

# SmartHDM User Manual



#### Foreword

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#### **Revisions**

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## **Safety Instructions**

### **Read This First**



SmartHDM is a medical device in the USA when used in conjunction with hemodialysis machines. In this case, only use the "Mesa SmartHDM" 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-510 System.
- Review the complete user manual of the devices that the SmartHDM-510 System will be used in conjunction with.
- Keep away the device from unauthorized persons.
- Never use the SmartHDM-510 System on a dialysis machine to which a patient is connected.
- Never use the SmartHDM-510 System on a dialysis machine with a connected battery charger.
- Never use the 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 calibrated.
- Prevent electrostatic discharge on the connectors. This can lead to substantial damage to the 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-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-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-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-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-510 device. Repair may only be performed by an authorized service.
- The SmartHDM system is not intended to be used in residential areas and cannot adequately protect radio reception in such environments.

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### 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 Modules which are Android-powered device with
- SmartHDM Software
- HDM18/19 Sensor Modules for Conductivity/Temperature, Pressure,
- HDU Sensors for Conductivity/Temperature, Pressure, Flow and pH
- 90XL Sensors for Conductivity/Temperature, Pressure 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

# Œ

### 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

HDC64 **Display- and Control Unit** HDC84 Display- and Control Unit HDC85 Display- and Control Unit HDU-CDTP Conductivity/Temperature Sensor HDU-PRH High Accuracy Pressure Sensor Family HDU-PRS Pressure Sensor Family HDU-FL Flow Sensor Family HDU-Pt100-I Interface for Pt100 Temperature Sensors Interface for pH-Sensor HDU-pH-I Interface for pH-Sensor and Pt100 Temperature Sensors HDU-pHPt-I HDM18 Sensor-Module HDM19 Sensor-Module

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 sensors sensor-modules and interfaces with a smart Android device for measuring, testing and quality control.



2.1. HDC DISPLAY DEVICES

The HDC-Module may be used to run the SmartHDM App.

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

- 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.

#### 2.3. HDM SENSORS

The HDM18 and HDM19 Sensor modules were designed for the service of hemodialysis machines. The modules can be used with any brand of dialysis machine.

#### 2.4. 90XL SENSORS

90XL Sensors were designed to be used by hemodialysis professionals to measure readings of conductivity, temperature, pH, and pressure of the dialysate fluids used in hemodialysis delivery systems. Water purification specialists may also use the 90XL meter to verify proper characteristics of the water used in hemodialysis. These parameters are key indicators of system performance that require periodic monitoring and adjusting to maintain safe and effective hemodialysis systems.

### 3. HDC-Display Modules

#### 3.1. HDC64 OVERVIEW

The HDC64 is a smart mobile device with an Android operating system and a USB Hub. The USB Hub has four USB-A ports to directly connect sensors or sensor modules.





Speaker volume buttons

Special function button (Not used with SmartHDM)

USB-A-Interface for the connection of sensors and modules



On/Off Button

Finger print sensor

Function button (Not used with SmartHDM)

#### 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 HDC64 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.



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<sup>™</sup> 2.0 compatible.

#### **Power Supply Mode Selection**





The USB Hub may not be used while the device is charging.

Press the power supply button to select the power supply mode.

- Green indicates that the four USB-A ports (USB Hub) for the sensors are on and powered by the internal battery.
- Red indicates that the battery is charging.
- Flashing Yellow indicates that the system is waiting for the charger to be plugged in.
- Yellow indicates that the USB Hub is powered by the charging cable, but the battery is not charging. This option gives the user a little more time to finish a task before charging the device.

### 3.1.1. TECHNICAL DATA

Android Device	The HDC64 is based on an Oukitel WP17 Rugged Outdoor Smartphone
Interface	4 x USB-A for Modules, Sensors and Interfaces, 1 x USB-C for charging only
Housing degree of protection	Android Device: IP69 USB-Hub: IP0X
Power supply	3,7 V / 8300 mAh Li-ion polymer battery Quick Charge 2.0 Compatible
Operation time	Approximately 12 hours from 100% to switching off Screen set to 50% brightness, always on 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: 2ANMU-WP17
Accessories	USB charger USB-C cable Holding clamp (Richter standard)

#### 3.2. 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 function as a standard Android device.



#### **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 HDC64 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.



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<sup>™</sup> 2.0 compatible.

#### 3.2.1. TECHNICAL DATA

Screen	8.0 inch Corning Gorilla IPS capacitive touch screen, 1280*800px
Memory	32 GB Flash Memory, 3 GB RAM 32GB ROM support TF card up to 64GB maximally
OS	Android 8.1
Cameras	2 MP front camera 16 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, TD-SCDMA: B34/B39 4G: FDD-LTE:B1/B2/B3/B4/B5/B7/B8/B17/B20/B28, TDD- LTE:B38/B39/B40/B41
Degree of protection	Android Device: IP68 USB-Hub: IP0X
Power supply	3,7 V / 8000 mAh Li-ion polymer battery Quick Charge 2.0 Compatible
Operation time	Approximately 8-10 hours from 100% to switching off Screen set to 50% brightness, always on 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: SY4-B01012
Accessories	USB charger USB-C cable
	Holding clamp (Richter standard)

#### 3.3. HDC85 OVERVIEW

The HDC85 is a smart tablet device with an Android operating system. The USB Hub has four USB-A ports to directly connect sensors or modules.

