA Technical Support for assistance with problems that cannot be resolved using the table above.**

Spare Parts and Accessories

Sr. No.	Material Description	Material Code
1.	SS Paddles	20570006
2.	Replenishing Paddle	20530110
3.	40 mesh Basket	20530105
4.	Monoshaft for Paddles & Baskets	20530038
5.	Polycarbonate Bowls	20540205
6.	Glass Bowls	20540204
7.	25mm of depth balls	20540707
8.	SS Paddles – Teflon Coated	20570002
9.	40 mesh Basket – Gold Plated	20530178
10.	Monoshaft for Paddles & Baskets – Teflon Coated	20530179
11.	SS Paddle with Monoshaft (6 Nos. / Set)	50500032
12.	SS Paddle with Monoshaft – Teflon coated (6 Nos. / Set)	50500030
13.	40 mesh Basket with Monoshaft (6 Nos. / Set)	50500038
14.	40 mesh Basket – Gold Plated with Monoshaft (6 Nos. / Set)	50500031
15.	Polycarbonate bowls Amber Colour	20540202
16.	Glass bowls Amber Color	20540203
17.	Glass Peak Vessels	20580001
18.	Acrylic Lid for Glass Bowl	20530106
19.	Bowl Centering Lid	29930209
20.	Bowl Stand	50500012
21.	Depth gauge balls 25mm	20540707
22.	Cannula (6 Nos. / Set)	50500011
23.	Cannula with extended length (6 Nos. / Set)	50500054
24.	Tygon tubing ID 1.52 (set of 12/24)	60530112
25.	15ml Bottles	20540636
26.	Teflon Carrier tubing and tubing connectors	50500041
27.	10 Micron filters (6/pk)	20530101
28.	Tachometer	29940688
29.	Wobbling Test Kit with Centering Jig	50500006
30.	10 Micron filters (6/pk) with SS adaptor	50500063
31.	Bowl Centering Jig	29930308
32.	Validation kit	50500015
33.	Vernier Caliper – small 6” – Optional	49971524
34.	Vernier Depth Gauge	50500043
35.	Sinkers (8mm)	20530312
36.	Sinkers (10mm)	20530310
37.	Sinkers (12mm)	20530311
38.	Vials (15ml bottles) for Sample Collector (72nos. / set)	20540636
39.	Vials (Open Mouth) for sample collector (72 nos./ set)	22180201
40.	Basket (20 mesh)	20530138
41.	Basket (60 mesh)	20530154
42.	Paddle Over Disc	20530144
43.	Circulation Pump - TOPS FLOW - TL-B10-A24-1208	69930106

44.	Low evaporation lids with gasket (set of 8)	50500046
45.	Vernier Depth Gauge	50500043
46.	Conversion Kit – 150ml beaker for Disso	50530102
47.	Glass bowl 150ml SV (6 Nos./Set)	20580003
48.	Rubber Ball 16mm (6 Nos. / Set)	20540708
49.	Paddle mini (6 Nos. / Set)	20570602
50.	Conversion Kit – 250ml Beaker for Disso	50530101
51.	Glass bowl 250ml (6 Nos. / Set)	20580002
52.	Enhancer Cell Kit for DS 8000 with Imported Ointment Cell	50500073
53.	Glass bowl 150ml OC (6 Nos. / Set)	20580004
54.	Height Gauge for Ointment Cell	20530188
55.	Paddle Mini for Enhance Kit Drg. No. 0502135/2 (6 Nos. / Set)	20530187
56.	Ointment Cell Imported (6 Nos. / Set)	60540601
57.	Enhancer Cell Kit for DS14000+ with Indian Ointment Cell	50500074
58.	Ointment Cell Assembly (6 Nos. / Set)	50500075
59.	Mains Power Cord - C13 to C14	29920128
60.	RS 232C Interface Data Cable	29920171
61.	SMPS - LRS-50-24V (Single O/P) [Meanwell]	20520127
62.	Step Down DC-DC Adjustable Voltage Regulator 3A Output (RKI-1305)	29921206
63.	DTS With 3 Pin Shell Connector, Dual DT - 540902	50500328

APPENDIX - A

- **PRINTER DIP SWITCH SETTINGS FOR COMMONLY AVAILABLE 80 - COLUMN DOT MATRIX PRINTERS**

1] EPSON LX-800 [WIPRO LX-800]

SWITCH BANK 1.

