

EnglishDeutschΕλληνικάEspañolΕστίλ κελ

Fetal spiral electrode for Corometrics™

Instructions for Use

REF 7000AA0 Vital Sign® Fetal Spiral Electrode for Corometrics™

Color Name **TERE1** Sterilized using irradiation

Lot Number Follow Instructions for Use

Quantity Storage Temperature Limit

Exp. Date For Single Use Only

Manufacturer U.S. Federal law restricts this device to use only on the order of a physician.

Consult Instructions for Use Do not use if package is damaged

Intended use

The spiral electrode is intended for use under the direct supervision of a licensed healthcare practitioner. This accessory electrode is intended for use with an electronic fetal monitor for internal monitoring of the fetal heart rate.

Low spiral electrode delivers a direct fetal heart rate signal. fetal electrocardiogram (FECG) by direct application/penetration of the fetal presenting part.



Figure 1

- Connector
- Electrode wire
- Shielded cable
- Drive tube grip
- Shielded cable
- Guide tube
- Reference electrode
- Reference electrode
- Spiral tip

Instructions for use

The spiral electrode is a sterile, single use, fetal monitor accessory. The electrode is connected to the cable/plug secured to the mother. Connections must be returned prior to the attachment of spiral electrode. Connections must be returned to the manufacturer's instructions for use.

- Verify that the expiration date is still effective. Using aseptic technique, open the package and remove the spiral electrode. Sterilize the electrode using the instructions to verify integrity of the electrode.
- The spiral tube curvature may be altered by carefully bending it to desired shape.
- Inspect the spiral electrode until spiral tip end is approximately one inch inside the drive tube.
- The patient should be in the dorsal lithotomy position. Perform a vaginal internal fetal presentation of 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 spiral reaches the presenting part. Maintain gentle pressure against the presenting part and rotate drive tube until the spiral electrode is fully engaged with the fetus.

NOTE: Full attachment should occur in 10 to 15% turns. Attachment is indicated by mild resistance to further rotation and loss of the drive tube grip.

- Do not rotate the spiral electrode.
- Do not rotate the drive tube grip.
- Do not rotate the spiral tip.

Figure 2

- Wrap around the connector end of the electrode. Insert connector end around the low plate interface cable until fully engaged.
- Secure attachment pad into place on low plate interface cable and apply to placenta.
- To remove the electrode, follow removal instructions below.

Removing spiral electrode

- Pull connector end of spiral electrode out of low plate interface cable.
- Remove spiral electrode by grasping the electrode wires as shown in figure 2.
- Inspect the spiral tip to make sure it is still attached to the hub. If the spiral tip remains attached to the hub, remove it from the presenting part using aseptic technique.
- Remove attachment pad from low plate interface cable.

Contraindications

The electrode should not be applied to the fetal face, fontanelle or genitalia, when placenta previa is present, when genital infections (e.g., herpes, Group B streptococcus, gonorrhea) or maternal acquired bacterial vaginosis (ABDV) exist, when the mother has genital herpes, when the fetus and the fetus is either affected or of unknown status, or when it is not possible to identify the position of the fetal body when application is contemplated.

Warning

- Steadily cannot be guaranteed if package is broken or opened.
- Because the tip of this electrode is designed to penetrate the fetal membranes, the possibility of trauma, hemorrhage and infection exists.
- Therefore be used only under the direct supervision of a physician. Connections must be returned prior to attachment of spiral electrode.
- Use only as directed in the instructions for use. The hub and frame in the fetal presenting part. (Reference Manual Step 3.)
- Use only as directed in the instructions for use. The hub and frame in the fetal presenting part. (Reference Manual Step 3.)
- Do not use electrode if you see any visual signs of damage.
- No modification is allowed.
- Do not use electrode unless designed to be reused. Reuse may cause a risk of cross-contamination, affect the measurement accuracy and/or system performance, or cause damage to the product being used.
- Physically damaged or used to measure, disinfection, re-sterilization and/or reuse is prohibited.

Technical description

For technical description see the most recent revision. This product conforms to IEC 60601-1-2.

Ordering information

For further information, please contact your local sales representative or visit www.vyairc.com.

Trademarks are the property of their respective owners.

©2019 Vyairc, the Vyairc logo and Vital Signs are trademarks or registered trademarks of Vyairc Medical, Inc., or one of its affiliates.

U.S. Federal Law restricts this device to use only on the order of a physician.

