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

سلطنة عُمان
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 234 **dated** 20/12/2022**Regarding NCMDR Field Safety Corrective Action of Philips Fetal Spiral Electrode from (mfr: Philips Healthcare).**

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**

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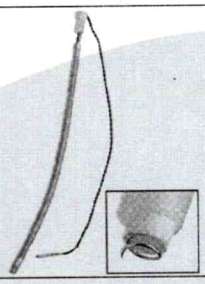
Circular No. 234 / 2022

26 -05-1444 H

20 -12-2022

Field Safety Corrective Action of Philips Fetal Spiral Electrode from Philips Healthcare.

Source	NCMDR- National Center for Medical Devices Reporting- SFDA https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=17349
Product	Philips Fetal Spiral Electrode.
Description	Fetal ECG Electrodes.
Manufacturer	Philips Healthcare.
Local agent	Mustafa Sultan Science & Industry.
The affected products	Model # 989803137631 UDI# 20884838007431.
Reason	Needle Tip Breaking.
Action	1. Refer to "Actions that should be taken by the customer / user 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 through the E-mail: Med-device@moh.gov.om

Dr. Mohammed Hamdan Al Rubaie

Director General

سلطنة عمان - وزارة الصحة
المديرية العامة للصيدلة والرقابة الدوائية
SULTANATE OF OMAN - MINISTRY OF HEALTH
DIRECTORATE GENERAL OF PHARMACEUTICAL AFFAIRS & DRUG CONTROL

PADC
المديرية العامة للصيدلة والرقابة الدوائية
Directorate General of Pharmaceutical Affairs & Drug Control

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

PHILIPS

URGENT Field Safety Notice

Philips Fetal Spiral Electrode
Needle Tip Breaking

Date of letter deployment: 18-NOV-2022

To: Customer Name:
Attention To:
Customer Response ID:
Street Address:
City, State, Zip Code:

This document contains important information for the continued safe and proper use of your equipment

Please review the following information with all members of your staff who need to be aware of the contents of this communication. It is important to understand the implications of this communication.

Please retain this letter for your records.

Dear Customer,

Philips has become aware of a potential safety issue with the Fetal Spiral Electrode (FSE) based on complaints related to the spiral tip of the FSE breaking off during use and requiring surgical intervention to remove the broken tip from the neonate patient. As a result, Philips has decided to discontinue the distribution of this product.

The Fetal Spiral Electrode is intended for patients requiring fetal heart rate monitoring during labor. FSEs are only used when traditional/external fetal monitoring is inadequate such as with high BMI patients or when external monitoring indicates that the fetus may be in distress. The device consists of a stainless-steel spiral needle electrode. It is fixed to the fetal scalp by penetration of the skin by the spiral needle and thereby obtains the fetal ECG signal.

This *URGENT Field Safety Notice is* intended to inform you about:

1. What the problem is and under what circumstances it can occur

- Philips has found that the spiral tip of the FSE may break off during use, potentially requiring surgical intervention to remove the broken tip from the patient. Based on Philips investigation, this can occur due to over rotation during attachment or pulling the tip from the fetal scalp.
- The FSE may also break off if the user **pulls** the spiral tip from the fetal skin, increasing the risk of the spiral tip detaching from the FSE during removal.

To date, our investigations have been unable to identify a product defect contributing to the observed issue; however, this result does not ensure that the above are the only root causes for the reported complaints. Due to inconclusive root cause investigation results and the increased rate of reported adverse events, Philips has decided to discontinue distributing the FSEs.

2. Hazard/harm associated with the issue

The hazardous situation that exposes the patient to harm is the spiral tip of the FSE breaking off in the patient's scalp requiring an additional procedure to remove the broken segment of the FSE from the patient. The hazardous situation can occur under various circumstances, as described above. See a picture of the FSE tip magnified in section 3 below.

