A Mesa Labs company

SmartHDM User Manual

Renal Care Technician Meter

MesaLabs

Foreword

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The screenshots in this manual are for illustration purposes only. The design on your screen may differ from the illustrations in this manual.

Revisions

Version	Date	Author	Remarks
1.0	*20.05.20*	Werner Pfingstmann	Initial Version P/51/40/25/40/10/30
1.1	*24.07.20*	Werner Pfingstmann	Safety instructions modified
1.2	*01.09.20*	Werner Pfingstmann	Safety instructions modified
1.3	*25.11.21*	Werner Pfingstmann	Minor corrections
1.4	*18.07.22*	Werner Pfingstmann	Minor corrections
1.5	*14.11.22*	Werner Pfingstmann	HDU Pressure correction, UKCA added
1.6	*24.02.23*	Werner Pfingstmann	HDM Module updated
1.7	*01.05.26*	Heidi Cha	Updates to product offering and features

Note: This user manual is applicable to software version 1.1.0

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Safety Instructions

For patient and operator safety, you must read, understand, and follow the safety instructions below before using this device..

SmartHDM is a medical device in the USA when used in conjunction with hemodialysis machines. In this case, only use the **Mesa SmartHDM-510** application version. International and in non-medical applications in the USA, you can use the **Mesa SmartHDM** version with extended functionality.

- Please read this User Guide in its entirety before using the SmartHDM/ SmartHDM-510 System.
- Review the complete user manual of the devices that the SmartHDM/ SmartHDM-510 System will be used in conjunction with.
- Keep away the device from unauthorized persons.
- Never use the SmartHDM/ SmartHDM-510 System on a dialysis machine to which a patient is connected.
- Never use the SmartHDM/ SmartHDM-510 System on a dialysis machine with a connected battery charger.
- Never use the SmartHDM/ SmartHDM-510 System in place of the hemodialysis machine's primary sensors.
- Operate the instrument only in a dry environment, and do not touch it with wet hands.
- Allow the system to acclimate to temperature.
- Ensure that no fluids intrude into the interior of the device or the sockets.
- Verify accurate function of the meter before taking measurements or whenever inaccurate readings are suspected.
- In case a measuring value does not change (potentially frozen), the sensor should be checked.
- In the event of a significant discrepancy between the measured value and the expected value, the sensor must be factory calibrated.
- Prevent electrostatic discharge on the connectors. This can lead to substantial damage to the SmartHDM/ SmartHDM-510 device and devices under test. Make sure the device is wholly discharged before touching the connectors or cables connected to the instrument.
- Only adjust the SmartHDM/ SmartHDM-510 System if you have understood the consequences to their full extent. Use only the recommended standards later in this manual.
- Do not use abrasive cleaning agents and/or full-strength bleach or acid to clean SmartHDM/ SmartHDM-510 System or the electrodes as this will cause damages.
- To avoid cross-contamination, disinfect sensors and modules that have been in contact with liquid regularly. We recommend the use of different sensors for use in conjunction with infected and non-infected dialysis machines. Mark the sensors accordingly to avoid confusion.
- Restart the SmartHDM/ SmartHDM-510 software on a daily basis to ensure the integrity of the database.
- In order not to overload the Android display module, do not connect more than ten sensors or modules. If the display module becomes too slow, reduce the number of sensors and modules.
- Devices with a battery do not arrive fully charged. The battery must be charged for at least two hours before use.
- Be careful when using headphones or speakers. Overuse can damage your hearing.
- Ensure that all sensors and sensor modules have valid calibration certificates.
- Prevent mechanical overstraining of electrical wires.
- The SmartHDM/ SmartHDM-510 system is not intended to be used in residential areas and cannot adequately protect radio reception in such environments.
- Do not open any SmartHDM/ SmartHDM-510 device. Repair may only be performed by IBP, Mesa Labs or an authorized service.

Table of Contents

1. Introduction

The SmartHDM System is a modular product family of highly accurate sensors designed for use by hemodialysis professionals to measure and display readings of the dialysate fluids used in hemodialysis machines. Any combination of sensors may be used. Only one display unit is needed.

This documentation describes the installation and use of the SmartHDM System. The description includes:

- Display (Android Operating System)
- SmartHDM Software
- HDU Sensors for Conductivity/Temperature, Pressure, Flow and pH

1.1. Intended Use of the SmartHDM System

The SmartHDM system is designed to be used in the biomedical, laboratory and environmental applications. Do not use any part of the system in life support applications.

1.2. Intended Use of the SmartHDM-510 System

The SmartHDM-510 System may be used by hemodialysis personnel to test the conductivity, temperature, pressure, pH and flow of the dialysate solution used with hemodialysis delivering systems.

The SmartHDM-510 system may also be used to test the conductivity/temperature and pH of acid and sodium bicarbonate dialysate concentrates and water used in hemodialysis applications.

The intended use is limited to periodic use for installation and maintenance of hemodialysis delivering systems and does not include the daily monitoring of hemodialysis delivering systems prior to treatment.

1.3. Declaration of Conformity

EC DECLARATION OF CONFORMITY

We with this declare that the following products conform to the below mentioned European Directive

Manufacturer **IBP Medical GmbH**
Ikarusallee 15
30179 Hannover, Germany

Products	**HDC84**	Display- and Control Unit
	HDU-CDTP	Conductivity/Temperature Sensor
	HDU-PRS	Pressure Sensor Family
	HDU-FL	Flow Sensor Family
	HDU-PT100-I	Interface for Pt100 Temperature Sensors
	HDU-pH-I	Interface for pH-Sensors
	HDU-PHPT-I	Interface for pH-Sensors and Pt100 Temperature Sensors

2004/108/EC

2006/95/EC

EN 61326-1

EN 61000-4-2:1996

Hannover 10.07.20

John Sakys
(Managing Director)

UK DECLARATION OF CONFORMITY

The certificate is available at:
www.ibpmt.com\d_pdf_general\UKCA Confirmation_EN.pdf

2. SmartHDM Overview

The SmartHDM system is a new approach to combine a family of intelligent sensor modules and interfaces with a smart Android device for measuring, testing and quality control.

The SmartHDM System includes:

+ HDC Display
+ SmartHDM Software
+ HDU Sensors and Sensor Interfaces

2.1. HDC Display

The HDC display comes pre-installed with the SmartHDM app.

The HDC display devices were developed for everyday use and feature:

+ Four USB-A interfaces for sensors
+ Robust housing for durability
+ Large battery for extended battery life with connected sensors
+ Bluetooth capabilities to connect with sensor modules

2.2. HDU Sensors

The HDU sensors and sensor interfaces are a product family of intelligent sensors that may be used by hemodialysis personnel to test the conductivity, temperature, pressure, pH and flow of the dialysate solution. These sensors may be used with any brand of dialysis machine.

3. HDC Display

3.1. HDC84 Overview

The HDC84 is a smart tablet device with an Android operating system. The USB hub has four USB-A ports to directly connect sensors or modules.

The buttons on the front of the device operate similarly to those on a standard Android device.

Speaker volume

Shows the main menu.

A short press shows the home screen. Long press shows the running apps.

Returns to the last screen.

F1 selects the SmartHDM List Screen F2 selects the SmartHDM Graphic Screen

Device ON/OFF

USB Interface

USB interface for the connection of sensors and modules

Pole Clamp

The pole clamp allows the device to be attached to an infusion pole or may be used as a stand for the device. Push the pole clamp into the mounting holes on the back of the HDC84 and lock it in place. The clamp itself may also be turned.

Charging Port

The USB-C charging port may only be used to charge the device. The USB-A Hub may not be used while the device is charging. The HDC84 must be turned off during charging.

For safety reasons and to ensure that the device recharges quickly, only the power supply that comes with the device may be used for charging.

The power supply is Quick Charge™ 3.0 compatible.

3.1.1. Technical Data

Screen:	8.0 inch Corning Gorilla IPS capacitive touch screen, 1280*800px
Memory:	64 GB Flash Memory, 4 GB RAM Supports TF card up to 128GB
OS:	Android 10
Cameras:	5 MP front camera 13 MP autofocus rear camera with flashlight
Interface:	4 x USB-A for Modules, Sensors and Interfaces, 1 x USB-C for charging only
SIM card:	Dual SIM card dual standby
Band:	2G: GSM850/900/1800/1900MHz, EVDO:BC0 3G: WCDMA: B1/B2/B5/B8, TDSCDMA: B34/B39 4G: FDDLTE:B1/B2/B3/B4/B5/B7/B8/B17/ B20/B28, TDDLTE:B38/B39/B40/B41
Degree of protection:	Android Device: IP68 USB Hub: IP0X
Power supply:	3.7 V / 8000 mAh 1S2P removable Li-ion polymer battery, Quick Charge 3.0 compatible
Operation time:	Approximately 8-10 hours from 100% to switching off screen set to 50% brightness, while one HDU-CDTP Sensor connected and active
Environmental conditions:	**Operating Temperature Range:** 0 to 50°C Storage **Temperature Range:** 0 to 50°C **Operating and Storage Humidity:** 85% max relative humidity non-condensing from 0 to 50°C
Weight:	0.75 Kg
Certification:	CE, FCC ID: SY4B01012
Accessories:	USB charger USB-C cable Holding clamp (Richter standard)

4. SmartHDM Sensors and Interfaces

The SmartHDM System has a broad selection of HDU sensors and interfaces to support measurement of various parameters.

4.1. HDU Sensors and Interfaces

HDU Sensors are a product family of high precision sensors for the testing and calibration of dialysis machines.

HDU-CDTP	Conductivity/Temperature Sensor
HDU-PRS	Pressure Sensor Family
HDU-FL	Flow Sensor
HDU-pH-I	Interface for pH-Sensor

5. Android OS

The SmartHDM HDC84 displays are based on the Android operating system.

The Android OS (operating system) quick start guide may be found by opening the Google Play Store on your Android device and searching for 'Android quick start guide'.

5.1. Keep Android Updated

To keep your system up to date, you need to set up a google account for your Android device.

For this you need a WLAN connection to an Internet access. Please ask your network administrator for the access data.

You can access the settings via *Settings > Network & Internet > WiFi*

6. SmartHDM Software

6.1. SmartHDM Installation

The latest version of the SmartHDM app is available through IBP/ Mesa Labs..

If you want to change the overall size of the display on the SmartHDM screen, try adjusting the display in the Android settings under 'Display/Screen Zoom' or 'Display/Screen Size' to suit your needs.