SW1	SW2	SW3	SW4	SW5	SW6	SW7	SW8
OFF	ON	ON	ON	OFF	ON	ON	ON

SWITCH BANK 2.

SW1	SW2	SW3	SW4
ON	OFF	OFF	OFF

→ Automatic line feed

2] TVSE

SW1	SW2	SW3	SW4	SW5	SW6	SW7	SW8
ON	OFF	OFF	OFF	OFF	OFF	OFF	OFF

NOTE :

After switches are correctly set turn the printer OFF and ON again to load the new settings.

3] TVSE – RP45 Shoppe Mini Dot Matrix Printer

NOTE :

Please refer printer manual supplied along with the RP45 Shoppe Printer.

Using operation panel change the character pitch setting (CPI) minimum 15cpi to 20cpi with EPSON Emulation Mode, Line Spacing 6LPI, Paper Width = 4 inch & Character set = INDIA with Serial Interface Setting : B : 9600, P: None, D:8 Bit, S:1 Bit, Protocol : XON/OFF or None (refer pg. no. 24, 25, 26 & 27 of TVSE-RP45 User Manual).

4] GP-80250IN Thermal Printer – Serial Input

NOTE :

Please refer printer manual supplied along with the GP-80250IN Printer.

Emulation mode : ESC/POS
Character / Line : 48 Column

APPENDIX – B

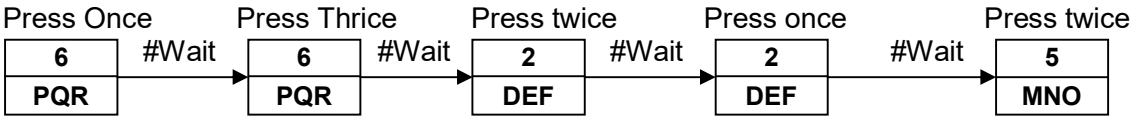
- **ALPHANUMERIC Data Entry**

Alpha numeric Entries are required for Sample Name & ID.NO.

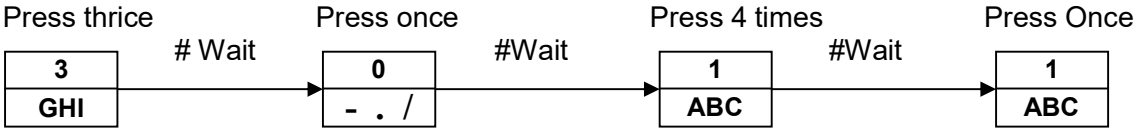
To enter SAMPLE NAME: e.g. PREDNI-1A

Please follow the Sequence for key entries
Display -

SAMPLE NAME (Maximum 20 characters) :
_



Proceed further to enter the other characters as given below,



Display reads,

SAMPLE NAME (Maximum 20 characters) :
PREDNI-1A

If any entry goes wrong press CE to re-enter

Press **ENTER** after alphanumeric entries are over .

The cursor advances automatically after 1-1.5 sec.

APPENDIX – C

DS8000/DS14000 – Data Downloading Capability to Personal Computer

Installation/setup Instructions:

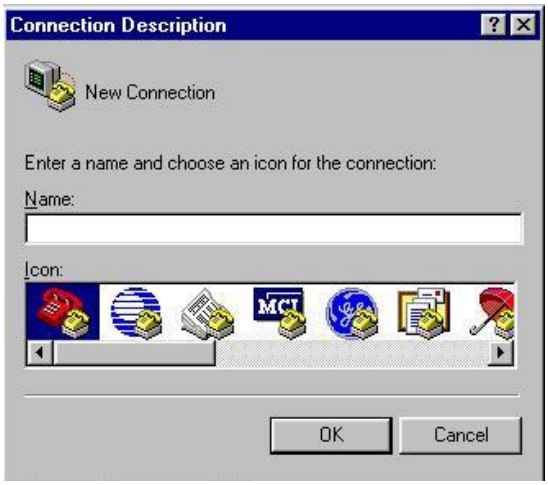
The instrument software has been incorporated with RS232C protocol interface for transferring the printable data to PC having standard data terminal software Windows **- Hyper terminal**.

