

Ludlow Technical Products
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A tyco INTERNATIONAL LTD. COMPANY

CITIZEN PETITION

The undersigned submits this petition 21 CFR §898.14 to request the Commissioner of Food and Drugs to allow a variance for Care Providers and their respective patients, to extend the effective date of 21 CFR Part 898 – PERFORMANCE STANDARD FOR ELECTRODE LEAD WIRES AND PATIENT CABLES from May 9, 2000 to August 9, 2000 for the Electrode, Circular (spiral), Scalp and Applicator, 21 CFR § 884.2675 for use on patients.

A. Variance Requested

The undersigned respectfully requests that the Commissioner allow a variance to extend the Care Providers conversion date specified in 21 CFR § 898.13(b) from May 9, 2000 to a new date of August 9, 2000 for the medical device listed under 21 CFR § 884.2675 as “Electrode, Circular (spiral), Scalp and Applicator,” commonly referred to as a “Fetal Scalp Electrode.” Ludlow Company LP will not manufacture or sell non-complaint products after May 9, 2000. We are only requesting a variance of an additional 90 day period for care Providers to evaluate and convert to compliant product.

The subject regulation reads as follows:

PART 898 – PERFORMANCE STANDARD FOR ELECTRODE LEAD WIRES AND PATIENT CABLES

- Sec.
- 898.11 Applicability.
- 898.12 Performance Standard.
- 898.13 Compliance dates.
- 898.14 Exemptions and variances.

AUTHORITY: 21 U.S.C. 351, 352, 360c, 360d, 360gg-360ss, 371, 374); 42 U.S.C. 262, 264.

Source: 62 FR 25497, May 9, 1997, unless otherwise noted.

Sec. 898.11 Applicability.

Electrode lead wires and patient cables intended for use with a medical device shall be subject to the performance standard set forth in Sec. 898.12.

Sec. 898.12 Performance.

(a) Any connector in a cable or electrode lead wire having a conductive connection to a patient shall be constructed in such a manner as to comply with subclause 56.3(c) of the following standard:

International Electrotechnical Commission (IEC)
601-1: Medical Electrical Equipment
601-1 (1998) Part 1: General requirements for safety

COP-0442

CP1

Amendment No. 1 (1991)
 Amendment No. 2 (1005).

(b) Compliance with the standard shall be determined by inspection and by applying the test requirements and test methods of subclause 56.3(c) of the standard set forth in paragraph (a) of this section.

Sec. 898.13 Compliance dates.

The dates for compliance with the standard set forth in Sec. 898.12(a) shall be as follows:

(a) For electrode lead wires and patient cables used with, or intended for use with, the following devices, the date for which compliance is required is May 11, 1998:

LISTING OF DEVICES FOR WHICH COMPLIANCE IS REQUIRED EFFECTIVE
 May 11, 1998

Phase	Product Code	21 CFR Section	Class	Device Name
1.....	73 BZQ	868.2375	II	Monitor, Breathing Frequency.
1.....	73 FLS	868.2375	II	Monitor (Apnea Detector), Ventilatory Effort.
1.....	74 DPS	870.2340	II	Electrocardiograph.
1.....	74 DRG	870.2910	II	Transmitters and Receivers, Physiological Signal, Radio Frequency.
1.....	74 DRT	840.2300	II	Monitor, Cardiac (including Cardiometer and Rate Alarm)
1.....	74 DRX	870.2360	II	Electrode, Electrocardiograph
1.....	74 DSA	870.2900	II	Cable, Transducer and Electrode, Patient (including Connector).
1.....	74 DSH	870.2800	II	Recorder, Magnetic Tape, Medical.
1.....	74 DSI	870.1025	III	Detector and Alarm, Arrhythmia.
1.....	74 DXH	870.2920	II	Transmitters and Receivers, Electrocardiograph, Telephone.

(b) For electrode lead wires and patient cables used with, or intended for use with, any other device, the date for which compliance is required is May 9, 2000.

Sec. 898.14 Exemptions and variances.

(a) A request for an exemption or variance shall be submitted in the form of a petition under Sec. 10.30 of this chapter and shall comply with the requirements set out therein. The petition shall also contain the following:

- (1) The name of the device, the class in which the device has been classified, and representative labeling showing the intended uses (s) of the device;
- (2) The reasons why compliance with the performance standard is unnecessary or unfeasible;
- (3) A complete description of alternative steps that are available, or that the petitioner has already taken, to ensure that a patient will not be inadvertently connected to hazardous voltages via an unprotected patient cable or electrode lead wire for intended use with the device; and
- (4) Other information justifying the exemption or variance.

