HAMILTON

OneFerm pH

Single Use pH Sensors

Operating Instructions

Hamilton Warranty

Please refer to the General Terms of Sales (GTS).

Important Note

Contents of this manual can be modified without previous announcement. Technical modifications reserved. Greatest possible care was used on the correctness of the information in this manual. If errors should be discovered nevertheless, Hamilton Bonaduz AG is pleased to be informed about it. Regardless of this, Hamilton Bonaduz AG cannot assume liability for any errors in this manual or for their consequences.

Table of Contents

1 General Information

1.1 Intended Use

The OneFerm pH sensor is a single use probe for the measurement of pH in aqueous solutions. It is an integral part of a single use container e.g. a bioreactor, a mixing bag or a chromatography column. Some models have a built-in temperature sensor (e.g. Pt1000) used for the temperature compensation of the pH signal. This temperature sensor must not be used for process control. The OneFerm pH sensor can be sterilized together with the single use container by high energy irradiation and is not autoclaveable.

1.2 About these Operating Instructions

These Operating Instructions describe the features and operation of the OneFerm pH sensor. After reading this manual the user should be capable of operating the OneFerm pH sensor.

⚠ **ATTENTION! Essential information for avoiding personal injury or damage to equipment.**

NOTE: Important instructions or interesting information.

2 Liability

The liability of Hamilton Bonaduz AG is detailed in the document «General Terms and Conditions of Sale and Delivery». Hamilton is expressly not liable for direct or indirect losses arising from use of the OneFerm pH sensor. It must in particular be insured in this conjunction that malfunctions can occur on account of the inherently limited useful life of the OneFerm pH sensor contingent upon their relevant applications. The user is responsible for the calibration and maintenance of the OneFerm pH sensor. In the case of critical applications, Hamilton recommends using back-up measuring points in order to avoid consequential damages. The user is responsible for taking suitable precautions in the event of a module failure.

3 Safety Precautions and Hazards

⚠ **ATTENTION! Read the following safety instructions carefully before installing and operating the OneFerm pH sensor.**

3.1 General Precautions

For safe and correct use of the OneFerm pH sensor, it is essential that both operating and service personnel follow generally accepted safety procedures as well as the safety instructions given in this document. For safe and correct use of the OneFerm pH sensor, it is essential that both operating and service personnel follow

generally accepted safety procedures as well as the safety instructions given in this document, the «OneFerm pH Operating Instructions». Cleaning, assembly and maintenance should be performed by personnel trained in such work. The OneFerm pH sensors are not intended to be removed from the SU container before or after the process. In case of the need of removing the OneFerm pH sensor, it is recommended to wear safety goggles and protective gloves.

The OneFerm pH sensor cannot be repaired by the operator and has to be sent back to Hamilton for inspection.

Necessary precautions should be taken when transporting the OneFerm pH sensor. Every OneFerm pH sensor sent back for repair must be decontaminated (see chapter 7.3 «Returning OneFerm pH for Inspection»). If the conditions described in these Operating Instructions are not adhered to or if there is any inappropriate interference with the equipment, all of our manufacturer's warranties become obsolete.

3.2 Operation of the OneFerm pH Sensors

OneFerm pH sensors must be used for their intended use (see chapter 1.1 «Intended Use») and in optimum safety and operational conditions. The specifications such as temperature or pressure defined in the Specification Sheet available at www.hamiltoncompany.com must not be exceeded under any circumstances. Potential hazards exist if the OneFerm pH sensor is not operated correctly.

Strictly follow the instructions given to connect (see chapter 6.1 «Connection to the transmitter») and disconnect (see chapter 6.4 «Disconecting the OneFerm pH sensor») the OneFerm pH sensor from a cable or Arc Module pH. Do not apply any forces to the bag or the OneFerm pH sensor. Failure to do so may break the OneFerm pH sensor and/or damage the bag integrity.

⚠ ATTENTION! Do not autoclave the OneFerm pH. Failure to do so will damage the sensor.

