TM

SCINTIGLO

Cutting Edge
Medical Devices Pvt. Ltd.

Born To Innovate...

USER MANUAL

INDEX

SCINTIGLO^{TM} PoC System

SCINTIGLO^{TM} Test kit includes:

1. Device SCINTIGLO
2. Charger with dedicated charging cable (micro USB type)5V, 1 ma
3. Data transfer cable
4. Cuvettes with reagent
5. User manual
6. Warranty Card

Introduction

Proteins are essential part of a body which helps in normal functioning of body by operating and regulating various life processes. Microalbuminuria is moderate increase in the level of urine albumin. It occurs when the kidney leaks small amounts of albumin into the urine. Normally, the kidneys filter albumin, so if albumin is found in the urine, then it is a marker of kidney disease.

Proteinuria is another condition where kidney starts to excrete excessive amounts of proteins in urine. In healthy person, urine contains no protein or very less proteins. Proteinuria is precursor for many serious diseases like Hypertension, Diabetes, Pre – eclampsia, Urinary Tract Infections and many others.

SCINTIGLO is a Point of Care Device that quantitatively estimates the amount of proteins in urine within few seconds.

Results displayed on the device are sorted quantitatively displaying range of quantities present in the urine. They are also given color codes.

Intended Use

"SCINTIGLO^{TM}" is a "Point of care" diagnostic device for quantitative estimation of microalbumin in a human spot urine sample. It is not to be used for any other body fluid or any other chemical. It detects only microalbumin using specially designed cuvette and reagent. SCINTIGLO^{TM} is intended to help evaluate microalbumin for the detection of kidney disease, pre-eclampsia, diabetic nephropathy, and hypertensive kidney damage. It provides results within 2 – 3 seconds with more than 95% accuracy.
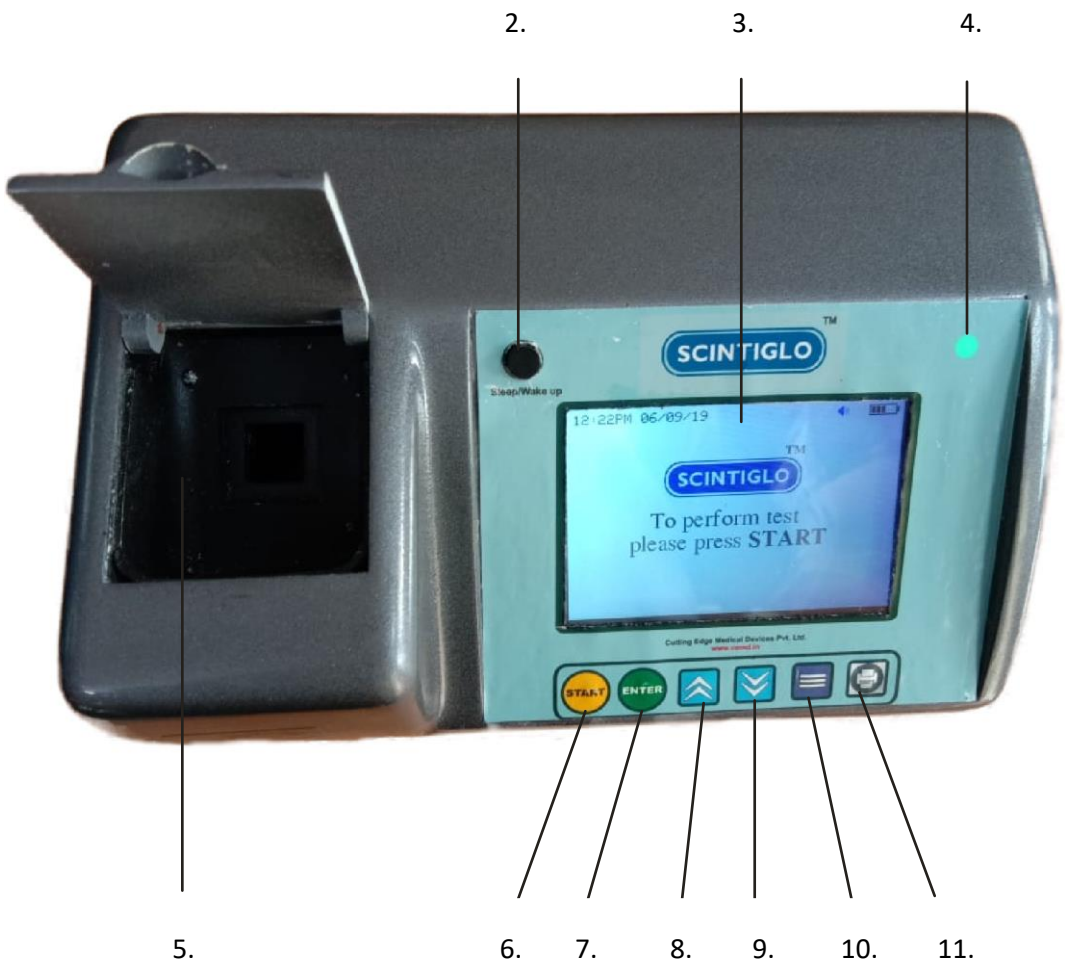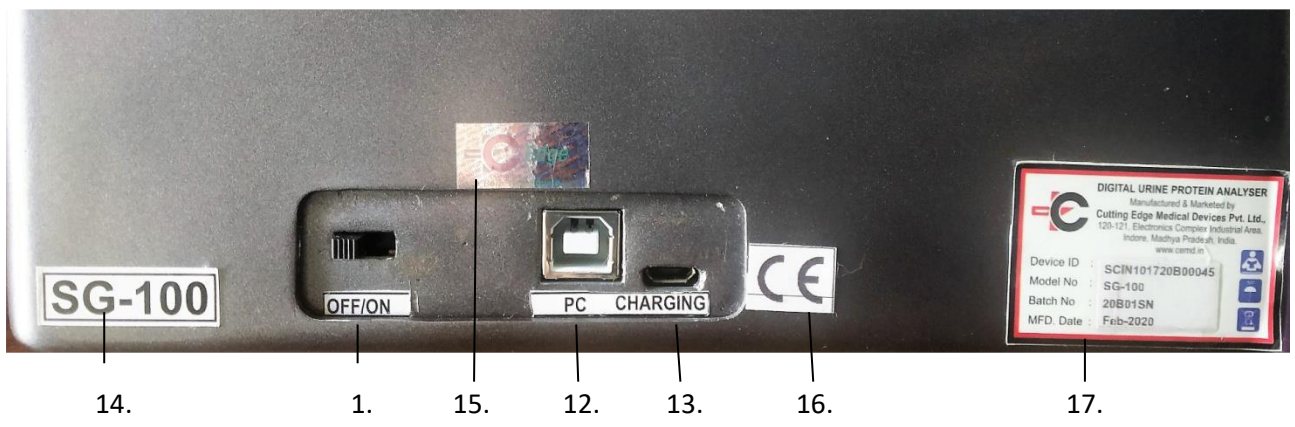
About SCINTIGLO

