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**CITIZEN PETITION
PURSUANT TO 21 C.F.R. § 10.30**

April 12, 2000

Dockets Management Branch
Food and Drug Administration
5630 Fishers Lane
Room 1061 (HFA-305)
Rockville, MD 20852

The undersigned submit this petition under 514(b)(4)(A) of the Federal Food Drug and Cosmetic Act, 21 U.S.C. § 360d(b)(4)(A), to request the Commissioner of Food and Drugs to grant a variance of the Performance Standard for Electrode Lead Wires and Patient Cables set forth in 21 C.F.R. Part 898, to extend the effective date of said standard as it applies to Fetal Scalp Electrodes from May 9, 2000 until September 9, 2000, as provided in 21 C.F.R. § 898.14. The variance should apply to the entire Fetal Scalp Electrode industry.

A. Action Requested

Petitioners request a temporary variance from the requirements of 21 C.F.R. Part 898, Performance Standard for Electrode Lead Wires and Patient Cables ("Performance Standard"), to extend the effective date of the Performance Standard as it applies to Fetal Scalp Electrodes ("FSEs") from May 9, 2000 until September 9, 2000. The Food and Drug Administration has classified these devices as Class II. 21 C.F.R. § 884.2675 (Fetal Scalp Circular (Spiral) Electrode and Applicator). Package labeling for FSEs marketed in the United States by the Petitioners are attached as Exhibits 1a and 1b

This temporary variance would allow practitioners to continue to directly monitor fetal ECG during delivery using FSEs, until the resolution of a shortage of the adapters required to connect FSEs meeting the Performance Standard to fetal/maternal monitors used in the United States. Without the variance, many hospitals and practitioners would be unable to procure FSEs that would function with their fetal/maternal monitors and would hence be unable to directly monitor fetal ECG during delivery. Such monitoring represents the standard of care in many types of delivery.

B. Statement of Grounds

The Petitioners

GE Marquette Medical Systems, Inc. ("GE") is a manufacturer of fetal/maternal monitors, through its Corometrics division ("Corometrics"). GE and Corometrics will be referred to collectively as GE in the remainder of this petition. GE also manufactures and distributes FSEs. GE holds several patents related to FSEs, as well as to connectors for FSEs.

Agilent Technologies, Inc. ("Agilent"), is also a manufacturer of fetal/maternal monitors, which use FSEs as accessories to monitor fetal electrocardiographs. Agilent is currently a subsidiary of

ODP-1258

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Hewlett-Packard Company ("HP"). Monitors manufactured prior to November 1, 1999, were manufactured by and sold under the HP name. Agilent and HP will be referred to collectively as Agilent in the remainder of this petition. Agilent is also a distributor of FSEs manufactured by GE.

Agilent, GE, their predecessors and subsidiaries have manufactured many of the fetal/maternal monitors in use in the United States. Agilent and GE will be referred to collectively to as Petitioners in the remainder of this petition.

GE and a third company, Ludlow Company LP ("Ludlow"), are major manufacturers of FSEs distributed in the United States. In January 2000, Kendall-LTP, a business unit of Ludlow, submitted a petition for a variance from the Performance Standard as it applies to FSEs, seeking somewhat different relief ("Ludlow Petition").

The Risk Associated with an Extension of the Effective Date Is Minimal

FSEs are inserted into the presenting part, often the scalp, of fetuses during delivery to provide direct ECG monitoring and are used in the highly controlled environment of the delivery suite. FSEs are removed promptly at delivery, when ECG monitoring can be provided through conventional, less-invasive ECG electrodes. The insertion of FSEs requires a high degree of skill and is only performed after a vaginal examination of the mother to identify the proper presenting part of the fetus.

The FSE is designed to connect to a connector/plate attached to the mother's leg, and the length of the electrode wire is only 55 cm. (See Exhibit 2 for a drawing depicting a typical connection of an FSE.) Because the electrode wire once inserted is not long enough to extend beyond the mother's body, the risk of connecting these electrodes to a high-voltage source is negligible. For reasons independent of FSE use, high-voltage receptacles are not placed on or immediately proximate to the mother's body.

Correspondingly, FSEs fall within that category of electrodes for which the Performance Standard would be phased in over a three-year period. 21 C.F.R. 898.13(b). FDA found that for electrodes in this category, accidental inappropriate connections could not reasonably be anticipated, nor had FDA received information of a connection of these electrodes to a high-voltage source. 62 Fed. Reg. 25,477, 25,479-80 (May 9, 1997). Neither Agilent nor GE has received any report of such an incident. Agilent has been manufacturing fetal monitors using FSEs for over seventeen years.