SAMSUNG HDM GR/ LIST 13.62 ms/cm 24.87. 405.0 mmHg 21.29°C 6.62<sub>PH</sub> 325 ml/min 21.29.



On/Off Button

Speaker volume buttons

Charger connector

USB-A-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 HDC64 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.



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<sup>™</sup> 2.0 compatible.

#### **Power Bank**



For extended battery life, the HDC85 has a separate power bank.

The charge status of the power bank is displayed after switching it on.

When the power bank is switched on, the Android device is supplied and charged from the power bank.

#### 3.3.1. TECHNICAL DATA

Android Device	The HDC85 is based on tablet Samsung Tab Active2			
Interface	4 x USB-A for Modules, Sensors and Interfaces, 1 x USB-C for charging only			
Housing degree of protection	Android Device: IP68 USB-Hub: IP0X			
Power supply	3,7 V / 4450 mAh Li-ion polymer battery 7,4 V / 4000 mAh backup battery Quick Charge 2.0 Compatible			
Environmental conditions	Operating Temperature Range: 0 to 50°C / 32 to 122°F Storage Temperature Range: 0 to 50°C/ 32 to 122°F Operating and Storage Humidity: 85% max relative humidity non-condensing from 0 to 50°C/ 32 to 122°F			
Weight	0,75 Kg/ 26 ounces			
Certification	CE, FCC ID: A3LSMT395			
Accessories	USB charger, USB-C cable, Holding clamp (Richter standard)			

### 4. SmartHDM Sensors and Modules

The SmartHDM System has a range of sensors available which include:

- HDU Sensors and Interfaces
- HDM Sensor Modules
- 90XL Sensors

#### 4.1. HDU SENSORS AND INTERFACES

HDU Sensors are a product family of high precision sensors for the tasting 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

#### 4.2. HDM - MODULES

The HDM-Modules product family is intended to be used in the service and maintenance of hemodialysis machines.

USB-Interface	USB- Interface	Bluetooth- Interface	Conductivity Temperature	Pressure Extern	Pressure Intern	Pressure relieve valve
HDM19-BO						
HDM19-UM						

Conductivity, Temperature and Pressure-Internal are measured in the flow-through path of the device. Pressure External is a pressure port for measuring external pressures.

#### 4.3. 90XL-Modules



The 90XL-Modules are Hemodialysis Sensor to be used in the service and maintenance of hemodialysis machines.

### 5. Android OS

The HDC Systems 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".

### 6. SmartHDM Software

#### 6.1. KEEP SmartHDM 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 -> Wi-Fi

#### 6.2. SmartHDM INSTALLATION

The latest version of the SmartHDM App is available through the Google Play store under Mesa SmartHDM.

To install the App, follow the instructions in the Google Play Store. Mesa SmartHDM works with Android version 7 and higher.

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/Display 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

In order to reduce the complexity of the program, the functionality of the SmartHDM-510 version is somewhat reduced. The reductions are:

- Runs only on HDC64 and HDC84
- Data acquisition up to 1Hz
- Language only in English
- Calculation module not available
- Demo mode not available



#### 7.1. REGISTERING YOUR DEVICE

Please register your device so that Mesa can keep you up to date with software changes. Click on "Start" under "Registration" in the app settings. Enter your data on the opening webpage. After entering your data, you will immediately receive the code for your device. Enter the code in the App settings. Until a registration code has been entered you will receive the message "Please register the app".

Select Settings in the Main Menu and scroll down to User Confirmation Code.

### 8. SmartHDM General Use

The SmartHDM App displays measurement values, both digitally and graphically.

#### 8.1. GENERAL FUNCTIONALITY



Header Area – allows the user to change settings and change the display

#### List Graphic +

The + allows the user to add a Calculation Module or Bluetooth connections of found devices.

If the display of the looks different than the picture on the left, it can be changed by following the directions below:

Open the Android Settings Select "Display" Select "Front and screen zoom" Change "Screen Zoom"

#### 8.2. HEADER AREA FUNCTIONALITY

Button Function



Basic settings can be found by touching the three dots button. Program Info – Shows the App release version Legal - Terms and conditions and Privacy Policy Show Event Log - Shows complete Event Log Feedback - In the case of App problems, the action log can be

Help - Allows the user to download the Quick Start Guide or User Manual

Exit - Terminates the App and ends the measurement



#### The List Menu allows to set up the List screen



shared

#### 8.3. List Display Functionality

Depending on the connected devices, different readouts are shown.