Features of PC data transfer,

1. Data transfer selectivity in function menu : Printer or Personal computer.
2. All reports - a) Run Report, b) Program Parameter and %D Report (without Graph) which are available for printing can be transfer to PC on-line/off-line (needs Hyper terminal active in the PC).
3. The data is captured as ASCII character via Hyper terminal software and then can be saved by the user as MS word doc or text file by Note Pad with suitable name by using Cut Paste utility. Since the communication is based in Terminal emulation mode for supporting Table borders – the Font also should be selected as "Terminal" only.

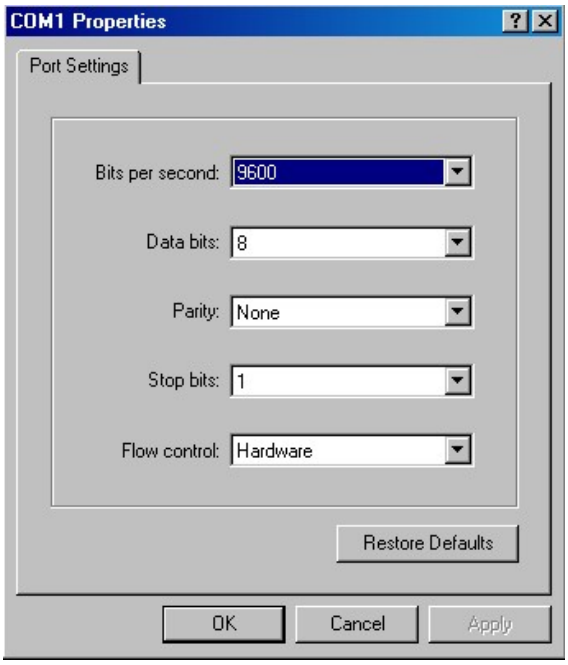
COM Port Configuration/Settings:-

Setting HYPERACCESS NEW CONNECTION and COM port selection:-

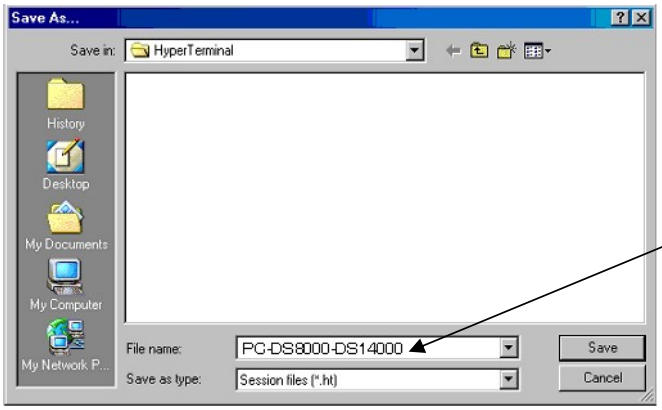


If the COM port chosen is not free or being used by another application a pop up screen will be displayed with message “Unable to Open COM”.

When a free Com port is selected The COM port Properties Pop up will be displayed on the screen.



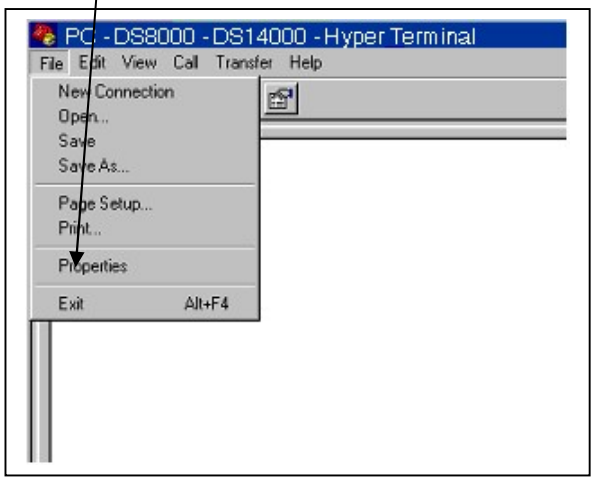
Set the Comm Port Properties,
Baud-9600, Data bits 8, Parity none, Stop bit 1, Flow Control- None or Xon/Xoff.