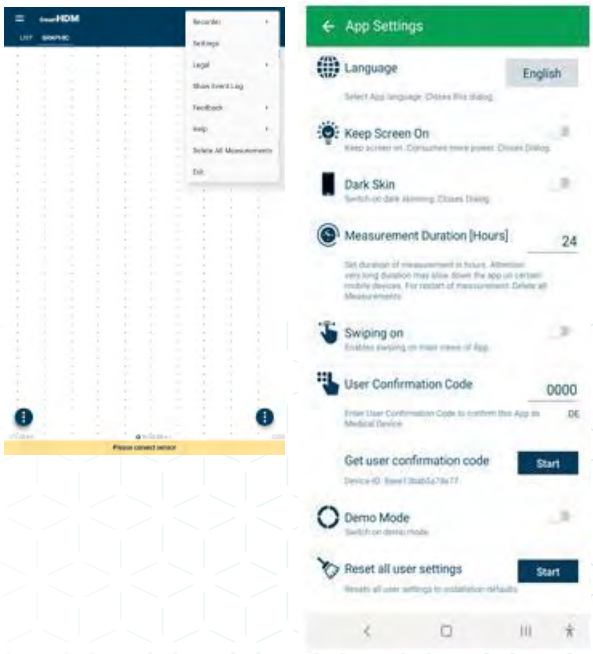
7. Medical Device

SmartHDM is a medical device in the USA when used in conjunction with hemodialysis machines. In this case, only use the **Mesa SmartHDM-510** version.

7.1 SmartHDM versus SmartHDM-510

The SmartHDM-510 software has been modified to comply with FDA requirements. These modifications include:

+ Installed only on HDC84
+ Data acquisition up to 1Hz
+ Language available only in English
+ Calculation and demo mode not available



8. SmartHDM General Use

The SmartHDM app displays measurement values from HDU sensors, both digitally and graphically.

8.1. General Functionality

Control Bar - Provides access to system settings and display configuration options

LIST | GRAPHIC | +
+ allows the user to activate calculation mode or add Bluetooth devices or Bluetooth connections of found devices.

To configure the display to match the image shown on the left, please follow the instructions below:

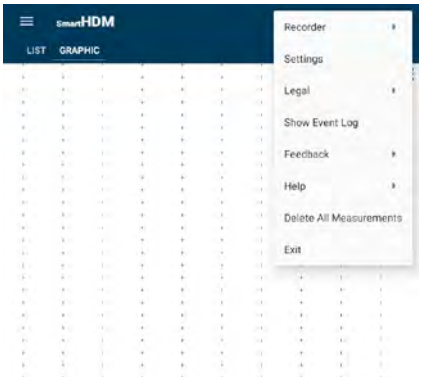
Open the Android Settings

Select *'Display'*

Select *'Front and screen zoom'*

Change *'Screen zoom'*

8.2. Control Bar Functionality



Basic Setting
By pressing the three dots on the upper right hand corner, basic settings can be accessed.

Recorder – to access sub-menu for recording function.

Settings – to open basic settings for SmartHDM.

Legal – to view version information, Terms & Conditions, Privacy Policy.

Show Event Log – to access complete list/ log of events.

Feedback – to share action log with developer in case of software issues/ malfunction.

Help – to access *'Quick Reference'*, *'User Manual'*, Mesa Labs/ IBP website.

Delete All Measurements – to delete all recordings and measurements stored on device.

Exit – to end all measurements and terminate the program.

List Menu
By pressing the three lines icon on the upper left hand corner, list screen settings can be accessed.


Drag and drop to change the order of a sensors in the list.


Click to change the height of the display.


Click to hide a sensor display.


Change sensor display to a graphic.

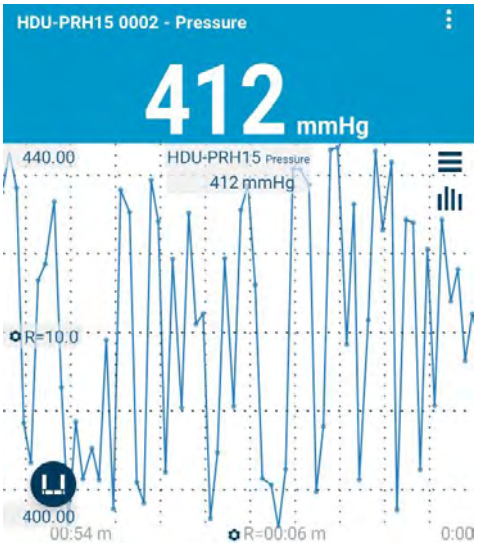
8.3. List Display Functionality

In this view, readings of the connected HDU sensors are displayed in a list format.

Element
This readout tile is a one value display without any additional functionality in the display area.

This is a two value display.
Here the upper value is the accumulated amount.

Here 'Dialysis Machine Standard' shows the selected conductivity temperature compensation coefficient.

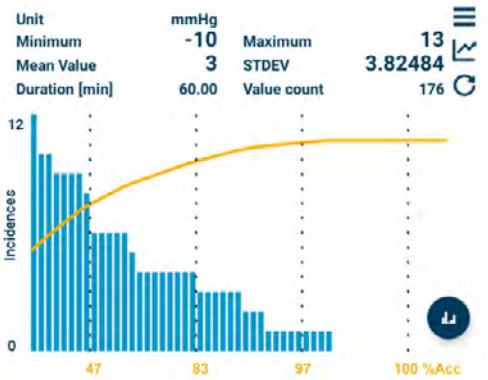


By touching anywhere on the value field, graph for this measurement value will open.

Settings of the graphs

Switches to the statistical view

Switches to "Full-time Axis"



Statistics
Use the horizontal lines to change the Graphics Settings
Switches back to the Graphic View
Starts a new statistical calculation

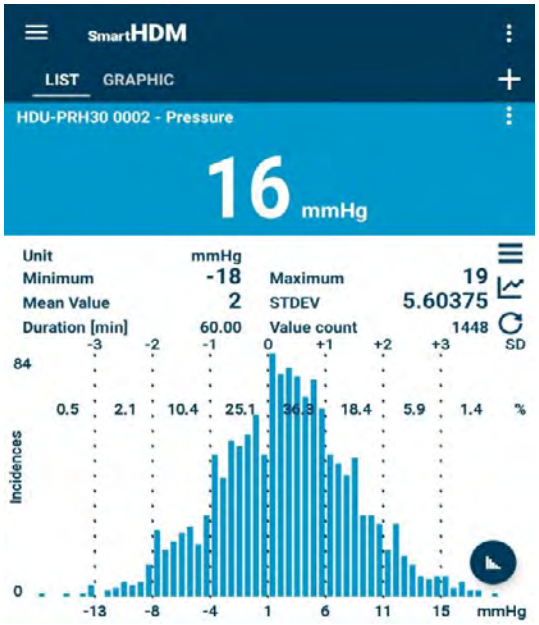
The Pareto distribution allows an assessment of the measured value stability

Switches to the histogram view

Shows settings for the particular sensor.

Interpretation of Diagrams

SmartHDM offers two different diagrams to assess measurement stability. Both diagrams provide statistical values for consideration.



This diagram shows that the value fluctuates around 0 mmHg.

Histogram

Settings

Return to graphic view

Rebuilds the diagram

Switch to Histogram

The statistic shows:

Minimal and maximal values (Unit)

The mean value (Unit) and the standard deviation (STDEV) Measuring duration (min) and the number of values

The upper scale in the diagram shows +/3 STDEV The second scale shows the percentage distribution. The bottom scale shows the +/- measuring values

The diagram shows that 83% of the values fall to the left of the second vertical line.

Pareto distribution

The corresponding pareto diagram looks as follows.

The statistic values are identical.

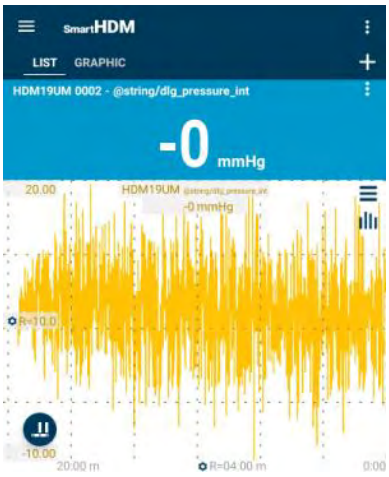
The blue bars represents a sorting according to the numbers of identical measured values.

The yellow line with the yellow x-scale gives the accumulated values in % which are to the left of the different percentage display.

Diagram Samples

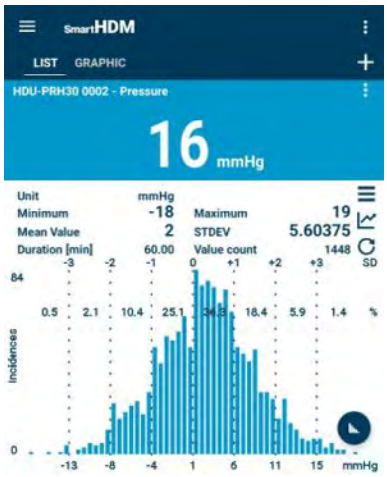
Sample 1

Measuring graph



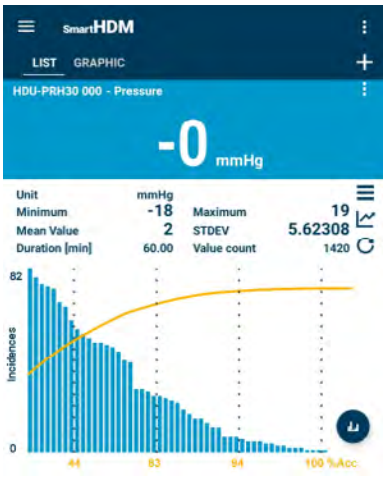
The graph shows that the measured value fluctuates significantly around 0 mmHg, within a range of ±20 mmHg.

Histogram



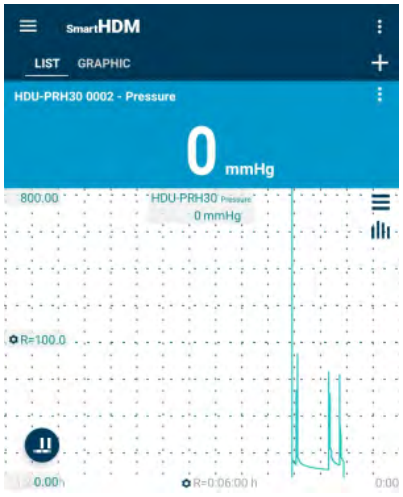
The histogram illustrates the fluctuations, ranging from −18 to +19 mmHg.

