

# **Internal Defibrillation Paddles**

## **Instructions for Use**



## Statement



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This manual provides the instructions necessary to operate the product in accordance with its function and intended use. Observance of this manual is a prerequisite for proper performance and correct operation, and ensures patient and operator safety.

Mindray is responsible for the effects on safety, reliability and performance of this product, only if:

- the product is used in accordance with the instructions for use.
- this product is not damaged by human factors. Human factors refer to unintentional falling, intentional damaging, etc.

In the event that it becomes necessary to return a unit to Mindray, please contact the Mindray Service Department and obtain a Mindray Customer Service Authorization Number. The Mindray Customer Service Authorization Number must appear on the outside of the shipping container. Return shipments will not be accepted if the Mindray Customer Service Authorization Number is not clearly visible. Please provide the model number, serial number, and a brief description of the reason for return. The customer is responsible for freight charges when this product is shipped to Mindray for service (including any relevant customs fees or other freight related charges).

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## Product Information

### Intended Use

The internal defibrillation paddles (in short, the internal paddles) are intended to deliver an electrical pulse directly to the patient's heart for the purpose of internal cardiac defibrillation during thoracotomy. Therapy energy is delivered by the operator's pressing the shock button on the defibrillator. The internal defibrillation paddles are intended to be used with Mindray Defibrillator/Monitor.

### Models

Model	Electrode diameter	Cable length
MR6501	2.5 cm (1 inch)	5.3 m
MR6502	5.1 cm (2 inch)	
MR6503	7.6 cm (3 inch)	

### Caution

- Choose the appropriate model based on size of the paddles and the practical situation of the patient.
- The MR6501 paddles does not comply with IEC 60601-2-4 for surface area recommendations for defibrillation paddles.



### Warnings

- The internal paddles shall only be used by trained clinical professionals and with Mindray BeneHeart series defibrillator/monitors. The operator shall be liable for understanding this manual or consulting with us to confirm the compatibility of internal paddles and defibrillator. Otherwise, product performance may be compromised or personal injury may occur.
- During charging or shock delivery, hold only the insulating parts of the electrode handles to avoid being shocked.
- Make sure your hands are dry to avoid being shocked.
- Make sure the internal paddles are sterilized before each use. Otherwise, severe infection may result.
- Protect the internal paddles from impact to each other, other instrument or hard surface when not in use.
- Dispose of internal paddles according to local regulations or your hospital's protocol.



## Warnings

- If any of the following conditions is found, remove the internal paddles from use immediately.
  - The sterile package of the paddles is damaged.
  - Paddle electrodes are scratched, pitted, or chipped conductive surfaces are bubbled, scratched, or chipped coating.
  - Paddle handles and cables get damaged, connectors have damaged pins or material deterioration.

## Preparation

To ensure successful defibrillation, follow the instructions below before each use:

### Visual Check

- Check if the sterile package of the paddles is intact.
- Check paddle electrodes for scratched, pitted, or chipped conductive surfaces and bubbled, scratched, or chipped coating.
- Check paddle handles, cables and connectors for damaged pins or material deterioration.

### Function Check

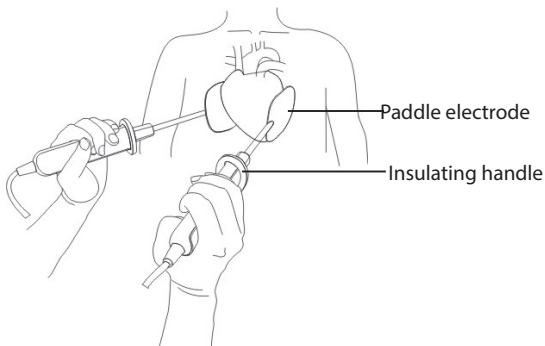
1. Turn on the defibrillator and enter the **Manual Defib** mode.
2. Select the appropriate paddle size.
3. Connect the paddles to the defibrillator by aligning the white pointer on the paddles cable with the arrow on the therapy port. Push until you hear it click into place.
4. Select energy by pressing the **[Energy Select]** key on the equipment's front panel. Make sure the maximum energy available is 50 Joules.
5. Press the **[Energy Select]** key repeatedly and select an energy of 2 Joules.
6. Charge the defibrillator by pressing the **[Charge]** key on the front panel.
7. Press the conductive surface of the paddle electrodes firmly together and press the Shock key on the front panel. Make sure that the message "**Impedance Too Low**" is displayed on the defibrillator.

## Caution

- Never short the paddle electrodes in any conditions other than function check.

## Using Internal Paddles

1. Make sure the preparation is finished as directed above.
2. Select energy by pressing the [**Energy Select**] key on the equipment's front panel.
3. Place the conductive surface of paddle electrodes against the patient's right atrium and left ventricle, as shown in the figure below.
4. Charge the defibrillator by pressing the [**Charge**] key on the front panel.
5. Make sure no one is touching the patient or anything connected to the patient.
6. Press the [**Shock**] key on the front panel.