⚠ ATTENTION! Do not twist or turn the OneFerm pH sensor to avoid damage or leakage and avoid vibration.

3.3 Chemical, Radioactive or Biological Hazard Precautions

Selection of the appropriate safety level and implementation of the required safety measures for working with the OneFerm pH sensor is the sole responsibility of the user.

If working with hazardous liquids, observe and carry out the maintenance procedures, paying particular attention to cleaning and decontamination. If the OneFerm pH sensor becomes contaminated with biohazardous, radioactive or chemical material, it should be cleaned. Failure to observe and carry out the maintenance procedures may impair the reliability and correct functioning of the measuring sensor.

4 Product Description

4.1 General Description

Optimal yields in bio-processes are only obtained with the use of extensive process control systems, especially the precise monitoring of pH value. The glass pH electrode is the most robust and reliable device available for

the measurement of pH. It is possible to utilize such reusable sensors in single use processes but it has major drawbacks, including laborious handling (Figure 1) and risk of contamination. Alternative sensor technologies such as optical pH are easier to implement but do not deliver the accuracy and measurement stability required for process control. The direct integration of a single use glass electrode eliminates laborious preparation steps (Figure 2) while providing high measurement quality during the process. The Hamilton OneFerm pH sensor is a single use glass electrode developed to this end. It retains the high accuracy performance of a glass electrode even after high energy irradiation and dry storage. It is delivered as an integrated part of a single use container to provide ease of use.

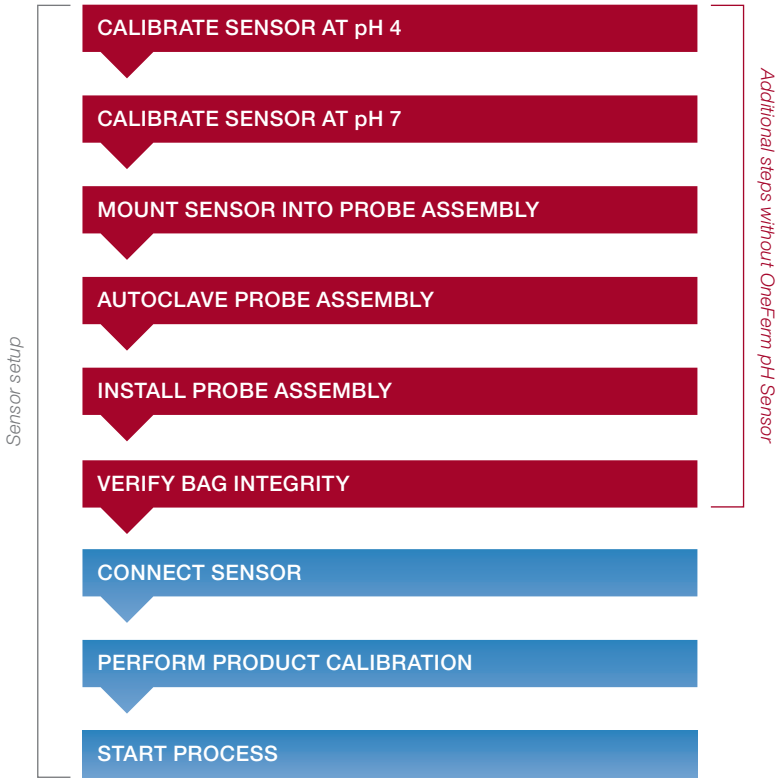


Figure 1: Tedious sensor setup using a multiuse pH sensor with a single use container.

