

September 12th, 2022

FIELD SAFETY NOTICE for HAMILTON-G5/S1/GALILEO/RAPHAEL distribution partners

Teledyne Oxygen sensor R-22A instead of R-22MED

- Recipients:**
- All distributors and health care facilities having received a Teledyne Oxygen sensor R-22A, PN396009, Batch number 20220530, Serial number 816051 until 816250 from Hamilton Medical AG
 - Given the urgency of this field safety notice we ask you to take the required action and send confirmation of this to Hamilton Medical AG within 30 working days after receipt of this information.

Product: Teledyne Oxygen sensor R-22A, PN396009, Batch Number 20220530, Serial number 816051 until 816250

Dear distribution partner,

Hamilton Medical AG has become aware that there has been one batch where instead of the Teledyne Oxygen Sensor R-22MED, the Teledyne Oxygen Sensor R-22A has been delivered to customers. The Teledyne Oxygen Sensor R-22A is an Oxygen Sensor not developed for medical use. Further details are given on page 2 of this document.

Please confirm with your signature on the enclosed confirmation sheet (page 4) that you, as the distribution partner, have received this FSN and have taken the actions specified by us.

**Reason for the
field safety notice:**

With this notice, we would like to inform you that within the shipment of product PN396009, Batch Number 20220530 (Serial number 816051 until 816250) an oxygen sensor not released for medical use has been delivered to distribution partners/customers.

How can this be detected?

The label on the pouch as well as on the product states class R-22A instead of R-22MED. Furthermore, the label on the product itself is yellow instead of white.



Correct



Needs to be returned!

Is there a risk to patients or user?

We have internally performed the calibration with the R-22A sensor in the service software as well as in the user software. Both calibrations were passed. Even when measuring different O₂ concentrations, the normative limit value of $\pm(2,5\% + 2,5\%$ of GAS LEVEL) according ISO 80601-2-55 was maintained at all measuring points. The R-22A sensor works in all devices HAMILTON-G5/S1/GALILEO/RAPHAEL like the R-22MED.

Furthermore, the HAMILTON-G5/S1/GALILEO/RAPHAEL has a separate gas path for the oxygen sensor and therefore no contact to the patient air flow.

However, the Teledyne oxygen sensor R-22A is not released for medical use. While we have not received complaints from the field indicating any performance issues, wrong values shown on the ventilator or adverse health consequences to patient, as this device is not released for medical use, it cannot be ensured that the sensor does not cause any technical or clinical issues when used in our HAMILTON-G5/S1/GALILEO/RAPHAEL ventilator. Furthermore, the HAMILTON-G5/S1/GALILEO/RAPHAEL is not able to detect the wrong oxygen sensor by alarming the user.

How to return the oxygen sensor R-22A?

Oxygen sensors labeled as R-22A on stock or currently in use in a HAMILTON-G5/S1/GALILEO/RAPHAEL need to be replaced by a R-22MED article. The R-22A shall be returned by the distribution partner to Hamilton Medical AG according to the instructions below.

**Actions to be taken
by distribution
partners:**

- Please sign the enclosed sheet confirming that you have received the FSN (field safety notice) and have passed it on to your end customers.
- Please organize the exchange of the oxygen sensor with your end customers, if applicable.
- Send all affected devices to Hamilton Medical AG's Technical Support immediately. You will receive a correct Oxygen Sensor as replacement. The individual RGAs have been registered for the sensor exchange.

**Actions to be taken
by end customers:**

- Even if you are impacted by this FSN, no action is necessary. You are going to be contacted by your distribution partner and they will coordinate with you the replacement of the oxygen sensor, if applicable.

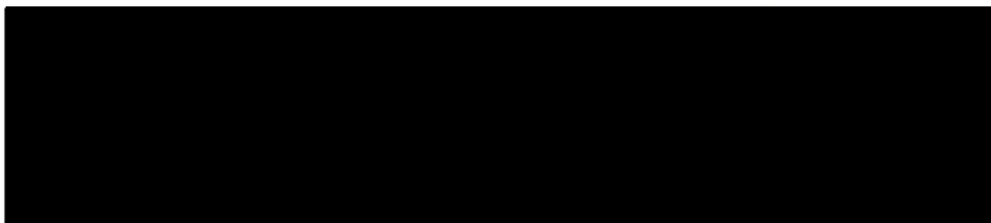
Manufacturer: Hamilton Medical AG
Via Crusch 8
CH-7402 Bonaduz
Switzerland

Contact: Should you have any questions please do not hesitate to get in contact with us.

Hamilton Medical AG
Technical Support
Parc Industrial Vial 10
CH-7013 Domat/Ems
Switzerland
Tel. +41 58 610 10 20
e-mail: techsupport@hamilton-medical.com

We appreciate your support in this matter and sincerely regret any inconvenience you may experience as a result of the issue described above.

Bonaduz, September 12th, 2022



**Confirmation Sheet - For HAMILTON-G5/S1/GALILEO/RAPHAEL Distribution
Partners that received a Teledyne R-22A oxygen sensor**

Field Safety Notice

Subject: Field Safety Notice Teledyne oxygen sensor R-22A not released for medical use

By signing this letter, I confirm that

- ☐ I have received, read, and understood the following documents:
(This confirmation should not be returned until all of the end customers have returned their confirmation.)

Field Safety Notice Teledyne oxygen sensor R-22A not released for medical use

Number of customers impacted: _____

I have informed (number of contacted customers): _____ customers

- ☐ All impacted customers have been informed of this field safety notice.
All impacted customers acknowledged receipt of this field safety notice.

Name:

Company:

Country:

Date:

Signature:

Sign and return this letter by email to Hamilton Medical AG's Technical Support team.