#### Element



#### Statistic



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 also provide statistical values for consideration.

#### 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

This diagram shows that the value fluctuates uneasily around 0 mmHg.

#### **Pareto distribution**

The corresponding Paetro diagram looks as follows.



The statistic values are identical.

The blue bars now show 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.

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

#### Sample 1

#### Measuring graph



The graph shows that the measured value fluctuates strongly around 0, +/- 20 mmHg.

#### Histogram



The histogram shows very nicely the fluctuations of -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 shows that also that most values are 0 mmHg and an outlier is a max. 817 mmHg.



The yellow line here shows how a largely stable measurement is shown in the Pareto diagram.

#### 8.4. ADD DEVICES AND CALCULATION MODULE

+	Opens the Add Devices and Calculation Modules functions
← Add I	Devices or Modules
Select	Device to add
Select a	Bluetooth Device to add.
Select	a Calculation Module to add
Math	1/U
Select a	previously created module to add.
Create a	Create Create

Selection for compatible Bluetooth devices. Make sure Bluetooth is enabled on your Android device.

Selection of created calculation modules to add to the list view.

Note that Calculation module functions are not available in the SmartHDM-510 Medical Device version.

Create a new calculation module

#### 8.5. CALCULATION MODULE



Change or set the name of the calculation module

Choose the Color of the List item of the Module

Set the decimal places and the Unit

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

Select desired calculation functions.

Field for entering the desired formula. Press enter to confirm.

Logic check for the formula. Valid after pressing Enter.

Deletes this calculation module.

#### 8.6. GRAPH DISPLAY FUNCTIONALITY

Depending on the connected devices, different readouts are shown.



Heading – allows selecting settings and the two main displays, List or Graphic

Zooming and Graph Settings

- By holding a graphic on the far-left corner or far right corner (depending on the positioning of the Y scale Options, also recognizable by the color gradient), you can move a graph manually and overlay it on another graph.
- To zoom in on the time scale, use a pinching motion.
- By swiping left or right, you can scroll threw the time scale (if swiping on, in the main app setting is deactivated)

Android Function Buttons

#### **Head Area Buttons**



- Change the Plot Line Width between thin, normal and thick in the graph
- Change which measuring points are shown in the graphic
- Turn on/off the color gradient on the Y-scale
- Change the Sample rate for all devices

Set the range for the statistical evaluation

Choose between Minutes or Stored Values



The graphic SideBar (top left corner) allows to set up the graphic screen



Touch and move to defining the order of a channel in the graph

Enable or disable a channel to be graphed

Allows toggling the position of the Y Scale Gradient (If selected in the Graphic Settings)

Access Y-Scale settings

#### **Function Buttons**



Left function button leads to 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



Right function button leads to 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 channels one below the other Arrange the channels on top of each other.

#### Identical scaling of identical units

If you like to have measuring channels with identical measuring units with the same scaling press the right function button choose "Identical scaling of identical units".

#### Export measuring data

Open the right function menu, press "Export measuring data".

R	The Export button the right export m	leads to Ienu	
←	Export Measuring Data		
Ľ	Description	Export	Name of the Export file
M	Timespan like Graphic Export with same timespan like graphic.		Exports only the data which is shown in the current graph.
4	Timespan Timespan for Export from now backwards	1 min	Export the last measured values Spanning the selected time period.
6	Only visible channels Export only in graphic visible channels.		Export only Channels, which are shown in the graphic view.
	Only marked values Export only maked values on/off.		Export only values that are marked in the graphic. This depends on the sample rate setting.
F	Start Export	Start	It starts the export in the background.

The export generates a zip file that contains a .txt file with the measured data. After starting the export, you can choose with which program you want to share the measurement data. For example, you can select the mailing program and forward it to your PC. After unpacking the file, you can import the .txt file, e.g., into excel.



### **⊅**R=

Y-Scale option (at left or right screen corner) button options



Change Name of the Sensor

Visibility on/off

Scale aligned to the left or right on the graphic screen

Change the Color of the plotline

Change the Brightness of the Y-Scale Grid

Toggle auto-scaling for the Y-Scale On or Off

If Autoscale is off, you can manually change the Minimum and Maximum of the Y-Scale. The smallest possible value is 1.

#### **X-Scaling**

¢R=

x-Scale option (at the bottom of the screen) button options

÷	Timescale Settings	
<b>@</b>	Grid Color	
	Select the color of the time axis, labels and grid.	
Ø	Brightness Set the brightness of the time axis grid.	•
+	Timescale Max	1 min
	Select the time span of the time scale.	
Ц	Time Axis Adjust the time span of the time scale to all measured values	Iscale
+ <del>+</del>	Autoscale Switch on Autoscaling for Timescale, shows always complete time. Ends after 1 hour of measurement.	
•••	Revert Timescale Show Timescale Origin on start of Timescale (left)	

Change Color of the X-Grid and the X Scale labeling

Change Brightness of the X-Scale Grid

Set the Maximum of the X-Scale

Set the Time Scale to fullscale

Turn auto-scaling for the X-Scale on/off

Change the starting point (0) of the X-Scale between right and left

### 9. Sensor Sub Menus

#### 9.1. CONDUCTIVITY/TEMPERATURE SENSOR SETTINGS (HDM18/19-Modules, HDU-CDTP and 90XL Cond/Temp)

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.



