

Autoclavable Internal Handles with Integrated Paddles



9650-0550 Rev. N

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If more than three years have elapsed since the issue date, contact ZOLL Medical Corporation to determine if additional product information updates are available.

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## Degree of Protection Against Electrical Shock

The ZOLL Autoclavable Internal Handles with Integrated Paddles are classified as Type CF, Defibrillator Protected equipment.

## Symbols Used on the Equipment

Any or all of the following symbols may be used in this manual or on this equipment:



Type B patient connection.



Type BF patient connection.



Type CF patient connection.



Defibrillator-proof type BF patient connection.

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Defibrillator-proof type CF patient connection.



**ATTENTION** Refer to manual for more information



Fusible Link.



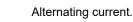
Protective (earth) ground terminal.



Equipotentiality



DANGER High voltage present



DA in ti ane

**DANGER** Risk of explosion if used in the presence of flammable anesthetics

(F

**Conformité Européenne** Complies with the Medical Device Directive 93/42/EEC.



Indicates a carrier that contains Unique Device Identifier information.



Indicates the item is a medical device.



Indicates the entity importing the medical device into the locale.



Indicates the authorized representative in Switzerland.



Authorized representative in the European Community.

#### **Notification of Adverse Events**

As a health care provider, you may have responsibilities under the Safe Medical Devices Act (SMDA) for reporting to ZOLL and possibly to the Food and Drug Administration (FDA), the occurrence of certain events. These events, described in 21 CFR Part 803, include device related death and serious injury or illness. In any event, as part of our Quality Assurance Program, ZOLL should be notified of any device failure or malfunction. This information is required to assure that ZOLL provides only the highest quality products.

If any serious incident has occurred in relation to the device, the incident should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

#### Service

#### **U.S.A.** Customers

Should the ZOLL Internal Handle set require service, contact ZOLL Medical Corporation at 1-800-348-9011 or 1-781-229-0020.

You will be given a Return Service Request number under which to return the ZOLL Internal Handles. Send the unit in its original packaging or equivalent to:

For customers	Return the unit to
In the U.S.A.	ZOLL Medical Corporation 269 Mill Road Chelmsford, MA 01824-4105
	Attention: Technical Service Department ( <i>SR number</i> )
	Telephone: 1-800-348-9011
In Canada	ZOLL Medical Canada Inc. 1750 Sismet Road, Unit #1 Mississauga, ON L4W 1R6
	Attention: Technical Service Department ( <i>SR number</i> )
	Telephone: 1-866-442-1011
In other locations	The nearest authorized ZOLL Medical Corporation representative.
	To locate an authorized service center, contact the International Sales Department at
	ZOLL Medical Corporation 269 Mill Road Chelmsford, MA 01824-4105
	Telephone: 1-978-421-9655

For additional information on the product, its preparation for use, cleaning, sanitizing, sterilizing or other questions on infection control procedures for this product, please contact ZOLL Technical Service at 1-800-348-9011 or 1-781-229-0020.

#### **International Customers**

Should the ZOLL Internal Handles require service, they should be returned, in their original container or equivalent, to the nearest authorized ZOLL Medical Corporation service center.

## **ZOLL** Autoclavable Internal Handles with Integrated Paddles

The ZOLL<sup>®</sup> Autoclavable Internal Handles with Integrated Paddles are designed for use with ZOLL R Series<sup>®</sup> and M Series<sup>®</sup> defibrillators to defibrillate the heart during open chest surgical procedures.

ZOLL defibrillators equipped with an advisory ECG analysis feature will only operate as manual defibrillators when the internal handles are attached.

The Operator's Guide for your ZOLL defibrillator must be used in conjunction with this guide.

Notes:

- This manual describes the use of the ZOLL Autoclavable Internal Handles with Integrated Paddles only. For instructions related to the use of other ZOLL internal handles, see the applicable Operator's Guide.
- Cleaning and sterilization protocols for other ZOLL internal handle sets differ significantly and instructions in the applicable Operator's Guide must be followed.
- The ZOLL Autoclavable Internal Handles with Integrated Paddles are intended for use by or under the direction of a physician.