An Extension of the Effective Date Is Necessary to Ensure Practitioner Access to Fetal ECG Monitoring

In the Ludlow Petition, it was estimated that there are 45,000 fetal monitors in the United States using three million FSEs per year. Petitioners believe that these figures are reasonably accurate.

A variance to extend the effective date of the Performance Standard beyond May 9, 2000, is necessary because of a serious shortage of a key part necessary for Agilent and GE fetal/maternal monitors to use new FSEs that meet the Performance Standard. We believe that this shortage could have a serious impact on public health unless older FSEs that do not meet the Performance Standard ("Pre-PS FSEs") remain available until the shortage is alleviated.

The part in shortage is the adapter that allows Agilent and GE fetal/maternal monitors to use new FSEs that meet the Performance Standard. The adapter requires a special connector that mates with the corresponding connector on new FSE. This connector is manufactured by GE and is protected by at least one GE patent. (See Exhibit 3 for a schematic view of the new connection system for Agilent fetal/maternal monitors.) The large number of connectors required to construct adapters for the tens of thousands of monitors currently in use has exceeded GE's manufacturing capacity for this type of part.

GE projects that it can manufacture the parts required for adapters for the tens of thousands of fetal/maternal monitors in use in the United States by August 2000. Allowing for the fabrication and distribution of the adapters, some hospitals and practitioners would require access to Pre-PS FSEs until September 9, 2000, when adapters could be supplied to them.

Based on Petitioners' long experience with fetal monitoring, we believe that the relief sought in Ludlow Petition is inadequate to ensure that hospitals and practitioners will be able to procure the FSEs that they require during the transition period. The Ludlow Petition did not request permission to continue to distribute Pre-PS FSEs, so that if a hospital exhausted its supply of FSEs, it could not replace them with usable electrodes unless it had new adapters.

C. Environmental Impact

The variance sought in this petition, a delay in the effective date of the Performance Standard for FSEs, is categorically excluded from the requirements of 21 C.F.R. Part 25 pursuant to 21 C.F.R. § 25.30(i), as correction or technical change to an existing regulation. Moreover, the existing regulation, 21 C.F.R. Part 898, specifically provides for such variances. 21 C.F.R. § 898.14.

D. Economic Impact

This information is not required pursuant to 21 C.F.R. § 10.30(b).

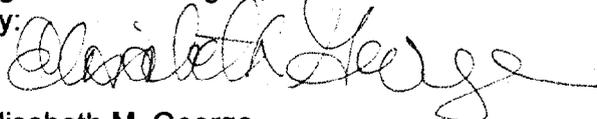
E. Certification

The undersigned certify, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the Petitioners which are unfavorable to the petition.

Respectfully submitted,

Agilent Technologies, Inc.

By:



Elisabeth M. George
Quality and Regulatory Manager
Patient Monitoring Division

GE Marquette Medical Systems, Inc.

By:



Pamela S. Krop
Vice President and General Counsel

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8200 W. Tower Ave.
Milwaukee, WI
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Disposable Spiral Electrode for Fetal Monitoring

Einmal-Spiralelektrode für die fetale Überwachung

Electrode spirale à usage unique pour la surveillance fœtale

Electrodo en espiral para monitorización fetal, desechable

Elettrodo monouso a spirale per monitoraggio fetale

Eléctrodo em espiral descartável para monitorização fetal

Spiraalelectrode voor Foetale Bewaking - voor Eenmalig Gebruik

Engangsspiralelektrode til fetal overvågning
Kertakäyttöinen kierukkaelektrodi sikiön valvontaan

Engangsspiralelektrode for fosterovervågning

Spiralelektrod för fosterövervakning, engångs

Spiralová elektroda pro monitorování plodu k jednorázovému použití

Egyszer használatra alkalmas spirálelektroda méhmagzatellenőrző megfigyelésre

Elektroda spiralna jednorazowego użytku do monitorowania płodu

Одноразовый спиральный электрод для обследования плода

Fetal Denetimde Kullanılır Atılır Helezonî Elektrot

Σπειροειδής Ηλεκτρόδιο για Εμβρυακή Παρακολούθηση

胎児用ディスプレイ・スパイラル電極

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www.hp.com/go/medsupplies

European Representative: Hewlett-Packard GmbH

Medical Production, 71034 Böblingen, Germany

www.hp.com/go/medsupplies

Made in USA

AW-15133-90030-2 Rev. A



+H17915133A7J

Disposable Spiral Electrode for Fetal Monitoring

For Use With: Monitors (General) 8030A, 8040A, 80120A, 80201A, M1310A, M1350A, M1350B, M1353A

Contents of unopened or undamaged package are sterile. Instructions inside.