Pareto distribution

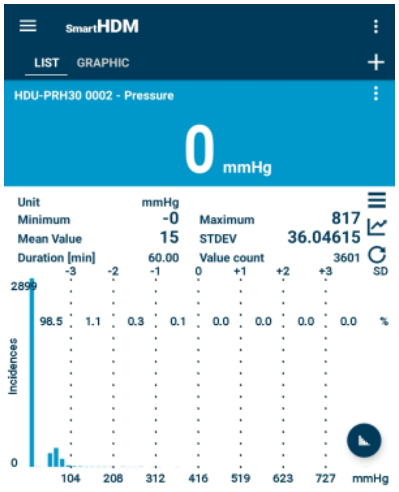


The yellow line here shows how an unstable measurement is shown in the Pareto diagram.

Sample 2



The graph shows that most values are at 0 mmHg, but a few outliers can be seen.



The histogram indicates that the majority of values are 0 mmHg, with a maximum outlier of 817 mmHg.

The yellow line shows how a stable measurement appears in the Pareto diagram.

8.4. Add Devices and Calculation Module

Opens *'Add Devices or Modules'* menu

Select compatible Bluetooth devices to add. Ensure Bluetooth is enabled on your device to view on this list.

Select a calculation module to add to the list view.

***Note**: Calculation module function is not available in the **SmartHDM-510** version.*

Create a new calculation module

8.5. Calculation Module

Change or set the name of the calculation module

Select the color of the view of the calculation module in the list view.

Set the decimal places and the unit of measurement.

Select a sensor or other module value to include in the calculation.

Select desired calculation functions.

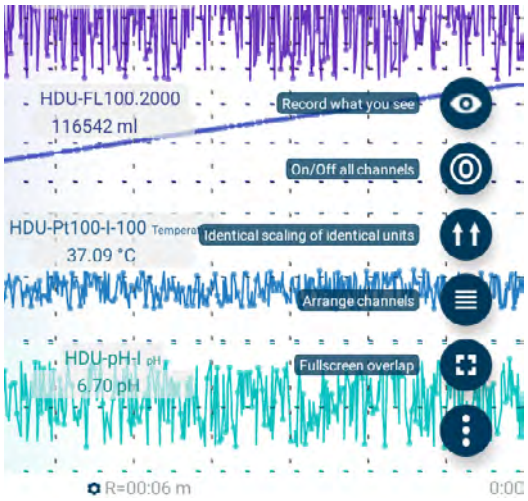
Enter desired formula.
Press *'ENTER'*.

Displays the status of the logic check of the formula.
Automatically validates after pressing 'ENTER'.

Deletes this calculation module.

8.6. Graph Display Functionality

In this view, readings of the connected HDU sensors are displayed in a graph format.



Gesture functions

To move a graph manually and overlay it on another, press and hold the graphic in the far left or far right corner (depending on the position of the Y-axis options, identifiable by the color gradient).

To zoom in on the time scale, use a pinching motion.

Swipe left or right to scroll through the time scale (if swiping is not disabled in the main app settings).

Control Bar

Zoom in or out for all plots.

Access graph settings

Set the plot line width in the graph to thin, normal, or thick.

Choose which measurement points are shown in the graph.

Enable or disable the color gradient on the Y-axis.

Change the sample rate for all devices.

Define the range for statistical evaluation.
(in *'Minutes'* or *'Stored Values'*)

Click on the three horizontal lines icon to access graphic screen setting.

Touch and drag to set the display order of channels in the graph.

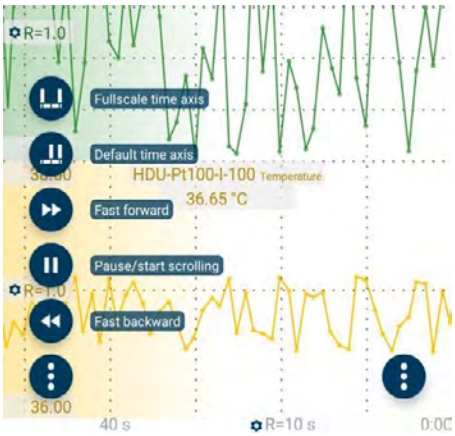
Enable or disable a channel to be graphed

Use this option to toggle the position of the Y-axis gradient *(if enabled in the graphic settings)*.

Access Y-scale setting.

Function Buttons

Press the three dots button on the lower left hand corner to access the following commands:



Shows the total measured values

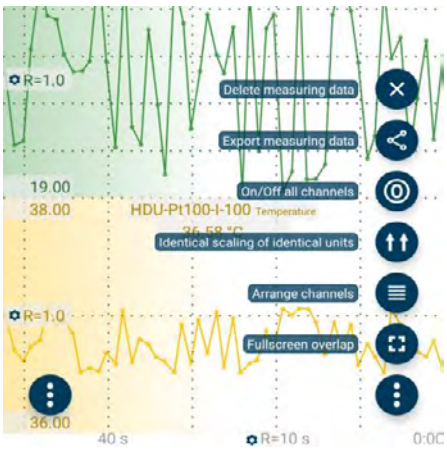
Sets the timeline to a default value

Scrolls the measurements forward

Stop the automatic scrolling and display a slider for scrolling

Scrolls the measured values backward

Press the three dots button on the lower right hand corner to access the following commands:



Deletes all measurement data

Leads to the export measuring data

Turn data acquisition ON / OFF

Sorts channels with identical units from one another

Arrange the order of the channels.

Enter full screen mode.

Identical scaling of identical units

If you like to have measuring channels with identical measuring units with the same scaling, press the three dots button on the lower right hand corner button choose *'Identical scaling of identical units'*.

Y-Scaling

Press to access Y-scale option (at left or right hand corner).

Enter name of the sensor.

Visibility ON/ OFF

Set axis alignment of the graph to be either left or right of the graph.

Change the color of the plot line.

Adjust the brightness of the Y-scale grid.

Toggle to turn on/ off for autoscale for Y-scale.

If autoscale is off, you can manually change the minimum and maximum of the Y-scale.

The smallest possible value is 1.

X-Scaling

Press to access X-scale option (at the bottom of the screen).

Change the color of the X-grid and the X-scale labels.

Adjust the brightness of the X-scale grid.

Set the maximum of the X-scale

Press to set the time axis to the full scale and display all measured values.

Toggle to turn on/ off for autoscale for X-scale.

Toggle on to change the starting point of the X-scale between right and left.

8.7 Recording Functionality

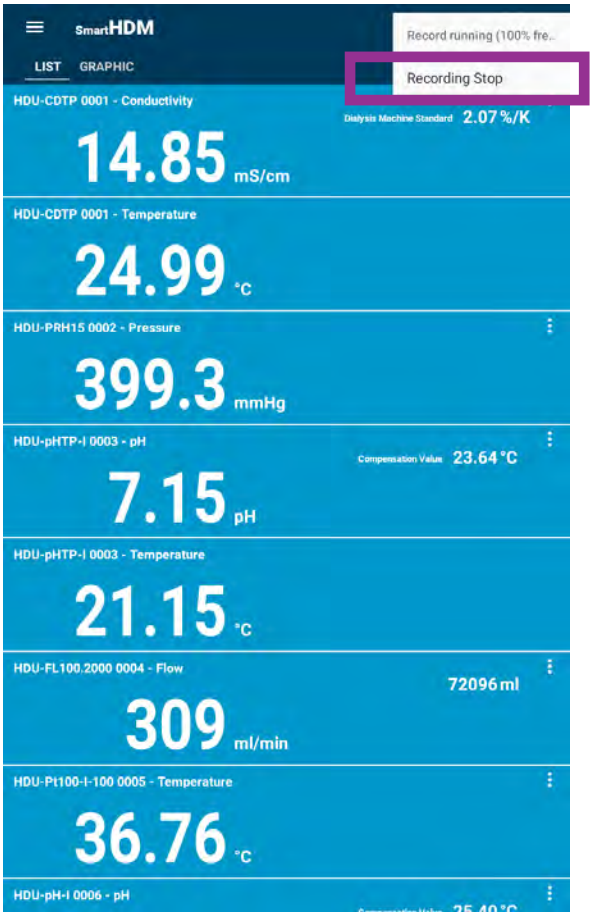
1. Start recording of data

While a measurement is in progress, you can initiate the recording function.

Click on the three dots icon in the upper right hand corner and **select** *'Recorder'*.

Then, **select** *'Recording Start (100% free)'* to begin capturing data.

After recording begins, a message will appear at the bottom of the screen. A flashing red dot in the upper right corner indicates that recording is active.

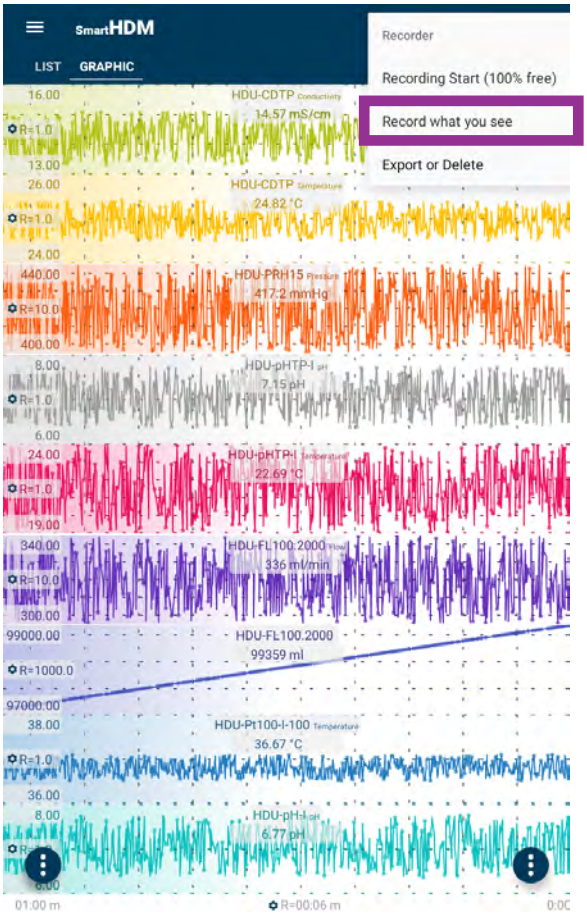


2. Stop recording

Click on the three dots icon in the upper right hand corner and **select** *'Recorder'*.

Then, **select** *'Recording Stop'* to stop recording.