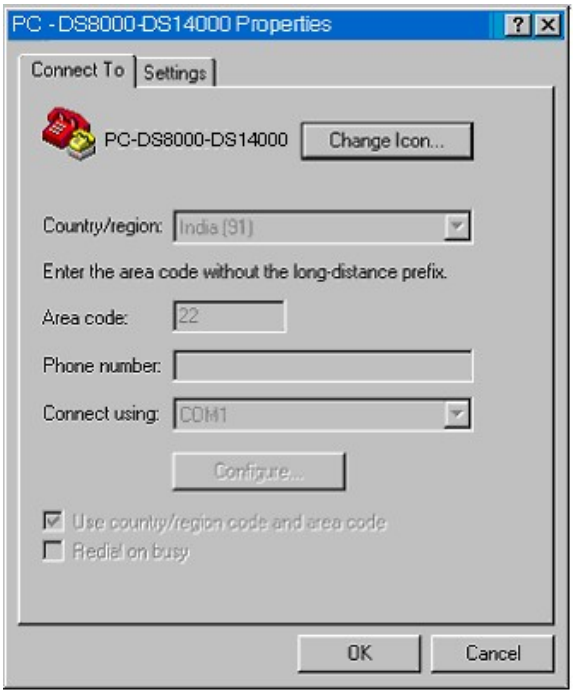


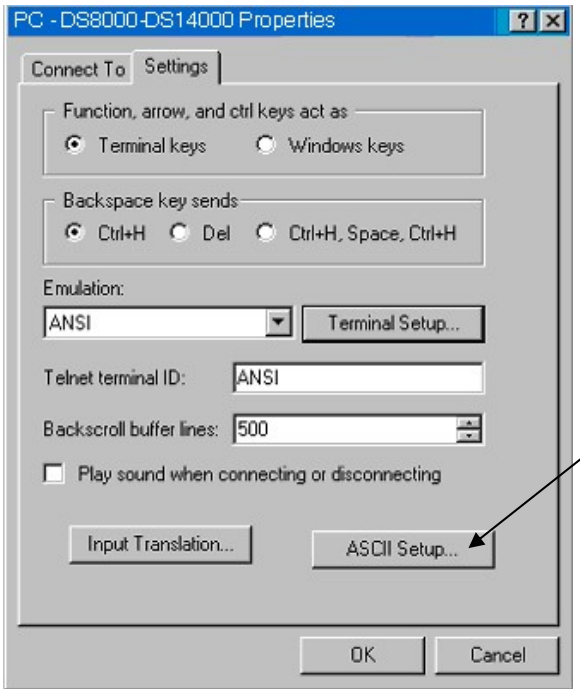
- Once the setting are done Save the Session so as the Session file is generated and can be run again to download the data from **PC - DS8000 - DS14000**

Now From the terminal window FILE menu select the Properties tool to set the Terminal Emulation mode and Data Line

Once You click on the Properties menu - Properties window will appear.







Select Settings option to set the Emulation mode and function setting.

Function:- Arrow & Ctrl Key as Terminal key.

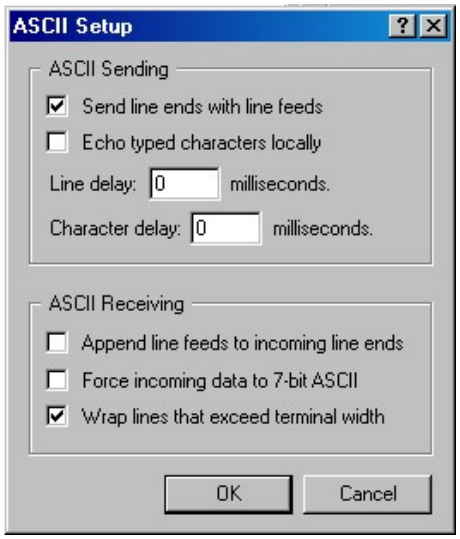
Backspace key sends: Ctrl+H

Emulation :- ANSI

Telnet id:- ANSI.

Now Setup the ASCII parameters

Click the ASCII setup icon to enter the setting window.



Click the Boxes as shown in the graphics for

- Line end with line feed and
- wrap lines that exceed terminal width
- Then Click OK to return to Properties window

Click OK Icon on the Properties window to complete the settings.

