



Web: www.therapyequipment.co.uk Email: sales@therapyequipment.co.uk

Ref: FSCA 2022-1_9505 Diamond Flowmeter

Urgent FIELD SAFETY NOTICE – 9505 0-15LPM Diamond Flowmeter & Probe – O2

Dear Sir or Madam,

Therapy Equipment Limited is conducting a Field Safety Corrective Action (FSCA) to undertake a factory-fitted modification to specific serial numbers of the 0-15 LPM Diamond Flowmeter from the market:

Product Code	Product Description	Batch and Serial Numbers
9505	0-15LPM Diamond Flowmeter	See Appendix 1

Reason for the Recall

Therapy Equipment Limited have identified a range of Serial Numbers that might be affected by an issue relating to the 0-15LPM Diamond Flowmeter & Probe – O2 which is used to regulate the flow of Oxygen to a patient.

When the 0-15LPM Diamond Flowmeter is set to flow rates of 2 litres per minute or lower, it has been identified that over a short period of time the flow may reduce to zero. This is a result of an issue with the tolerance parameters affecting the spindle and its inter-relationship with other internal components. This issue has been traced to a change in spindle component supplier covering the period from September 2020 to December 2022 for the above-mentioned product. This FSCA is limited to a range of serial numbers highlighted in Appendix 1.

Therapy Equipment Limited have implemented a minor modification to the spindle in November 2022 and following verification and validation testing, the Company can confirm that the testing indicates that the issue is now resolved. Therapy Equipment limited will monitor the performance of the affected Flowmeters to assess the effectiveness of the modified spindle for a further 12 months at which point a review of the need for on-going testing will be undertaken.



Therapy Equipment Ltd

UNIT 1, CRANBOURNE AVENUE, CRANBOURNE INDUSTRIAL ESTATE
POTTERS BAR, HERTS, EN6 3JN TEL: 01707 652270 FAX: 01707 652622



Certificate Number MD 595894

Web: www.therapyequipment.co.uk **Email:** sales@therapyequipment.co.uk

Actions to be taken

Therapy Equipment Limited ask that you initiate the following activities immediately and with priority:

- Review this FSCA in its entirety and ensure that all users of the above-mentioned product in your organisation are informed about this Notice.
- If you are a distributor, please forward this Notice to your customer (s).
- Identify, and quarantine any flowmeters exhibiting the issue, and return those products to Therapy Equipment Limited for the company to undertake a factory-fitted replacement to the spindle component and return the product to you. This will be undertaken under the terms of the Company's warranty..
- Advise users not to use affected devices at flow rates of 2 litres per minute or less until a replacement spindle has been fitted..
- Confirm receipt of this information by completing the attached acknowledgement form and return this to Therapy Equipment using the contact details provided.

For stock/returns please send using reference FSCA 2022-1_9505 Diamond Flowmeter to:

Jas Singh

Managing Director

Jas.singh@therapyequipment.co.uk

Tel: (0)1707 652270

This potential issue has been reported to the appropriate Regulatory Agencies.

Therapy Equipment Limited apologises for any inconvenience this may cause and thanks you for your cooperation. If you have questions, please speak with your Therapy Equipment sales representative or contact me direct.

Yours sincerely

Jas Singh

Managing Director, Therapy Equipment Limited



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Please complete this form and return to
Jas Singh
Managing Director
Jas.singh@therapiequipment.co.uk
Tel: (0)1707 652270

Product Code	Product Description	Serial numbers
9505	0-15LPM Diamond Flowmeter & Probe – O2	See Appendix 1

- We have received the Field Safety Notice and confirm that we have no remaining products in stock.
- We have received the Field Safety Notice and confirm that we have quarantined the stock and wish to return the following:

Product Code	Quantity to be returned	Serial Numbers

- We have not shipped any products affected by this Field Safety Notice to third parties.
- We have notified our customers who are affected by this recall notice, and we will contact our customers to arrange collection of any affected products for onward return to Therapy Equipment Limited.

Company Name/Trust name:
Name:
Title/position held:
Email address:

APPENDIX 1

Product Code	Product description	Serial Numbers	Batch / Lot Numbers
9505	0-15LPM Diamond Flowmeter & Probe – O2	298230 to 355746	157379 to 171941