CE 0337

100014002A, 2019-02

Technical description

For technical description see the most recent revision. This product conforms to IEC 60601-1-2.

Ordering information

For further information, please contact your local sales representative or visit www.vyairc.com.

Trademarks are the property of their respective owners.

©2019 Vyairc, the Vyairc logo and Vital Signs are trademarks or registered trademarks of Vyairc Medical, Inc., or one of its affiliates.

U.S. Federal Law restricts this device to use only on the order of a physician.

CE 0337

100014002A, 2019-02

Technical description

For technical description see the most recent revision. This product conforms to IEC 60601-1-2.

Ordering information

For further information, please contact your local sales representative or visit www.vyairc.com.

Trademarks are the property of their respective owners.

©2019 Vyairc, the Vyairc logo and Vital Signs are trademarks or registered trademarks of Vyairc Medical, Inc., or one of its affiliates.

U.S. Federal Law restricts this device to use only on the order of a physician.

CE 0337

100014002A, 2019-02

Technical description

For technical description see the most recent revision. This product conforms to IEC 60601-1-2.

Ordering information

For further information, please contact your local sales representative or visit www.vyairc.com.

Trademarks are the property of their respective owners.

©2019 Vyairc, the Vyairc logo and Vital Signs are trademarks or registered trademarks of Vyairc Medical, Inc., or one of its affiliates.

U.S. Federal Law restricts this device to use only on the order of a physician.

CE 0337

100014002A, 2019-02

Technical description

For technical description see the most recent revision. This product conforms to IEC 60601-1-2.

Ordering information

For further information, please contact your local sales representative or visit www.vyairc.com.

Trademarks are the property of their respective owners.

©2019 Vyairc, the Vyairc logo and Vital Signs are trademarks or registered trademarks of Vyairc Medical, Inc., or one of its affiliates.

U.S. Federal Law restricts this device to use only on the order of a physician.

CE 0337

100014002A, 2019-02

Technical description

For technical description see the most recent revision. This product conforms to IEC 60601-1-2.

Ordering information

For further information, please contact your local sales representative or visit www.vyairc.com.

Trademarks are the property of their respective owners.

©2019 Vyairc, the Vyairc logo and Vital Signs are trademarks or registered trademarks of Vyairc Medical, Inc., or one of its affiliates.

U.S. Federal Law restricts this device to use only on the order of a physician.

CE 0337

100014002A, 2019-02

Technical description

For technical description see the most recent revision. This product conforms to IEC 60601-1-2.

Ordering information

For further information, please contact your local sales representative or visit www.vyairc.com.

Trademarks are the property of their respective owners.

©2019 Vyairc, the Vyairc logo and Vital Signs are trademarks or registered trademarks of Vyairc Medical, Inc., or one of its affiliates.

U.S. Federal Law restricts this device to use only on the order of a physician.

CE 0337

100014002A, 2019-02

Technical description

For technical description see the most recent revision. This product conforms to IEC 60601-1-2.

Ordering information

For further information, please contact your local sales representative or visit www.vyairc.com.

Trademarks are the property of their respective owners.

©2019 Vyairc, the Vyairc logo and Vital Signs are trademarks or registered trademarks of Vyairc Medical, Inc., or one of its affiliates.

U.S. Federal Law restricts this device to use only on the order of a physician.

CE 0337

100014002A, 2019-02

Technical description

For technical description see the most recent revision. This product conforms to IEC 60601-1-2.

Ordering information

For further information, please contact your local sales representative or visit www.vyairc.com.

Trademarks are the property of their respective owners.

©2019 Vyairc, the Vyairc logo and Vital Signs are trademarks or registered trademarks of Vyairc Medical, Inc., or one of its affiliates.

U.S. Federal Law restricts this device to use only on the order of a physician.

CE 0337

100014002A, 2019-02

Technical description

For technical description see the most recent revision. This product conforms to IEC 60601-1-2.

Ordering information

For further information, please contact your local sales representative or visit www.vyairc.com.

Trademarks are the property of their respective owners.

©2019 Vyairc, the Vyairc logo and Vital Signs are trademarks or registered trademarks of Vyairc Medical, Inc., or one of its affiliates.

U.S. Federal Law restricts this device to use only on the order of a physician.

CE 0337

100014002A, 2019-02

Technical description

For technical description see the most recent revision. This product conforms to IEC 60601-1-2.