## Using the Internal Handles with R Series Defibrillators

The use of the Autoclavable Internal Handles with Integrated Paddles with R Series defibrillators is subject to the following restrictions when used in a 220/240 VAC 50 Hz or 60 Hz power environment:

#### WARNING

DO NOT OPERATE AUTOCLAVABLE INTERNAL HANDLES, REF 8011-0139-xx (with 10 ft. cable), in 220/240 VAC 50 HZ OR 60 HZ POWER ENVIRONMENTS. The use of these internal handles in a 220/240 VAC 50 HZ OR 60 HZ power environment may result in unacceptably high leakage currents and compromise patient safety.

To use Autoclavable Internal Handles with Integrated Paddles with a ZOLL R Series Defibrillator in a 220/240 VAC 60 Hz environment, you must use only the Autoclavable Internal Handles with Integrated Paddles, REF 8011-0141-xx (with 7 ft. cable), with the ZOLL One-Step Cable (REF 1009-0913-01) or ZOLL Multifunction (MFC) Cable (REF 1009-0913-03).

## Using the Internal Handles with M Series Defibrillators

To use of the Internal Handles with Integrated Paddles with an M Series Defibrillator, the defibrillator *requires* software revision 3.5 or higher, and is subject to the following restrictions when used in a 220/240 VAC 50 Hz or 60 Hz power environment:

#### WARNING

Do not operate Autoclavable Internal Handles unless your M Series device has software revision 3.5 or greater.

DO NOT OPERATE AUTOCLAVABLE INTERNAL HANDLES, REF 8011-0139-xx (with 10 ft. cable), in 220/240 VAC 50 HZ OR 60 HZ POWER ENVIRONMENTS. The use of these internal handles in a 220/240 VAC 50 HZ OR 60 HZ power environment may result in unacceptably high leakage currents and compromise patient safety.

DO NOT OPERATE AUTOCLAVABLE INTERNAL HANDLES, REF 8011-0141-xx (with 7 ft. cable), in 220/240 VAC 60 HZ POWER ENVIRONMENTS. Use of the Internal Handles with Integrated Paddles under these conditions may result in unacceptably high leakage currents and compromise patient safety.

To determine the revision of your M Series defibrillator, perform the following steps:

- 1. Ensure the defibrillator has been turned OFF for more than 10 seconds.
- 2. Turn the Selector Switch to MONITOR.
- **3.** Observe the system software revision, displayed briefly in the lower right corner of the screen (during power up).
- **4.** If the system software revision is less than 3.5, call ZOLL Technical Service Department @ 1-800-348-9011 or 1-978-421-9655 to request a software upgrade kit.

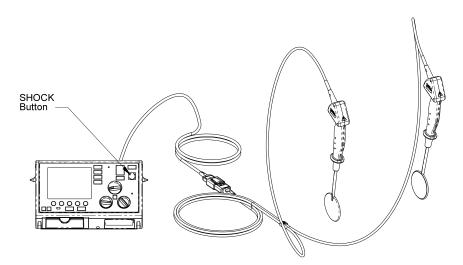
#### Internal Handle with Integrated Paddles Sets

The Internal Handles with Integrated Paddles Sets are available in two styles (shown below). Style A internal handles (**REF** 8011-0139-xx and **REF** 8011-0041-xx) include a button on the apex handle whose activation initiates discharge of the attached defibrillator. Style B internal handles (**REF** 8011-0140-xx) do not include a discharge button. Discharge of the defibrillator is affected by the depression of the front panel SHOCK button when using Style B internal handles.

Please note that both internal handle styles are available with several different integrated paddle/spoon sizes. See the "Ordering Additional Parts" table at the end of this manual to determine the appropriate value of -xx, shown in these part numbers.



Style A Internal Handles with Discharge Button



Style B Internal Handles without Discharge Button

Connection of the internal handle set to the appropriate defibrillator automatically causes the unit to limit its energy output to a maximum of 50 Joules.

The internal handle set can be sterilized by autoclaving according to the guidelines provided in this document.

