

ViewDx

Biochemistry Analyzer



#31, Venkat Reddy Layout, 80 feet road, 6th block
Koramangala, Bengaluru, Karnataka – 560095
<https://spotsense.in>
viewdx@spotsense.in

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ABOUT SPOT HEALTHCARE SOLUTIONS PVT. LTD.

SpotSense was started with the intent of creating non-invasive tests for new-borns but has evolved into a platform of highly accurate point-of-care bedside diagnostics. Our products integrate our technological expertise, minimalism in design and a in-depth understanding of the immune system. Our platform product for sepsis is the first product ever developed especially for new-borns making both NICU and community integration easier.

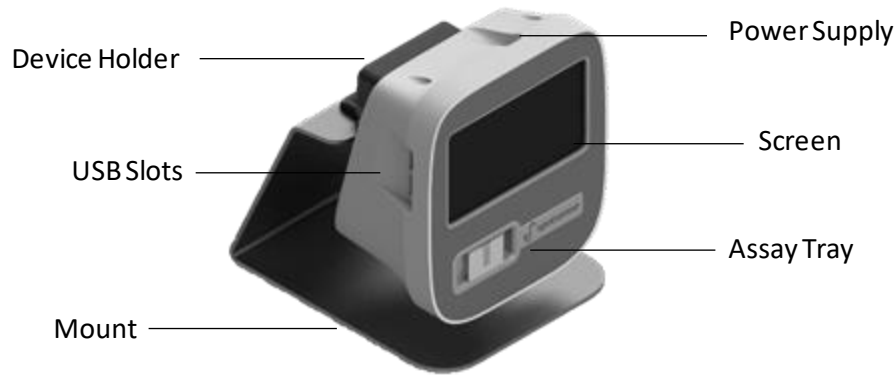
INTENDED PURPOSE

VIEWDx is a compact table-top instrument used for semiquantitative analysis of colorimetric lateral flow assays frequently used in pathology labs for measurement of analytes in human body fluids. The test result is only to be used as an aid in clinical diagnosis. The VIEWDx can be applied to laboratory and point of care testing.

VIEWDx has inbuilt calibration curves for test kits as listed in Appendix A. If calibration support for additional products are required, these can be requested at the time of installation.

INDICATIONS FOR USE

- Installation of the VIEWDx must be performed by following the Quick Startup Guide then proceeding to the on-screen directions
- Carefully attach the device to the provided mount.
- Use a provided Power supply adapter and connect it to the device.



TECHNICAL SPECIFICATIONS

Model	VIEAS
Part Number	SEA001
Throughput	One test at a time
Inbuilt Test Menu	Refer to Annexure A
Light Source	White Light
Calibration	External calibration not required. Calibration Id per test type and batch should be generated by the user.
Dimensions	148mm x 164mm x 950mm
Power Supply	Adapter Input: 150 – 240V, 0.3A Device Input: 5V, 3A
Weight	700 Grams (without mount)
System Module	Raspberry Pi 3B+
Language	English
Test Analysis Mode	Reflectance Photometry
Connectivity	Wi-Fi and USB

PRODUCT DESCRIPTION

VIEWDx can be a benchtop device or as a bedside diagnostic device. Reagents may be stored within the device or reagent strips may be inserted into a slot. External components typically include a tray and onscreen keypad or touchscreen display, and ports to connect to a printer, external keyboard and mouse. Internal components include a light source and camera to analyze the sample.

PRINCIPLE OF USE

VIEWDx is a camera-based quantitative lateral flow assay reader that utilizes image processing techniques to precisely obtain the colour signal data, calculate the concentration, coeff. of variation and stores results based on date and requisition id, for retrieval at a later date.

DIRECTIONS: Once the sample is added to the Lateral Flow assay and control and test lines have developed without any significant background:

1. The assay is to be inserted in the tray slot of VIEWDx
2. The application is to be started in Test Run Mode
3. The test id is to be entered. Patient Id can be added or skipped.
4. Once the test is read, results will be displayed on the final screen.
5. The result can be saved or exported for further distribution.