A message at the bottom of the screen will indicate *'Recording Stopped.'*



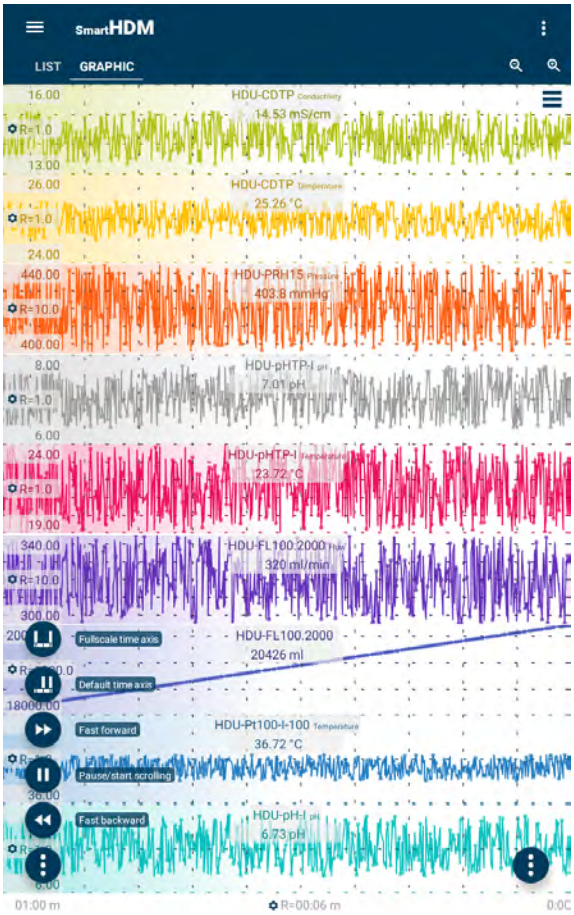
3. Recording in graphical mode

In graphical mode, you can record all data displayed on the screen, allowing you to export data from previous measurements.

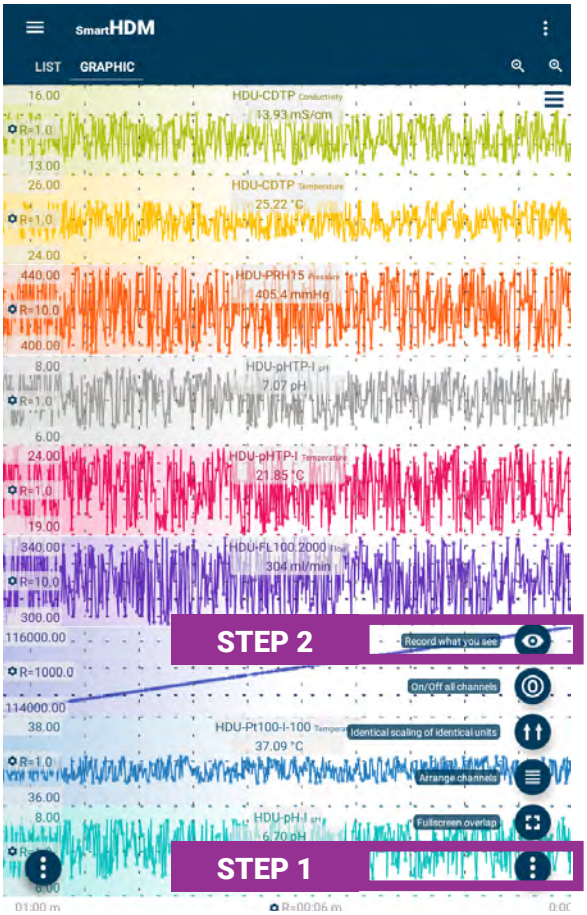
To navigate, use the menu in the lower left corner and apply touch gestures such as “drag” and “zoom” directly on the screen.

While in graphical mode, **click** on the three dots icon in the upper right hand corner, then select *‘Recorder’* in the sub-menu, then **select** *‘Record what you see’*.

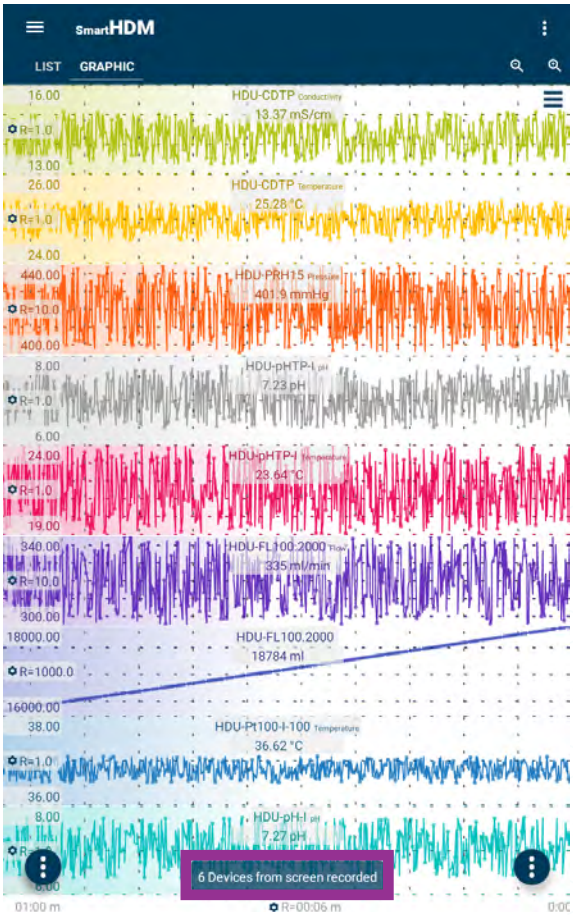
By selecting this option, you will be able to export all data currently visible on the screen.



Use the menu in the lower left hand corner to navigate within the graphical mode.

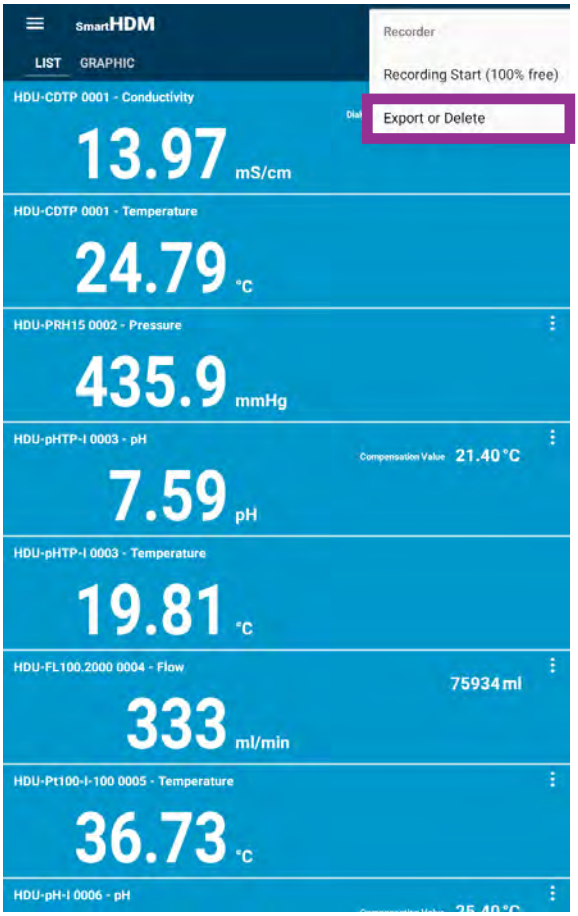


'Record what you see' is also available through a menu on the lower right hand corner.



Once the screen recording is active, a message will be displayed on the bottom: *'[#] Devices from screen recorded'*.

It will clearly indicate how many parameters are being captured. Please note that some sensors will display more than one parameter, thus will have multiple channels displayed.



4. Export recorded data

When recorded data is available, the *'Export or Delete'* option in the *'Recorder'* sub-menu will become selectable.

Select this option to export the recorded data.

A list of available recordings will be displayed.

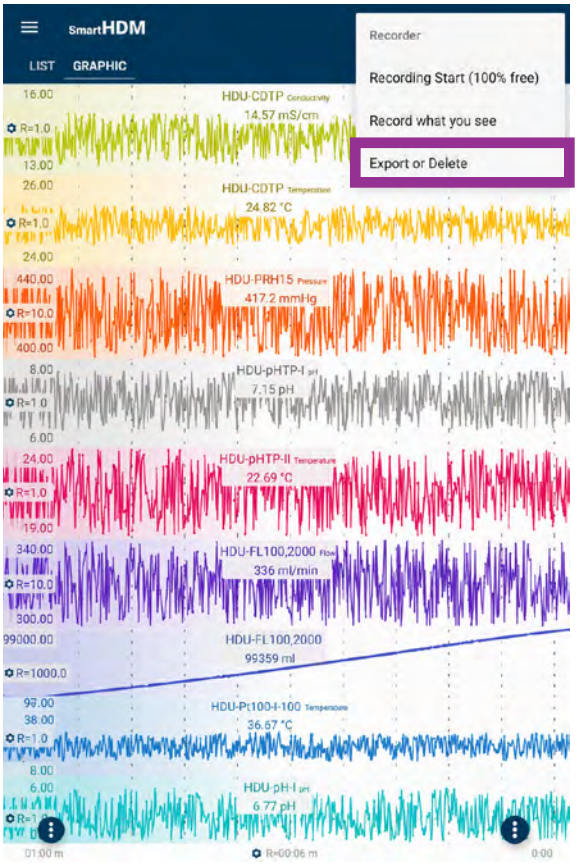
From this list, please select desired individual sensor readings to be exported.

Note: *The most recent recordings are highlighted with a red border.*

Once you have completed your selection, in the *'Start Export'* section, **press** *'Start'*.

In the *'Description'* section, **enter** a name for the file to be exported.

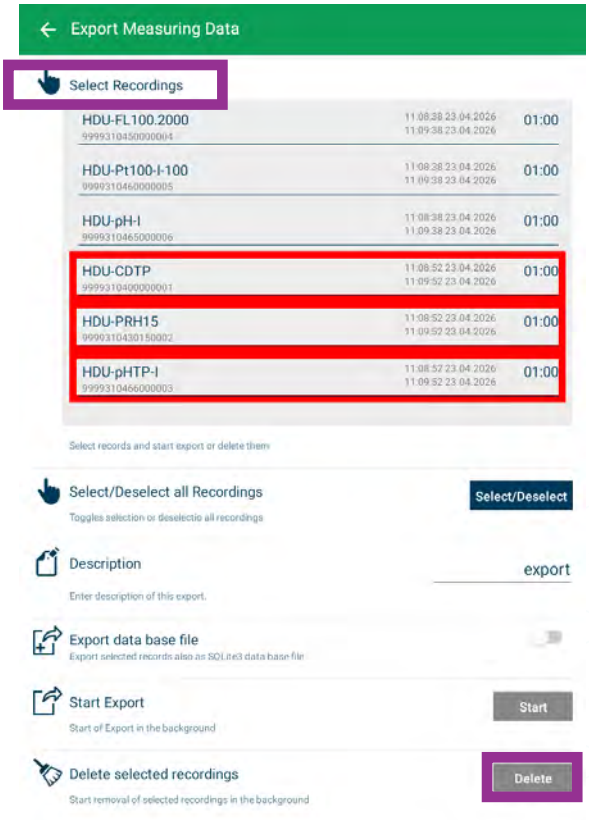
Once the export is complete, a message of *'Export finished'* will be displayed at the bottom of the screen.