Figure 1 SCINTIGLO

Figure 2 Back view of SCINTIGLO with Switches

1. POWER SWITCH: Back Side of the device; Switches ON/ OFF the device.

2. POWER BUTTON: On the face of the device; switches ON/ OFF the screen.

3. SCREEN: Touchscreen; displays the results.

4. DISPLAY LIGHT: green lights

5. CUVETTE HOLDER: To place the cuvette filled with sample for the test.

6. START: To begin the test.

7. ENTER: To save the values entered for the test.

8. UP: To move among the displayed values up on the screen.

9. DOWN: to move among the displayed values down on the screen.

10. MENU: To access the items in Menu like Bluetooth, Memory etc.

11. PRINT: To print the result via a Printer (if purchased)

12. DATA TRANSFER: To transfer the data stored device to PC

13. CHARGING SLOT: To charge the device.

14. MODEL NUMBER
15. HOLOGRAM
16. CE QUALITY MARK
17. DEVICE DETAILS

ACCESSORIES-

1. REAGENT DROPPER BOTTLE WITH CUVETTES

2. CHARGER

3. DEVICE BAG

Scope of Testing

How to charge the Device

Connect device with the charger. Switch on mains power, during charging red LED blinks. It takes 2 hours for full charging.
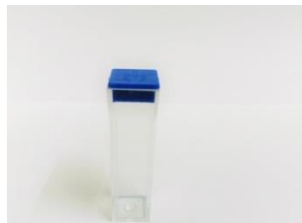
How to perform the test on the device "SCINTIGLO"

STEPS:

1. Turn on the device through on/off switch on the back side of the device.

2. Now press the SLEEP/WAKE button on the face of the device to turn it ON from the sleep mode.
3. Take a fresh cuvette.
4. Fill the cuvette with 3-3.5 ml fresh urine sample.