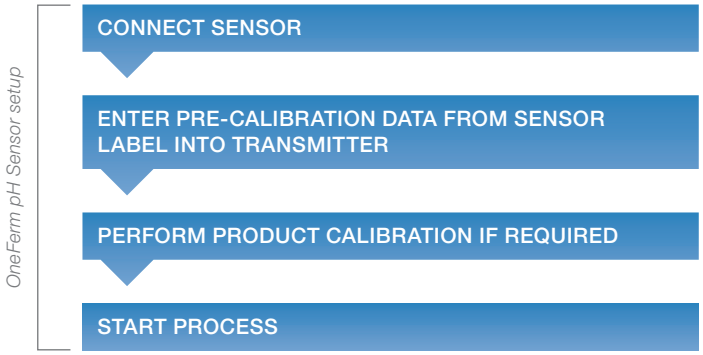


Figure 2: Sensor setup using a single use container with integrated OneFerm pH sensor.

4.2 Hardware Description

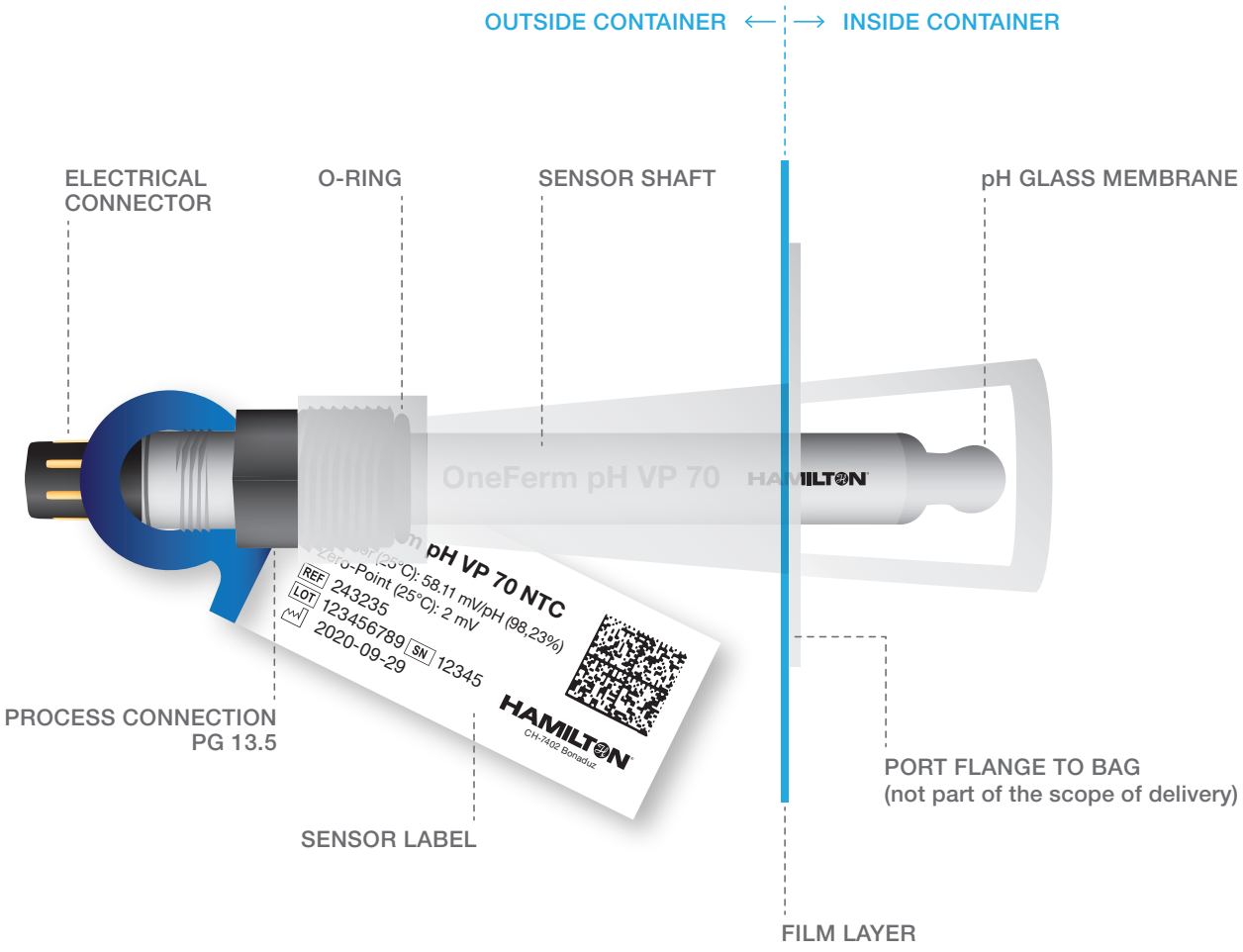


Figure 3: OneFerm pH sensor description.