Using internal paddles for synchronized cardioversion requires that the patient's ECG be acquired through a standard ECG cable. The patient's ECG acquired through the internal paddles may be unreliable for synchronized cardioversion due to excessive noise or artifact causing inappropriate R-wave detection.

## Note

- When internal paddles are used for defibrillation, the energy selection is automatically limited to 50 joules because of possible cardiac damage from higher energies.

## Cleaning, disinfection and Sterilization

Clean and sterilize the internal paddles after each use. Do not allow the insulating handles or paddle electrodes to dry after use and before cleaning. Items contaminated with blood and /or other protein materials cannot be effectively cleaned if allowed to dry.

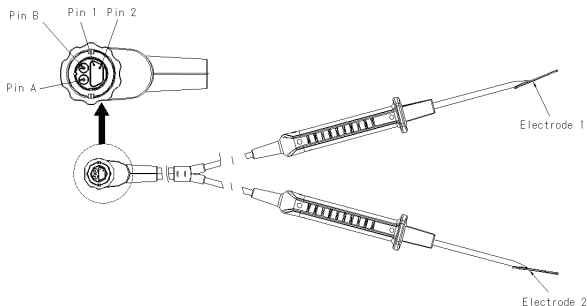
For more details, please refer to *Appendix Reprocessing Instructions*.

## Continuity Check

To ensure quality operation of the internal paddles, perform the following test every three months of normal use.

To Perform the test, follow this procedure:

1. Remove the internal paddles from the defibrillator.
2. Use a volt/ohm meter or a digital multimeter to verify the resistance between the test points in the following table. Be sure that good electrical contact is made between the test probes and the test points.



Pin A to Electrode 2:	< 1 ohm
Pin B to Electrode 1:	< 1 ohm
Pin 1 to Pin 2:	4.1 k $\Omega$ to 4.6 k $\Omega$

## Caution

- The internal paddles must be sterilized at the completion of the continuity check.



## Symbols



Refer to instruction manual/ booklet



DEFIBRILLATION-PROOF TYPE CF APPLIED PART



Not made with natural rubber latex.



Batch code



Authorized representative in the European community



Serial number



Date of manufacture



Manufacturer

**Rx Only**

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



Mark of conformity to European Medical Device Directive 93/42/EEC

## Operation and Storage Environment

Operating temperature:	0 to 45°C
Storage temperature:	-30 to 70°C
Operating humidity:	10% to 95%, non-condensation
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Operating altitude:	-381 m to + 4575 m (106.2kPa to 57kPa)
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## Standard

The equipment meets the requirements of IEC 60601-1-2.

## Appendix Reprocessing Instructions

### Processing of resterilizable products according to din en ISO 17664:2004

**Device:** reusable internal paddles, comprising cables, connector, handles and spoons.

**Note:**

- Reusable internal paddles including three different types which are with coated spoons of 1-inch, 2-inch and 3-inch diameters respectively.

Warnings	<ul style="list-style-type: none"> <li>● Stainless steel spoons could be damaged by acidic detergents and solutions. Do not soak in NaCl solution to avoid corrosion.</li> <li>● Please observe the information and user instructions provided by the manufacturers of washer-disinfector, sterilizer and the detergent.</li> <li>● Open the package just before the use to avoid the sterilized internal paddles being contaminated.</li> <li>● Check the wrap before use. Remove the internal paddles from use in case that package is damaged.</li> <li>● Use before sterilization expiry. Sterilize the internal paddles again in case of expiry.</li> </ul>
Limitation and restrictions on reprocessing	<p>The internal paddle set could withstand 50 cycles of moist heat sterilization using the provided sterilization parameters.</p> <p>Remove the internal paddle set from use in case of the following problems:</p> <ol style="list-style-type: none"> <li>1. Cable conductors, cable are damaged.</li> <li>2. Insulation coating on the stainless steel spoons is detached from the stainless steel surface.</li> <li>3. Insulation coating is frayed, damaged or have burrs.</li> <li>4. The internal paddle set has cracks, notches, and worn parts.</li> </ol>