FILL SAMPLE UPTO THIS LEVEL

5. Add 5 drops of reagent.
6. Cover the cuvette with cap.
7. Mix it properly by turning the capped Cuvette upside-down gently.
8. Insert the cuvette in the Cuvette holder provided on the device (the steps 3-7 should be completed within 10-15 seconds).
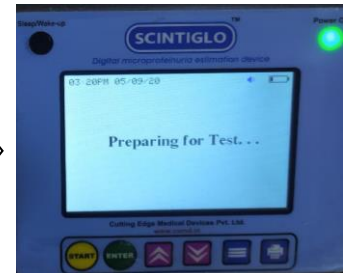

No light when holder is empty.   Red light will turn on when cuvette is placed.

9. Press the "START" button. If you didn't insert or forgot to insert the cuvette in the cuvette holder then the device starts to beep but if you did then the screen will display a message and again press "START."

10. Wait for a few seconds till the screen shows Processing."
11. Give the sample ID up to 12 digits.
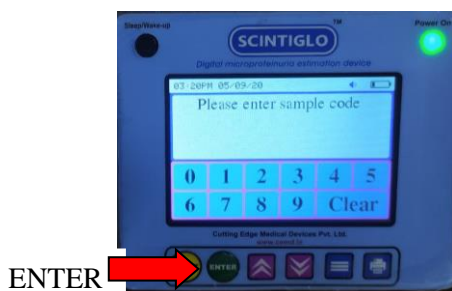
DATE, TIME, S.NO AND ID IS SHOWN ON THE SCREEN ALONG WITH THE RESULT

ENTER

12. Press "ENTER" to save the data.
13. Results are shown on display screen as "Quantity of proteins in sample: …..mg/100 ml."

Color coding of Results:

S. No.	Result Range (….mg/100 ml)	Risks	Color
1.	Absent	Normal	Light Green
2.	2 – 5	Normal	Green
3.	5 – 10	Moderate low	Yellow
4.	10 – 20	Moderate	Orange
5.	20 – 30	High	Red
6.	30 – 50	High	Red
7.	> 50	High	Red

SCINTIGLO Android Application

How to Connect

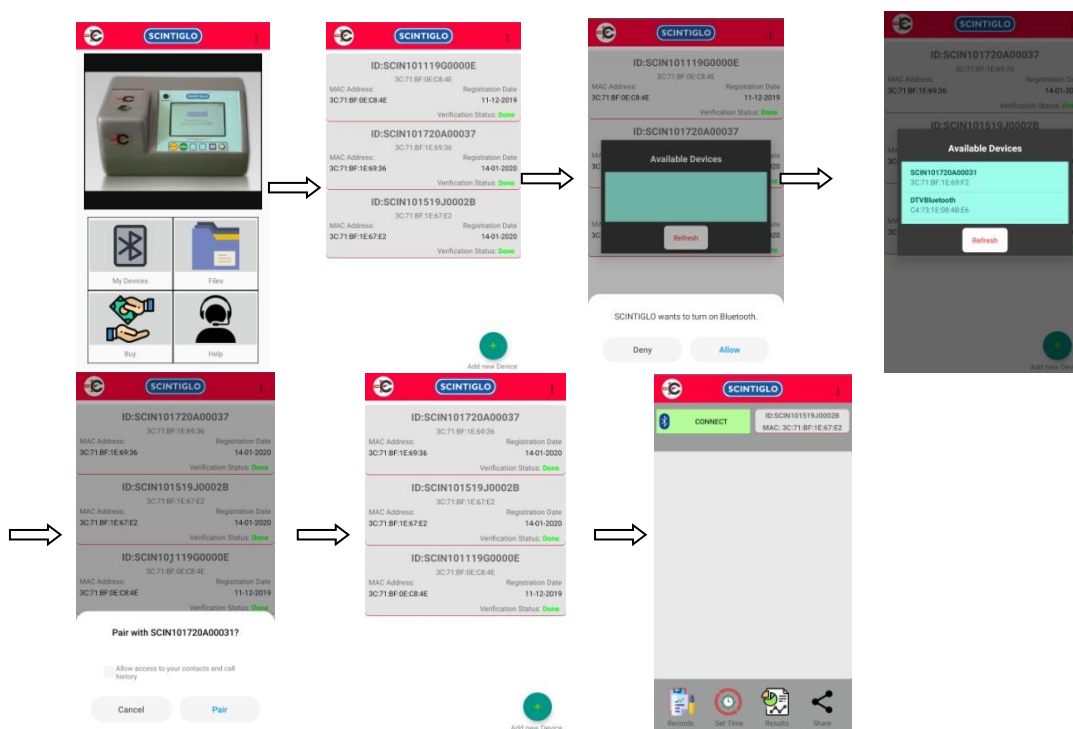Steps:

1) Install the SCINTIGLO APP from the GOOGLE PLAY STORE on your android smartphone. Please sign in/ register using your default/available email account on your phone. Please provide Name, Mobile number and address to register. Please "ALLOW" permissions sought by the app.
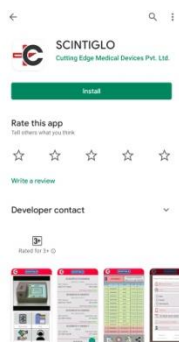
2) Turn on the Bluetooth on the device SCINTIGLO going from the menu button on the Key-strip (Menu → Bluetooth→ ON).

3) Open the APP on your phone> press my devices> press add new devices. App will ask you to turn on the Bluetooth, press yes and a list of available SCINTIGLO devices would appear. Now select the device ID and press pair to connect. Again select the device ID and press connect.

How to Transfer Data

Steps:

1) Press the MENU [icon] button and select Bluetooth from the options displayed.
2) Turn ON the Bluetooth visibility and then connect with the SCINTIGLO^{TM} android app.
3) Turn on the Bluetooth on your Android Smartphone.
4) Now open the SCINTIGLO ^{TM} app, select "My Devices" and click on "Add new" button, it will list up the available Bluetooth devices in the surroundings.
   (Please refer to above figure given)
5) Click on the device name and press "Connect."
6) Select the "Result" option to reveal 3 more options:
   (a) 'LAST READING' will show the latest test reading
   (b) 'LAST 10 READING' will list up the last 10 reading of sample
   (c) 'ALL' will list up all readings.

Selecting any of the above three options will transfer the data from device to the phone. Subsequent commands for saving the data as PDF or CSV files can be done on your phone.

The Data saved shall be stored in the folder named SCINTIGLO***

How to Print

1) Immediate print out of the test result: One time linking of the Bluetooth thermal printer with the device SCINTIGLO needs to be done. Connect device with the special Bluetooth thermal printer (if purchased) through SCINTIGLO android application. Switch ON the printer by pressing the ON/ OFF button on the face. Then open the SCINTIGLO android application → Select My Devices → Select the Device ID → Press Connect → Press Menu option → Press Link Printer. Select the Patient detail from the memory or perform the test and give the print command by pressing the Print button on the face of the device. The Thermal printer pops out the print result.

2) Last Test: To get a print out of your last result, press the menu button→ then press memory →then press last→ then tap the print button and your printout will pop-out.

3) Previous Tests: To get a printout of your previous results, select a previous test by toggling up & down by the UP & DOWN buttons on the key strip.(Press menu button → then press memory → then press last → then tap the up & down buttons → then press the print button and your printout will pop-out)

<div align="center">OR</div>

You can simply enter the patient's ID and get a printout of the result. (Press menu button then press memory → then press find →then enter the patient's ID → then tap enter → then tap the print button and your printout will pop-out).
Refer above photographs.

Once the Bluetooth thermal printer is linked with the device, there is no need to link it again***

How to Generate Patient's Report

Open the SCINTIGLO application on your smart phone, Press My devices → Results → Select Last Result/Last 10 Result/All Result → Select the patient's result → Press generate → Fill in the details of the patient → Again press generate → provide your digital signature → press submit.
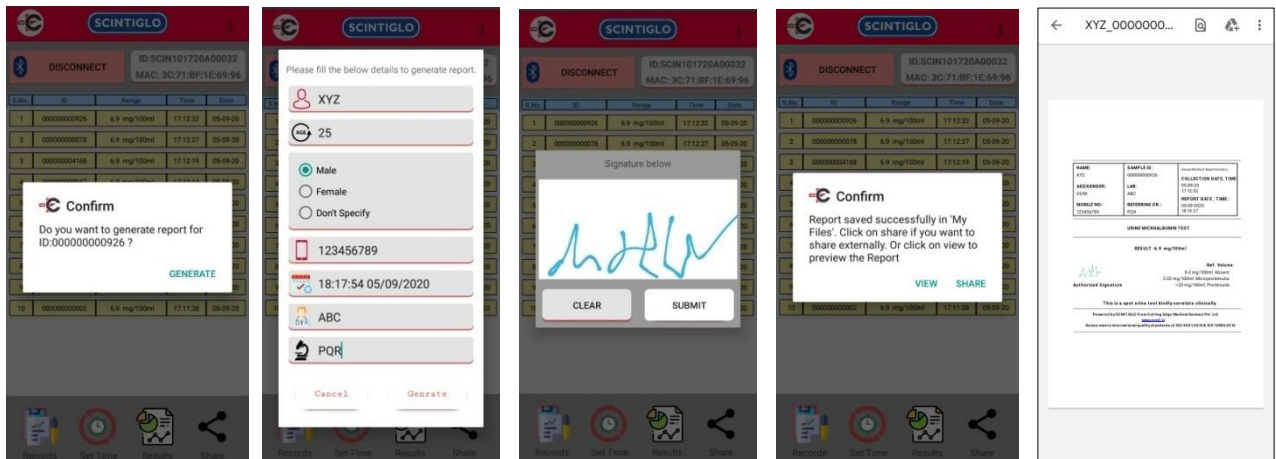

