OneFerm pH Single Use pH Sensors

Operating Instructions





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Hamilton Warranty

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

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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 is not autoclavable but has been beta- or gamma irradiated along with the single use container it has been integrated in.

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 the use of the sensors. The user is responsible for taking suitable precautions in the event of a sensor failure. 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 sensor failure.

3 Safety Precautions and Hazards

△ ATTENTION! Read the following safety instructions carefully before operating the OneFerm pH sensor.

3.1 General Precautions

For safe and correct use of the OneFerm pH sensor, it is essential that operating personnel follow generally accepted safety procedures as well as the safety instructions given in this document. The technical specifications (see chapter 8) such as operating temperature or pressure may under no circumstances be exceeded. Inappropriate use or misuse can be dangerous. Since the sensors are made of glass, they should be handled with care. If the conditions described in these Operating Instructions are not adhered to or if there is any inappropriate use 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 and in optimum safety and operational conditions. Please follow carefully the handling instructions delivered with the single use container to avoid mechanical damages due to vibration, bending or torsion.

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

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. Please follow the disposal instructions provided in chapter 7.



4 Product Description

4.1 General Description

Optimal yields in bioprocesses are only obtained with extensive process control, especially precise monitoring of pH. Trusted sensor technologies have been implemented for this purpose. 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 beta or gamma irradiation and dry storage. It is delivered as an integrated part of a single use container to provide ease of use.

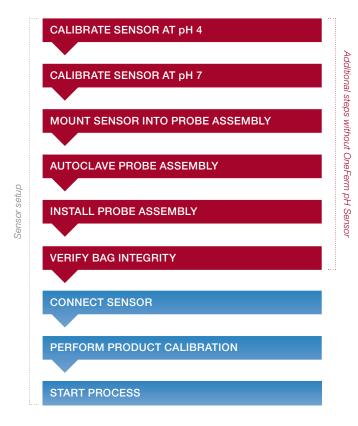


Figure 1: Tedious sensor setup using a multiuse pH sensor with a single use container.

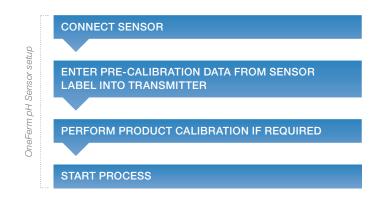


Figure 2: Sensor setup using a single use container with integrated OneFerm pH sensor.

4.2 Hardware Description

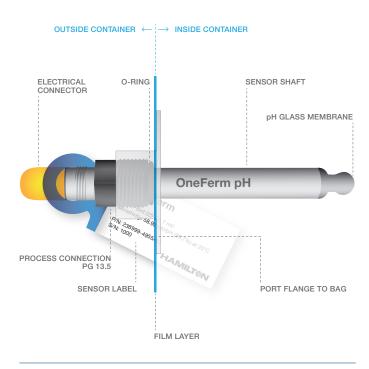


Figure 3: OneFerm pH sensor description.

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.



PRODUCT DESCRIPTION OPERATION

4.3 pH measurement principle

pH glass sensors are the most robust and reliable tools to measure pH. The pH glass membrane forms a gel layer, which is highly sensitive 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.

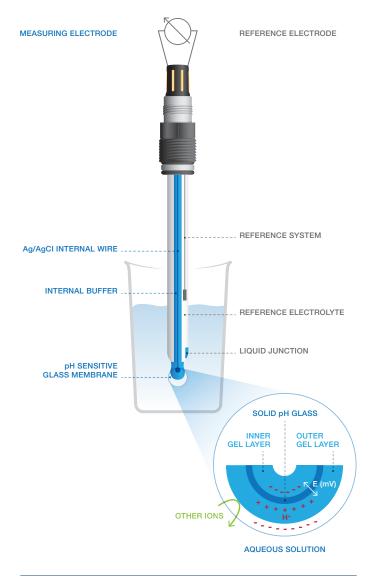


Figure 4: Measurement principle of an electrochemical pH sensor.

5 Operation

5.1 Unpacking

Please refer to the manufacturer instructions of the single use container for unpacking and installation guidelines.

5.2 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.

5.3 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 sensitivity (slope) can be found on the label attached to the sensor head.

- 1. Read the zero point (mV) and sensitivity (mV/pH or %) written on the sensor label (see figure 5).
- 2. Enter the zero point and sensitivity values into the transmitter.
- 3. If required perform a product calibration step to increase accuracy to \pm 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.

5.4 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.



Maintenance 6

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

Disposal



The OneFerm pH sensor is a single use device that has to be disposed at the end of the process. If the process requires decontamination, the sensor must be decontaminated prior to disposal.

The design of Hamilton sensors optimally considers environmental compatibility. In accordance with the EC guideline 2002/96/EG Hamilton sensors that are worn out or no longer required must be sent to a dedicated collection point. Sensors should not be sent to an unsorted waste disposal point.

Technical Specifications

The technical specifications of the OneFerm pH sensors e.g. the measuring range, accuracy or operating temperature range can be found and downloaded at www.hamiltoncompany.com.

Troubleshooting

No signal

Transmitter is not switched on	Switch on transmitter.
Inappropriate connection	Check if cable is connected properly.
Defective cable	Check cable for damages and replace cable if required.
Defective sensor	Check for sensor damages and contact container manufacturer if necessary.

Unstable signal / long response time

Moisture in the connector	Clean the connector head with a paper towel moistened with ethanol. Dry the connector head after this procedure with a dry paper towel.
Electromagnetic interferences	Use the appropriate shielded coaxial cable. Contact the container manufacturer for identifying the appropriate cable.
Defective cable	Check cable for damages and replace cable if required.
Drift too high after wet-in	
Wet-in time too short	Extend wet-in time until the signal is stable.
Wrong measurement results	s
Wrong calibration values	Verify that the calibration values (zero point / sensitivity) are entered correctly.
Shift after storage	Carry out product calibration.

10 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.



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REF 624844/01 — w 05/2015

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