Do not use if package is opened or damaged.

Warning: Connection of electrode leads to devices other than indicated in instructions for use may result in serious injury or death.

Warning: Because the tip of this electrode is designed to penetrate the fetal epidermis, the possibility of trauma, hemorrhage and infection exists. It should therefore be used only under aseptic conditions. Membranes must be ruptured prior to attachment of spiral electrode.

In rare instances the spiral tip may break free from the hub and remain in the fetal presenting part. (Reference step 10 below.)

Contraindications: The electrode should not be applied: to fetal face, fontanels or genitalia; when placenta previa is present; when genital infections (e.g., herpes, Group B streptococcus, gonorrhea) exist; or when it is not possible to identify the portion of the fetal body where application is contemplated.

Unpack and remove wires from between the drive and guide tubes.

1. Before use, check that the reference electrode fits snugly into the slot at the distal end of the guide tube. If it does not, turn the electrode head assembly until the reference electrode engages fully in the slot.
2. The patient should be in the dorsal lithotomy position. Perform a vaginal examination and clearly identify the fetal presenting part. Place guide tube firmly against fetal presenting part.
3. Be certain spiral electrode is retracted within the guide tube.
4. Hold the drive tube grip firmly between fingers. Advance the drive tube and spiral electrode at a right angle until the electrode reaches the presenting part. Maintain pressure against the presenting part with the guide and drive tube. Rotate the drive tube by rotating the drive tube grip clockwise until mild resistance is met.
5. Attachment is indicated by resistance to further rotation and recoil of the drive tube grip, which usually occurs after one turn.
6. Release the locking device on the drive tube grip by pressing the arms together.
7. Carefully slide the drive and guide tubes off the electrode wires while holding locking device open.
8. Attach the green and red electrode wires to the terminals on the leg plate cable block.
9. To remove spiral electrode, grasp and twist counterclockwise until free from fetal presenting part. Do not pull the electrode from the fetal skin.
10. Whenever a spiral electrode is removed inspect the spiral tip to make sure it is still attached to the hub. If the spiral tip has separated from the hub, remove it from the presenting part using aseptic technique.

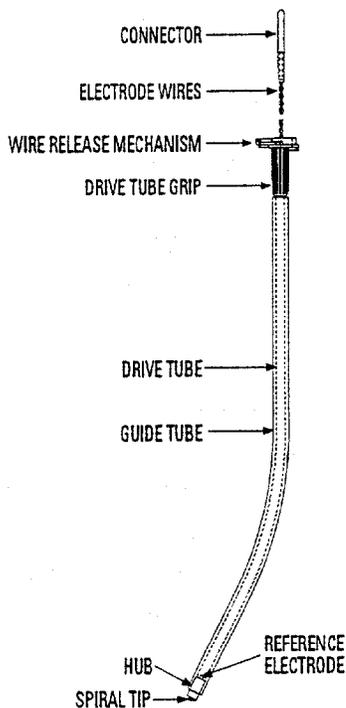
This product complies with the requirements of the Council Directive 93/42/EEC of 14 June 1993 (Medical Device Directive.)

 USA: 1-800-225-0230; U.K.: (+44) 13 4 4 369 269;
South Africa: (+27) 11-800 600 370; Australia: (+61-3) 131147;
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Toronto; Hong Kong: (+952) 2599-7777; Singapore/ Southeast Asia:
(+65) 472-2731.

EXHIBIT 1b

2000536-001 Rev. B (pouch) Final.FH8 Mon Apr 10 11:17:49 2000

REORDER REF 7000AAO
COROMETRICS®
QWIK CONNECT PLUS™ SPIRAL ELECTRODE
 PATENT PENDING



WARNING:

Because the tip of this electrode is designed to penetrate the fetal epidermis, the possibility of trauma, hemorrhage and infection exists. It should therefore be used only under aseptic conditions. Membranes must be ruptured prior to attachment of spiral electrode.