5. Delete recorded data

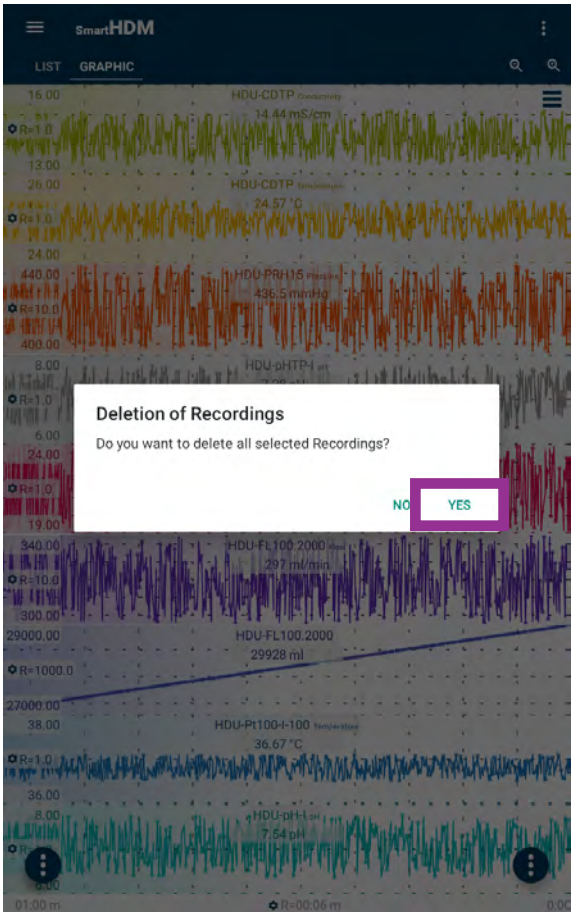
When recorded data is available, the *'Export or Delete'* option in the *'Recorder'* sub-menu will become selectable.

Select this option to delete the recorded data.

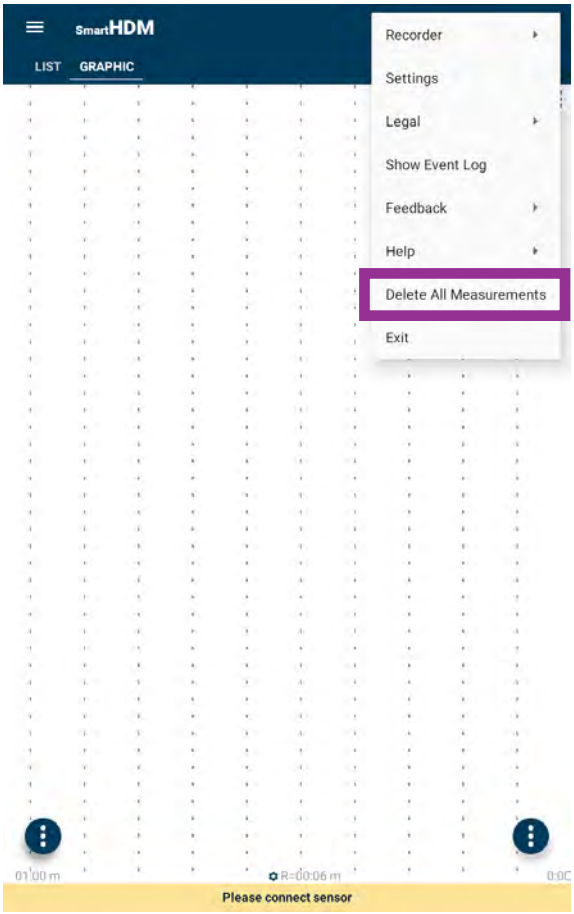


Select all recordings you want to delete.

Press *'Delete'*

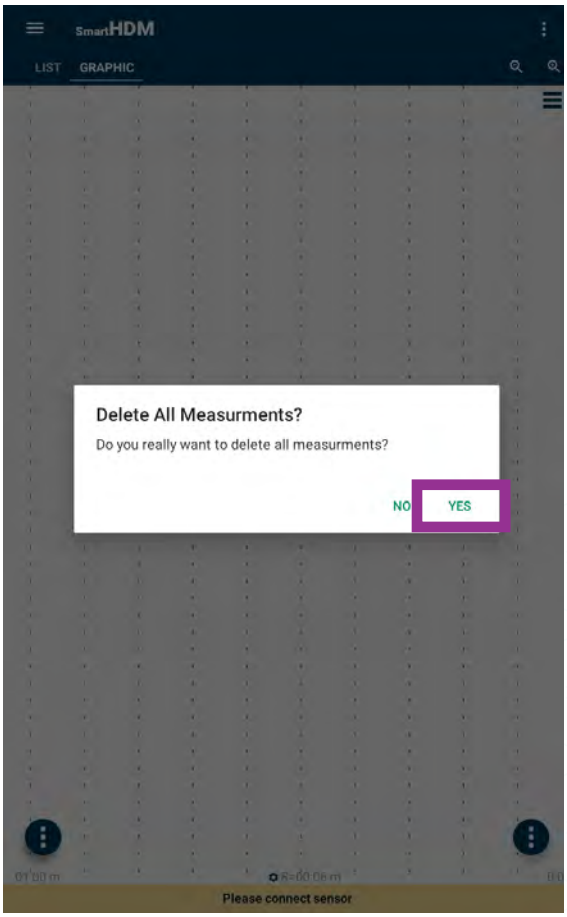


To confirm deletion of the recording, **press** *'YES'* .

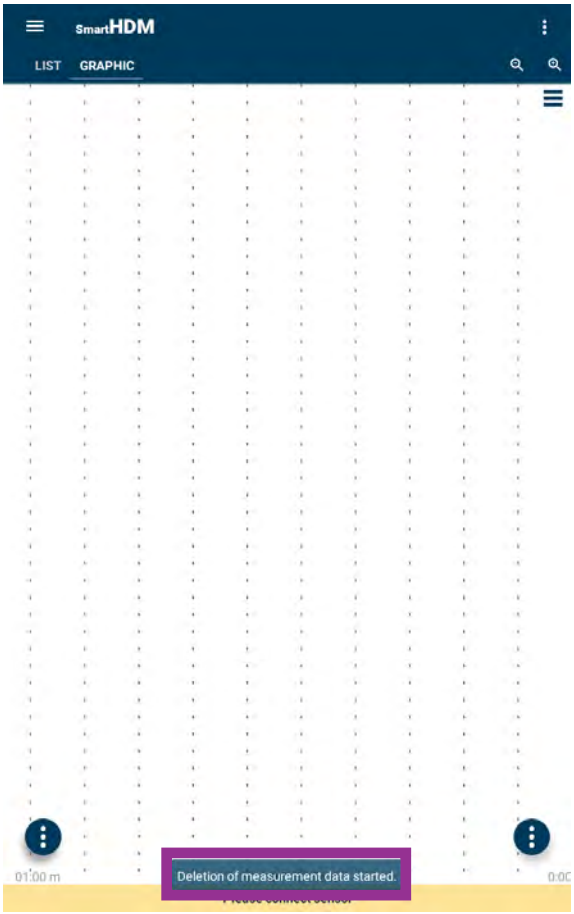


6. Delete all measurements

To delete all recordings and measurements stored on the device, under the *'Recorder'* submenu, **select** *'Delete All Measurements'*.



To confirm deletion of all recordings and measurements, **select** *'YES'*.



Once the deletion is in progress, a message of *'Deletion of measurement data started'* will be displayed at the bottom of the screen.

7. Additional information

To access the exported data, please navigate to tablet's **Downloads** folder, then select **SmartHDM** or **SmartHDM-510** subfolder.

The exported ZIP file contains a text/CSV file that can be easily imported into Excel or LibreOffice Calc.

The file may be saved to a USB flash drive or may be sent via email.

Note: *If a recording is still in progress and you attempt to exit the SmartHDM application, the application will display a message will indicate that recording is still in progress.*

If the HDC84 device powers off (e.g., due to low battery) during a recording in progress, a message will appear upon the next startup indicating that unsaved recordings are available that can be exported.

9. Sensor Sub Menus

9.1. Conductivity/Temperature Sensor Settings (HDU-CDTP)

The following menu shows the settings for conductivity sensors. SmartHDM remembers settings of sensors and rewrites the sensor settings every time the sensor is connected again. If an unknown conductivity sensor is connected in addition to an already known conductivity sensor, the value of the temperature coefficient of the first conductivity sensor is set.

Displays the serial number of the connected sensor.

Displays the measuring range of the connected sensor.

Displays the date of the last time the sensor has been calibrated. Format: YYYY/MM/DD.

Change the measurement channel name. If left blank, only the unit of measurement will be shown.

Note: This function is only available in the basic settings of the HDM sensors.

Select the color of the list measurement tile.

The selected unit is used only in the graph display. Units in the list display update automatically.

Enter the number of decimal places to be displayed. Changing this does not affect the accuracy of the sensor.

Select the conductivity temperature compensation coefficient. For more details, please read the chapter about temperature compensation coefficient.

Use the *'Adjustment'* function only if you are fully aware of the impact of the adjustment. Wrong adjustment values will lead to false measurement values. Please calibrate the sensor after adjustment.

Refer to section 9.1.1 further instructions.

Displays current reading for conductivity, temperature and cell constant.

Press *'Reset!'* to reset the conductivity adjustment back to factory setting.

Displays the firmware version of the sensor.

Displays the device status errors of the device.

9.1.1 User Adjustment Procedure for Conductivity

Attention: adjusting the device will invalidate any existing Certificate of Calibration

1. For the adjustment, use the IBP or Mesa Labs 14 mS/cm sodium chloride reference solution.
2. Select the *'Temperature Compensation Coefficient'* , then *'Reference Solution'*.
3. Enter the value of the reference solution into the adjustment field.
4. Warm or cool the solution so that the temperature is between 24.8 and 25.2 °C
5. When the reading has stabilized, press the *'Adjust'* button.
6. After the adjustment is complete, verify the sensor calibration by checking that the measured reference solution value is properly displayed.
7. If needed, you can reset your adjustment to the original factory values, by pressing the *'Reset'* button.

9.1.2 Background of Temperature Coefficients

This is a topic that is frequently misunderstood and often neglected in hemodialysis.

