IMPORTANT INFORMATION

Rx only

Infant/Child Reduced Energy Defibrillation Electrodes are to be used by authorized personnel only.

Responsibility for Information

It is the responsibility of our customers to ensure that the appropriate person(s) have access to the information in these instructions for use.

Operators should be thoroughly familiar with their defibrillator operating instructions before using therapy electrodes.

These instructions are specific to Infant/Child disposable products and are intended to complement local protocol and your defibrillator operating instructions.
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GENERAL WARNINGS

The following are general warning statements.

Warning: Hazards or unsafe practices that may result in serious personal injury or death.

**WARNINGS!**

**Shock hazard.**

When discharged, a defibrillator delivers up to 360 joules of electrical energy. Do not touch the paddle electrode surface or the Infant/Child electrodes when discharging the defibrillator.

**Shock hazard.**

If a person is touching the patient, bed, or any conductive material in contact with the patient during defibrillation, the delivered energy may be partially discharged through that person. Make sure that everyone stands away from the patient, bed, and other conductive material before discharging the defibrillator.

**Ineffective energy delivery.**

Do not use Infant/Child electrodes on adults or large children. Delivering defibrillation energy (<100J) with these electrodes will reduce effectiveness.

**Possible skin burns.**

During defibrillation air pockets between the skin and Infant/Child electrodes can cause patient skin burns. Apply Infant/Child electrodes so that entire electrode adheres to skin. Do not reposition the electrodes once applied. If the position must be changed, remove and replace with new electrodes.

**Possible skin burns and ineffective energy delivery.**

Infant/Child electrodes that are dried out or damaged may cause electrical arcing and patient skin burns during defibrillation. Do not use electrodes that have been removed from foil package for more than 24 hours. Do not use electrodes beyond Use By date. Check that electrode adhesive is intact and undamaged.

**Possible fire or explosion.**

Do not use a defibrillator in the presence of flammable gases or anesthetics. Use care when operating this device close to oxygen sources (such as bag-valve-mask devices or ventilator tubing). Turn off gas source or move source away from patient during defibrillation.

**Possible fire, burns, and ineffective energy delivery.**

Do not discharge standard paddles on top of Infant/Child electrodes or ECG electrodes. Do not allow Infant/Child electrodes to touch each other, ECG electrodes, lead wires, dressings, transdermal patches, and the like. Such contact can cause electrical arcing and patient skin burns during defibrillation and may divert defibrillating energy away from the heart muscle.

**Possible interference with implanted electrical device.**

Defibrillation may cause implanted electrical devices to malfunction. Place Infant/Child electrodes away from implanted devices if possible. Check implanted device function after defibrillation.

**Possible electrical interference with device performance.**

Equipment operating in close proximity may emit strong electromagnetic or radio frequency interference (RFI) which could affect the performance of this device. RFI may result in improper device operation, distorted ECG, and failure to detect a shockable rhythm. Avoid operating the device near cauternizers, diathermy equipment, cellular phones, or other portable and mobile RF communications equipment. Maintain equipment separation of at least 1.2 m (4 ft) and do not rapidly key EMS radios on and off. Contact a technical support representative if assistance is required.

**Shock or fire hazard.**

Do not immerse any portion of the therapy cables or electrodes in water or other fluids. Avoid spilling any fluids on the adapters, cables, connectors, or Infant/Child electrodes. Do not autoclave, steam, or gas sterilize unless otherwise specified. Do not clean the Infant/Child electrodes or their permanently attached electrode cables with isopropyl alcohol.
WARNING!

Safety risk and possible equipment damage.

Monitors, defibrillators, and their accessories (including electrodes and cables) contain ferromagnetic materials. As with all ferromagnetic equipment, these products must not be used in the presence of the high magnetic field created by a magnetic resonance imaging (MRI) device. The high magnetic field created by an MRI device will attract the equipment with a force sufficient to cause death or serious personal injury to persons between the equipment and the MRI device. Skin burns will also occur due to heating of electrically conductive materials such as patient leads and pulse oximeter sensors. This magnetic attraction may also damage the equipment. Consult the MRI manufacturer for more information.