Serial Number of the connected Sensor

Measuring Range of the connected Sensor

Last Time the Sensor has been calibrated. Format YYYY/MM/DD

Allows modifying the name of the measuring channel. If a "blank" is entered in the list display only the measuring unit will be displayed. **Note**: This function is only available in the base settings of the HDM-Modules.

Allows selecting the color of the list measuring tile.

The selected unit is used in the Graph display only. In the List display the available units update automatically.

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

Allows selecting the conductivity temperature compensation coefficient. For more details please read the chapter about temperature compensation coefficient.

Note: This function is not available with 90XL sensors.



Use the adjustment functions only if you are fully aware of their consequences. Wrong adjustment values will lead to false measurement values which could create a hazard for patients. Please calibrate the sensor after adjustment.

To adjust the conductivity sensor please read the chapter about adjustment. **Note**: This function is not available with 90XL sensors.

Current reading of conductivity, temperature and cell constant.

This function allows Resetting the conductivity adjustment back to factory settings.

Note: This function is not available with 90XL sensors.

Shows the firmware version of the device.

Shows the device status errors of the device. **Note**: This function is not available with 90XL sensors.

#### 9.1.1. ADJUSTMENT PROCEDURE FOR CONDUCTIVITY



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

- 1. For the adjustment, use the supplied 14 mS/cm sodium chloride reference solution.
- 2. Select in the App the Temperature Compensation Coefficient "Reference Solution"
- 3. Enter the value of the reference solution into the adjustment field in the App
- 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	%/К	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 YOU SHOULD 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 Non-linear Function (nLF) according to ISO7888 – EN27888.

For tap, purified and wastewater, we recommend using the Non-linear 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, only change the temperature coefficient, 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 double-checking 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 AK-Type 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	Non-Linear Function for tap, purified and wastewater.	According Standard ISO7888 – DIN EN27888	
RO-DWA	Reverse Osmosis DWA DWA GmbH & Co. KG Ubstadter Straße 28 76698 Ubstadt-Weiher	0,00 %/K	RO-DWA
RO-HERCO	Reverse Osmosis Herco <b>Herco Wassertechnik GmbH</b> Planckstraße 26 71691 Freiberg	2,200 %/K Reference temperature 25°C	RO-HERCO
RO-LAUER	Reverse Osmosis Lauer LAUER MEMBRAN WASSERTECHNIK GmbH Industriegebiet Speichermatt 79599 Wittlingen	nLF-ISO according Standard ISO7888 – DIN EN27888 Reference temperature 25°C	RO-LAUER
RO-DWA	Reverse Osmosis DWA <b>DWA GmbH &amp; Co. KG</b> Ubstadter Straße 28 76698 Ubstadt-Weiher	0,00 %/K	RO-DWA
RO-HERCO	Reverse Osmosis Herco <b>Herco Wassertechnik GmbH</b> Planckstraße 26 71691 Freiberg	2,200 %/K Reference temperature 25°C	RO-HERCO
RO-PPW	Reverse Osmosis PPW <b>Phoenix Pure Water GmbH</b> Siemens Technopark Werner-von-Siemens-Str. 2-6 D-76646 Bruchsal - Germany	2,200 %/K Reference temperature 25°C	RO-PPW

#### 9.2. TEMPERATURE SENSOR DETAILS (HDU-PT100)

The following menu shows the settings for temperature sensors.

÷	Temperature
÷	Serial Number 9999310460000005 Serial number of the device.
	Measuring Range       0.00 100.00 °C         Measuring range of measuring channel.         Last Calibration       17-01-07         Calibration is valid for one year.
F	Name HDU-Pt100-I-100 Edit device name for measuring list and plot.
P	Listitem Color
E	Unit C Select unit for plot.
ţ↓	Number of decimal places 2 Set number of decimal places, does not change measurement accuracy.
	Firmware Version 0.1.2 Version of firmware in measuring device.
~	Device Status Last status reported by device. OK

#### 9.3. PRESSURE SENSOR DETAILS (HDM18/19, HDU-PRx and 90XL-Pressure)

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.

