Sultanate of Oman
Ministry of Health
Directorate General of Pharmaceutical Affairs
and Drug Control
MUSCAT

سلطنة عمان
وزارة الصحة
المديرية العامة للصيدلة
والرقابة الدوائية
مسقط

To:
THE DIRECTOR GENERAL OF HEALTH SERVICES IN ALL GOVERNORATES
Commanding Officer, Armed Forces Hospital (Al Khoudh & Salalah)
Director General of Engineering Affairs, MOH
Director General of Royal Hospital
Director General of Khoula Hospital
Director General of Medical Supplies (MOH)
Director General of Pvt. Health Est. Affairs (to kindly arrange distribution to all Pvt. Hospitals)
Hospital Director (Al Nahda Hospital)
Hospital Director (Al Massara Hospital)
The Head of Medical Services in SQU Hospital
The Head of Medical Services in Royal Oman Police
The Head of Medical Services in Ministry of Defence
The Head of Medical Services in The Diwan
The Head of Medical Services in The Sultan's Special Force
The Head of Medical Services in Internal Security Services
The Head of Medical Services in Petroleum Development of Oman
The Head of Medical Services in LNG Oman
ALL PRIVATE PHARMACIES & DRUG STORES

After Compliments,

Please find attached our Circular No. 13/21 **dated** 18/1/21 **Regarding NCMDR Field Safety Corrective Action of AQT90 FLEX analyzers from (Radiometer Medical).**

Copy to:

- **Director, Office of H.E. The Undersecretary for Health Affairs**
- **Director of Medical Device Control, DGPA&DC**
- **Director of Pharmacovigilance & Drug Information Dept, DGPA&DC**
- **Director of Drug Control Department, DGPA&DC**
- **Director of Pharmaceutical Licensing Department, DGPA&DC**
- **Director of Central Quality Control Lab., DGPA&DC**
- **Supdt. of Central Drug Information**

ص . ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩ البريد الإلكتروني : dg-padc@moh.gov.om
P.O. Box: 393 Muscat, Postal Code: 100, Tel: 22357111 - Fax: 22358489 - E-mail: dg-padc@moh.gov.om

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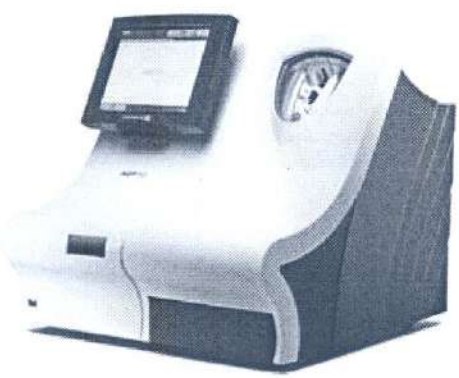
Circular No. 13 / 2021

04 -06 -1442 H

18 -01-2021

Field Safety Corrective Action of AQT90 FLEX analyzers from Radiometer Medical.

Source	NCMDR- National Centre Medical Device Reporting https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=10&rid=15486
Product	AQT90 FLEX analyzers.
Description	Instrument/analyser IVDs.
Manufacturer	Radiometer Medical.
Local Agent	Mustafa Sultan Science & Industry Co.L.L.C.
The affected products	All AQT90 FLEX analyzers with serial numbers of 393-838R0564 onwards and all E3800 spare part CPU units, 910-415.
Reason	AQT90 FLEX with E3800 CPU unit - Risk of incorrect time on display and patient results.
Action	1. Please check if the time displayed on the analyzer screen correct, and then follow the instructions in the attached FSN. 2. Contact the local agent for remedial action.
Product image	
comments	Healthcare professionals are encouraged to report any adverse events Suspected to be associated with the above device or any other medical device to Department of Medical Device Control contact E-mail: Med-device@moh.gov.om