The OneFerm pH sensor is an electrochemical pH probe, which is available as integral part of a single use container. It combines a pH electrode, a reference electrode and an optional temperature element (e.g. Pt1000) in one sensor. The pH sensitive part is a pH glass membrane. Several electrical connectors are available e.g. VP, K8 and S8.

4.3 pH measurement principle

pH glass sensors offer the most robust and reliable measurement for the pH-value. The pH glass membrane forms a gel layer, which is highly sensitve to protons and non-sensitive to other ions. The H^+ ions create a small electrical potential over the pH glass membrane, which is directly proportional to pH.

To learn more about the electrochemical pH measurement principle, please watch the «Hamilton pH Basics» video.

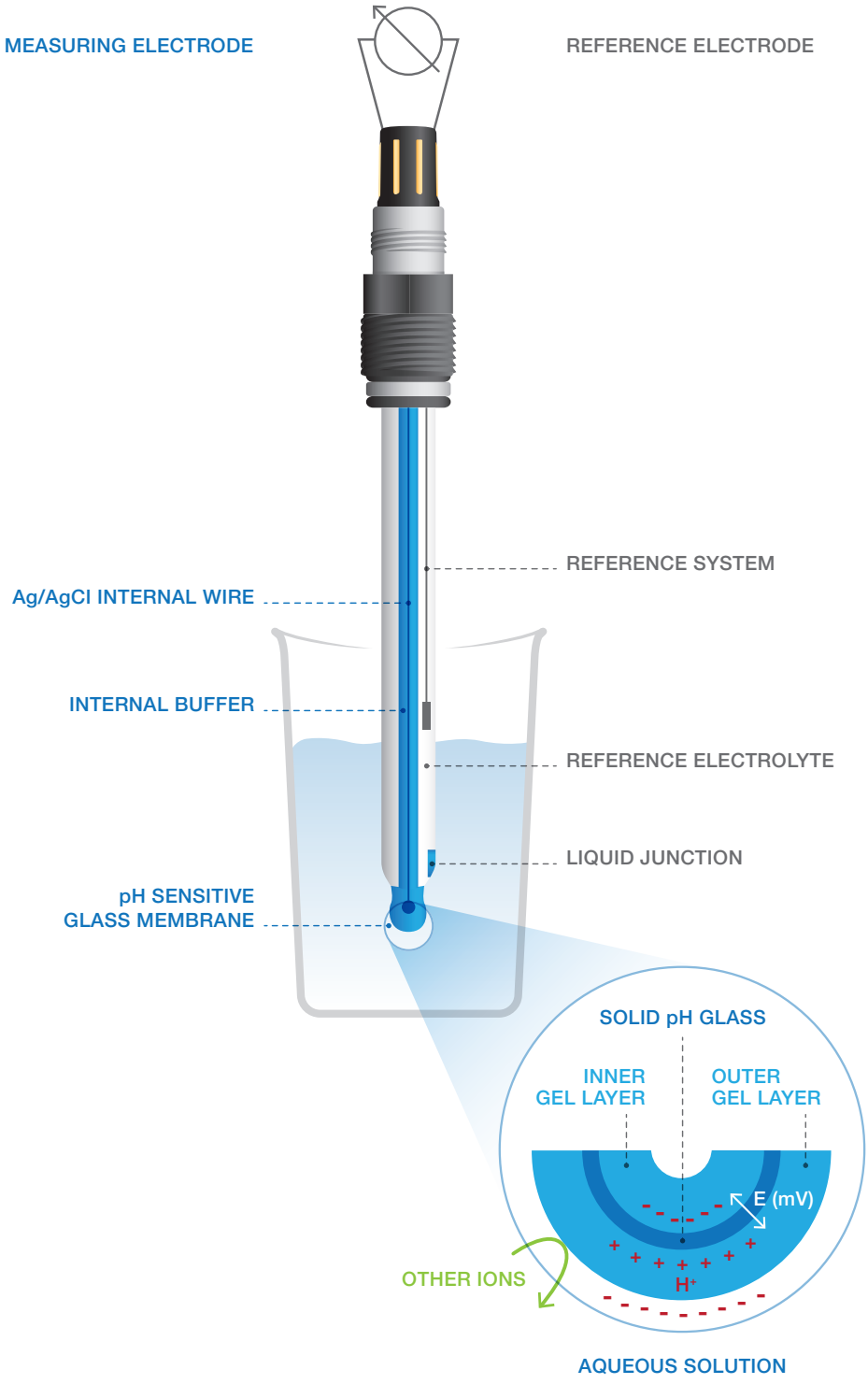


Figure 4: Measurement principle of an electrochemical pH sensor.

5 Installation

5.1 Unpacking and Cleaning (for OEM Customers only)

1. Carefully unpack the OneFerm pH sensor. Enclosed you will find the OneFerm pH sensor with the watering cap on, the declaration of conformity (DoQ) and the product lable with the needed sensor information.
2. Inspect the OneFerm pH sensor for shipping damages or missing parts.
3. To clean the OneFerm pH sensor, soak a paper towel with Isopropanol 70 - 80% or Ethanol 70 - 80% and wipe down the sensor.

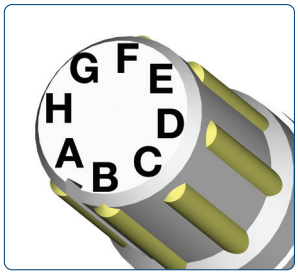
After cleaning the sensor, air dry the solvent prior to installing it into the SU container. Make sure that all contacts of sensor are completely dry to prevent electrical damage (short circuit).