÷	Pressure	
- -	Serial Number 3211310430500003 Serial number of the device.	Serial Number of the connected Sensor
Judului	Measuring Range     -700.00 2580.00       Measuring range of measuring channel.     mmHg	Measuring Range of the connected Sensor
×	Last Calibration     2019/03/03       Calibration is valid for one year.	Last Time the Sensor has been calibrated. Format YYYY/MM/DD
e B	Name HDU-PRH50 Edit device name for measuring list and plot.	Allows modifying the name of the measuring channel. If a "blank" is entered in the list display only the measuring unit will be displayed.
•	Listitem Color	Allows selecting the color of the list measuring tile.
E	Unit mBar	The unit can be changed between mmHg, mBar, kPa and psi.
ţ↓	Number of decimal places 2 Set number of decimal places, does not change measurement accuracy.	Sets the number of decimal places to be idsplayed. Changing this does not affect the accuracy of the sensor.
Ø	<b>Tare Tare</b> -2.52	Allows taring (zeroing) the sensor.
2	Damping Factor 0	Allows selecting the damping factor.
2	Pressure Change Measurement Switches Display for Measurement on/off.	Starts a pressure change measurement. Activation creates a new tile in the List view for this function
	Measurement Duration 01:00	Sets the Duration for the Pressure Change Measurement
	System Leakage 0.0 Corrects the Difference/Minute Result. mBar/min	Set a system leak rate if needed. This is helpful if the system you want to monitor has a systemic leakage you want to account for.
~	Device Status OK	Shows the firmware version of the device. <b>Note</b> : This function is not available with 90XL sensors.
	Firmware Version       1.2.0         Version of firmware in measuring device.	Shows the device status errors 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.

÷	Flow
	Serial Number 332931045000008 Serial number of the device.
<u>Indunut</u>	Measuring Range 0.00 2000.00 ml/min Measuring range of measuring channel.
×	Last Calibration     19-08-06       Calibration is valid for one year.
Ē	Name HDU-FL100.2000 Edit device name for measuring list and plot.
	■ ■ ■ ■ ■ ■ ■ ■ ■ ■ ■ ■ ■ ■ ■ ■ ■ ■ ■
E	Unit Sensor ml/min
E	Unit Accumulation ml Select measurement unit for accumulation.
10	Reset Accumulation Reset Reset the accumulation.
1	Damping Factor 0
	Firmware Version 1.3.1 Version of firmware in measuring device.
*	Device Status OK Last status reported by 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.

÷	рН	
Ŧ	Serial Number 3319310465000001 Serial number of the device.	
Internet	Measuring Range 0.00 14.00 pH Measuring range of measuring channel.	
×	Last Calibration 2019/03/03 Calibration is valid for one year.	
F	Name HDU-pH-I	
	Edit device name for measuring list and plot.	
<b>₽</b>	Temperature Sensor for Compensation	
	Manual Select which temerature sensor should be used for compensation.	
	Manual Compensation Value	
	°C 25.4	
	Enter a manual compensation value.	
<b>@</b>	Listitem Color	
2	Adjustment Adjust all adjustment points one after the other. To do this, select the desired pH buffer and immense the pH probe in the buffer. As soon as the pH reading is stable, press "Confirm".	
	Point 1 pH Confirm After confirmation continue with point 2.	
	Point 2 pH 7.00 After confirmation continue with point 3.	
	Point 3 8.00	
	Once all adjustment points are confirmed, the adjustment values are stored in the sensor. The next step is for verification of adjustment and must be processed.	
	Control pH 6.00 If the slope is negative or greater than 120% the adjustment has failed and must be repeated.	
	Measuring Values	
	рН 7.00	
	Temperature 25.40 °C	
	Slope - OK 100.39 %	
C	Adjustment Reset Reset!	
	Firmware Version 1.3.0 Version of firmware in measuring device.	
*	Device Status OK	

Serial Number of the connected Sensor

Measuring Range of the connected Sensor

Last Time the Sensor has been calibrated. Format JJJJ/MM/DD

Allows modifying the name of the measuring channel. If a "blank" is entered in the list display, only the measuring unit will be displayed.

Allows selecting the source for the temperature compensation. **Note**: This function is not available with 90XL sensors.

Allows input of manual compensation value if no temperature sensor is available.

Allows selecting the color of the list measuring tile.

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

Note: This function is not available with 90XL sensors.

Current reading of pH, temperature and Slope

Temperature and slope reading are not available with 90XL sensors.

This function allows Resetting the pH adjustment back to factory settings.

**Note**: This function is not available with 90XL sensors. Read also: Mandatory calibration of pH-Probe

Shows the5 firmware version of the device.

Shows the device status errors of the device. **Note:** This function is not available with 90XL sensors.

#### 9.6. MANDATORY CALIBRATION OF PH-PROBE



To counteract aging and storage effects, the pH-Electrode must be calibrated (adjusted) periodically. For accurate measurements, an 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 KCI-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. 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. We recommend pH 6 for Point 1, pH 7 for Point 2 and pH 8 for point 3, although other solutions may be used. 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

÷	рН
4	Adjustment Adjust all adjustment points one after the other. To do this, select the desired pH buffer and immense the pH probe in the buffer. As soon as the pH reading is stable, press "Confirm".
	Point 1 pH6.00 Confirm
	After confirmation continue with point 2.
	Point 2 <sub>pH</sub> 7.00
	After confirmation continue with point 3.
	Point 3 <sub>pH</sub> 8.00
	Once all adjustment points are confirmed, the adjustment values are stored in the sensor. The next step is for verification of adjustment and must be processed.
	Control <sub>pH</sub> 6.00
	If the slope is negative or greater than 120% the adjustment has failed and must be repeated.