A solution's conductivity will change according to temperature. With increasing temperatures, the measured solution's conductivity will increase too. To achieve meaningful measurement results, the conductivity value displayed is compensated to 25°C. In other words, the display is always converted to a solution temperature of 25°C. The temperature coefficient with the displayed value is compensated with is expressed as %/°C. Unfortunately, different solutions also have different temperature coefficients. To achieve an exact reading, the instrument will have to be adjusted to the temperature coefficient of the current solution. The commonly used temperature coefficient for dialysates is 2.07 %/K. For naturally occurring solutions, a value of 1.97 %/°C is frequently used. Many measuring devices not specially tailored to dialysis will use this value.

Dynamic temperature compensation

Dynamic temperature compensation is achieved by calculating a temporary temperature coefficient for the measured temperature using a set of two coefficients for 25°C and 37°C respective. This temporary temperature coefficient is then applied to the current measured conductivity to calculate the conductivity at the common reference temperature. The following table shows the usage of dynamic temperature coefficients used to a NaCl solution of 14mS/cm.

Temperature	Conductivity NaCl 14 mS/cm without compensation	Temperature coefficient	Conductivity Readout
25 °C	14.00 mS/cm	2.000%/K	14.00 mS/cm
31 °C	15.71 mS/cm	2.035 %/K	14.00 mS/cm
37 °C	17.48 mS/cm	2.070 %/K	14.00 mS/cm

The values 2.00 %/K at 25°C and 2.07 %/K at 37°C are defaults for the respective dialysis machine or values entered by the user. For demonstration purposes the temperature coefficient for 31°C is mentioned, which is calculated by the sensor from the values for 25°C and 37°C by linear interpolation.

The calculation below shows the drastic effects of an incorrect temperature coefficient.

Example calculation for an incorrect temperature coefficient, using a dialysate with a temperature coefficient of 2.07 %/°C:

Conductivity of solution	Temperature of solution	Temperature coefficient of meter	Meter display	Difference in values
mS/cm	°C	%/K	mS/cm	%
14.00	37.0	2.07	14.00	0.00
14.00	37.0	1.97	14.17	1.21

9.1.3. Which Temperature Coefficient Should You Use

First of all, please double check the temperature coefficient with the machine manual.

If you have machines from one manufacturer only in your use, the temperature coefficient that the dialysis machine is using for compensation.

If you have different types of dialysis machines in your unit, the best solution is to use a temperature coefficient of 2.07 %/°C for **all** machines. This avoids confusion with different readings of the conductivity on different machines.

For your water treatment system, use the values according to the list below. If the manufacturer is not in this list, use the Nonlinear Function (nLF) according to ISO7888 – EN27888.

For tap, purified and wastewater, we recommend using the Nonlinear Function (nLF) according to ISO7888 – EN27888.

9.1.4. Selecting the Temperature Coefficient

Be aware that changing the temperature coefficient will lead to changes in values displayed by the meter. Therefore, change the temperature coefficient only, if you are fully aware of its consequences. If the temperature coefficient setting is wrong, it will lead to false display values.

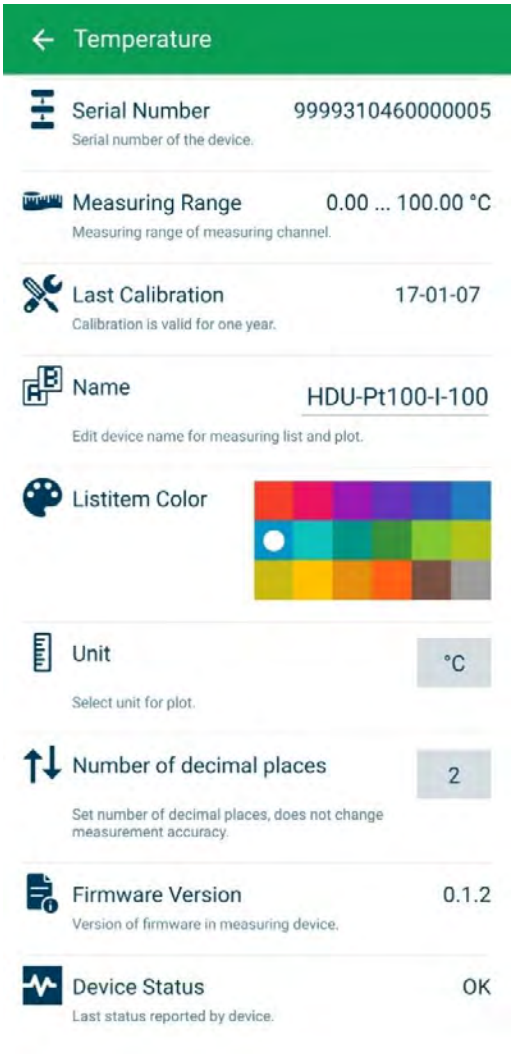
9.1.5. Temperature Coefficient Selection

Listed below are the temperature coefficients used by most major hemodialysis machines and reverse osmosis manufacturers. We recommend validating this data with documentation from your machine's manufacturer.

Display	To use for	Temperature coefficient at 25°C	Temperature coefficient at 37°C
BAXTER	Baxter (Europe Dialysis Machine)	2.200 %/K	2.200 %/K
BELLCO	Bellco	2.000 %/K	2.100 %/K
B.BRAUN	B.Braun	2.000 %/K	2.100 %/K
FRESENI	Fresenius	2.000 %/K	2.100 %/K
GAMBRO	Gambro AKType and Phoenix Machines	2.000 %/K	2.070 %/K
HOSPAL	Hospal	2.000 %/K	2.070 %/K
NIK ALL	Nikkiso Overall Conductivity	2.050 %/K	2.050 %/K
NIK BIC	Nikkiso Bicarbonate Conductivity	2.200 %/K	2.200 %/K
STANDARD	Other Dialysis Machines	2.000 %/K	2.070 %/K
USER TC	Adjustable	0 … 5.000 %/K	0 … 5.000 %/K
nLF-ISO	NonLinear Function for tap, purified and wastewater.	According Standard ISO7888 – DIN EN27888	
RO-DWA	Reverse Osmosis DWA **DWA GmbH & Co. KG** Ubstadter Straße 28 76698 UbstadtWeiher	0.00 %/K	RODWA
RO-HERCO	Reverse Osmosis Herco **Herco Wassertechnik GmbH** Planckstraße 26 71691 Freiberg	2.200 %/K Reference temperature 25°C	ROHERCO
RO-LAUER	Reverse Osmosis Lauer **LAUER MEMBRAN WASSERTECHNIK GmbH** Industriegebiet Speichermatt 79599 Wittlingen	nLFISO according Standard ISO7888 – DIN EN27888 Reference temperature 25°C	ROLAUER
RO-DWA	Reverse Osmosis DWA **DWA GmbH & Co. KG** Ubstadter Straße 28 76698 UbstadtWeiher	0.00 %/K	RODWA
RO-HERCO	Reverse Osmosis Herco **Herco Wassertechnik GmbH** Planckstraße 26 71691 Freiberg	2.200 %/K Reference temperature 25°C	ROHERCO
RO-PPW	Reverse Osmosis PPW **Phoenix Pure Water GmbH** Siemens Technopark WernervonSiemensStr. 26 D76646 Bruchsal - Germany	2.200 %/K Reference temperature 25°C	ROPPW

9.2. Temperature Sensor Details (HDU-PT100)

The following menu shows the settings for temperature sensors.



Displays serial number of the connected sensor.

Displays measuring range of the connected sensor.

Displays the date of the last time the sensor has been calibrated. Format: YYYY/MM/DD.

Change the measurement channel name. If left blank, only the unit of measurement will be shown.

Select the color of the list measurement tile.

Select the unit of measurement between °C or °F . This is only possible for single temperature sensors.

Enter the number of decimal places to be displayed. Changing this does not affect the accuracy of the sensor.

Displays the firmware version of the device.

Displays the device status errors of the device.

9.3. Pressure Sensor Details (HDU-PRS)

The following menu shows the settings for pressure sensors. SmartHDM remembers settings of sensors and rewrites the sensor settings every time the sensor is connected again.

Displays the serial number of the connected sensor.

Displays measuring range of the connected sensor.

Displays the date of the last time the sensor has been calibrated. Format: YYYY/MM/DD.

Change the measurement channel name. If left blank, only the unit of measurement will be shown.

Select the color of the list measuring tile.

Select the unit of measurement between mmHg, mBar, kPa and psi.

Enter the number of decimal places to be displayed. Changing this does not affect the accuracy of the sensor.

Select to tare (zero) the sensor.

Select the damping factor.

Toggle on to start viewing pressure change measurement . Activation creates a new tile in the list view for this function.

Enter the duration of pressure change measurement.

If needed, enter a system leak rate. This is helpful if the system you want to monitor has a systemic leakage you want to account for.

Displays the device status errors of the device.

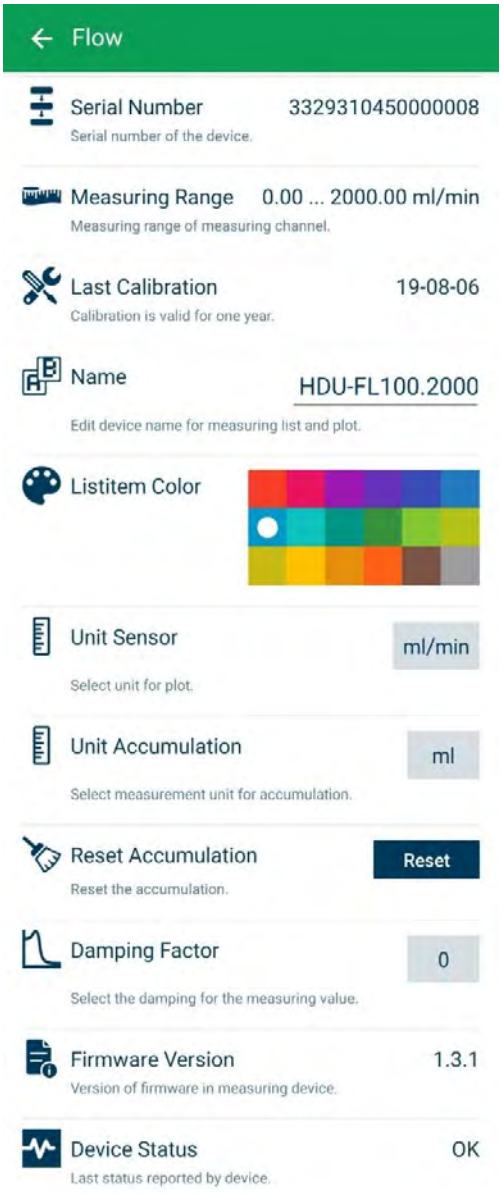
Shows the firmware version of the device.

9.3.1. Offset Balancing (Tare or Zero)

Caused by a drift of the pressure probe, the pressure display may wander slightly around zero. The tare function sets the value to zero if drift occurs. While performing this function there must not be any pressure on the pressure transducers inlet. This is assured when the pressure tube is not connected. Then the environmental pressure represents zero.