Now once again Save the Session to store the settings.

To Generate the Icon for the DISSO connectivity with PC, right click on the file name being in the Hyper terminal Window – select Create Shortcut to desk top.

Click on the Icon and start the application. An Terminal Window will open automatically and now the PC is ready to receive the data from DS8000/DS14000 dissolution test apparatus.

Chapter 6

Warranty & Service

TEST CERTIFICATE

TO WHOMSOEVER IT MAY CONCERN

THIS IS TO CERTIFY THAT ..... UNDER SERIAL NO. ..... MANUFACTURED BY LABINDIA ANALYTICAL INSTRUMENTS PVT. LTD. , EL-72, TTC INDUSTRIAL AREA, THANE- BELAPUR ROAD, NEW BOMBAY - 400 705, AND SUPPLIED TO ....IS TESTED BY US FOR ITS SPECIFICATIONS. THE INSTRUMENT WORKS SATISFACTORILY WITHIN ITS SPECIFICATIONS.

NAME : _____ SIGNATURE : _____

For LABINDIA ANALYTICAL INSTRUMENTS PVT. LTD.

DATE : .....

WARRANTY CERTIFICATE

All instruments manufactured by LABINDIA ANALYTICAL INSTRUMNETS PVT. LTD., Plot No. EL – 72, Electronic Zone, TTC MIDC Area, Thane – Belapure Road, Navi Mumbai – 400 705, are guaranteed for one year from the date of supply (invoice date) provided they are used within their electrical, mechanical and environmental limitations. During this period, free replacement of the faulty parts or components will be made as per the Terms of Warranty mentioned overleaf of this certificate.

INSTRUMENT DETAILS

MODEL : .....

SERIAL NO. : .....

DATE OF INSPECTION : .....

INSPECTED BY : .....

CUSTOMER NAME AND ADDRESS : .....

.....

.....

.....

DEPARTMENT : .....

(AUTHORISED SIGNATORY)
For LABINDIA ANALYTICAL INSTRUMENTS PVT. LTD.

DATE : .....

TERMS OF WARRANTY

LABINDIA ANALYTICAL INSTRUMENTS PVT LTD., hereinafter known as Manufacturer, warrants all their products manufactured and sold by them or through their authorized distributors, to be free of any defect in material and workmanship, subject to Manufacturer's inspection by their authorized personnel within the following terms and conditions: -

1) **Period of Warranty:** Free Warranty period is applicable only for those cases where full payment is received as follows:
   (1) 18 months if the full payment is received against supply and presentation of documents.
   (2) 15 months if the full payment is received within 30 days of supply irrespective of installation.
   (3) 12 months from the date of installation for the cases where full payment is not received till installation. However, in this case, period between the date of installation and date of receipt of full payment will be deducted from 12 months and reduced period of Warranty will only be applicable.

2) **Scope:** **(a)** Any part found defective by reason of faulty workmanship or defective material (fair wear & tear expected) will be repaired or replaced free of charge.

(b) All pH/Ion/Conductivity instruments are to be returned freight to pay basis to us on following address*. We after repair will send them to the customer freight paid. Since these are low priced items, offering free service at buyer's place by deputing our Engineer is not feasible. You are therefore requested to co-operate with this request.

In case you need repair at your place we will depute our Engineer provided you agree to pay 1st or 2nd A/C return railway fare, hotel & incidental expenses, etc. of our Engineer. In this case please note that we will not charge you for our Engineer's time, etc. This payment will be in advance and visit duration will be only for one day. On your request we will be happy to furnish you our quotation for this repair.

Other instruments will be serviced by our factory-trained engineers at buyer's place.

(c) Following items are not covered by warranty: -
   (1) All Electrical Displays (LCD, LED etc.)
   (2) All glass parts like pH Electrodes, Bowls, Slides, Cover Slips, Beakers or Capillaries, etc.
   (3) Parts made out of any type of glass such as Lenses, Prisms, Reaction Tubes, Glass heating elements, etc.