In rare instances the SPIRAL TIP may break free from the HUB and remain in the fetal presenting part. (Reference Removal Step 3 below.)

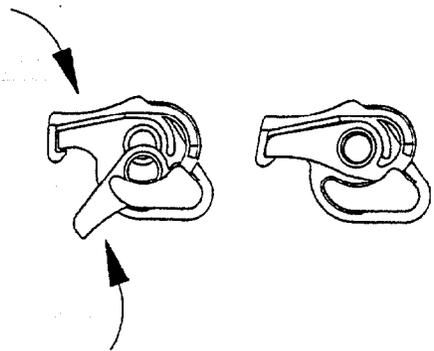
CONTRAINDICATIONS:

The electrode should NOT be applied: to the fetal face, fontanels or genitalia; when placenta previa is present; when genital infections (e.g., herpes, Group B streptococcus, gonorrhoea) or maternal acquired immune deficiency syndrome (AIDS) exist; when the mother is a confirmed carrier of hemophilia and the fetus is either affected or of unknown status; or when it is not possible to identify the portion of the fetal body where application is contemplated.

This product does not contain latex.

APPLICATION

- Using aseptic technique, open the package and remove the SPIRAL ELECTRODE. Straighten the ELECTRODE WIRES if necessary.
 - The GUIDE TUBE curvature may be altered by carefully bending it to desired anatomical curvature.
 - RETRACT Spiral Electrode until SPIRAL TIP end is approximately one inch inside GUIDE TUBE.
 - The patient should be in the dorsal lithotomy position. Perform a vaginal examination and CLEARLY IDENTIFY THE FETAL PRESENTING PART. Place GUIDE TUBE firmly against fetal presenting part.
 - Hold the DRIVE TUBE GRIP firmly between fingers. Advance the DRIVE TUBE and SPIRAL ELECTRODE at a right angle until the electrode reaches the presenting part. Maintain gentle pressure against the presenting part and rotate DRIVE TUBE GRIP clockwise until MILD resistance is met.
- NOTE:** Full attachment should occur within 1X to 1½ turns. Attachment is indicated by MILD resistance to further rotation and RECOIL of the DRIVE TUBE GRIP.
- PINCH scissors-like ends of WIRE RELEASE MECHANISM together and carefully slide the DRIVE and GUIDE TUBES over wires and CONNECTOR end of Spiral Electrode.



7. Wipe clean the CONNECTOR end of the electrode. Insert CONNECTOR end securely into Leg plate Interface Cable until fully engaged.

8. Secure Attachment Pad into place on Leg plate Interface Cable and apply to patient.

REMOVAL

- Pull CONNECTOR end of spiral electrode out of Leg plate Interface Cable.
- Remove SPIRAL ELECTRODE by grasping the ELECTRODE WIRES as close to the fetal presenting part as possible and twist counter-clockwise until free from the presenting part. DO NOT PULL THE ELECTRODE FROM THE FETAL SKIN OR PULL WIRES APART TO FACILITATE REMOVAL.
- Inspect the SPIRAL TIP to make sure it is still attached to the HUB. If the SPIRAL TIP has separated from the HUB, remove it from the presenting part using aseptic technique.
- Remove Attachment Pad from Leg Plate Interface Cable.

If you have any problems with this product please contact GE Medical Systems Customer Access Center at 800-558-5102 / 262-521-6856.

CAUTION: For the United States of America, Federal Law restricts this device to sale by or on the order of a physician.

Electrode assembly manufactured in Costa Rica.



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GE Medical Systems

GE Medical Systems - Milwaukee, WI - U.S.A.

Authorized European Representative:

GE Marquette Hellige GmbH - Freiburg - GERMANY

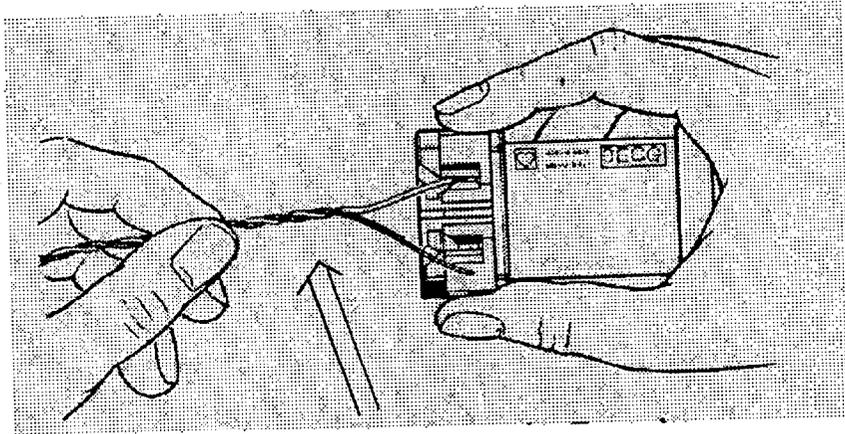
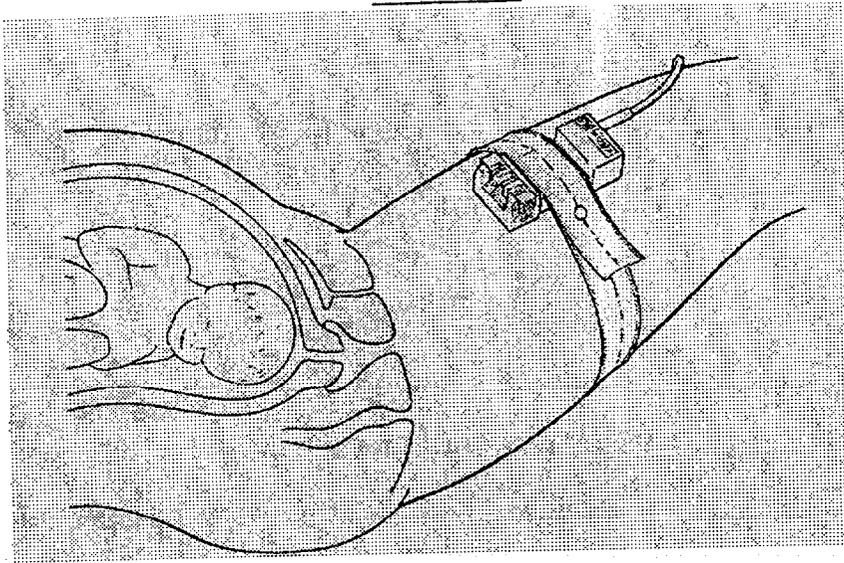
STERILITY CANNOT BE GUARANTEED IF PACKAGE IS BROKEN OR OPENED.