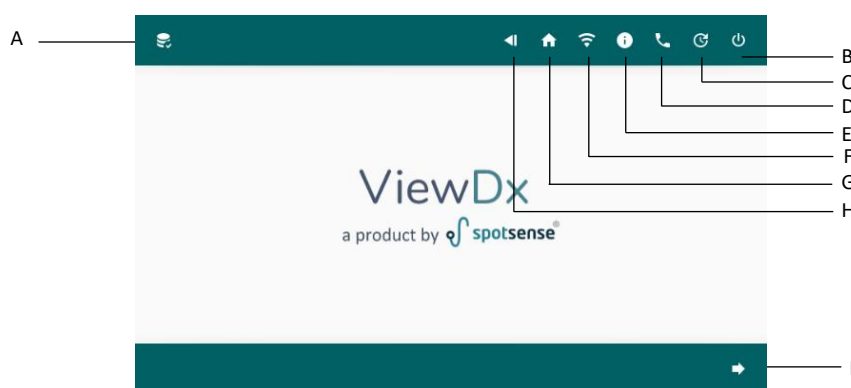
WORKING PRINCIPLE

The combination of the antigens in the sample, the gold-label antibody in the colloidal gold pad or nitrocellulose membrane, and the antibody pre-coated on the test line can form a purplish red streak on the test line. The colour intensity of the test line is proportionate to the quantity of antigens detected in the sample. The analyzer system can obtain a colour-based signal intensity of the complex by scanning the test strip. Then the intensity peaks across the strip are plotted and analyzed. The peak heights have a linear relationship with the antigen concentration in detectable range which can be used to calculate the antigen concentration. The relationship has been established for different measured parameters in our application notes.

In conclusion, the antigen concentration in whole blood, plasma, serum, urine or saliva can be calculated quantitatively in one-step according to the colour intensity of the test line.

INSTALLATION

1. Take VIEWDx out of the box and put it on a table of other flat surfaces. Avoid dusts, vibrations, noises and power interferences, direct sunshine, hot sources and wind.
2. Use the power adapter provided within the box. Only use adapter having:
Input: 150 – 240V AC, >0.3A, 50/60Hz
Output: 5V DC, >2A
3. Each device comes with a unique device identification number.
4. As the device starts, it will check its hardware components automatically. After self-check is finished, the system will launch the application and enter the main screen.

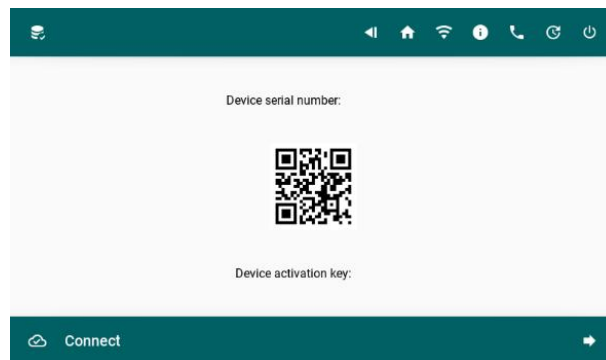


- A Result History Button
- B Shutdown Button
- C Update Button
- D Technical Support Button
- E Device Information Button
- F Wi-Fi Button
- G Home Button
- H Universal Back Button
- I Universal Forward Button

5. At this point the device checks for Wi-Fi connection, internet availability and software updates.

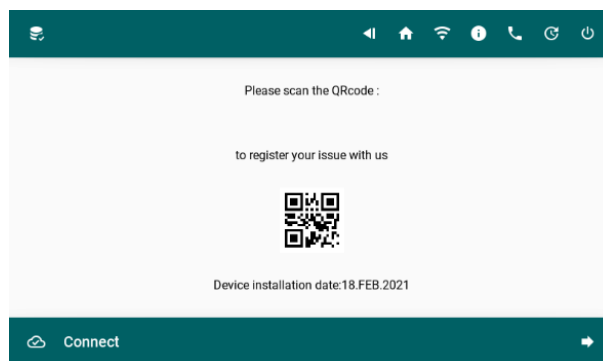
DEVICE INFORMATION

This screen shows the device identification number, device passcode and along with a QR code for DMS Portal (<https://dms.spotsense.in/>).