Ordering information

For further information, please contact your local sales representative or visit www.vyairc.com.

Trademarks are the property of their respective owners.

©2019 Vyairc, the Vyairc logo and Vital Signs are trademarks or registered trademarks of Vyairc Medical, Inc., or one of its affiliates.

U.S. Federal Law restricts this device to use only on the order of a physician.

CE 0337

100014002A, 2019-02

Technical description

For technical description see the most recent revision. This product conforms to IEC 60601-1-2.

Ordering information

For further information, please contact your local sales representative or visit www.vyairc.com.

Trademarks are the property of their respective owners.

©2019 Vyairc, the Vyairc logo and Vital Signs are trademarks or registered trademarks of Vyairc Medical, Inc., or one of its affiliates.

U.S. Federal Law restricts this device to use only on the order of a physician.

CE 0337

100014002A, 2019-02

Technical description

For technical description see the most recent revision. This product conforms to IEC 60601-1-2.

Ordering information

For further information, please contact your local sales representative or visit www.vyairc.com.

Trademarks are the property of their respective owners.

©2019 Vyairc, the Vyairc logo and Vital Signs are trademarks or registered trademarks of Vyairc Medical, Inc., or one of its affiliates.

U.S. Federal Law restricts this device to use only on the order of a physician.

CE 0337

100014002A, 2019-02

Technical description

For technical description see the most recent revision. This product conforms to IEC 60601-1-2.

Ordering information

For further information, please contact your local sales representative or visit www.vyairc.com.

Trademarks are the property of their respective owners.

©2019 Vyairc, the Vyairc logo and Vital Signs are trademarks or registered trademarks of Vyairc Medical, Inc., or one of its affiliates.

U.S. Federal Law restricts this device to use only on the order of a physician.

CE 0337

100014002A, 2019-02

Technical description

For technical description see the most recent revision. This product conforms to IEC 60601-1-2.

Ordering information

For further information, please contact your local sales representative or visit www.vyairc.com.

Trademarks are the property of their respective owners.

©2019 Vyairc, the Vyairc logo and Vital Signs are trademarks or registered trademarks of Vyairc Medical, Inc., or one of its affiliates.

U.S. Federal Law restricts this device to use only on the order of a physician.

CE 0337

100014002A, 2019-02

Technical description

For technical description see the most recent revision. This product conforms to IEC 60601-1-2.

Ordering information

For further information, please contact your local sales representative or visit www.vyairc.com.

EnglishDeutschΕλληνικάEspañolΕστίλ κελ

Fetal spiral electrode for Corometrics™

Instructions for use

REF 7000AA0 Vital Sign® Fetal Spiral Electrode for Corometrics™

Color Name **TERE1** Sterilized using irradiation

Lot Number Follow Instructions for Use

Quantity Storage Temperature Limit

Exp. Date For Single Use Only

Manufacturer U.S. Federal law restricts this device to use only on the order of a physician.

Consult Instructions for Use Do not use if package is damaged



Figure 1

- Connector
- Electrode wire
- Shielded cable
- Drive tube grip
- Shielded cable
- Guide tube
- Reference electrode
- Reference electrode
- Spiral tip

Instructions for use

The spiral electrode is a sterile, single use, fetal monitor accessory. The electrode is connected to the cable/plug secured to the mother. Connections must be returned prior to the attachment of spiral electrode. Connections must be returned to the manufacturer's instructions for use.

- Verify that the expiration date is still effective. Using aseptic technique, open the package and remove the spiral electrode. Sterilize the electrode using the instructions to verify integrity of the electrode.
- The spiral tube curvature may be altered by carefully bending it to desired shape.
- Inspect the spiral electrode until spiral tip end is approximately one inch inside the drive tube.
- The patient should be in the dorsal lithotomy position. Perform a vaginal internal fetal presentation of 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 spiral reaches the presenting part. Maintain gentle pressure against the presenting part and rotate drive tube until the spiral electrode is fully engaged with the fetus.

NOTE: Full attachment should occur in 10 to 15% turns. Attachment is indicated by mild resistance to further rotation and loss of the drive tube grip.

- Do not rotate the spiral electrode.
- Do not rotate the drive tube grip.
- Do not rotate the spiral tip.

Figure 2

- Wrap around the connector end of the electrode. Insert connector end around the low plate interface cable until fully engaged.
- Secure attachment pad into place on low plate interface cable and apply to placenta.
- To remove the electrode, follow removal instructions below.