After submit, two options will appear:

1) View: Press view to preview the patient's report.
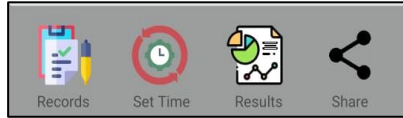2) Share: Press share to share the patient's report externally.

Functions

1) **My devices**: This feature shows the available SCINTIGLO devices and the devices which were connected to the application.

- Records: This feature helps to show all the tests which has been conducted on the SCINTIGLO device after connecting the device to the android application.

  i) Share as PDF: This feature helps to share the records to other device through various applications in the form of PDF.

  ii) Share as CSV: This feature helps to share the records to other devices through various applications in the form of CSV (Microsoft excel format).

  iii) Generate PDF: This feature helps to convert & save the records in the form of PDF.

  iv) Generate CSV: This feature helps to convert & save the records in the form of CSV (Microsoft excel format).

  v) Generate Graph: This feature helps to generate graph on the basis of test records.

  vi) My Files: This feature helps to save the PDF & CSV format records in the application.

  vii) Search: This feature helps to search result by providing ID, Timestamp, Proteins contain level, Month and Year.
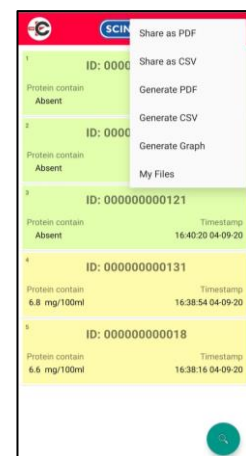
The records generated and shared in the form of PDF and CSV will be saved in "My Files" in the android application and in "File Manager" in smart phone***

- Set Time: This feature helps to set Date & Time on the device through the smart phone.
- Results: This feature helps to show all test results on the smart phone.
    - i) Last Result: This feature helps to show the last test result performed on the device.
    - ii) Last 10 Results: This feature helps to show the last 10 test results performed on the device.


    iii) All Results: This feature helps to show all the test results performed on the device.

    The patient's report generated in Results will be saved in "My Files" in the android application and in "File Manager" in smart phone in the form of PDF ***

- Share: This feature helps to share the results to other devices through various applications like Email, Whatsapp^{TM} etc.
- Additional features **:** After the device is selected , some additional features are there to make the process easy :

    i) Set Firm Name: It helps the user to set a firm /Path lab name which will be printed on the results printed by thermal printer (if purchased).
        The Firm name will appear on the thermal printer's result, PDF and CSV generated and shared***

    ii) Set Device Name: It helps the user to set a device name according to his/her will.
        The Device name will appear on the past connected device list under the device ID***
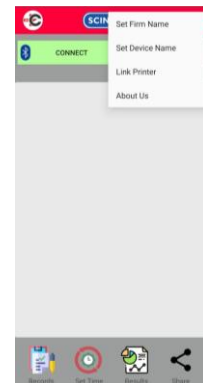
    iii) Link printer: This feature helps the device to link with a Bluetooth thermal printer for an easy and convenient printout service.
        Once the printer is linked to the device, there is no need to link it again***

    iv) About Us: This feature leads directly to the cobweb where one can gather information about the SCINTIGLO device and company as well.
   Refer above photographs attached.

2) **Files**: This feature shows the information and results in the form of PDF & CSV of the devices which were connected to the application.

3) **Buy**: This feature leads directly to the cobweb where one can buy more devices and all the components as well.