NOTE: The performance of the OneFerm pH sensor can change by damage of the electrodes in aggressive media, high temperature, or by contamination of the electrodes during the sensor's lifetime. The quality of the OneFerm pH sensor can be detected by a high deviation of the zero point from the pre-calibration when performing a product calibration.

5.2 Electrical Connection

The OneFerm pH sensor is fitted with a VP6 socket head. The six golden contacts are denoted as pin A to pin F. For easy identification of each pin, the head has a notch between pin A and pin B.

For the easiest and safest connection of OneFerm pH sensor, always use Hamilton VP 6 or VP8 cables, available in a range of different lengths. The most safe signal stability can be achieved by using the Arc Module pH SU. To ensure the highest signal quality standard, a cable between the OneFerm pH sensor and the Arc Module SU pH is not recommended.



VP Pin	Function
A	Kathode
B	Anode
C	not connected
D	not connected
E	Temperature sensor 1
F	Temperature sensor 2

6 Operation

6.1 Connection to the transmitter

1. Remove the protective cap from the electrical connector.
2. Verify that the sensor and cable connectors are dry and clean.
3. Connect the transmitter to the OneFerm pH sensor using the appropriate cable.
4. Switch on the transmitter or controller and verify reading.

6.2 Calibration

The OneFerm pH sensor has been pre-calibrated at pH 4 and pH 7 at 25° C temperature; hence calibration prior to your process is not necessary. The calibration values for zero point and slope can be found on the label attached to the sensor head.

1. Read the zero point (mV) and slope (mV/pH or %) written on the sensor label (see figure 5).
2. Enter the zero point and slope values into the transmitter.
3. If required perform a product calibration step to increase accuracy to ± 0.1 pH (valid within 2 pH units from the product calibration point and at measurement temperature).

