TriMedika Ltd

Unit 3, E3 Building
Springfield Campus

398 Springfield Road

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Belfast NI BT12 7DU

16th July 2020

Urgent Field Safety Notice

Product	TriTemp TR 1 Non-Contact Infra-Red Thermometer,
TriMedika Reference	FSN-2020-07-14
Type of Action	Advisory

Details on affected devices:

See Attachment 2 for product Lots affected.

Dear Customer,

TriMedika Ltd has initiated a voluntary Field Safety Corrective Action for the above listed Non-Contact Infra-Red Thermometer and associated lot numbers as per Appendix 2.

Description of the Problem

We have updated our Instructions for Use for the TriTemp Thermometer to include some additional information related to Section IX How to take a patient temperature and Section XI Adjustment of MODE settings.

This revised Instructions for use Revision No. 0720 provides additional information to help prevent users unintentionally accessing the MODE settings and to ensure that if you inadvertently enter the MODE settings you will be aware of this action and will understand how to exit these settings.

The revised Instructions for use Rev 0720 is provided with this Field Safety Notice, (Attachment 3) to replace Instructions for Use Revision 0320 which you will have received with your Thermometer(s).

To date we have not received any reports of Users inadvertently accessing MODE settings, however TriMedika is providing this updated Instructions for use as a preventative measure.

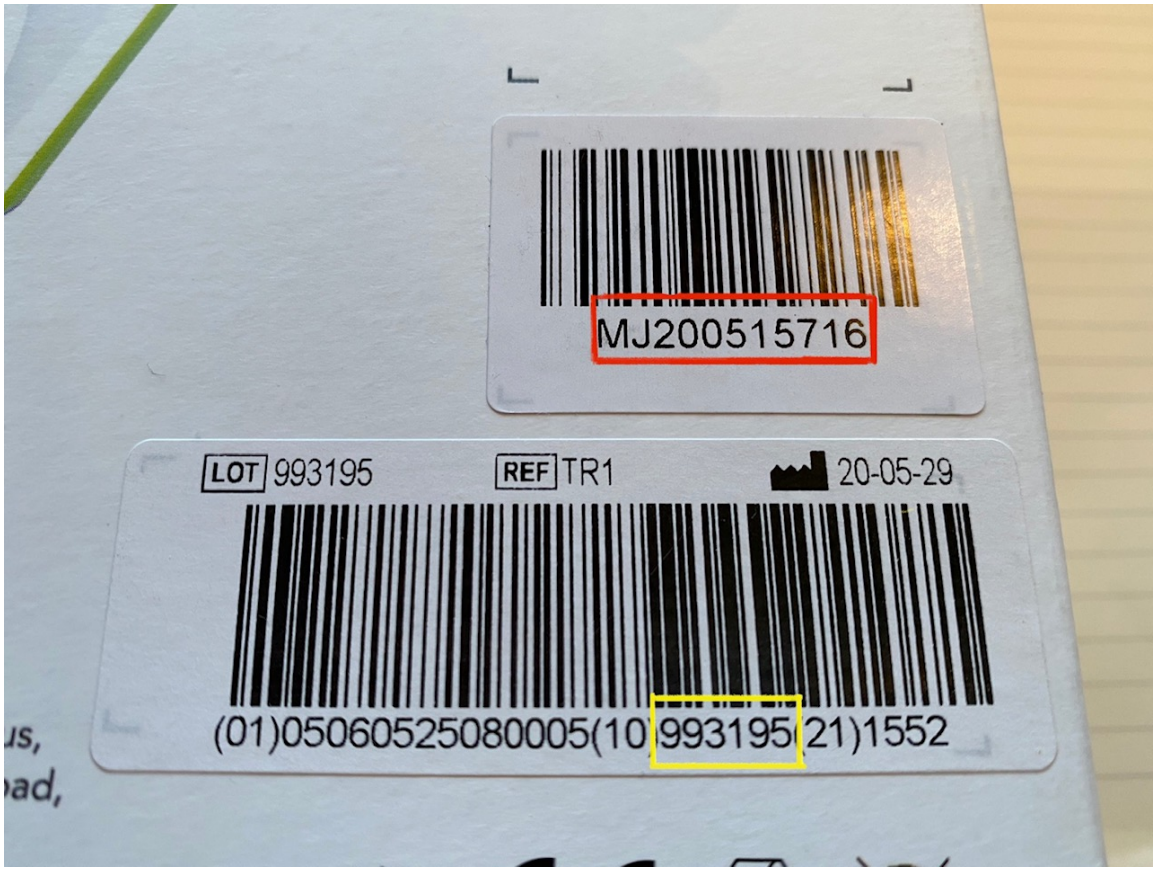
Our records indicate that you have received TriTemp Thermometers that are subject to this action.

There is no requirement for Customers to return any TriTemp Thermometers to TriMedika as these devices can continue to be used in accordance with the updated IFU provided with this FSN.