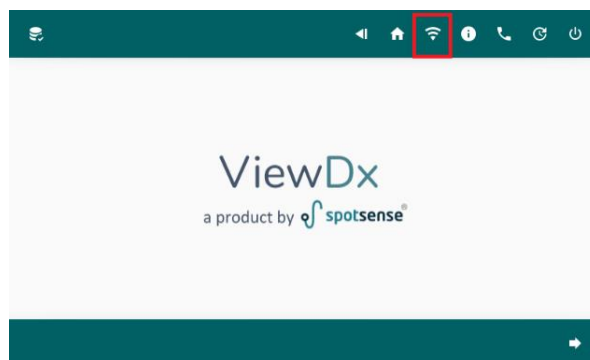
TECHNICAL SUPPORT

This screen shows a QR code for technical support. So that users can report any issues to the technical team.

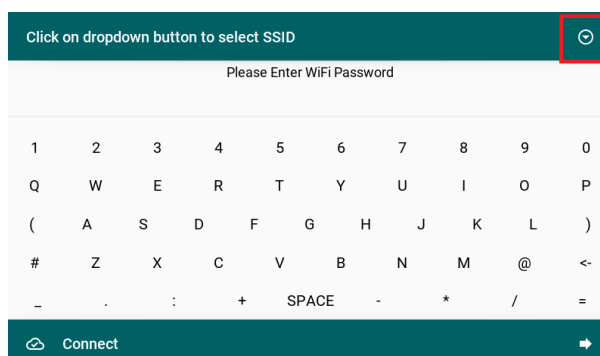


CONNECTING TO WIFI

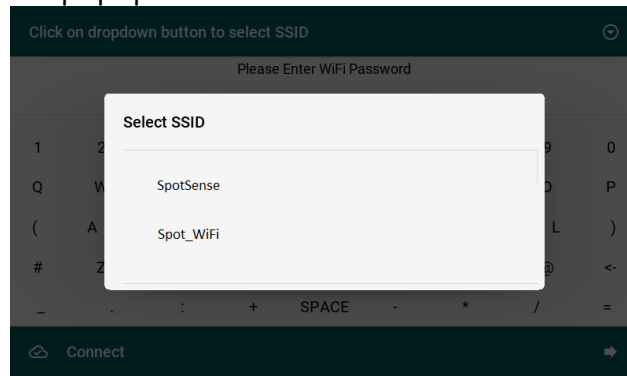
1. Go to Wi-Fi screen by clicking on the Wi-Fi icon button either on the home screen or any other screen with top navigation bar.



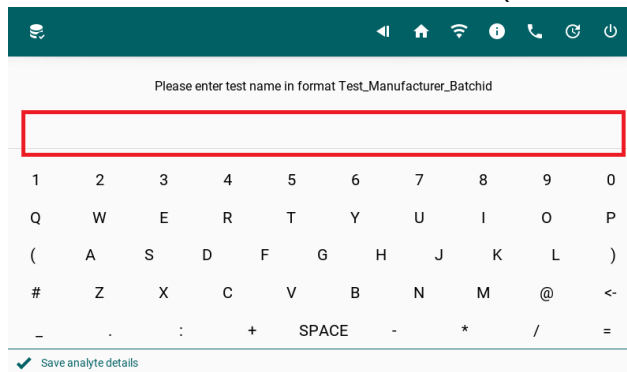
2. Click on the Dropdown menu (top right) to select Wi-Fi SSIDs.



3. Select desired SSID from the popup list.



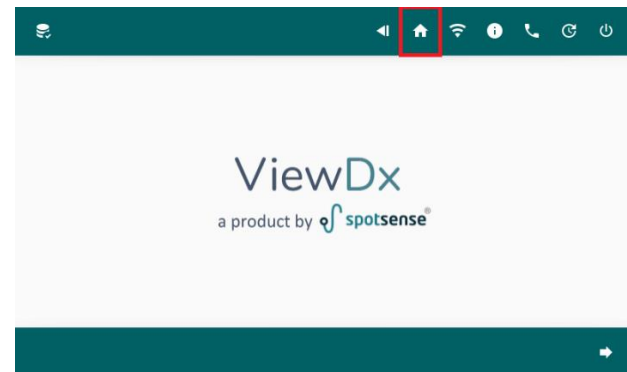
4. Next enter the Wi-Fi Password and click the connect button (bottom right).