4) **Help**: This feature leads directly to the cobweb where clients can ask any questions related to the product.
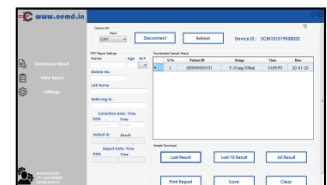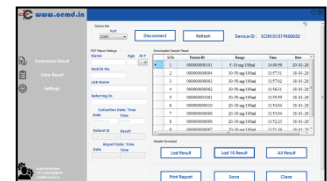
SCINTIGLO Windows Application

How to Connect

Steps:

1) Install the SCINTIGLO application on your system. (Open the software → Press next → Press I agree → Press Install → Press finish).
2) Connect the device SCINTIGLO to your system through data cable.
3) Open the application on your system → Press download result → Press port and select your device → Press connect.
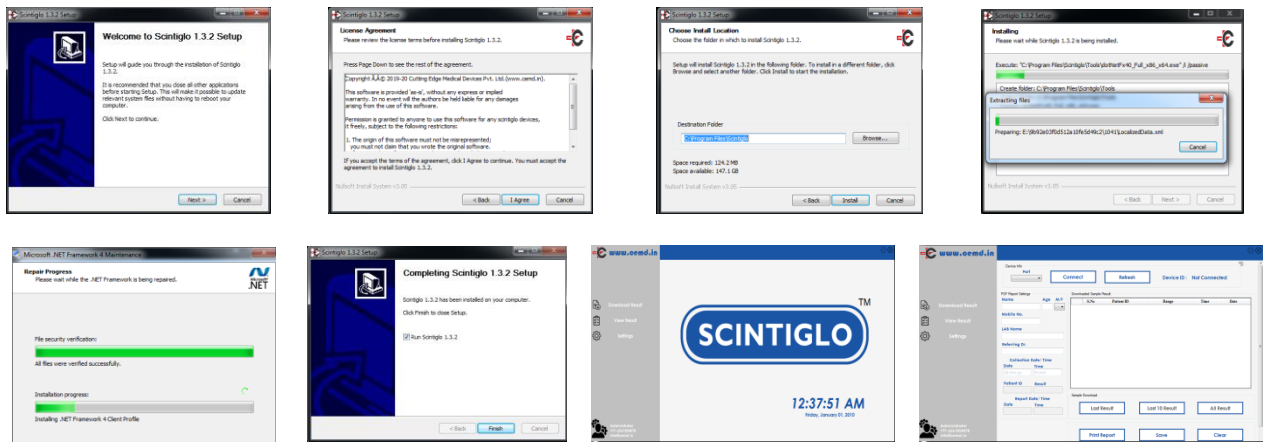
How to Transfer Data

Steps:

1. Connect the device to the PC using the data cable provided with the device.
2. Open SCINTIGLO Windows app and click on "Download Result".
3. Click on the "Port", select the device and click "Connect".
4. Once the device is connected, device ID is displayed on the screen.
5. Select any one of the three options among:

(a) 'LAST READING' will show the latest test reading

(b) 'LAST 10 READING' will list up the last 10 reading of sample

(c) 'ALL' will list up all readings.

6. After selecting the one of the three options, click on "SAVE", give your file a name and choose the file format and save the file in your PC.

How to print

After connecting device SCINTIGLO to the windows application, Press Last result/Last 10 results/All results → then select the result from the list → then press print report.(When you press print report button the application will ask you to save the result first, so save the result and press print button to get a printout).
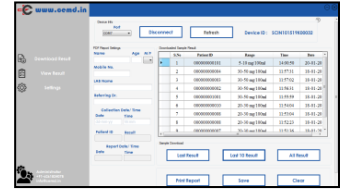
How to Generate Patient's Report:

Open the application on your system, connect the device, Press Last result / Last 10 results / All results → Select the test result → Fill in the patient's details → Press save button to save the report in your system or print button to get a printout of the report you generated.

Functions:

1) **Download result**: This feature helps you to connect device SCINTIGLO to the system. It also shows the Last result, Last 10 results and All results. It also gives the option of saving and printing the results.

- Device Info:
  i)   Port: This feature helps to choose a port of the device.
  ii) Connect: This feature helps to connect the device to the Windows application.
  iii) Refresh: This feature helps to refresh all the ports available.

- Downloaded Sample Result Window: It is an area where Last Result/Last 10 Result/All Result of the device appears.