## **Cleaning and Sterilization**

#### NOTES:

- The following process for cleaning and sterilization of the Autoclavable Internal Handles with Integrated Paddles has been validated to be effective in the disinfection of these products. Product users are responsible for qualifying any deviation from this recommended method of processing.
- All cleaning agents should be prepared and used according to the manufacturer's instructions and product labeling.

Do not allow the internal handle sets to dry after use and before cleaning. Items contaminated with blood and/or other protein materials cannot be effectively cleaned if allowed to dry.

The Internal Handle Set (including the connector) and Integrated Paddles may be immersed, if necessary during cleaning.

The handle set must be hand washed or machine washed. Do not subject them to ultrasonic washing machines.

To ensure the integrity of the internal handle set, perform a functional test prior to each use (see "Verification of Operation Prior to Use").

Do not disassemble the internal handle sets. Any attempt to disassemble the internal handle sets will void any applicable warranties.

The Internal Handle with Integrated Paddles can be sterilized by either Steam Sterilization in a Pre-Vacuum Autoclave according to the guidelines provided in this document or by the STERRAD ® 100S/NX Sterilization System.

## CAUTIONS

- The Autoclavable Internal Handles with Integrated Paddles are sold and shipped in a non-sterile condition. They should be cleaned and sterilized following the procedures outlined below prior to their first use and after each reuse.
- Do not drop, bump or knock the internal paddles. Damage to the insulating coating of the paddle may occur.
- Inspect each internal paddle after cleaning and prior to each use for:
  - 1. Nicks or burrs that may injure patient tissue
  - 2. Scratches, pits, or gouges in the paddle surface
  - 3. Loose or damaged insulating coating
  - 4. Cracks in the paddle's overmolded plastic

If any of these conditions are observed, remove the handle set from use.

- Autoclavable Internal Handles with Integrated Paddles are constructed from high quality materials. The severe conditions of sterilization, however, will limit their useful life. Thus, the useful life of the internal handle set is limited primarily by the frequency of sterilization rather than the age of the internal handle set.
- Inspect the Handles frequently for signs of deterioration such as cracks, crazing, damaged cables, and damaged switch covers. Replace if deterioration is noted.
- Do not clean the handles in ultrasonic cleaners. Hand or machine wash only.
- Do not expose the handles to any product containing organic solvents such as acetone, ketones, chlorinated hydrocarbons or aromatic hydrocarbons. Exposure to these solvents may degrade the handle materials.
- Keep the connector as free from contamination as possible. The connector may be immersed and cleaned with the rest of the assembly but is difficult to clean properly because of its shape and function.
- The Connector cap must remain in place at all times to protect the contact sockets, except when in use and during cleaning.
- Repeated sterilization cycles may cause the cable insulation to blister or bubble. This is considered normal and will not affect the function of the internal handle set. Replace the internal handle set if the cable insulation is cracked or cut.

In the following sections we describe the procedures to follow for both Manual Washing and Mechanical Washing.

#### MANUAL WASHING METHOD AND STERILIZATION

The handles, paddles, cable connector and connector cap must be thoroughly cleaned prior to each sterilization.

Follow his procedure for manual washing ZOLL's internal handles with integrated paddles:

1. Prepare enzymatic detergent as recommended by the manufacturer's product labeling (e.g. solution temperature, concentration, etc.). Submerge the handle set in enzymatic detergent and scrub with a soft bristled brush. Soak for five (5) minutes.

Following the soak period, scrub the handles, paddles, cable connector, and connector cap again with a soft bristled brush. Visually inspect the handles, paddles, cable connector, and connector cap for cleanliness. If necessary, repeat the process above. The handles, paddles, cable connector, and connector cap must be free of any visible contamination prior to rinsing.

2. Rinse

Rinse the handles, paddles, cable connector, and connector cap for at least 30 seconds under running water. When rinsing the Internal Handles, be sure to rinse the cable connector, connector cap and the handle end thoroughly.

If the manufacturer of the cleaning agent recommends a rinse protocol, this should be followed.

3. Air Dry

Allow the handles, paddles, cable connector, and connector cap to air dry prior to wrapping for sterilization. Air drying may be performed in a drying oven whose temperature does not exceed 120° C (250° F).