#### Measuring Values

рН	5.98
Temperature	25.40 °c
Slope - OK	96.34 %



#### 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 the Confirmation button.

After pressing the "Confirm" button the adjustment will move to the next Point.

Note: This function is not available with 90XL sensors.

Current reading of pH, temperature and Slope. Temperature and slope reading are not available with 90XL sensors.

#### 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 2<sup>nd</sup> pH-Value. After the value has stabilized, press the Confirmation button.

After pressing the "Confirm" button the adjustment will move to the next Point.

Note: This function is not available with 90XL sensors.

Current reading of pH, temperature and Slope. Current reading of pH, temperature and Slope. Temperature and slope reading are not available with 90XL sensors.

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÷	рН
2	Adjustment Adjust all adjustment points one after the other. To do this, select the desired pH buffer and immense the pH probe in the buffer. As soon as the pH reading is stable, press "Confirm".
	Point 1 pH6.00 After confirmation continue with point 2.
	Point 2 pH 7.00 After confirmation continue with point 3.
	Point 3 pH 8.00 Confirm
	values are stored in the sensor. The next step is for verification of adjustment and must be processed.
	CONTROL pH 6.00 If the slope is negative or greater than 120% the adjustment has failed and must be repeated.
	Measuring Values

8.00

25.40 °c

98.53 %

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 the Confirmation button.

After pressing the "Confirm" button the adjustment will move to the Confirmation Point. Note: This function is not available with 90XL sensors.

Current reading of pH, temperature and Slope. Temperature and slope reading are not available with 90XL sensors.

#### **Confirming the adjustment**

Note: This function is not available with 90XL sensors.

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

After confirmation continue with point 2.

Point 1 <sub>pH</sub> 6.00

pН

← pH

Temperature

Slope - OK

Adjustment

<sub>pH</sub>\_7.00 Point 2 After confirmation continue with point 3.

<sub>pH</sub> 8.00 Point 3

Once all adjustment points are confirmed, the adjustment values are stored in the sensor. The next step is fo verification of adjustment and must be processed.

Adjust all adjustment points one after the other. To do this, select the desired pH buffer and immense the pH probe in the buffer. As soon as the pH reading is stable, press "Confirm".

Control <sub>pH</sub> 6.00

Confirm

If the slope is negative or greater than 120% t adjustment has failed and must be repeated. the

#### **Measuring Values**

рН	6.00
Temperature	<b>25.40</b> ℃
Slope - OK	98.17 %

With the confirmation button, you confirm that the sensor is measured against the first measuring point, in this case the used buffer solution is pH 6.

After pressing the "Confirm" button 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.

**Note**: The following function is not available with 90XL sensors.

In case the SmartHDM-App detects an Error that wasn't detected by the Sensor, SmartHDM will mark the calibration Date as 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.

рН	6.01
Temperature	<b>25.40</b> °c
Slope - OK	98.87 %
рН	2.51
Temperature	<b>25.40</b> °c

рН	8.18
Temperature	<b>25.40</b> ℃
Slope - Error	167.22 %

#### 9.1. ADJUSTMENT PROCEDURE FOR 90XP pH-Module

The following must be observed when adjusting the 90XL pH module. The pH electrode must be adjusted before use. If the electrode on a SmartHDM system has not yet been adjusted, pH7 and pH4 must be adjusted. Otherwise, you can only adjust the pH7 value. However, both values must be adjusted for an accurate measurement.



### 10. HDU-Sensors and Interfaces

#### **10.1. INTERFACE CABLE**

In conjunction with HDC- or other Android-Devices, one of these cables is needed for each HDU-Sensor. Different cable versions are available:



HDU-Sensor cable USB-A, 1.8 m/ 5.9ft 31.0485.20 Needed in conjunction with the HDC Devices. HDU-Sensor cable USB-C, 1.8 m/ 5.9ft 31.0485.31

To be used in conjunction with Smartphones.

#### **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 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 Android 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 use.

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

#### 10.4.1. TECHNICAL DATA

Conductivity	Quadrupole carbon Compound electrode. Four measuring ranges. The temperature compensation coefficient may be adjust		
	Range:	0200.00 mS/cm	
	Cell constant:	0,54 1/cm	
	Accuracy:	0199 uS/cm 0,3% ± 0.6 uS/cm	
		2001999 uS/cm ± 6 uS/cm	
		211.99 mS/cm ± 0.06 mS/cm	
		1219.99 mS/cm ± 0.03 mS/cm	
		20200 mS/cm ± 0.6% of reading	
Temperature	Sensor integrated into the conductivity electrode		
	Range:	0100 °C	
	Resolution:	0.01 °C	
	Accuracy:	± 0.1°C	
Calibration	PTB/NIST traceable		
Degree of protection	IP67		
Power supply	3.3 to 5 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.