3) **Limitations**: The Warranty shall not apply if: -
   (a) the instrument is subjected to abnormal use or not used, stored or not maintained in accordance with the instructions given in the user's manual or by our engineer during installation, or any damage caused by accident, collision, or fire.
   (b) the instrument has been modified in any way.
   (c) the claims are made without proof of purchase (i.e. invoice, bill, cash memo, etc.)
   (d) if it is noticed that attempts were made to repair the instrument by outsider or customer's untrained instrument engineer, etc.

- Please send the goods on following address for repair :-

ATTN. : SERVICE MANAGER

Labindia Analytical Instruments Pvt Ltd
Plot No.EL-72, Electronic Zone, TTC Industrial Area,
Thane-Belapur Road
Navi Mumbai – 400 705
Tel: (022) 27626661/2/3
Fax: (022) 27683549 Email: service.mfg@labindia.com

Sales & Service Centers

Head Office
201, Nand Chambers
L. B. S. Marg, Nr. Vandana Cinema
Thane (W) – 400 602

Tel : +91-22-25986000/25445000
Fax : +91-22-25335940
Email : labindia@bom3.vsnl.net.in

Delhi Office
G-4, Pal Mohan Sadan
26/32, East Patel Nagar
New Delhi – 110 008

Tel : +91-11-43306001/10
Fax : +91-11-25851066
Email : lipldelhi@vsnl.net

Gurgaon Office
Plot No. 372, Udyog Vihar Phase II
Gurgaon – 122 015,
Haryana

Tel : +91-124-2843300/2843600
Fax : +91-124-2843399
Email : lipldelhi@vsnl.net.in

Chandigarh Office
S.C.O. 208-209, 4th Floor, Basera
Building, Sector-34 A,
Chandigarh - 160 022, U.T.

Tel : +91-172-4090001-07/4090009
Fax : +91-172-4090008

Lucknow Office
403, 4th Floor, Sahara Shopping
Center, Faizabad Road,
Indira Nagar Lucknow - 226016.

Tel : +91-522-2346535/2346496
Fax : +91-522-2348847
Email : lipllko@sancharnet.in

Chennai Office
B-1, Alwarpet, Alsa Regency
165, Eldams Road,
Chennai – 600 018

Tel : +91-44-24347008/24320352
Fax : +91-44-24346328
Email : liplchn@md3.vsnl.net.in

Kolkata Office
165-A, S. P. Mukherjee Road
Kolkata – 700 026

Tel : +91-33-24661396/24663362
Fax : +91-33-24661352 (Extn.30)
Email : lipical@giascl01.vsnl.net.in

Baroda Office
605, Imperial Heights,
Akshar Chowk,
Old Padra Road,
Vadodara – 390020.

Tel : +91-265-2986005, 2986006

Email : libindiabrd@vsnl.net

Hyderabad Office
6-3-1090/1/1, Uma Hyderabad House
2nd Floor, Somajiguda,
Raj Bhavan Road,
Hyderabad – 500 082

Tel : +91-40-65504133/23313300
Fax : +91-40-23313312
Email : hyd2_liplhyd@sancharnet,in

Bangalore Office
#105, Bhimajyothi Colony, West of
Chord Road, Basaveshware Nagar,
Above Coffee Day,
Bangalore - 560 079

Tel : +91-80-23230923 / 21
Fax : +91-80-23230924
Email : lipl_blr@dataone.in

Thiruvananthapuram Office
Mega Complex, Gr. Floor,
TC No. 26/857
Women's College Road,
Thycaud,
Thiruvananthapuram – 695 014

Tel : +91-471-2324064 / 2320082
Fax : +91-471-2320082
Email : labindia@md3.vsnl.net.in

UAE Office
Lab Gulf fzc
P.O. Box 9668
125 M2 Warehouse Q4-203
Sharjah Airport International Free
(SAIF) Zone, Sarjah, UAE

Tel : +971 6557 9893
Fax : +971 6557 9894
Email : labsales@eim.ae

Factory – I
Plot No. EL-72, Electronic Zone,
TTC Industrial Area,
Thane – Belapur Road,
Navi Mumbai – 400 705

Tel : +91-22-27626661 / 2 / 3
Fax : +91-22-27626664
Email : service.mfg@labindia.com

Application & Training Centre
R–909, TTC Industrial Area,
Thane – Belapur Road,
Rabale – 400 701

Tel : +91-22-27606955
Fax : +91-22-27606706