#### Inspect

Inspect the clean handles, paddles, cable connector, and connector cap for any residual contaminants.

Inspect the internal handle set for signs of deterioration such as cracks, crazing, damaged cables, connector pins or switch covers.

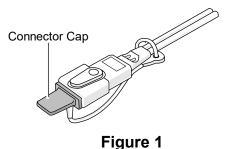
Repeated sterilization cycles may cause the cable insulation to blister or bubble. This is considered normal and will not affect the function of the handle set. Replace the handle set if the cable insulation is cracked or cut.

Inspect the paddles for damaged insulating coating, or other mechanical damage such as: scratches, pits, gouges, nicks or burrs that may injure patient tissue.

If any of these conditions are observed, remove the Internal Handle Set from use.

### Secure the Connector Cap

Attach the connector cap, located on the cable of the internal handle set, securely to the cable connector (Refer to Figure 1). The Connector cap must remain in place at all times to protect the contact sockets, except when in use and during cleaning.



### Sterilize

#### Steam Sterilization Method

**Wrap:** Before wrapping the Internal Handle with Integrated Paddles sets, be sure the cable is coiled with a diameter larger than 6 inches (15 cm). Never wrap the cables around the handles. This may hinder proper sterilization.

Wrap the internal handles and paddles in sterile wrapping sheets according to your wrapping procedures.

**Sterilize:** Sterilize the wrapped Internal Handles with Integrated Paddles using a Pre-Vacuum Steam Autoclave. The autoclave cycles should have the following characteristics:

Autoclave Cycle Characteristic	Pre-Vacuum (Wrapped) Standard Cycle	Pre-Vacuum (Wrapped) Optional Long Cycle (May be used instead of
		Standard Cycle)
Sterilization Temperature	132.2º - 135º C (270º - 275º F)	132.2° - 135° C (270° - 275° F)
Sterilization Exposure Time	4 – 5 minutes	18-20 minutes
Drying Time	10 – 12 minutes	20-30 minutes

When using Hand Washing, the Internal Handles with Integrated Paddles are capable of withstanding 100 steam sterilization cycles.

#### STERRAD ® 100S/NX Hydrogen Peroxide Gas Plasma Sterilization Method

The Internal Handles with Integrated Paddles are capable of withstanding 100 STERRAD 100S/NX cycles.

**Wrap:** Before wrapping the Internal Handle with Integrated Paddles sets, be sure the cable is coiled with a diameter larger than 6 inches (15 cm). Never wrap the cables around the handles. This may hinder proper sterilization.

Wrap the internal handles and paddles in sterile wrapping sheets according to your wrapping procedures.

**Sterilize:** Sterilize the wrapped Internal Handles with Integrated Paddles using the STERRAD 100S or NX equipment.

When using Hand Washing, the Internal Handles with Integrated Paddles are capable of withstanding 100 STERRAD 100S/NX cycles.

# Note: Ensure that the Internal Handles are wrapped properly before sterilization.

#### MECHANICAL WASHING METHOD AND STERILIZATION

ZOLL's internal handles with integrated paddles have been validated for mechanical washing using the Hamo LS-1000 mechanical washer.

The mechanical washer cycle parameters for the Hamo LS-1000 (or an equivalent mechanical washer) are as follows:

Treatment	Time (mm:ss)	Temperature	Cleaning Solution (Alkaline Detergent)
Pre Wash	04:00	Cold Water	Neodisher FA
			(or equivalent)
Rinse	01:00	Cold Water	Not Applicable
			No Cleaning Solution
Wash	11:30	50-55° C	Neodisher FA
		(122-135° F)	(or equivalent)
Neutralize	02:00	Warm Water	Neodisher Z
			(or equivalent)
Rinse II	01:00	Warm Water	Not Applicable
			No Cleaning Solution
Disinfect	05:00	90-95° C	Di water
		(194-203° F)	
Dry	15:00	110º C	Not Applicable
		(230° F)	No Cleaning Solution

The Internal Handles with Integrated Paddles are capable of withstanding 50 mechanical washing cycles.

#### Inspect

Inspect the clean handles, paddles, cable connector, and connector cap for any residual contaminants.