9.4. Flow Sensor Details (HDU-FL100.2000)

The following menu shows the settings for flow sensors. SmartHDM remembers settings of sensors and rewrites the sensor settings every time the sensor is connected again.



Displays serial number of the connected sensor.

Displays measuring range of the connected sensor.

Displays the date of the last time the sensor has been calibrated. Format: YYYY/MM/DD.

Change the measurement channel name. If left blank, only the unit of measurement will be shown.

Select the color of the list measuring tile.

Select the unit of measurement between ml/min and l/min.

Select the unit of accumulation between ml and l.

Select *'Reset'* to reset the flow accumulation back to zero.

Select the damping factor.

Displays the firmware version of the device.

Displays the device status errors of the device.

9.5. pH Sensor Details (HDU-pH-I)

The following menu shows the settings for the IBP pH sensors settings. SmartHDM remembers settings of sensors and rewrites the sensor settings every time the sensor is connected again.

Displays the serial number of the connected sensor.

Displays the measuring range of the connected sensor.

Displays the date of the last time the sensor has been calibrated. Format: YYYY/MM/DD.

Change the measurement channel name. If left blank, only the unit of measurement will be shown.

Select the source for the temperature compensation.

Enter the manual compensation value if no temperature sensor is available.

Select the color of the list measuring tile.

To adjust the pH sensor, please read the sections below and follow the adjustment procedures exactly.

Displays current reading of pH, temperature and Slope.

Select *'Reset'* to reset the pH adjustment back to factory setting.
Note: *Please read the section on mandatory calibration of pH probe.*

Displays the firmware version of the device.

Displays the device status errors of the device.

9.6. Mandatory User Calibration of pH-Probe

To counteract aging and storage effects, the pH electrode must be calibrated (adjusted) periodically. For accurate measurements, a user adjustment is necessary directly before the measurement is made. Please use the supplied pH buffer solutions for adjustment. IBP devices with pH channel are supplied with a basic adjustment. Ideal voltage values are used to simulate the corresponding pH levels. The results in the calibration certificate document the pH channel of the device with applied voltages to simulate the pH levels. It is, therefore, mandatory to adjust the pH electrode in connection with the IBP device before the first measurement or Adjustment Reset.

9.7. Background of pH Measurement

For measuring pH, a combined electrode is used. Combination pH electrodes are combinations of one reference electrode and one measuring electrode in a glass tube. The pH value in the dialysate is measured by an unbreakable pH electrode. The glass body is protected with a plastic coat and due to the jelly electrolyte filling, it is maintenance-free. This electrode's diaphragm must be stored in 3 mol/l KCl solution. The protective cap must be refilled every three to four weeks to prevent the electrode from drying out. Before using the electrode must be checked for exterior damage and crushed glass. Crusts caused by leaking electrolyte can be removed easily by rinsing with reverse osmosis-treated water.

The sample volume should be 100 ml of dialysate or 1 liter of untreated water. The sample should be poured into a clean glass container with a tube or hose, coming into as little contact with air as possible. The pH value must be measured immediately in the same container. Make sure that the display stabilizes before the value is read. In stirred solutions, the response rate is faster; the value, however, must be measured at resting fluid.

The pH electrode must be dabbed only with a lint-free cloth and never rubbed dry. Rubbing destroys the jelly layer on the glass surface, which results in longer response time for the electrode.

Pressure and fluid currents have considerable influence on the pH measurements. For high accuracy pH measurement, it is essential to take the pH measurement in a resting solution at environmental pressure.

9.8. User Adjustment Procedure for IBP pH-Interfaces

The IBP pH Sensors are using a three-point adjustment. Therefore, you need three different pH buffer solutions in ascending order for the procedure. Between each measurement, you should clean the pH electrode with deionized water. At the end of the adjustment procedure, a check is made with the pH buffer solution of Point 1 to validate the slope.

Recommended Mesa Labs pH Buffer Solution

PN 02.0030	pH Buffer Solution 7.00 pH / 16 oz
PN 02.0031	pH Buffer Solution 7.00 pH / 1 qt.
PN 02.0032	pH Buffer Solution 4.00 pH / 16 oz
PN 02.0034	pH Buffer Solution 10.00 pH / 16 oz

Value 1 adjustment

After rinsing the pH electrode with deionized water, place it in the first pH Solution.

The value input field can be edited. In this case pH 6. After the value has stabilized, **press** *'Confirm'*.

After pressing *'Confirm'* the adjustment will move to the next Point.

Current reading of pH, temperature and Slope.

Value 2 adjustment

After rinsing the pH electrode with deionized water, place it in the second pH Solution, in this case pH 7

Enter the 2nd pH Value.
After the value has stabilized, **press** *'Confirm'*
.

After pressing *'Confirm'* the adjustment will move to the next Point.

Current reading of pH, temperature and Slope.

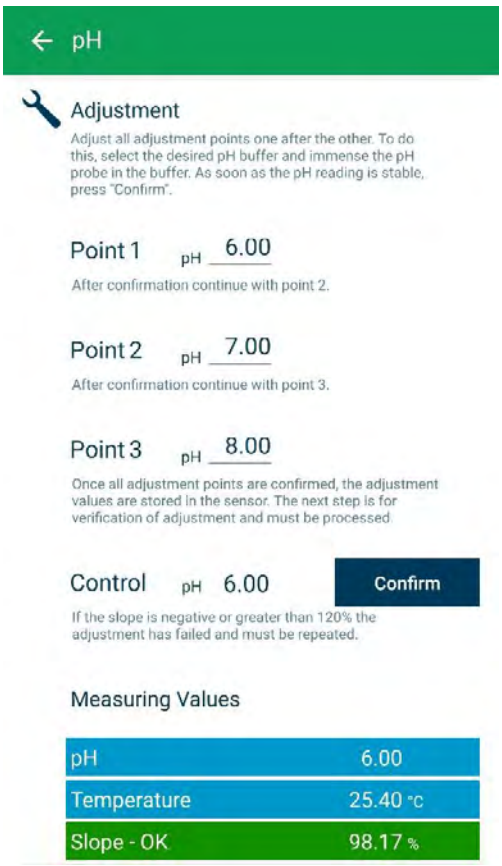
Value 3 adjustment

After rinsing the pH electrode with deionized water, place it in the third pH Solution, in this case pH 8.

Enter the 3rd pH Value.
After the value has stabilized, press *'Confirm'*.

After confirming, the adjustment will move to the confirmation point.

Current reading of pH, temperature and Slope.



Confirming the adjustment

After rinsing the pH electrode with deionized water, place it in the first pH Solution, in this case pH 6.

By pressing 'Confirm', the sensor is measured against the first measuring point, in this example, pH 6 buffer solution is used.

After confirming, the adjustment procedure is completed.

Once the adjustment points are finished, the adjustment values are stored automatically in the sensor. If something is wrong with the adjustment, the sensor will not accept the values and an error message will be shown.

In case the SmartHDM software detects an error that wasn't detected by the sensor, SmartHDM will mark the calibration Date invalid with an *'E'*.

The sensor calculates and shows the slope of the pH probe.

Slope < 75% *the pH electrode is considered defective and must be replaced.*

Slope > 75% to 85% *the pH electrode is critical*

Slope > 85% to 120% *the pH electrode is OK*

Slope > 120% or negative, *it is likely that the adjustment went wrong (e.g., use of wrong value solutions)*

Three possible slope results.

10. HDU Sensors and Interfaces

10.1. Interface Cable

Interface cable is required to connect each HDU sensor to HDC84 or other Android devices. Different cable versions are available:

Article No: 31.0485.20

HDU-Sensor Cable USB-A, 1.8 m/ 5.9ft: *Needed in conjunction with the HDC Devices.*

Article No: 31.0485.31

Sensor Cable USB-C, 1.8 m/ 5.9ft: *To be used in conjunction with other Android devices.*

10.2. Connecting a Sensor

When connecting a sensor to the SmartHDM system, first connect the sensor to the interface cable then connect the cable to the USB port.

10.3. Hook & Mechanical Interface

Most of the HDU sensors come equipped with a hook that allows the sensor to be hung.

Most of the HDU sensors feature a mechanical interface that allows the sensor to be connected to different adapters, i.e., flow-through and pressure adapter.

10.4. HDU-CDTP Conductivity/Temperature Sensor

The sensor can be used as a flow-through or a dip sensor.

The flow-through adapter can be disconnected for immersion usage by pressing the release button.

The preferred orientation of the adapter is vertical. The axial connector must point down (see picture). Before measurement, shake the adapter slightly so that air bubbles trapped inside can pass off through the outlet.

The setting for the temperature compensation coefficient of first time connected sensors will be set to the value last time used on the display device.

Never touch the carbon ring electrode surfaces with your fingers or other objects.

To avoid deposits in the conductivity electrode, the flow channel must be flushed with RO water after each use.

To disinfect the flow channel, connect the HDM module to a dialysis machine and start a disinfection program.

WARNING: If the disinfection program of the dialysis machine exceeds the specification of the sensor, it may cause internal damage to the sensor.

10.4.1. Technical Data

Conductivity:	Quadrupole carbon compound electrode. Four measuring ranges. The temperature compensation coefficient may be adjusted.	
	Range:	0…200.00 mS/cm
	Cell constant:	0.54 1/cm
	Accuracy:	0…199 uS/cm 0.3% ± 0.6 uS/cm 200…1999 uS/cm ± 6 uS/cm 2...11.99 mS/cm ± 0.06 mS/cm 12...19.99 mS/cm ± 0.03 mS/cm 20...200 mS/cm ± 0.6% of reading
Temperature:	Sensor integrated into the conductivity electrode	
	Range:	0...100 °C
	Resolution:	0.01 °C
	Accuracy:	± 0.1°C
Refresh rate:	Five times per second	
Calibration:	PTB/NIST traceable	
Degree of protection:	IP67	
Power supply:	3.3 to 5.0 V, max. 80 mA via RS485- or USB-Interface	
Environmental conditions:	**Ambient Operating Temperature Range:** 0 to 50°C **Storage Temperature Range:** 40 to 80°C **Operating and Storage Humidity:** 85% max relative humidity non-condensing from 0 to 50°C	
Dimensions:	124 x 34 mm	

10.4.2. Caring for the Conductivity/Temperature Electrode

Thorough cleaning of the electrode is particularly important for measuring low conductivities.

Water-soluble substances must be removed by rinsing with deionized water. Remove lime and hydroxide crusts with a 10% citric acid solution or use the NeoCare solution (Mesa Labs PN 02.0013). To do this, immerse the electrode in the solution for 30 minutes at room temperature, then rinse it thoroughly with deionized water. Do not touch the electrode surface with your fingers.