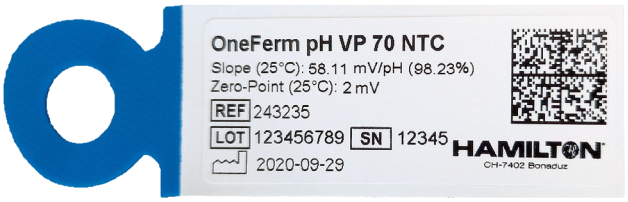


Figure 5: Example sensor label with calibration values.

6.3 Measurement

1. Let the OneFerm equilibrate in process media. A stable signal should be obtained within 30 minutes of wet-in time.
2. Carry out a product calibration if required (see Calibration).
3. Start measurement.

6.4 Disconecting the OneFerm pH sensor

⚠ ATTENTION! Do not unscrew the OneFerm pH sensor while disconnecting the Arc Module SU pH or cable to avoid any leakage.

1. Hold the connector or Arc Module SU pH housing
2. Unscrew the coupling nut
3. Remove the cable or Arc Module SU pH from the OneFerm pH sensor

7 Troubleshooting

7.1 Maintenance and errors

The OneFerm pH sensors have been designed for single use. No maintenance measures are required.

Errors (failures)	Cause	Solution
No pH reading	Transmitter not powered	Power or switch on the transmitter
	The OneFerm pH sensor is not properly immersed in solution (media/buffer) or is broken	Immerse the tip of the probe in solution (media/buffer) Replace the OneFerm pH sensor
	Inappropriate connection	Check if cable is connected properly or defective
Unstable pH reading	Contaminated connector	Clean the connector head (see chapter 5.1 «Unpacking and Cleaning») Dry the connector head with a dry paper tissue
	Electromagnetic interferences	Use the appropriate shielded interferences coaxial cable Contact the container manufacturer for identifying the appropriate cable
Drift too high after wet-in	Wet-in time too short	Extend wet-in time until the signal is stable
Wrong measurement result	Wrong calibration values	Verify and set the calibration values (zero point and slope)
	Shift after storage	Carry out product calibration
Glass resistance too high	The OneFerm pH sensor is not properly immersed in solution (media/buffer) or is broken	Immerse the tip of the probe in solution (media/buffer) Replace the OneFerm pH sensor
Glass resistance too low	The reference system of the OneFerm pH sensor is broken	Replace the OneFerm pH sensor
No temperature reading	The temperature sensor in the OneFerm pH sensor is broken	Replace the OneFerm pH sensor Compensate pH reading with external sensor

7.2 Getting Technicall Support

If a problem persists even after you have attempted to correct it, contact Hamilton`s Customer Support: Please refer to the contact information at the back of this Manual.

7.3 Returning OneFerm pH for Inspection

The OneFerm pH sensor cannot be repaired by the operator and has to be sent back to Hamilton for inspection. Before returning an OneFerm pH to Hamilton for inspection, contact our Customer Service and request a Returned Material Authorization (RMA) number. Do not return an OneFerm pH to Hamilton without a RMA number. This number assures proper tracking of your sensor. OneFerm pH that are returned without an RMA number will be sent back to the customer without being repaired. Decontaminate the OneFerm pH and remove health hazards, such as radiation, hazardous chemicals, infectious agents, etc. Provide the complete description of any hazardous materials that have been in contact with the sensor.

8 Disposal

The design of Hamilton sensors optimally considers environmental compatibility. In accordance with the EC guideline 2012/19/EU Hamilton sensors that are worn out or no longer required must be sent to a dedicated collection point for electrical and electronic devices, alternatively, must be sent to Hamilton for disposal. Sensors must not be sent to an unsorted waste disposal point.

有害物質表，請參閱www.hamiltoncompany.com, 章節過程分析，符合性聲明

9 Ordering Information

The OneFerm pH sensor is delivered as fully integrated part of a single use container. It is not meant to be supplied as stand-alone product. Please contact the container manufacturer for further information on available features and accessories.