Dr. Mohammed Hamdan Al Rubaie

DIRECTOR GENERAL

ص . ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩ البريد الإلكتروني : dg-padc@moh.gov.om
P.O. Box : 393-Muscat, Postal Code: 100, Tel: 22357111 - Fax: 22358489 - E-mail: dg-padc@moh.gov.om

Field Action Notice

RADIOMETER

Product:	**AQT90 FLEX with E3800 CPU unit**	**December 8, 2020**

Subject: Risk of incorrect time on display and patient results

Background: Radiometer has become aware of a potential issue with AQT90 FLEX analyzers with serial numbers of 393-838R0564 onwards. The issue relates to the AQT90 FLEX's internal clock and impacts the time shown on the display as well as the time stamp for calibration adjustment results, LQC results and patient results (all assays), both when viewed on the analyzer screen and on external systems such as AQURE and HIS/LIS.

The issue may be triggered in case power is abruptly removed from the analyzer, by e.g. toggling the power switch on the analyzer itself or at the wall outlet, or a power failure occurs on the mains supply. When the analyzer is switched on again, the analyzer's internal clock may behave as in the example below:

- The clock starts at 08:00
- The clock runs normally until it reaches 08:59:59
- The clock resets to 08:00

Once the issue has been triggered the clock will continue to run in an infinite loop between 08:00 and 08:59 and the date will remain the same.

This means that all patient samples run after the issue has been triggered will have a time stamp suggesting they have been run between 08:00 and 08:59 on the same day.

Affected Product: **In scope for this field action is:**
All AQT90 FLEX analyzers with serial numbers of 393-838R0564 onwards and all E3800 spare part CPU units, 910-415.

User Action: Based on the above Radiometer kindly requests you to check if the time displayed on the analyzer screen correct, and then:

A. If the time is correct perform the actions under "***Time is correct***"
B. If the time is **not** correct perform the actions under "***Time is not correct***"

Time is correct:

Perform the following actions:

1. Ensure that the AQT90 analyzer never loses power. This may be ensured in two ways:
   a. Install a UPS (Uninterruptable Power Source, a battery backup) for the analyzer.
      OR
   b. Have your in-house technical department confirm that your institution's emergency power system is capable providing an uninterrupted supply for the analyzer in case of mains power loss.
2. Instruct the employees handling the AQT90 FLEX analyzer to always shut down the analyzer, if needed, as per the procedure in the instructions for use, as follows:

   On the screen tap "Menu", then "Utilities, and finally "Shutdown".

   Do not use the power switch to shut down the analyzer.

Please note that:

- If you cannot ensure an uninterrupted supply for the analyzer the operators must check that the time displayed on the screen is correct prior to inserting any test tube into the inlet wheel going forward.
- If the power, by mistake, has been abruptly removed from the analyzer the operator must check that the time displayed on the screen is correct prior to inserting a test tube into the inlet wheel.
- If, at any point in the time displayed on the screen becomes incorrect perform the actions under "Time is not correct"

Time is not correct:

1. Cease using the AQT90 FLEX analyzer for patient samples until your Radiometer representative has reset the analyzer's internal clock
2. Report the occurrence to your Radiometer representative who may then visit and reset the analyzer's internal clock.

Important

Once the time has been reset by your Radiometer representative the actions under "Time is correct" above apply.

Subsidiary/ Distributor Action: **Please carry out the following actions for existing customers:**

1. Translate the customer advisory letter into your local language(s) and print it on your official company paper.
2. Compose complete list of affected customers (AQT90 FLEX analyzers with serial numbers of 393-838R0564 onwards) – one row per analyzer. For subsidiaries and distributors covering more countries, the list must be divided into countries.
3. Contact each affected customer (AQT90 FLEX analyzers with serial numbers of 393-838R0564 onwards) as follows,
   - Submit the customer information letter to the customers, or
   - Visit the customer to hand over the customer advisory letter and explain the problem (with the current COVID-19 situation the first option should be preferred).
4. Consolidate recall response forms in the "Customer Response and Upgrade Sheet" (excel) enclosed with this FAN, and submit to RMED.