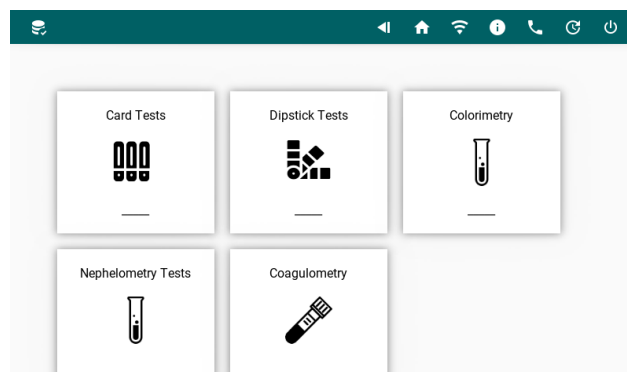
Note: Connecting to Wi-Fi is optional. But limits some functionalities, data storage is limited to local database and OTA Updates will not be available.

CALIBRATION

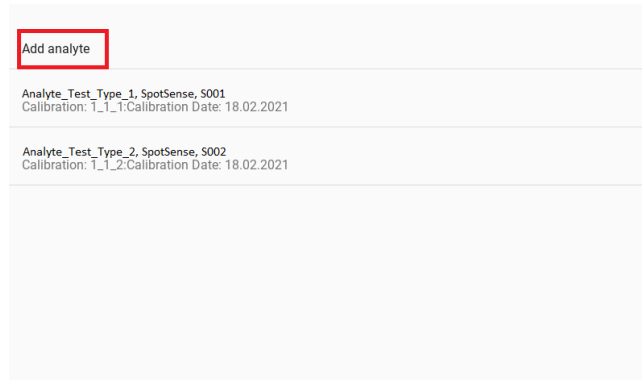
- Go to Home Screen by clicking Home Screen button in navigation menu.



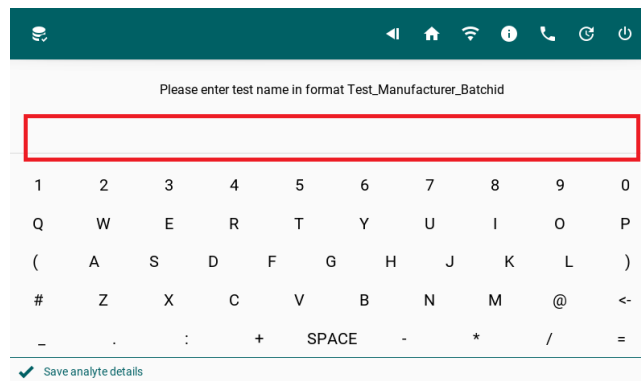
- Select Test Type from Home Screen.



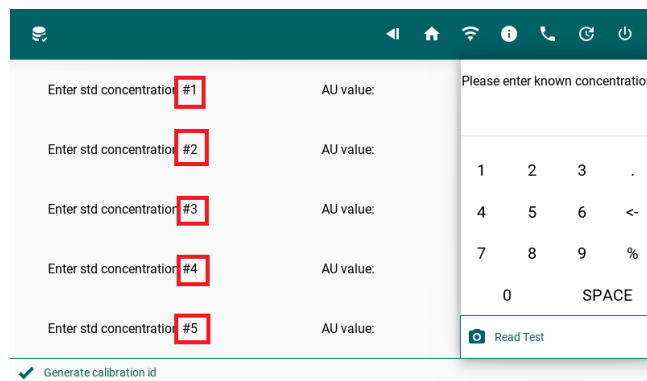
- Click on Add analyte.



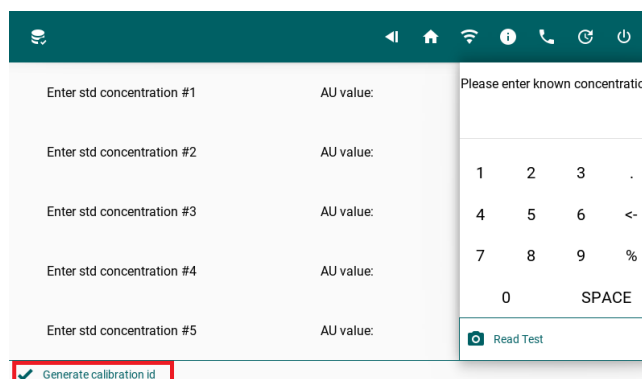
- Input the requested information Test Name, Manufacturer and Batch ID. Each value separated with under scroll (_), such as CRP_Spotsense_S0112.