(b) An exemption or variance is not effective until the agency approves the request under Sec. 10(e)(2)(i) of this chapter.

B. Statement of grounds

1. *The medical device for which the variance is requested.*

The subject medical device is commonly referred to as a Fetal Scalp Electrode (hereinafter "FSE"). FDA classifies the FSE as a Class II medical device under 21 CFR 884.2675 Electrode, Circular (spiral), Scalp and Applicator.

§ 884.2685 Fetal scalp circular (spiral) electrode and applicator.

(a) Identification. A fetal scalp circular (spiral) electrode and applicator is a device used to obtain a fetal electrocardiogram during labor and delivery. It establishes electrical contact between fetal skin and an electrical monitoring device by a shallow subcutaneous puncture of fetal scalp tissue with a curved needle or needles. This generic type of device includes nonreusable spiral electrodes and reusable circular electrodes.

(b) Classification. Class II (performance standards).

In particular, the medical devices for which the variance is requested are referred to as the LifeTrace® FSE 1000 Fetal Spiral Electrode and FSE 2020 Fetal Spiral Electrode manufactured by Graphic Controls Canada, LTD, a division of Ludlow Company LP, and sold by Ludlow's business unit, Kendall-LTP. The current labeling for these products are located in Appendix 1. Drawings of the products are located in Appendix 2.

2. *Fetal Monitoring in the United States.*

There are approximately 45,000 fetal monitors in the U.S., and approximately 3 million FSEs are used per year. The two major U.S. manufacturers for Fetal monitoring equipment are Agilent Technologies (a division of Hewlett Packard) and Corometrics (a division of GE-Marquette Medical Systems), which represents approximately 90% of the market. The three major U.S. suppliers of disposable FSEs and accompanying cables are Agilent, Corometrics, and Kendall-LTP. None of the current FSE systems on the market are compliant today.

Corometrics has strong patents that covers design embodiments for connection means that strongly limits the implementation of safety solutions for Agilent and Ludlow. However, through a diligent engineering effort we have developed a solution. Based upon the numbers stated above, we are presently making sure the design is robust and that we have enough inventory to ensure a smooth transition for the Care Providers and Patients. Ludlow is not aware of Corometrics having made their safety system available to the marketplace, nor is Ludlow knowledgeable as to Corometrics' plans for complying with the May 9th date.

Agilent and Ludlow are working jointly on a standard safety solution for Agilent's monitoring equipment. Ludlow is also working to provide its safety solution for the Kendall-LTP direct market as an alternative supply to OEM manufacturers.

3. *The likelihood of an accidental connection to a hazardous voltage during this variance period is negligible.*

There are two compelling reasons why the risk involved in granting this variance for the patient is negligible. The first reason is the design and use of the Fetal Scalp Electrode. The Fetal Scalp Electrode's lead wires, which are only 18" long, reside between the mother's legs, naturally limiting the probability for a shock hazard. The environment in which the FSE is used is controlled, typically with limited medical equipment, and the patient is under direct care of a clinician.

The second reason there is negligible risk is the lack of any occurrences where a Fetal Scalp electrode was involved in an accidental electrical shock. Neither Graphic Controls (dating back to 1982), Kendall-LTP, nor Agilent have received complaints of accidental electrical shock involving FSEs for each company's history with the device. Further, FDA's Maude Database shows no Medical Device Reports (MDRs) on Fetal Scalp Electrodes related to accidental electrical shock.

4. *Ludlow Company, LP will not manufacture or sell non-safety Fetal Scalp electrodes after May 9, 2000.*

Ludlow will be in compliance with the mandate, however, we feel strongly that the Care Providers and their Patients should be allowed a grace period to use existing products concurrently while they evaluate the new safety solutions. In order for the Care Providers to select the best, safest, most cost-effective solution, there needs to be time for this to occur and all products need to be on the market. The Care Provider can not make an educated decision until they are assured that the product they are selecting is in fact their product of choice and readily available. For this reason, the variance is being requested.

Ludlow has established aggressive timetables to begin the conversion process to the compliant FSE. The Kendall-LTP sales force has already initiated training and education of Care Providers on the regulation and our plans for compliance. In March, samples of the safety solution design will be available for Care Providers to begin their evaluation. In April, Kendall-LTP will begin filling orders for the safety solution design.

C. Certification

The undersigned certifies, 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 petitioner which are unfavorable to the petition.