Basically, the conductivity measuring cell does not decay over time. Particular measuring media (for example, strong acids and caustic solutions, organic solvents), or too high temperatures shorten the service life considerably, and/or lead to damage.

10.5. HDU-PRS30 Pressure Sensor

10.5.1. Technical Data

Pressure

All Versions

Reading:	Readings as mmHg, kPa, Bar or PSI
Measuring:	Temperature compensated
Pressure Connection:	IBP Sensor Port and G1/8" Female internal thread
Membrane	HDU-PRS versions have a stainless steel membrane which is fluid resistant
Refresh rate:	Five times per second
Calibration:	PTB/NIST traceable
Degree of protection:	IP67
Power supply:	3.3 to 5.0 V (max 60 mA) via RS485- or USB-interface
Environmental conditions:	**Ambient Operating Temperature Range:** 0 to 50°C **Storage Temperature Range:** 40 to 80°C **Operating and Storage Humidity:** 85% max relative humidity non-condensing from 0 to 50°C
Dimensions:	80 x 34mm

HDU-PRS30

Range:	- 13.5 to 36.7 psi - 0.90 to 2.5 bar - 700 to +1900 mmHg
Resolution:	0.01 mmHg
Accuracy:	0 to 300 mmHg ± 1 mmHg Otherwise ± 2 mmHg
Media Compatibility:	Gasses and Fluids
Overpressure	1.5 x full scale

HDU-PRS100

Range:	- 13.5 to 100 psi - 0.90 to 6.9 bar - 700 to 5150 mmHg
Resolution:	0.1 mmHg
Accuracy:	0.1% full scale
Media Compatibility:	Gasses and Fluids
Overpressure	120 psi with IBP sensor port 150 psi if using G1/8” female internal thread

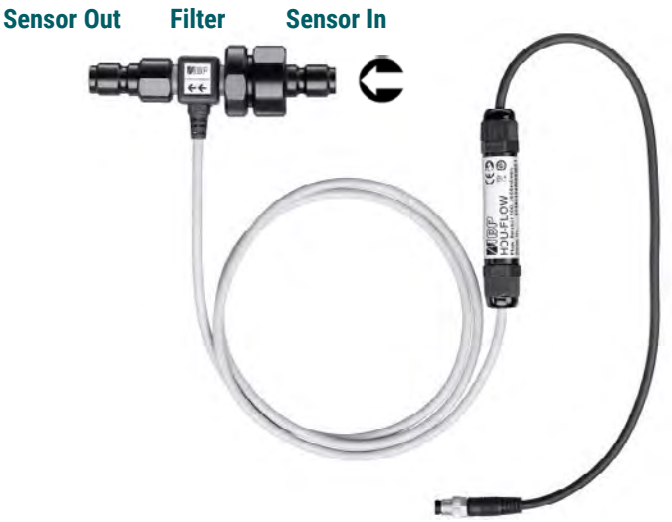
10.5.2. Measuring Adapter

For HDU pressure sensors is a tubing set available including for male and female Luer adapter that allows connecting the sensor to typical biomedical applications. Fresenius pressure port adapter is also available.

Luer fitting and tubing set

Optional Fresenius Dialysis Machine Pressure Port Adapter

10.6. HDU-FL Flow Sensors



To avoid malfunction of the sensor, please make sure to connect fluid correctly the sensor. The sensor has a label showing the flow direction.

After use make sure to rinse the flow sensor with deionized water for a couple of minutes.

Do not store the sensor in wet conditions.

Clean the inlet filter on a regular basis.

Use the sensor only in the indicated flow direction. Incorrect flow direction can damage the sensor.

10.6.1. Technical Data

HDU-FL100.2000

Measuring principal:	Turbine
Range:	100 to 2000 ml/min H_2O at 22°C / 71.6°F
Resolution:	1 ml/min
Accuracy:	± 2.0 % of reading
Fluid temperature:	-20°C to +80°C
Pressure:	0 to 5 bar at 22°C

Calibration:	PTB/NIST traceable
Degree of protection:	IP67
Power supply:	3.3 to 5.0 V, 60 mA via RS485- or USB-Interface
Environmental conditions:	**Operating Temperature Range:** 0 to 50°C **Storage Temperature Range:** -40 to 80°C **Operating and Storage Humidity:** 85% max relative humidity non-condensing
Dimensions:	30 x 30 mm

10.7. HDU-Pt100-I Interface for Pt100 Temperature Sensors

10.7.1. Technical Data

Temperature HDU-Pt100:

Range: -50...100 °C

Resolution: 0.01 °C

Accuracy: 25 ... 40°C ± 0.1 °C

Otherwise ± 0.2 °C *(if Sensor and interface are adjusted together)*

Calibration: PTB/NIST traceable

Communication rate: Five times per second

Degree of protection: IP54

Power supply: 3.3 to 5.0V, max. 70 mA via RS485- or USB-Interface

Environmental conditions:

Ambient Operating Temperature Range: 0 to 50°C

Storage Temperature Range: -40 to 80°C

Operating and Storage Humidity: 85% max relative humidity non-condensing from 0 to 50°C

Dimensions: 64 x 45 x 25 mm

10.8. Pt100 Sensors Temperature Sensor Family

Rugged Pt100 temperature sensor family

RS485 Interface

Pt100 Interface

General - Dip **Surface** **Laboratory**

Technical data of the sensors are available at:
http://www.ibpmt.com/hdu_e/adoc.asp?hdu_e/hdu_tps.htm

10.9. HDU-pH-I Interface for pH Electrodes

To counteract aging and storage effects, the pH electrode must be readjusted cyclically. For accurate measurements, a three-point adjustment is necessary directly before the measurement. Use IBP or Mesa Labs pH buffer solutions for adjustment.

HDU-pH-Interfaces are supplied with a basic adjustment. Ideal voltage values are used to simulate the corresponding pH levels. The results in the calibration certificate document of the device show the simulated pH levels.

It is mandatory to adjust the pH electrode in connection with the pH-Interface device before the first measurement.

Use the user adjustment functions of the SmartHDM software only if you are fully aware of the consequences. Wrong adjustment values will lead to false measurement values.

pH:	**Range:** 0...14 pH **Resolution:** 0.01 pH **Accuracy:** ± 0.02 pH
Degree of protection:	IP54
Power supply:	3.3 to 5.0 V, max. 80 mA via RS485- or USB-Interface
Environmental conditions:	**Operating Temperature Range:** 0 to 50°C **Storage Temperature Range:** -40 to 80°C **Operating and Storage Humidity:** 85% max relative humidity non-condensing from 0 to 50°C
Dimensions:	64 x 45 x 25 mm

11. User Adjustment and Calibration

Use the user adjustment functions only if you are fully aware of their consequences. Wrong adjustment values will lead to false measurement values and in consequence, these false values may potentially lead to hazards for patients.

In the event of a significant discrepancy between the measured value and the expected value, the user should verify meter accuracy using appropriate conductivity or pH solutions

11.1. Definition - Adjustment

An adjustment is a process in which properties of a measuring device are changed in that way that its scale or display reads the same as a reference device or standard.

11.2. Definition - Calibration

Calibration is the process of establishing the relationship between a measuring device and the units of measure. This is done by comparing a device or the output of an instrument to a standard having known measurement characteristics. For example, the length of a stick can be calibrated by comparing it to a standard that has a known length. Once the relationship of the stick to the standard is known, the stick can be used to measure the length of other things. Adjustments are checked by performing a calibration.

11.3. General

It is mandatory that the references to adjust or calibrate the HDM devices have at least three times higher accuracy.

After a channel has been adjusted, it is necessary to calibrate it afterward. If inconclusive or incomprehensible values are shown in the display, it is highly recommended to send to IBP or Mesa Labs for a factory calibration. .

The procedure of calibration and adjustment is slightly different for each channel. Proceed with user adjustment only if you have fully understood the procedure.

If you are uncertain of entering the correct adjustment values, you can discard the values and cancel the adjustment procedure at any time.

11.4. Handling of Reference Solutions

IBP Medical and Mesa Labs standard solutions are produced under ISO13485 quality management. They are traceable to NIST and PTB Standards Reference Materials and are sealed with tamper-evident packaging.

To ensure standard solution and calibration/verification accuracy

- Keep solutions tightly capped to avoid evaporation
- Do not return used solutions to the storage bottle
- Do not remove solutions from their original bottle
- Keep the solutions in a cool place
- Use only fresh reference solutions for calibration and verification
- Use the solution immediately after pouring; evaporation will cause errors
- Discard solution the appropriate number of days after opening the bottle
- Discard solution after the expiration date

12. Maintenance

Operate the SmartHDM display unit in a dry environment, and do not touch it with damp hands. Ensure that no fluids intrude into the interior of the display unit, or into the USB hub.

There are no user-serviceable parts. Contact our technical support team in the event of any malfunction. If the device should become damaged or malfunction, send it to IBP or Mesa Labs.

12.1. Storage

Keep the devices in a dry place. Suitable are, for example, the original packaging in which you have received the SmartHDM devices or the carrying case offered by IBP as an accessory. If you do not use the device over a longer period of time, you should connect it to the included charging device about every month for one hour to avoid exhausting the batteries.

12.2. Cleaning

Never clean any device with any fluids! If the display unit of the SmartHDM needs to be cleaned, the surface may be wiped with a dry and clean cloth.

12.3. Sterilization

There is no sterilization requirement for the SmartHDM-510 system.

To avoid cross-contamination, disinfect sensors and modules that have been in contact with liquid regularly. We recommend the use of different sensors for use in conjunction with infected and non-infected dialysis machines. Mark the sensors accordingly to avoid confusion.

12.4. Calibration Period

When delivered new from the factory, each device is adjusted and calibrated before shipment. To ensure reliability, we recommend the following intervals for factory calibration:

Parameter	Calibration period
Temperature	*Once per year*
Conductivity	*Once per year*
Pressure	*Once per year*
Flow	*Once per year*
pH	*Before each use*

A complete function test and factory calibration of the device should be done once a year.

Factory calibrations use the most robust standards and specifications to ensure the device calibration remains reliable while in use. This is done to minimize any risk of using a device which is out of tolerance. Factory calibration performed at IBP and Mesa Labs or authorized service provider is a proprietary process. For yearly factory calibrations, please send sensors to IBP or Mesa Labs or an authorized service provider. For a list of authorized service provider, please contact IBP.

Verification of meter accuracy may be performed at shorter intervals using Mesa Labs or other calibration solutions in accordance with the users SOPs. In the event of a significant discrepancy between the measured value and the expected value, the user should verify meter accuracy using appropriate conductivity or pH solutions and if needed perform an adjustment or return the meter for factory calibration.