- Enter up to 5 known concentrations to calculate au values respectively.

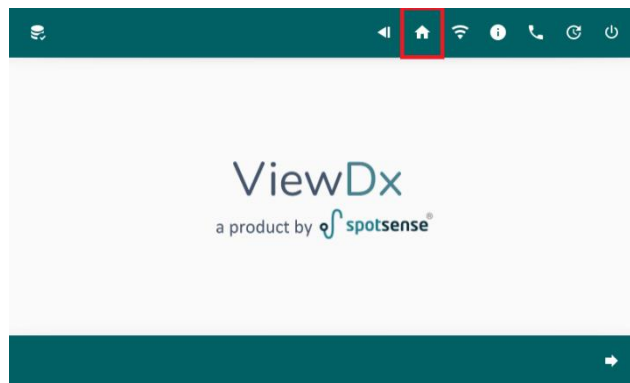


- Finally click on the Generate calibration Id button to get calibration id.

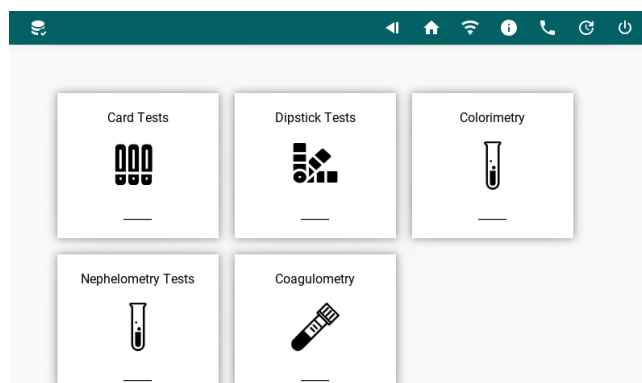


TESTING

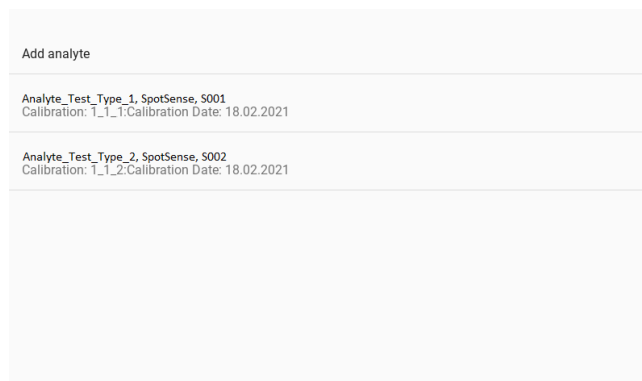
- Go to Home Screen by clicking Home Screen button in navigation menu.



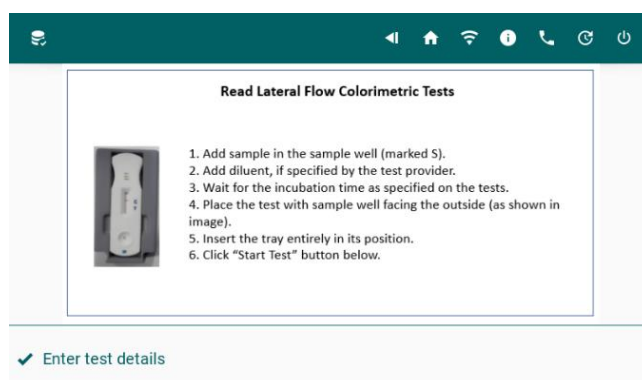
- Select Test Type from Home Screen.



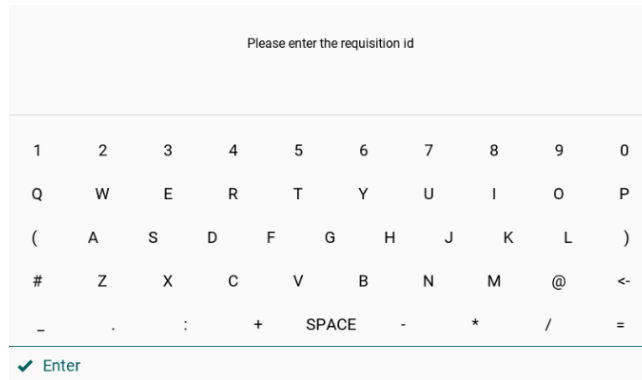
- Choose the required Analyte.