SYMBOLS

The following symbols may appear on the Infant/Child Reduced Energy Defibrillation Electrodes or on the packaging:

- **LOT**
  - Lot code

- **REF**
  - Use by date shown: yyyy-mm-dd or yyyy-mm

- **CAT #**
  - Reorder number

- **MIN**
  - Catalogue number

- **Single use only**

- **Attention, consult only accompanying documents**

- **BF patient connection**

- **Warning, high voltage**

- **Infant Child Reduced Energy Electrodes are not compatible with QUIK-COMBO defibrillation and therapy cables. To use Infant/Child Electrodes, connect Infant/Child electrodes directly to the AED.**

- **Mark of conformity according to the European Medical Device Directive 93/42/EEC**

- **Canadian Standards Association certification for Canada and the United States**

- **For USA audiences only**

- **Federal (USA) law restricts this product to sale by or on the order of a physician.**

- **Latex-free**
**Indications for Use**

**INDICATIONS FOR USE**

Use Infant/Child Reduced Energy Defibrillation Electrodes on an infant or child patient who is up to 8 years old or weighs up to 25 kg (55 lbs). **Do not delay therapy to determine precise age or weight.**

These electrodes are to be used only with LIFEPAK CR® Plus and LIFEPAK EXPRESS® defibrillators and biphasic LIFEPAK® 500 AEDs configured with a pink cable connector.

Store in a cool, dry location (0° to 50°C or 32° to 122°F)

Two electrodes in one package

One package in one shelf-pak

Twenty-five shelf-paks in one case

Open package

Remove electrodes

Plug connector into the LIFEPAK CR Plus or LIFEPAK EXPRESS defibrillator

Plug connector into LIFEPAK 500 AED

Remove release liner

Apply pads and follow voice prompts
LIFEPAK CR Plus and LIFEPAK EXPRESS defibrillators and biphasic LIFEPAK 500 AEDs are indicated for use on patients in cardiopulmonary arrest. The patient must be unconscious, not breathing normally, and showing no signs of circulation (for example, no pulse, and/or no coughing, no movement) before the device is used to analyze the patient’s ECG rhythm.

LIFEPAK CR Plus and LIFEPAK EXPRESS defibrillators and biphasic LIFEPAK 500 AEDs are intended to be used by personnel who are trained on the device operation and in basic life support or other physician-authorized emergency medical response system.

**ABOUT THE ELECTRODES**

Infant/Child Reduced Energy Defibrillation Electrodes are pre-gelled, self-adhesive, therapy electrodes that allow hands-free defibrillation. These electrodes reduce the energy delivered to the patient by a factor of 4:1.

Infant/Child electrodes are not compatible with any other AED or manual LIFEPAK defibrillator/monitor, such as the LIFEPAK 12 and 20 defibrillators, because of safety considerations. (There is a risk that the defibrillator operator may not take into account the 4:1 energy reduction of the Infant/Child electrodes and inadvertently deliver less energy than expected when manually selecting a pediatric dose.)

Use adult QUIK-COMBO™ electrodes for larger children and if the adult electrodes fit completely on the torso as pictured in the placement figure on page 5.

To help prevent damage to Infant/Child electrodes:

- Do not trim the electrodes.
- Do not crush, fold, or store the electrodes under heavy objects.
- Store electrodes in a cool, dry location. These electrodes are designed to withstand environmental temperature fluctuations between -40° to 50°C (-40° to 122°F). Continuous exposure to temperatures above 23°C (73°F) will reduce the shelf life of electrodes.

Medtronic Emergency Response Systems electrodes are latex-free.

**WARNING!**

**Delay of therapy**

The QUIK-COMBO defibrillation cable is not compatible with Infant/Child Reduced Energy Defibrillation Electrodes. To use Infant/Child electrodes, remove the defibrillation cable and connect the Infant/Child electrodes to the AED.

**PROCEDURE FOR USE**

- Remove all clothing from the patient's chest.
- Clean and dry the skin, if necessary. Do not use alcohol or tincture of benzoin.
• Open package and remove the electrodes.

• Disconnect and remove the adult defibrillation electrodes from the defibrillator.

• Insert the pink Infant/Child electrode connector into the defibrillator.

• Slowly remove the release liner from each electrode.

• If the infant has not experienced obvious trauma, place the electrodes on the front and back of the infant's bare chest as shown on each electrode.

• If the child's chest is large enough or if the child has experienced any type of trauma, this placement is encouraged (approximately 1 inch is required between electrodes for safe use).