#### 10.5.1. **TECHNICAL DATA**



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

#### Pressure

HDU-PRH5		HDU-PRS5	
Range:	-5 to 5 psi -0.34 to 0,34 bar -258 to +258 mmHg	Range:	-5 to 5 psi -0.34 to 0,34 bar -258 to +258 mmHg
Resolution:	0.01 mmHg	Resolution:	0.01 mmHg
Accuracy:	General 0.05% full scale	Accuracy:	General 0.1% full scale
Media Compatibility:	Gasses	Media Compatibility:	Gasses and Fluids
Overpressure	2 x full scale	Overpressure	2 x full scale
HDU-PRH15		HDU-PRS15	
Range:	- 13,5 to 15 psi -0.90 to 1 bar -700 to +775 mmHg	Range:	- 13,5 to 15 psi -0.90 to 1 bar -700 to +775 mmHg
Resolution:	0.01 mmHg	Resolution:	0.01 mmHg
Accuracy:	General 0.05% full scale 0 to 300 mmHg ± 0.4 mmHg	Accuracy:	General 0.1% full scale
Media Compatibility:	Gasses	Media Compatibility:	Gasses and Fluids
Overpressure	2 x full scale	Overpressure	2 x full scale

#### HDU-PRH30

Range:	-13,5 to 36,7 psi -0.90 to 2.5 bar -700 to +1900 mmHg	Range:	-13,5 to 36,7 psi -0.90 to 2.5 bar -700 to +1900 mmHg
Resolution:	0.01 mmHg	Resolution:	0.01 mmHg
Accuracy:	0 to 300 mmHg ± 0,8 mmHg Otherwise ± 1 mmHg	Accuracy:	0 to 300 mmHg ± 1 mmHg Otherwise ± 2 mmHg
Media Compatibility:	Gasses	Media Compatibility:	Gasses and Fluids
Overpressure	1.5 x full scale	Overpressure	1.5 x full scale

HDU-PRS30

	HDU-PRH50		HDU-PRS100	
	Range:	-13,5 to 50 psi -0.90 to 3,4 bar -700 to 2580 mmHg	Range:	-13,5 to 100 psi -0.90 to 6,9 bar -700 to 5150 mmHg
	Resolution:	0.1 mmHg	Resolution:	0.1 mmHg
	Accuracy:	0.05% full scale	Accuracy:	0.1% full scale
	Media Compatibility:	Gasses	Media Compatibility:	Gasses and Fluids
	Overpressure	2 x full scale	Overpressure	2 x full scale
	HDU-PRH100			
	Range:	-13,5 to 100 psi -0.90 to 6,9 bar -700 to 5150 mmHg		
	Resolution:	0.1 mmHg		
	Accuracy:	0.05% full scale		
	Media Compatibility:	Gasses		
	Overpressure	2 x full scale		
Calibration	PTB/NIST trace	able		
Communication rate	Five times per	second		
Degree of protection	IP67			
Power supply	3,3 to 5 V, max via RS485- or U	. 60 mA ISB-Interface		
Environmental conditions	Operating Tem Storage Tempe Operating and relative humidi from 0 to 50°C	perature Range: 0 to 50°C erature Range: -40 to 80°C Storage Humidity: 85% max ity non-condensing		
Dimensions	80 x 34 mm			

#### 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. A 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:	<b>100 to 2000 ml/min</b> H <sub>2</sub> O 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 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

**Temperature HDU-Pt100** 

#### 10.7.1. TECHNICAL DATA



	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 V, 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		

Range:

-50...100 °C

#### **10.8. Pt100 SENSORS TEMPERATURE SENSOR FAMILY**



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 the supplied 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 adjustment functions of the SmartHDM App only if you are fully aware of their consequences. Wrong adjustment values will lead to false measurement values and in consequence these false values lead to hazards for patients.

рН	Range: Resolution: Accuracy:	014 pH 0.01 pH ± 0.02 pH
Degree of protection	IP54	
Power supply	3,3 to 5 V, m via RS485- or	ax. 80 mA r USB-Interface
Environmental conditions	Operating Temperature Range: 0 to 50°C Storage Temperature Range: -40 to 80°C Operating and Storage Humidity: 85% ma relative humidity non-condensing from 0 to 50°C	
Dimensions	64 x 45 x 25	mm



### 11. HDM19 Modules

Hemodialysis Sensor Modules.





ON/OFF Button In case of communication via USB-Connection, the device cannot be switched OFF.

Connection indication USB Bluetooth

**Connection Selection** 

#### **11.3. VENTILATION VALVE**

The ventilation valve allows opening the flow-through measuring cell to environmental

This option can be used in the calibration of Fresenius dialysis machines.



To be able to switch the valve from the SmartHDM App, please activate the ventilation valve function in the module settings menu. This displays a button for the valve in the list display.