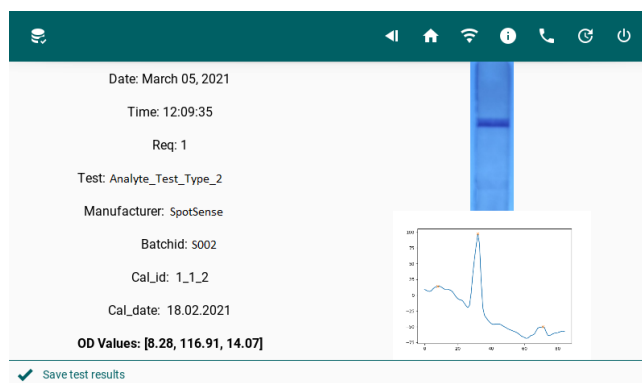
- Follow the displayed instructions and click on Enter test details button.



- Enter Requisition ID for that test and continue.



- On the next screen, it displays the test details – Date, Time, Requisition ID, Test Type, Manufacturer, Batch ID, Calibration ID, Calibration Date & Test Readings along with strip and peaks image.



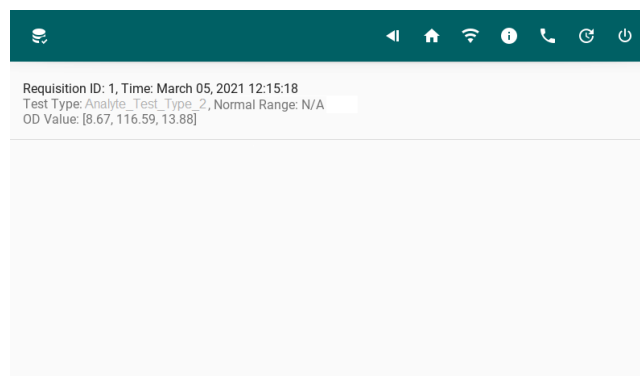
- If satisfied with results, click on Save test results to save data to database and generate PDF.

DATA STORAGE

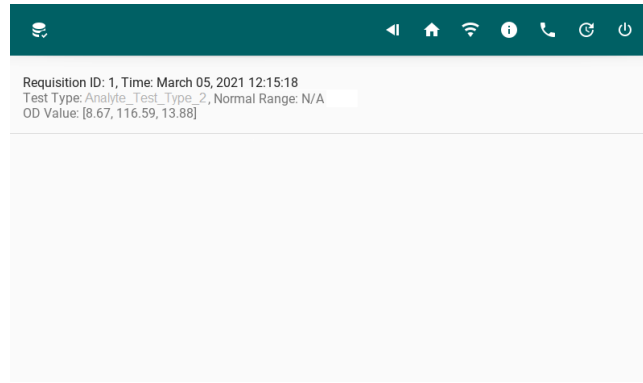
Each and every VIEWDx device stores the data in two different databases, one is local (within the device) and other is in the cloud. Users can have complete control over where to store their data. Storing data to the cloud requires the user to be connected to Wi-Fi with internet connection. Users can retrieve, view, delete and can take other actions from the device as well as in DMS Portal (<https://dms.spotsense.in/>), along with an option to sync the local data to cloud storage.

RESULTS HISTORY

To view the saved test data from both the local database and cloud, click on the **Result History icon button** (top left).



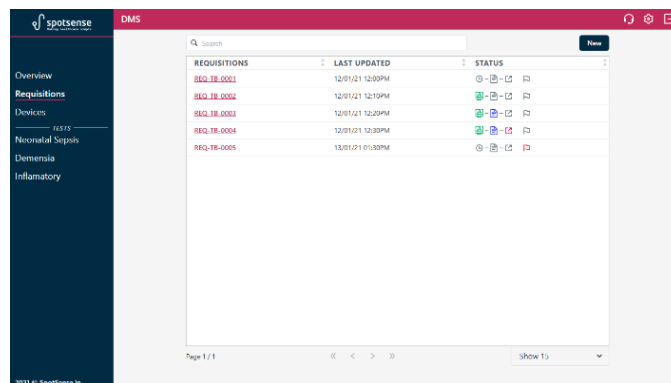
Clicking on an individual item from the list, takes to a new screen with additional options.