<b>Instructions</b>	
<b>Preparation at the point of use</b>	<p>Remove contamination from surface immediately after use with soft paper/cloth; or,</p> <p>Rinse the product with running tap water (&lt;40°C) for at least one minute until all visible residues are removed.</p> <p><b>Note:</b></p> <ul style="list-style-type: none"> <li>● Do not use a fixating detergent or hot water (&gt;40°C) as this can cause the fixation of residua which may influence the result of the reprocessing process.</li> </ul>
<b>Transportation</b>	<p>Reprocess the product as soon as possible after use. Safe storage and transportation to the reprocessing area to avoid any damage to the product and contamination to the environment.</p>
<b>Preparation before cleaning</b>	<p>No particular requirements.</p> <p>Disassembly not required.</p>
<b>Manual cleaning and disinfection method</b>	<ol style="list-style-type: none"> <li>1. Dampen the surface of the product with running water prior to cleaning.</li> <li>2. Add appropriate volume of pH-neutral enzymatic detergent at a concentration of 0.5% to the surfaces according to the instructions from the supplier of the detergent.</li> <li>3. Apply the cleaning agent to all the surfaces of the product for 5 minutes at 55°C (no less than 40°C) with soft brush.</li> <li>4. Rinse the product using running water from external surfaces for a minimum of 1 minute until there is no visual contaminant.</li> <li>5. Rinse the product using running water for at least 2 minutes.</li> <li>6. Rinse the product using de-ionized water for 5 minutes at 93°C (no less than 88°C).</li> <li>7. Check the protein residue with 3M protein residue swab.</li> </ol>

Automated cleaning and disinfection method	<p>Set the program according to washer-disinfector manufacturer's instruction and add appropriate volume of cleaning detergent at a concentration of 0.5% into the chamber according to the instruction of cleaning detergent.</p> <ul style="list-style-type: none"> <li>● Washing at 55°C for 5 minutes.</li> <li>● Rinsing with running water for 1 minute.</li> <li>● Rinsing with running water for 2 minutes.</li> <li>● Rinsing with de-ionized water at 93°C for 5 minutes.</li> </ul>								
Manual drying	After cleaning, dry the product in the oven at 99°C for 15 minutes.								
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Packaging	<p>Seal the product into a standard pouch that is compatible with moist heat sterilization using the heat sealing machine. Ensure that the pack is large enough to contain the paddles without stressing the seals.</p> <p>If other standard packaging material would be used, use the recommended method and parameters offered by the package supplier.</p>								
Sterilization	<p>Mindray has tested and approved internal paddles: 1-inch internal paddles, 2-inch internal paddles and 3-inch internal paddles for material compatibility and sterilization efficacy up to 50 cycles of moist heat sterilization, wrapped using the following parameters.</p> <table data-bbox="308 890 854 1018"> <thead> <tr> <th style="text-align: center;">Parameters</th> <th style="text-align: center;">Value</th> </tr> </thead> <tbody> <tr> <td style="text-align: center;">Sterilization Temperature</td> <td style="text-align: center;">134°C</td> </tr> <tr> <td style="text-align: center;">Exposure time</td> <td style="text-align: center;">20 minutes</td> </tr> <tr> <td style="text-align: center;">Dry time</td> <td style="text-align: center;">Up to 30 minutes</td> </tr> </tbody> </table> <p>When sterilizing multiple instruments in one cycle, ensure that the sterilizer's maximum load is not exceeded.</p>	Parameters	Value	Sterilization Temperature	134°C	Exposure time	20 minutes	Dry time	Up to 30 minutes
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Storage	<p>Store the product in a dry, clean, and dust-free environment at moderate temperature.</p> <p>Store the packed internal paddles as directed by the instructions on the package.</p>										
Reprocessing validation study information	<p>The following test instructions, materials and machines were used during the validation.</p> <table data-bbox="311 310 956 529"> <tr> <td data-bbox="311 310 591 336"><b>Cleaning agents</b></td> <td data-bbox="591 310 956 336">Neodisher, Dr. Weigert</td> </tr> <tr> <td data-bbox="311 342 591 368"><b>Washer-disinfector</b></td> <td data-bbox="591 342 956 368">G7895, Miele</td> </tr> <tr> <td data-bbox="311 374 591 400"><b>Protein residue swab</b></td> <td data-bbox="591 374 956 400">Protein residue swab, 3M</td> </tr> <tr> <td data-bbox="311 407 591 432"><b>Packaging materials</b></td> <td data-bbox="591 407 956 497">Fully Peelable Gussetted Pouch, 360mm×60mm×500mm AMCOR FLEXIBLES SPS</td> </tr> <tr> <td data-bbox="311 503 591 529"><b>Sterilizer</b></td> <td data-bbox="591 503 956 529">5075ELV, TUTTNAUER</td> </tr> </table>	<b>Cleaning agents</b>	Neodisher, Dr. Weigert	<b>Washer-disinfector</b>	G7895, Miele	<b>Protein residue swab</b>	Protein residue swab, 3M	<b>Packaging materials</b>	Fully Peelable Gussetted Pouch, 360mm×60mm×500mm AMCOR FLEXIBLES SPS	<b>Sterilizer</b>	5075ELV, TUTTNAUER
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Additional information	<p>If the above-mentioned chemicals and machines are not available, the user is obliged to validate his procedure accordingly.</p>										
Manufacture contact	<p>See the backcover of this manual.</p>										

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