#### 11.4. IV-POLE HOLDER



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 module and lock it in place. The clamp itself may also be turned to keep the device upright on a flat surface.

#### 11.5. ACCURACY OF CONDUCTIVITY AND TEMPERATURE MEASUREMENT



It should be noted that after measuring high temperatures (> 60°C), the HDM18/19 must be acclimatized for approx. 30 minutes in order to be able to carry out highly accurate conductivity or temperature measurements afterwards. For this purpose, rinsing with the measurement medium at low or target temperature is sufficient.

#### **11.6. BATTERY CHARGING**



For safety reasons and to ensure that the unit is quickly recharged, please use only the power supply delivered with the device. The power supply is Quickcharge 2.0 compatible.

Do not extend the interface cable while charging the device.

#### **11.7. BLUETOOTH CONNECTION**



To communicate with the HDM19 via Bluetooth, please turn on the Bluetooth connection on the Android device. Pair the HDM19 with the Android device exclusively via the + function in the head of in SmartHDM App.

In the case of radio interference with other sources like WLAN, a stable Bluetooth connection is not possible. For safety reasons, the SmartHDM software will then terminate the communication. Alternatively, please use the USB connection. If measured values are frequently displayed as "error", please also connect the device via the USB interface.

#### 11.8. RINSING & DISINFECTING



To avoid deposits in the conductivity electrode, the flow channel must be flushed with RO water after use. Do not store the sensor in wet conditions.

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

#### **11.9. TECHNICAL DATA**

Conductivity	Four measuring ranges - Quadropole electrode
	Temperature compensation is user-selectable depending
	on the brand of dialysis machine.

Range:	0 to 30.00 mS/cm
Cell constant:	typical 0,54 1/cm
Accuracy:	0 to 199 uS/cm ± 0.6 uS/cm
	200 to 1999 uS/cm ± 6 uS/cm
	2 to 11.99 mS/cm ± 0.06 mS/cm
	12 to 15.99 mS/cm ± 0.03 mS/cm
	16 to 30 mS/cm ± 0.06 mS/cm

Temperature	Sensor integrated into the conductivity electrode		
	Range:	0 to 100 °C	
	Resolution:	0.01 °C	
	Accuracy:	± 0.1°C	
Pressure Internal Flow through path	Reading selectable as r Range:	mmHg, kPa, Bar or PSI -700 to +1900 mmHg	
	Resolution:	0.01 mmHg	
	Accuracy:	± 2 mmHg	
	Overpressure:	2 x full scale	
	Media Compatibility:	Gasses and Fluids	
Pressure External External connector	Range:	-700 to +1900 mmHg	
	Resolution:	0.01 mmHg	
	Accuracy:	0 to 300 mmHg ± 1 mmHg Otherwise ± 2 mmHg	
	Media Compatibility:	Gasses and Fluids	
	Overpressure:	2 x full scale	
Degree of protection	IP67		
HDM19	3,7 V / 5500 mAh Li-ion polymer battery		
Power Supply	DCP Charge Compatible 5 V, 1.5 A		
Dimensions	110 x 110 x 40 mm		
Weight	0.5 Kg		

### 12. 90XL-Modules

Hemodialysis Sensor Modules.



#### 12.1. OVERVIEW

With a special USB interface cable, 90XL sensors may be connected to the SmartHDM. The SmartHDM App automatically detects the various sensors. Not all advanced 90XL functions are supported by the HDC system.



#### 12.2. Details

Further information on the sensors can be found in the User's Guide of the 90XL Meter.

The order data of the interface are as follows: Article No.: 31.0486.20 SmartHDM USB-A to 90XL Adapter Cable



#### **12.3. 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.

### 13. Adjustment and Calibration



Use the 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 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

#### 13.1. 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.

#### **13.2. 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.

#### 13.3. 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 do a calibration.

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

- Conductivity is adjusted only at one sampling point. No further points are needed due to the high linearity of the conductivity probe.
- The temperature sensor drift is very little. Normally there is no adjustment necessary. The adjustment is done by using two set points. Adjustment can only be carried out by IBP or Mesa.
- The pressure transducers drift is linear within its tolerances, so there is a tare (zeroing) function (see chapter "Measuring"). Normally there is no adjustment necessary.
   The adjustment is made by using seven sampling points. The adjustment can only be carried out by IBP or Mesa.
- Due to the kind of technology, it is necessary to adjust pH probes periodically. This is done using three set points.

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

#### **13.4. 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

### 14. Maintenance

Generally, all SmartHDM devices can be considered as easy-care. Like all measuring instruments, there is a minimum of maintenance and care necessary to ensure that all functions work flawlessly.

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 parts in the SmartHDM devices which you can repair yourself. Contact our technical support team in the event of any malfunction. If the device should become damaged or malfunction, send it to IBP or your distributor for repair.

#### 14.1. 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.

#### 14.2. 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.

#### 14.3. 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.

#### 14.4. 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 calibration:

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

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



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.