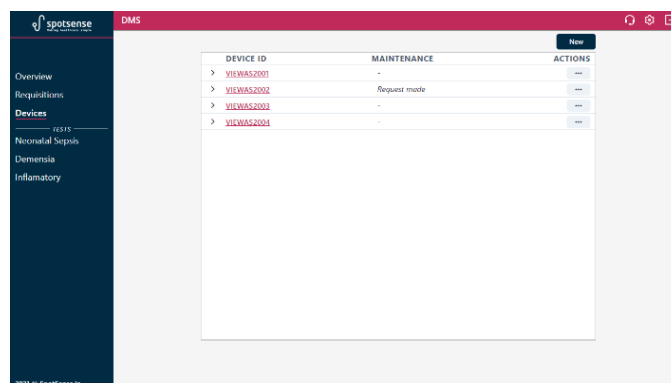
DEVICE MANAGEMENT SYSTEM (DMS) PORTAL

DMS is an online web portal where users can login and manage their device data. Online portal provides some useful functionalities, such as

- Remote monitoring and managing of all devices.
- View requisition/report current status.
- Accessing test data and taking necessary actions.
- Provides signing and printing option for test reports.
- Technical support functionality
- Tests to perform (Neonatal Sepsis, Dementia, Inflammatory)



Requisitions/Tests Monitoring in DMS



Device Management in DMS

CAUTIONS AND WARNINGS

ELECTRICAL

- NEVER insert the power plug into power sockets other than AC100-240V.
- Avoid damage to the power cord. Unplug by gripping the plug NOT by pulling the cord.
- If the VIEWDx emits unusual odours or smoke, switch the VIEWDx off, unplug the power cord and contact the Spot Healthcare Solutions personnel immediately.
- Do not spill fluids on or inside the VIEWDx. Do not place metal objects such as staples or paper clips on the VIEWDx as these could cause a short circuit.
- In the event of a short circuit switch the VIEWDx off, unplug the power cord and contact the Spot Healthcare Solutions personnel immediately

BIOHAZARD

- All parts and surfaces of the VIEWDx as well as assays, strips and contents must be regarded as potentially infectious due to its contact with blood.
- Use protective lab coat, disposable gloves and mask when operating or maintaining the VIEWDx.
- NEVER touch the VIEWDx, accessories or waste fluids with bare hands.
- Should you inadvertently come in contact with potentially infectious materials or surfaces immediately rinse the affected skin area thoroughly with water and follow your facilities prescribed cleaning and decontamination procedures.
- After completion of work with the VIEWDx wash your hands thoroughly with soap and water or a disinfectant hand cleanser.

TERMS AND CONDITIONS

Terms and conditions of Use

The device must be used in accordance with the instruction manual and due training should be provided by the purchasing party to their employees or the user. Any changes made to the custom software or any installations performed outside of the custom software will void the device warranty and the manufacturer shall not be liable for product failures.

Integration of Test Panels

No physical alterations should be made to the device for integration of test panels and the device should not be dismantled at any cost. In case of dismantling, the manufacturer shall not be liable for any product defects and subscription to the device management system will be discontinued.

Design Copyright

The device design is copyrighted to SpotSense and should not be replicated, reformed, relabelled or disfigured under any circumstances.

Changes

SpotSense reserves the right to make design and functionality changes to the product, subproducts and support systems. Any such changes will be made available in the public domain. SpotSense also reserves the right to discontinue a product or service without individual notice to each customer

Jurisdiction

Any disputes arising out of this Agreement shall be referred to the Sole Arbitrator appointed in accordance with the Rules of Arbitration and Conciliation Act, 1996 ("Rules") to which both the Parties agree. The decision given by the Arbitrator shall be final and binding upon the Parties. The Arbitration proceedings shall be conducted in English language and venue of such Arbitration shall be at Bangalore. Costs of the Arbitration shall be borne by the Party against whom the Arbitrator decides.

Document Number: IFU-V01
Revision Number: 1
Revision Date: 15 March 2021

For any technical assistance or training requirements, please write to us at viewdx@spotsense.in.

MANUFACTURER DETAILS

Spot Healthcare Solutions Private Limited

#31, Venkat Reddy Layout, 80 feet road,
Koramangala, 6th Block, Bengaluru,
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