- PDF Report Settings: This feature helps the user to feed all the patient's details to generate a report.
  i)   Name: Name of the patient whose report needs to be generated.
  ii)   Age: Age of the patient whose report needs to be generated.
  iii) M/F: This option helps the user to select the gender of the patient.
  iv)   Mobile No: Mobile number of the patient whose report needs to be generated.
  v)   Lab Name: Name of the lab where the patient's test has been conducted.
  vi)   Referring Dr: Name of the doctor who's been examining the patient.
  vii) Collection Date / Time: Date and Time of the patient's urine sample when it is collected.
  viii) Patient ID: ID of the patient whose report has been generated.
  ix)   Result: Result of patient's test conducted on the device.
  x)   Report Date / Time: Date and Time of the patient's test when it is conducted.

- Sample Download:
  i)   Last Result: This feature helps to show the last test result performed on the device.
  ii)   Last 10 Results: This feature helps to show the last 10 test results performed on the device.
  iii) All Results: This feature helps to show all the test results performed on the device.
  iv)   Print Report: This feature helps to print a patients report generated.
  v)   Save: This feature helps to save the results and patient's report generated in the system.

The results saved in the system will be in the form of PDF & CSV (Microsoft excel format)***

    vi) Clear: This feature helps to clear the results appeared before in the downloaded sample result.

2) **View result**: This feature helps you to show files of particular results. You can also browse any file by just providing patient's id or any other information.

- View Result File:
    i)   Browse File: This option helps the user to search saved SCINTIGLO files in the system.
    Only CSV formatted files (Microsoft excel format) saved in
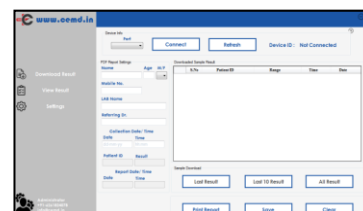
    ii) Search Data: This feature helps the user to search test result by providing Patient ID, Range, Time and Date.
    iii) Search: Press "Search" to search data of the tests conducted on the device.
    iv) Restore Search: This feature restores all the data one has browsed.

- Result File Data Window: It is an area where the browsed results will appear.

- PDF Report Settings: This feature helps the user to feed all the patient's details to generate a report.
    i)   Name: Name of the patient whose report needs to be generated.
    ii)   Age: Age of the patient whose report needs to be generated.
    iii) M/F: this option helps the user to select the gender of the patient.
    iv) Mobile No: Mobile number of the patient whose report needs to be generated.
    v)   Lab Name: Name of the lab where the patient's test has been conducted.
    vi) Referring Dr: Name of the doctor who's been examining the patient.
    vii) Collection Date / Time: Date and Time of the patient's urine sample when it is collected.
    viii) Patient ID: ID of the patient whose report has been generated.
    ix) Result: Result of patient's test conducted on the device.
    x)   Report Date / Time: Date and Time of the patient's test when it is conducted.

- Print Report: This feature helps to print a patients report generated.

- Save: This feature helps to save the results and patient's report generated in the system. The results saved in the system will be in the form of PDF & CSV (Microsoft excel format) ***

- Clear: This feature helps to clear the results appeared before in the downloaded sample result.

3) **Settings**: This feature helps you to set various functions of the SCINTIGLO device.

- Device Info:
    i)   Port: This feature helps to choose a port of the device.
    ii)   Connect: This feature helps to connect the device to the Windows application.
    iii) Refresh: This feature helps to refresh all the ports available.

- Date and Time Settings: This feature helps to update Date and Time of the SCINTIGLO device.
  - i) Update: This option helps to update the Date and Time of the device according to his/her will.
  - ii) Auto Update: This option helps to automatically update the network provided Date and Time on the device.

- Firm Name Settings: It helps the user to set a firm / Path lab name which will be printed on the results printed by thermal printer (if purchased).
  - i) Update: This option helps the user to set or change a firm name / Path lab name.
  - ii) Check: This option helps the user to check whether the firm name has been set or not.
  The Firm name will appear on the thermal printer's result***

Device Memory & Disposal

How to access Device Memory

1. Press the MENU button and select Memory from the options displayed.
2. Select either of the two options shown i.e. Find or Last
3. Selecting "Find" option will ask you to enter the patient ID of which you want to view the result and choosing "Last" will display the latest result.
4. One can browse through the memory by using UP and DOWN buttons.

How to Dispose / Discard

- Dispose the disposable materials like cuvettes, sample etc. as per prevailing norms of Hospitals/Clinics/Pathology laboratories or local authorities.

- End users like lay – persons should discard the cuvette and its cap in dry, non – biodegradable waste after discarding the urine sample in the toilet pan.