• If the child's chest is small and the child has not experienced obvious trauma, this alternate placement may be used.
CLEANING AND STERILIZING

Infant/Child electrodes are not sterile or sterilizable. They are disposable and intended only for single use. Do not autoclave, gas sterilize, immerse in fluids, or clean electrodes with alcohol or solvents.

PRODUCT RECYCLING INFORMATION

Recycle this product at the end of its useful life.

Recycling Assistance
The product should be recycled according to national and local regulations. Contact your local Medtronic representative for assistance.

Preparation
This product should be clean and contaminant-free prior to being recycled.

Recycling of Disposable Electrodes
After disposable electrodes are used, follow your local clinical procedures for recycling.

Packaging
Packaging should be recycled according to national and local regulations.

ORDERING INFORMATION

To order Infant/Child electrodes (Catalog Number 11101-000016), contact your local Medtronic sales or service representative. In the USA, call the Medtronic PARTSLINE™ at 1.800.442.1142.

Infant/Child Reduced Energy Defibrillation Electrodes: Catalog Number 111101-000016 (outside USA)

SPECIFICATIONS

The following performance specifications are for a specially configured biphasic LIFEPAK 500 AED or a LIFEPAK CR Plus or LIFEPAK EXPRESS defibrillator connected directly to the Infant/Child Reduced Energy Defibrillation Electrodes.

All specifications are at 20°C (68°F) unless otherwise stated.
Defibrillator Compatibility

Defibrillator Compatibility: Medtronic biphasic LIFEPAK 500 AEDs with pink patient connectors and LIFEPAK CR Plus and LIFEPAK EXPRESS defibrillators only

Waveform Parameters for Pediatric Defibrillation

Waveform: Biphasic Truncated Exponential

Energy Delivered (25 – 125Ω): AED device energy ÷ 4, 86 J Max

Energy Accuracy (50Ω):

<table>
<thead>
<tr>
<th>AED DEVICE Energy (Joules)</th>
<th>Energy Delivered to Pediatric Patient (Joules)</th>
</tr>
</thead>
<tbody>
<tr>
<td>150*</td>
<td>38 ±15%</td>
</tr>
<tr>
<td>175*</td>
<td>44 ±15%</td>
</tr>
<tr>
<td>200</td>
<td>50 ±15%</td>
</tr>
<tr>
<td>225</td>
<td>56 ±15%</td>
</tr>
<tr>
<td>250</td>
<td>63 ±15%</td>
</tr>
<tr>
<td>275</td>
<td>69 ±15%</td>
</tr>
<tr>
<td>300</td>
<td>75 ±15%</td>
</tr>
<tr>
<td>325</td>
<td>81 ±15%</td>
</tr>
<tr>
<td>360</td>
<td>86 ±15%</td>
</tr>
</tbody>
</table>

* Energy settings available outside the USA only. Consult the specifications section of the defibrillator operating instructions for energy selection information.

Phase 2 Duration: 2/3 Phase 1 duration ±200µs

Tilt: 50 – 75%

Phase 1 Duration:

<table>
<thead>
<tr>
<th>Patient Impedance</th>
<th>LIFEPAK CR Plus and LIFEPAK EXPRESS Duration (ms)</th>
<th>LIFEPAK 500 Duration (ms)</th>
</tr>
</thead>
<tbody>
<tr>
<td>25</td>
<td>7.5 ±0.8</td>
<td>7.9 ±0.8</td>
</tr>
<tr>
<td>50</td>
<td>8.0 ±0.9</td>
<td>9.0 ±0.9</td>
</tr>
<tr>
<td>100</td>
<td>8.4 ±0.9</td>
<td>10.6 ±1.1</td>
</tr>
<tr>
<td>125</td>
<td>8.6 ±0.9</td>
<td>11.3 ±1.2</td>
</tr>
</tbody>
</table>
Specifications

Energy Parameters for Pediatric Defibrillation

Using Infant/Child Reduced Energy Defibrillation Electrodes:

Sample nominal doses delivered to a 50-ohm load

<table>
<thead>
<tr>
<th>Age</th>
<th>50th Percentile Weight* (Kg)</th>
<th>Energy Dose in Joules Per Kilogram for Adult Energy Settings</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>200 J</td>
</tr>
<tr>
<td>Newborn</td>
<td>3.6</td>
<td>13.9</td>
</tr>
<tr>
<td>1 year</td>
<td>10.3</td>
<td>4.9</td>
</tr>
<tr>
<td>2 years</td>
<td>12.7</td>
<td>3.9</td>
</tr>
<tr>
<td>3 years</td>
<td>14.3</td>
<td>3.5</td>
</tr>
<tr>
<td>4 years</td>
<td>16.0</td>
<td>3.1</td>
</tr>
<tr>
<td>5 years</td>
<td>18.0</td>
<td>2.8</td>
</tr>
<tr>
<td>6 years</td>
<td>21.0</td>
<td>2.4</td>
</tr>
<tr>
<td>7 years</td>
<td>23.0</td>
<td>2.2</td>
</tr>
<tr>
<td>8 years</td>
<td>25.0</td>
<td>2.0</td>
</tr>
</tbody>
</table>

*Doses indicated are based on CDC growth charts for the 50th percentile weights for boys. National Center for Statistics in collaboration with the National Center for Chronic Disease Prevention and Health Promotion (2000).

http://www.cdc.gov/growthcharts

Electrode Pads

Conductive/Gel Surface Area: 52 cm² (104 cm² combined)

Overall Size: 8.9 x 10.2 cm (3.5 x 4 in)

Standard Pad Placement: Anterior-Lateral or Anterior-Posterior
Specifications

Environmental

**Note:** All performance specifications defined assume that the unit has been stored (two hours minimum) at the operating temperature prior to operation.

- **Shelf Life:** 30 months
- **Operating Temperature:** 0°C to 50°C (32° to 122°F)
- **Storage Temperature:** -30°C to 65°C (-22° to 149°F), maximum exposure time limited to one week
- **Relative Humidity:** 5 to 95% (non-condensing)
- **Atmospheric Pressure:** 760 to 439 mmHg, 0 to 15,000 feet above sea level

Clinical Studies

The Shock Advisory System™ in the biphasic LIFEPAK 500 AED and the LIFEPAK CR Plus and LIFEPAK EXPRESS defibrillators was tested using an ECG database of shockable and non-shockable rhythms from a broad range of pediatric patients. The results indicate the Medtronic Shock Advisory System can be used safely and effectively for both adults and children. Refer to defibrillator operating instructions for results.

Non-Clinical Studies

The safety and effectiveness of the Medtronic ADAPTIV™ Biphasic waveform was studied thoroughly using a pediatric animal cardiac arrest model across the weight range of the intended population and across the range of energy settings available on the compatible AEDs. This study demonstrated that these attenuated biphasic shocks successfully resuscitated a significantly higher percentage of animals than did monophasic shocks of 2–4 J/kg.¹ ²

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² RA Berg, FW Chapman, RW Hilwig, KB Kern, MD Berg, and GA Ewy. Piglet biphasic defibrillation with the same dosage over a wide weight range is as safe as monophasic weight-based dosing. *Critical Care Medicine* 2003 (in press), abstract.
EC DECLARATION OF CONFORMITY

<table>
<thead>
<tr>
<th>Manufacturer’s Name:</th>
<th>Medtronic Emergency Response Systems, Inc.</th>
</tr>
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</table>
| Manufacturer’s Address: | 11811 Willows Road NE  
Redmond, WA 98052-2003 USA |
| declares that the CE-marked product | |
| Product Name: | Infant/Child Reduced Energy Defibrillation Electrodes |
| Part Number(s): | 3202380 |
| Complies with: | 93/42/EEC (Medical Device Directive) class IIb. Conformity assessed per Annex II. |
Type BF  
IEC 60601-2-4:1983 |
| Supplementary Information: | For use only with LIFEPAK CR® Plus defibrillators,  
LIFEPAK EXPRESS® defibrillators, and specially configured biphasic LIFEPAK® 500 AEDs. |

Redmond, November 17, 2005

James W. Dennison  
Vice President, Quality and Regulatory Affairs

This declaration applies to CE marked devices produced after the date of issuance of this declaration and before it is either superseded by another declaration or withdrawn.

Authorized EC Representative: Medtronic B.V., Earl Bakkenstraat 10, 6422 PJ Heerlen, The Netherlands