

QMT-Tech AB

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E-mail: info@qmt3.com
Website: www.qmttech.se

Date: _____

To:

Medical Engineering / Medical Technology Department (Responsible for medical gas systems and accessories)

CC:

Patient Safety Function / Relevant Technical Management

FIELD SAFETY NOTICE (FSN)

IMPORTANT SAFETY NOTICE

Legacy male probes manufactured prior to November 2013

This Field Safety Notice consolidates, and supplements information previously issued in 2013 and 2016 regarding legacy male probes manufactured prior to November 2013.

Products concerned:

- QMTC7150RS1 [Q204834] – Oxygen
- QMTC7150RS3 [Q204837] – Medical Air
- QMTC7150RS4 [Q204838] – Air for driving surgical tools

Please complete verification and return the acknowledgement form (section 7) within 60 calendar days from receipt of this Field Safety Notice.

1. BACKGROUND

QMT-Tech AB wishes to provide information regarding a historical dimensional deviation affecting certain straight male probes for medical gases manufactured **prior to November 2013**.

In **November 2013**, during commissioning of a medical gas system, it was identified that certain QMT-Tech male probes with an increased internal through-hole diameter may not fully actuate some terminal units, potentially resulting in restricted gas flow.

Following investigation, QMT-Tech implemented corrective actions on **12 November 2013**, including:

- update of technical drawings
- implementation of corrected manufacturing dimensions
- scrapping of affected stock devices



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- replacement/recall activities for delivered products known to be affected

In **April 2016**, QMT-Tech distributed additional information and a **STOP/GO verification gauge** to support identification of legacy devices remaining in the field.

2. DESCRIPTION OF IDENTIFIED COMPATIBILITY ISSUE

To QMT-Tech's current knowledge, the identified compatibility issue has historically been observed in certain terminal units manufactured by **Greggersen**, due to dimensional characteristics of the terminal unit opening mechanism.

However:

Healthcare providers are encouraged to verify legacy male probes irrespective of terminal unit manufacturer.

QMT-Tech cannot exclude the possibility that compatibility issues may occur with other terminal units having similar opening mechanism dimensions.

3. POTENTIAL RISK

For affected legacy male probes manufactured prior to **November 2013**, incomplete opening of a terminal unit may result in:

- restricted gas flow
- delayed gas delivery
- impaired function of connected equipment

Depending on clinical circumstances, this may lead to delay of treatment.

No issue has been identified for devices manufactured **from November 2013 onwards**, following implementation of corrected dimensions.

4. VERIFICATION OF LEGACY MALE PROBES

Healthcare providers are requested to verify whether legacy male probes manufactured prior to **November 2013** remain in service.

Verification method 1 – Measurement (recommended)

Measure the **internal through-hole diameter** using suitable measuring calipers.

Acceptance criteria:

Ø4.7 mm ±0.1 mm = acceptable / current design

Male probes with larger internal diameter shall be considered affected legacy devices and should be removed from service and replaced.

Verification method 2 – STOP/GO gauge

Verification may alternatively be performed using a **QMT STOP/GO gauge**.

Interpretation:



STOP position

Gauge stops halfway →

Device manufactured according to current design (**November 2013 onwards**)

GO position

Gauge enters fully →

Device corresponds to earlier design (**prior to November 2013**)

QMT-Tech can provide STOP/GO gauges upon request.

5. RECOMMENDED ACTION

Required actions to be taken by healthcare providers

1. Verify whether male probes manufactured prior to November 2013 remain in use.
2. Inspect identified devices using one of the verification methods described in this notice.
3. Remove affected legacy devices from service and replace them where appropriate.
4. Complete and return the acknowledgement form to QMT-Tech AB within 60 calendar days from receipt of this Field Safety Notice.
5. Contact QMT-Tech AB if assistance or clarification is required.

6. CONTACT INFORMATION

For questions, technical support, or requests regarding verification gauges, please contact:

QMT-Tech AB

Amerikavägen 6
393 56 Kalmar, Sweden

Tel: +46 (0)480 44 02 00

E-mail: info@qmt3.com

QMT-Tech AB appreciates your assistance in verifying legacy devices and maintaining safe operation of medical gas systems.

On behalf of QMT-Tech AB

Name: _____

Title: _____

Signature: _____

Date: _____



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7. RECIPIENT ACKNOWLEDGEMENT AND CONFIRMATION OF ACTION

Please ensure this notice is communicated to all relevant departments and personnel involved in installation, maintenance, procurement, and use of medical gas equipment within your organization.

Please complete and return this form to QMT-Tech AB within 60 calendar days from receipt of this Field Safety Notice.

Hospital / Healthcare Provider:

Department:

Responsible Contact Person:

Telephone / E-mail:

We confirm that:

This Field Safety Notice has been received and communicated internally to relevant personnel.

Verification of male probes manufactured prior to November 2013 has been performed.

Outcome of verification:

No affected male probes identified.

Affected male probes identified and removed from service.

Number of affected probes identified (if applicable):

Actions taken:

Signature: _____

Name: _____

Position: _____

Date: _____

Please return to:

info@qmt3.com

Subject: **FSN-QMT-2026-001 acknowledgement**



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