- Discard the device as Electronic Waste as per the prevailing local authorities/rules

DO's and DONT's

1. Do not perform test while charging.

2. Do not use Refrigerated/Frozen samples, use fresh samples only.

3. If the sample is refrigerated and needs to be tested then warm the sample in the cuvette to around 30-35ºC (near body temperature, as of the fresh urine) before adding reagent in the special dry heater available.

4. Keep the device lid closed while testing.

5. Cuvette is for single use only. It needs to be discarded after use as per norms.

6. 5 drops of reagent is mandatory for one test.

7. Tighten the cap of the reagent dropper bottle after use.

8. Keep the reagent in a cool, dark and dry place.

9. Don't forget to insert the cuvette in cuvette holder and if you did then the device will start to beep.

10. Use the reagent within 6 months of opening of reagent bottle.

11. Handle the reagent with care avoid contact with eyes or skin, if accidental contact happens immediately wash it with flowing cold water and consult a Doctor if irritation persists and treat like Acid contact.

12. Do not ingest, it may be poisonous. If ingested immediate take medical help and treat like acid ingestion.

Limitation of testing

Not to be used for
1. Turbid
2. Highly tinted (Darkly colored)
3. Blood stain

Probable Sources of Error

1. Low battery
2. Solution temperature too low in case of a refrigerated sample
3. Quantity of reagent added is less than 5 drops as prescribed
4. Open lid while testing
5. Reused cuvette
6. Sample without reagent

Limitation of test procedure

It is a screening device for microalbuminuria, it gives result in different ranges. It is designed to test from 2 mg/dL up to 50mg/dL (1dL = 100 ml) of proteins in spot urine sample.

Handling of the Device and Reagent

- Device should be kept on clean, smooth and flat surface.
- Device should not mishandled as it should not be shaken vigorously, not thrown and do not place near / over hot surfaces like oven, incubator etc.
- Reagent should be stored in room temperature. Do not refrigerate.
- Water should never be added to the reagent
- Please store the device, its accessories and reagent in clean, dry atmosphere.
- To clean the device never use any organic solvents, always clean it with moist swab do not splash or allow any liquids to fall on or in the device or its accessories. All warranties void if any type of fluids enter the device.
- The "Touch Screen" is a delicate and fragile component of the device it is based on the Resistive touch Technology and responds to only one touch impulse at a time.

- The device needs to be charged regularly and if using it after long time of storage. Please charge it with the provided chargers.
- Please use only the provided Charger do not use any other charger of different current or Voltage ratings as this may damage the voltage protection circuitry.
- Do not over-charge the battery. Normally the device gets full charged with in 90 – 120 minutes. Do not charge beyond 2 hours.

The company or any of its allies or representative do not hold any responsibility for any damage loss or injury of any kind to any person directly or indirectly due to improper handling or non-intended usages of the device.

- **Only for human health care use**
- **Only for in-vitro diagnostics use**

Specifications

Assay Method	Nephelometry
Battery Performance	Up to 200 tests on continuous run / 4 hrs. stand-by
Battery Life	1 Year warranty
Power Source	3.7 V, 1200 mAH Li – ion battery, BIS Certified.
Device Measurements (LxWxH)	204 x 132 x 98 mm
Device Weight	510 gm
Measurement Units	mg/dL (1 dL= 100 ml)
Result Range	0 to 50 mg/dL
Sample	Only Fresh Urine
Sample Temperature	Room Temperature (30-35 deg. Celsius)
Testing Time	3-5 seconds
Display	3.5 inches, multi color LCD resistive touch
Memory	100 sample test– Rolling data retained – means last 100 sample test data will be stored
Operating relative humidity	5% to 80% (non condensing)
Operating temperature	5 to 45˚C
Cuvette	Virgin Plastic, single use
Cuvette Cap	Virgin/recycled plastic single use,
Reagent	15 ml (Bottle Capacity: 18 ml) Dropper bottle, self-piercing made with virgin material
Minimum Sample in Cuvette	3 – 3.5 ml
Reagent quantity to add	5 Drops on urine sample in cuvette approx. 250 micro liter
Charger	5V / 1A. SMPS type with 6 months warranty
Printer (if purchased)	2” Thermal Printer with rechargeable battery power.

Symbol References

		Harmful if Swallowed.
		Causes severe skin burns and eye damage.
		Date of Manufacture.
	IVD	In vitro diagnostic medical device.
		Consult instructions for use or consult electronic instructions for use.
		Keep away from sunlight.
		Keep away from rain.
		Separate collection for waste of electrical and electronic equipment.

In case of any complaints or queries please contact

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