Customer Action List 1:

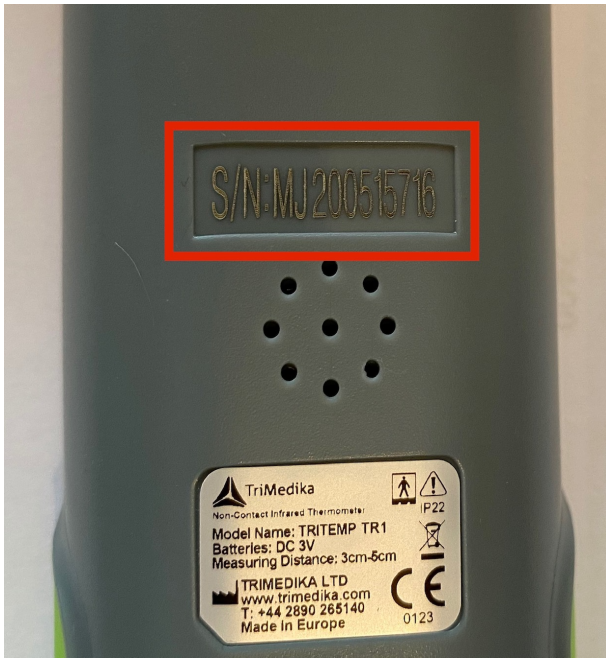
- Please check your inventory both in use and stored to determine if you have TriTemp Thermometers from the affected Lot numbers as per the listing provided in Attachment 2.

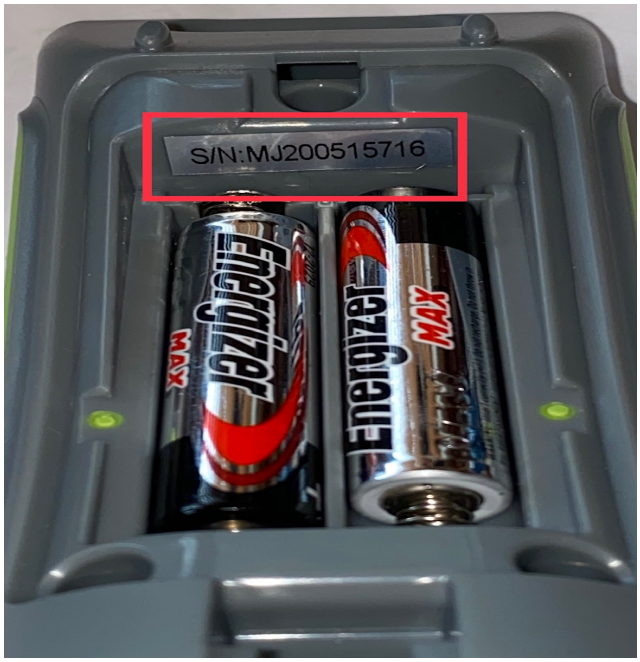
- If your stock is unopened and in its original box you can check the Lot number on the box barcode label, (see Lot number identified in yellow box below)



- If the outer box has been discarded you can check the serial number of the devices which you have in use and if the serial number starts with MJ200XXXXXX then this device is subject to this Field Safety Notice.

- The Serial Number of the device can be checked in two locations on the rear of the actual device, as marked in Red below a) above the CE label and b) on the inside of the Battery Compartment.





- Once you determine that you have product within the scope of this FSCA we request that you remove the Instructions for Use Revision 0320 and replace with the attached Instructions for Use Revision 0720.
- Please complete the Acknowledgement Form attached in Attachment 1 and return this form to your Distributor.

Distributor Action List 2

- Read the Customer Action List No. 1 above and ensure that you understand the Customers tasks.
- Provide this Field Safety Notice to all Customers who have received product in scope of this FSCA. Your Customer is then required to complete the Acknowledgement Form attached in Attachment 1 and return this form to you.
- We request that you check your inventory for product within the scope of this FSCA.
- Affix a copy of this notice to each individual product prior to shipping to your customers.

- Upon completion of your actions please forward the completed Acknowledgement Forms to TriMedika Ltd at the contact information provided.

Transmission of this Field Safety Notice:

This notice needs to be passed on all those who need to be aware within your organisation or to any organisation/department where the potentially affected devices have been transferred. (If appropriate)

Please provide TriMedika with details of any affected devices that may have been transferred to other Organisations. (If appropriate)

I can confirm that this notice has been notified to the appropriate Regulatory Agencies.

We regret any inconvenience that this action may cause and we appreciate your understanding and co-operation.

If you have any questions or would like assistance with this Field Safety Notice, please contact your local Sales Representative.

Yours Sincerely

XXX

Attachment 1	**Acknowledgement Form**
Attachment 2	**Lot Numbers affected List**
Attachment 3	**Instructions for Use Ref CW017 Rev 0720**

Attachment 1

Field Safety Notice Acknowledgement Form

TriTemp TR1 Non-Contact Infra-Red Thermometer

Please read in conjunction with Field Safety Notice FSN-2020-07-14 and return to (TriMedika at _____ or your distributor at _____) as soon as possible.

Yes, I can confirm that I have;

- Read and Understood the Field Safety Notice.
- Informed all appropriate personnel of this FSN
- Identified the Devices which are subjected to this FSN.
- Replaced the existing Revision 0320 IFU with the new IFU Revision 0720, and/or
- Attached the new IFU, Revision 0720, to all boxes in inventory from the affected lots.

Organisation/Hospital/Clinic;	
Department (if applicable);	
Address:	
Contact Name;	
Job Title;	
Contact Telephone Number;	**Contact Email Address;**
Signature:	**Date:**

TriMedika
INNOVATIVE MEDICAL DEVICES

Attachment 2

List of Product Lot Numbers

Lot Numbers of TriTemp TR 1 Thermometers		
996964	997841	993192
996965	997842	993193
996966	997843	993194
997840	993191	993195