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Appendix 1 : Representative Labeling



Product Description
Safelinc™ FSE

REF Reorder No.
31479549

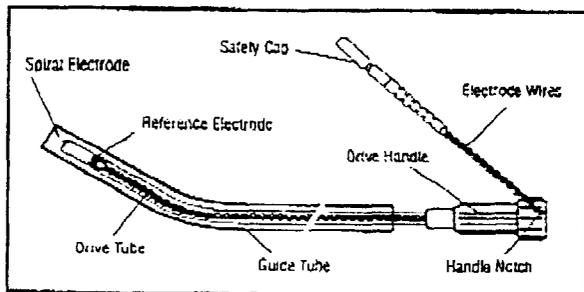
Fetal Spiral Electrode: Single Helix

STERILE R and Disposable

Contents of unopened and undamaged package are sterile



+H593314795490D



WARNING: Single use only - discard after use. The fetal electrode tip is designed to penetrate the epidermis of the fetus; therefore, trauma, hemorrhage and/or infection can occur. The electrode should be used with strict adherence to aseptic technique. Amniotic membranes must be ruptured prior to attaching the spiral electrode. The spiral electrode should be removed from the patient before performing any electro-surgical procedures.

PRECAUTION: U.S. Federal Law restricts this device to sale by or on the order of a physician. Sterility cannot be guaranteed if package is broken or opened. Sterilized by gamma radiation. Do not re-sterilize.

CONTRAINDICATIONS: The fetal spiral electrode should not be applied to the fetal face, fontanelles or genitalia. Do not apply when placenta previa is present; when the mother has visible genital herpes lesions or reports symptoms of prodromal lesions; when the mother is HIV sero-positive; when mother is a confirmed carrier of hemophilia and the fetus is affected or of unknown status; or when it is not possible to identify fetal presenting part where application is being considered. Application when fetus is extremely premature, or in the presence of a maternal infection such as Hepatitis B, Group B hemolytic strep, syphilis or gonorrhoea is not recommended but may be acceptable if a clear benefit to the fetus or mother can be established.

Directions For Use

1. Remove from package, leaving the Electrode Wires locked in the Handle Notch
2. Gently form the Guide Tube to the desired angle
3. With the patient in the dorsal lithotomy position, perform a vaginal examination and clearly identify the fetal presenting

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Directions For Use

1. Remove from package, leaving the Electrode Wires locked in the Handle Notch
2. Gently form the Guide Tube to the desired angle
3. With the patient in the dorsal lithotomy position, perform a vaginal examination and clearly identify the fetal presenting part.
4. Holding the Drive Handle, ensure the spiral electrode is retracted approximately one inch (2.5 cm) from the distal end of the Guide Tube.
5. Place the Guide Tube firmly against the identified presenting part.
6. Maintain pressure against the fetal presenting part with Guide and Drive Tubes. Turn the Drive Tube by rotating the Drive Handle clockwise until gentle resistance is encountered. Resistance to further rotation and recoil of the Drive Handle indicates attachment. This will usually occur after one complete rotation.
7. Release the Electrode Wires from the Handle Notch and straighten them. Slide the Drive and Guide Tubes off the Electrode Wires.
8. Insert the Safety Cap into the Life Trace Leg Plate Cable.

To detach the Fetal Spiral Electrode, rotate the FSE counter-clockwise until it is free from the fetal presenting part. Do not pull the electrode from the fetal skin.

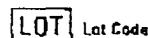
Manufactured for

KENDALL-LTP

Made in Canada
By **Graphic Controls Canada Ltd.**
Gananoque, Ontario,
Canada K7G 2Y7
USA: 1-800-669-1009
Canada: 1-800-267-9498
International: 1-716-847-7582



Control Gráficos Ibéricos, S.A.
Campezo, 6 (Polígono Las Mercedes),
228022
Madrid, Spain



Patent Pending
18C2 00

Appendix 2 : Product Drawings

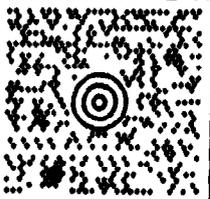
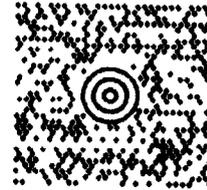
LETTER

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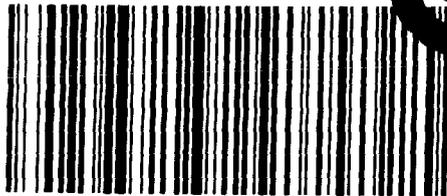


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