- Immediate and Long-Term Consequences:

The tip of the FSE detaching in situ could result in a retained foreign body in the scalp of the fetus. Consequently, medical intervention may be required to remove the FSE tip (or tip fragments). Additionally, an infection, abscess, and wound/tissue damage may also occur and could require antibiotic treatment in the vulnerable neonate population. An x-ray, which would expose a neonate to radiation, may also be required to aid health care professionals locate the detached FSE tip/fragments.

3. Affected products and how to identify them

Philips Fetal Spiral Electrode: Model # 989803137631 UDI# 20884838007431

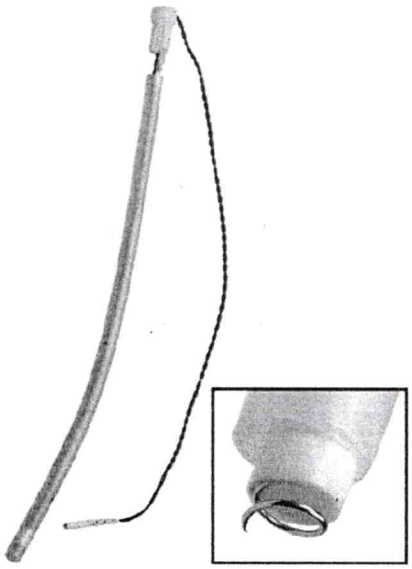


Figure 1. Fetal Spiral Electrode

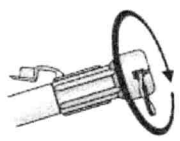
4. Actions that should be taken by the customer / user in order to prevent risks for patients or users

Important actions to follow in the Instructions for Use (IFU) state the following:

- Do not over-rotate Spiral Tip during attachment.
- Do not pull the Spiral Tip from the fetal skin. Do not pull the FSE wires apart.

Figure 2. Warnings – Fetal Spiral Electrode IFU (page. 2)

Turn
Turn the Grip clockwise—typically 1 full turn using the Protection Tab as a visual guide—until mild resistance indicates full attachment.



WARNING: Do not over-rotate.

Figure 3 in the IFU, page 4 and warning below: Applying FSE

Grasp the FSE electrode wires as close as possible to the fetal presenting part, turning them counterclockwise until the Spiral Tip comes free from the fetal skin.

Figure 4 in the IFU, page 5: Removing the FSE

WARNING: Do not pull the Spiral Tip from the fetal skin. Do not pull the FSE wires apart.

Inspect the Spiral Tip to ensure that it is still attached to the FSE Hub. If the tip has separated from the hub and remains embedded in the presenting part, remove it using aseptic technique. Remove the Attachment Electrode from the Legplate Adapter Cable.

Figure 5 in the IFU, page 5: Removing the FSE

In addition to the above:

- Customer should complete the Urgent Field Safety Notice Response Form online to submit both their acknowledgement of this recall **(mandatory)** and actions taken, as well as request for credit (*optional*). To request credit go to URL: https://forms.office.com/r/GsLVh2gYZi

- Pass this notice to all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred. (If appropriate).

If you choose, discard all FSEs sold by Philips and source from an alternative supplier available in your country. If you choose to discard the FSEs, we will issue a credit after you complete the online response form.

Important! When completing the online response form and to receive credit, please provide the information listed below:

1. The Customer Response ID provided on the top of this letter.
2. Quantity (counted by each or individual) of Philips Fetal Spiral Electrode to be credited.

PHILIPS

5. Actions planned by Philips Hospital Patient Monitoring to correct the problem

- Philips is continuing to investigate additional root causes with FSE supplier
- Philips will immediately discontinue selling the FSEs
- Philips will reimburse for any discarded FSEs

If you need any further information or support concerning this issue, please contact your local Philips representative: Met.quality@philips.com

This notice has been reported to the appropriate Regulatory Agencies. Adverse reactions or quality problems experienced with the use of this product may be reported to Met.quality@philips.com

Philips regrets any inconvenience caused by this problem.

Sincerely,

Jeffrey Hoebelheinrich
Head of Quality
Medical Consumables & Supplies
Philips Healthcare