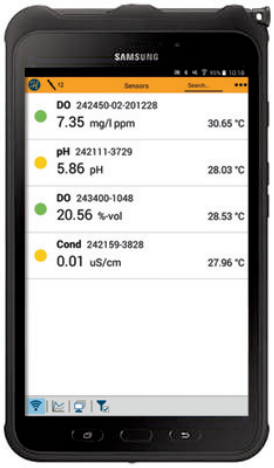
9.1 OneFerm pH Sensor

Ref	Description	Length
243235	OneFerm pH VP70 NTC	70
243236	OneFerm pH VP120 NTC	120

9.2 Arc Module SU pH

Ref	Description
243233	Arc Module SU pH

9.3 Parts and Accessories



Ref	Product Name
10071111	Arc View Mobile Basic for none Ex environment

Description: The pre-configured Arc View Mobile, Hamilton's mobile solution for monitoring measurement values, calibrating Arc sensors and configuring various parameters with the unified user interface for pH, DO, Conductivity and ORP. The Arc View Mobile is based on the Samsung Galaxy Tab Active tablet and comes pre-configured with the ArcAir basic, app blocker application, power supply cable, instruction manual and Hamilton quick guide.

10071113	Arc View Mobile Advanced for none Ex environment

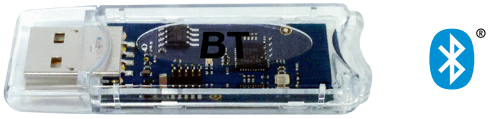
Description: The pre-configured Arc View Mobile, Hamilton`s mobile solution for monitoring measurement values, calibrating Arc sensors and configuring various parameters with the unified user interface for pH, DO, Conductivity and ORP. The Arc View Mobile is based on the Samsung Galaxy Tab Active tablet and comes pre-configured with the ArcAir advanced application, including features for CFR 21 Part 11 and Eudralex Volume 4 Annex 11 compliance, app blocker application, power supply cable, instruction manual and Hamilton quick guide.

Ref	Description
243490-01	Arc USB Power Cable with VP8 connector (for the Arc Wi 1G Adapter BT)
243490-02	Arc USB Power Cable with M12 8-pole connector (for the Arc Wi 2G Adapter BT)

Description: The Arc USB Power Cable provides power supply via USB port for Arc sensors and digital communication.

Ref	Description
243460	Arc Wi 1G Adapter BT
243470	Arc Wi 2G Adapter BT

Description: Designed to add Bluetooth communication to the Arc Module SU pH when connecting directly to the PLC via modbus. The Arc Wi 2G Adapter BT also simplifies analog connection (4-20 mA) to the PLC.



Ref	Description
243499	Arc Wireless Converter BT
242333	Arc Wireless Converter BT Advanced

Description: Designed for wireless communication between ArcAir and Arc Wi Adapter BT.

Ref	Description	Ref	Description
355263	Sensor Data Cable VP8, 1m	355266	Sensor Data Cable VP8, 10m
355264	Sensor Data Cable VP8, 3m	355267	Sensor Data Cable VP8, 15m
355265	Sensor Data Cable VP8, 5m	355268	Sensor Data Cable VP8, 20m

Ref	Description	Ref	Description
10070910	Data Cable VP8 / M12, 1m	10067844	Data Cable VP8 / M12, 5m
10071905	Data Cable VP8 / M12, 3m	10067846	Data Cable VP8 / M12, 10m

9.4 Services

Hamilton service engineers provide customers with on-site services. Hamilton offers a wide range of services from technical support to initial operation, qualification and maintenance of the sensors.

Various tailored services are offered especially for OEM customers. Experienced service engineers ensure an optimal and professional service.

In order to find your local service support please visit: www.hamiltoncompany.com/process-analytics/support

Overview of service offers

- Online service
- Technical support
- Initial Operation/Calibration
- Qualification (IQ/OQ)
- Service packages
- Maintenance
- Training

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