



FIELD SAFETY NOTICE

Dear Customer,

the purpose of this letter is to inform you about the immediate action to be taken on some GMM devices in order to guarantee their reliability over time.

Involved devices: tables serial number, listed in the attached list, according to the following names:

<i>Name</i>	<i>Brand</i>
Opera T90-SH	General Medical Merate
Opera T90-SHX	General Medical Merate

Description:

Due to an event and subsequent investigations, GMM has ascertained that the front lever chain of the Opera T90-SH / SHX devices might have a reduction of its reliability over time. This could be determined by a series of multiple causes including, by the way of example, the lack of maintenance on the device.

Attention please:

If a high and persistent noise is heard from the device during the tilting or elevation movement of the tabletop (according to the example audio file), please check the correct tightening of the floor plate fixing bolts. If the noise persists, the device must be blocked immediately, in a horizontal position at maximum height (as shown in the picture), with consequent stop of the device and of the diagnostics room.

If the above-described case happens, after the stop of the device, please immediately report the situation to international_service@gmmspa.com and you will be supported by the Service team with the necessary tests and assistance.

Nonetheless, the actions described must be taken in order to prevent a potential risk.

General Medical Merate S.p.A.

Stabilimento

Sede Legale ed Amministrativa:

Via Partigiani, 25 - 24068 SERIATE - BG - ITALIA - Tel. +39 035 4525311 - Fax +39 035 299537/297787

Stabilimento: viale Unità d'Italia, 40 - 70020 CASSANO DELLE MURGE (BA) - Tel. +39 080 763121 - fax +39 080 764306

Ufficio: via Tiraboschi, 7/B - 00141 ROMA - telefono +39 06 8274437 - fax +39 06 8274455

Partita I.V.A., Cod. Fiscale e Registro Imprese di BG n° 00225500164

Mincomes N. BG 12002139 - Capitale Sociale € 5134376,00 I.V.

C.C.I.A.A. R.E.A. Bergamo 138291 - C.C. Postale 15218241 - RAEE: IT08020000000663 - Registro Pile: BG-000016

www.gmmspa.com - info@gmmspa.com - Posta Certificata: rosangela.zenoni@pec.gmmspa.com



Cert. N.
9120.GNM1



Cert. N.
9124.GNM2



Corrective action:

A specific kit has been created for the purpose of being implemented on the devices installed base, in accordance to the serial numbers provided here above.

The kit contains all the parts and instructions necessary to replace the components.

Warning!

The instructions must be filled in completely and returned to the manufacturer by e-mail or fax to the following address:

GENERAL MEDICAL MERATE S.p.A.

email qara@gmmspa.com and international_service@gmmspa.com

or fax to +39 035 29 77 87

We would like to point out that, to the present date, no event has been reported of damage or major injuries to persons related to what is described in this communication.

Nevertheless, the actions described must be undertaken to mitigate a potential risk that could reduce the safe use of the equipment.

The kit will be progressively available and shipped within July 2024 and must be implemented progressively during the first ordinary/extraordinary maintenance and, in any case, **no later than the timing here below** from receipt of the kit itself, prioritizing the devices according to the attached list:

<i>Priority</i>	<i>Device serial number</i>	<i>To be done within*</i>
1	listed in the attached list	3 months
2	listed in the attached list	9 months

* starting from the date of receiving of the kit.

Counting on your attention in relation to this notice, GMM declines all responsibilities in case of non-application of the above-described measures within the period of time stated in this communication.

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If the device has been sold and/or scrapped and it is therefore no longer in your possession, we invite you to forward this safety notice to the new owner, and tell us its name, or provide us with notification of the scrapping.

Please also ensure that all end users are aware of this security notice and of its recommended actions.

GMM technical assistance service is available for any further request for information and / or support (international_service@gmmspa.com)

(picture 1) machine in a horizontal position at maximum height



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