BIOLOGICALLY TESTED

2000536-001

Rev. B

EXHIBIT 2



Fetal Scalp Electrode

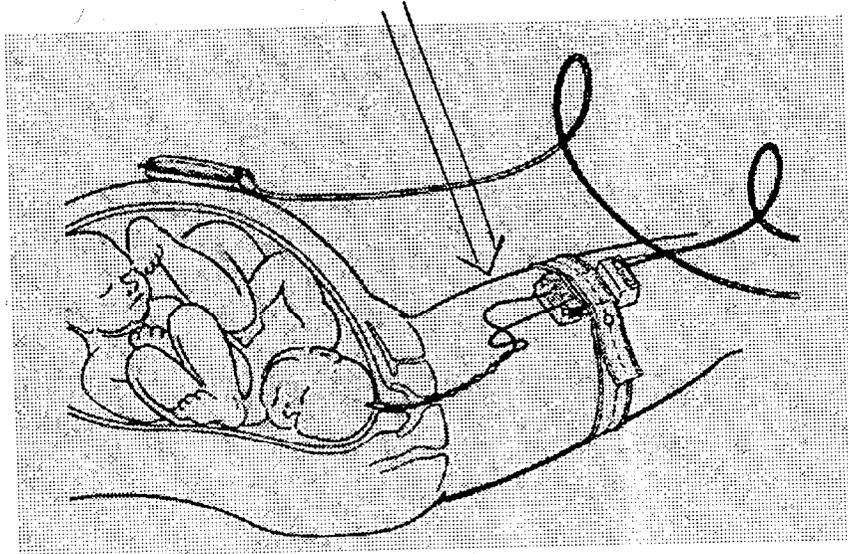
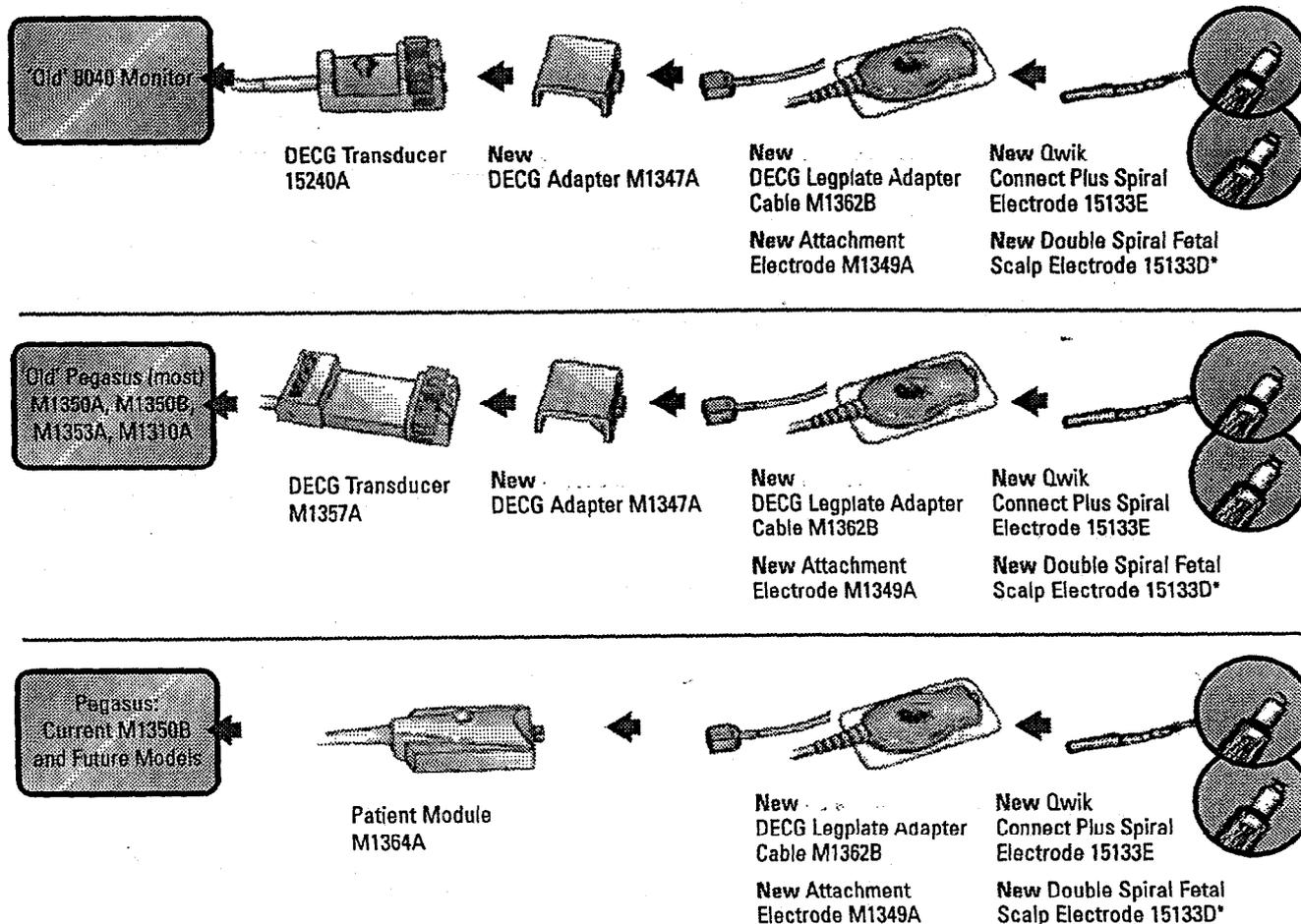


EXHIBIT 3

Agilent Technologies New Generation of Fetal Scalp Electrodes

Ordering Guide



Agilent Technologies' new design fetal scalp electrodes and connection system provide you with

- electrodes that meet the full requirements of the newest FDA and IEC safety standards.
- a simple, one-step, plug-in connector for quick, easy and secure connections, and for reliable and accurate fetal heart monitoring.
- increased comfort for the mother, because you can get rid of uncomfortable leg belts. Awkward DECG Transducers** and patient modules are moved from the birthing area.

The use of these electrodes with your existing Agilent Technologies or Hewlett-Packard fetal monitoring equipment requires no more than an adapter fitting for your existing DECG Transducer (not required for the M1346A patient module), and a standard adapter cable.

* Europe only
** Attention: The 'old' DECG Transducer must make contact to the mother's skin.