Removing spiral electrode

- Pull connector end of spiral electrode out of low plate interface cable.
- Remove spiral electrode by grasping the electrode wires as shown in figure 2.
- Inspect the spiral tip to make sure it is still attached to the hub. If the spiral tip remains attached to the hub, remove it from the presenting part using aseptic technique.
- Remove attachment pad from low plate interface cable.

Contraindications

The electrode should not be applied to the fetal face, fontanelle or genitalia, when placenta previa is present, when genital infections (e.g., herpes, Group B streptococcus, gonorrhea) or maternal acquired bacterial vaginosis (ABDV) exist, when the mother has genital herpes, when the fetus and the fetus is either affected or of unknown status, or when it is not possible to identify the position of the fetal body when application is contemplated.

Warning

- Steadily cannot be guaranteed if package is broken or opened.
- Because the tip of this electrode is designed to penetrate the fetal membranes, the possibility of trauma, hemorrhage and infection exists.
- Therefore be used only under the direct supervision of a physician. Connections must be returned prior to attachment of spiral electrode.
- Use only as directed in the instructions for use. The hub and frame in the fetal presenting part. (Reference Manual Step 3.)
- Use only as directed in the instructions for use. The hub and frame in the fetal presenting part. (Reference Manual Step 3.)
- Do not use electrode if you see any visual signs of damage.
- No modification is allowed.
- Do not use electrode unless designed to be reused. Reuse may cause a risk of cross-contamination, affect the measurement accuracy and/or system performance, or cause damage to the product being used.
- Physically damaged or used to measure, disinfection, re-sterilization and/or reuse is prohibited.

Technical description

For technical description see the most recent revision. This product conforms to IEC 60601-1-2.

Ordering information

For further information, please contact your local sales representative or visit www.vyairc.com.

Trademarks are the property of their respective owners.

©2019 Vyairc, the Vyairc logo and Vital Signs are trademarks or registered trademarks of Vyairc Medical, Inc., or one of its affiliates.

U.S. Federal Law restricts this device to use only on the order of a physician.

CE 0337

100014002A, 2019-02

Technical description

For technical description see the most recent revision. This product conforms to IEC 60601-1-2.

Ordering information

For further information, please contact your local sales representative or visit www.vyairc.com.

Trademarks are the property of their respective owners.

©2019 Vyairc, the Vyairc logo and Vital Signs are trademarks or registered trademarks of Vyairc Medical, Inc., or one of its affiliates.

U.S. Federal Law restricts this device to use only on the order of a physician.

CE 0337

100014002A, 2019-02

Technical description

For technical description see the most recent revision. This product conforms to IEC 60601-1-2.

Ordering information

For further information, please contact your local sales representative or visit www.vyairc.com.

Trademarks are the property of their respective owners.

©2019 Vyairc, the Vyairc logo and Vital Signs are trademarks or registered trademarks of Vyairc Medical, Inc., or one of its affiliates.

U.S. Federal Law restricts this device to use only on the order of a physician.

CE 0337

100014002A, 2019-02

Technical description

For technical description see the most recent revision. This product conforms to IEC 60601-1-2.

Ordering information

For further information, please contact your local sales representative or visit www.vyairc.com.

Trademarks are the property of their respective owners.

©2019 Vyairc, the Vyairc logo and Vital Signs are trademarks or registered trademarks of Vyairc Medical, Inc., or one of its affiliates.

U.S. Federal Law restricts this device to use only on the order of a physician.

CE 0337

100014002A, 2019-02

Technical description

For technical description see the most recent revision. This product conforms to IEC 60601-1-2.

Ordering information

For further information, please contact your local sales representative or visit www.vyairc.com.

Trademarks are the property of their respective owners.

©2019 Vyairc, the Vyairc logo and Vital Signs are trademarks or registered trademarks of Vyairc Medical, Inc., or one of its affiliates.

U.S. Federal Law restricts this device to use only on the order of a physician.

CE 0337

100014002A, 2019-02

Technical description

For technical description see the most recent revision. This product conforms to IEC 60601-1-2.

Ordering information

For further information, please contact your local sales representative or visit www.vyairc.com.

Trademarks are the property of their respective owners.

©2019 Vyairc, the Vyairc logo and Vital Signs are trademarks or registered trademarks of Vyairc Medical, Inc., or one of its affiliates.

U.S. Federal Law restricts this device to use only on the order of a physician.