Inspect the internal handle set for signs of deterioration such as cracks, crazing, damaged cables, connector pins or switch covers.

Repeated sterilization cycles may cause the cable insulation to blister or bubble. This is considered normal and will not affect the function of the handle set. Replace the handle set if the cable insulation is cracked or cut.

Inspect the paddles for damaged insulating coating, or other mechanical damage such as: scratches, pits, gouges, nicks or burrs that may injure patient tissue.

If any of these conditions are observed, remove the Internal Handle Set from use.

### Secure the Connector Cap

Attach the connector cap, located on the cable of the internal handle set, securely to the cable connector (Refer to Figure 1). The Connector cap must remain in place at all times to protect the contact sockets, except when in use and during cleaning.

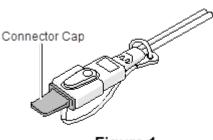


Figure 1

### Sterilize - Steam Sterilization Only

**Wrap:** Before wrapping the Internal Handle with Integrated Paddles sets, be sure the cable is coiled with a diameter larger than 6 inches (15 cm). Never wrap the cables around the handles. This may hinder proper sterilization.

Wrap the internal handles and paddles in sterile wrapping sheets according to your wrapping procedures.

**Sterilize:** Sterilize the wrapped Internal Handles with Integrated Paddles using a Pre-Vacuum Steam Autoclave. The autoclave cycles should have the following characteristics:

Autoclave Cycle Characteristic	Pre-Vacuum (Wrapped) Standard Cycle	Pre-Vacuum (Wrapped) Optional Long Cycle
		(May be used instead of Standard Cycle)
Sterilization Temperature	132.2º - 137º C (270º - 278.6º F)	132.2º - 137º C (270º - 278.6º F)
Sterilization Exposure Time	4 – 5 minutes	18-20 minutes
Drying Time	10 – 12 minutes	20-30 minutes

When using Machine Washing, the Internal Handles with Integrated Paddles are capable of withstanding 50 steam sterilization cycles.

**Note:** When using the Autoclavable Internal Handles with Integrated Paddles, **REF** 8011-00141-xx, with a ZOLL R Series defibrillator in a 220/240 VAC 60 Hz power environment, the internal handles can withstand a maximum of 50 steam autoclave cycles.

#### WARNING

*Do not* use the STERRAD 100S/NX Hydrogen Peroxide Gas Plasma Sterilization Method when using the Mechanical Washing Method. The use of the STERRAD 100S/NX sterilization method after mechanical washing will damage the Internal Handles with Integrated Paddles.

When using the Mechanical Washing Method to clean the Internal Handles with Integrated Paddles, use *only* the Steam Sterilization Method.

## **Verification of Operation Prior to Each Use**

## WARNINGS

- ZOLL Autoclavable Internal Handles with Integrated Paddles require <u>two</u> <u>qualified persons</u> to operate, one person (**USER1**) to operate the controls on the ZOLL defibrillator and a second person (**USER2**) to position the paddles on the patient.
- Do not use ZOLL Internal Handles in the presence of flammable agents, oxygen rich atmospheres, or flammable anesthetics. Using the paddles in the presence of such agents may cause an explosion.
- Users of the handle set should assess the defibrillator's performance in their typical environment of use for the possibility of interference from high power radio or electro-surgical units. This interference may be observed as shifts in monitor baseline, trace compression, or transient spikes on the defibrillator display.
- Users of the handle set should assess the defibrillator's performance in their typical environment of use for the possibility of interference with the operation of other devices.
- Verify that no one is in contact with monitoring cables, leads, bed rails, or any other potential current pathway prior to defibrillator discharge.
- All persons nearby must be warned to *STAND CLEAR* prior to defibrillator discharge.
- When performing pre-use checks, keep hands away from the Paddles while pressing the **Shock** button.
- When verifying high voltage wiring, the paddles must be held firmly together so that the plates are not damaged.
- Inspect each paddle prior to use for:
  - 1. Nicks or burrs that may injure patient tissue
  - 2. Scratches, pits, or gouges in the paddle surface
  - 3. Loose or damaged insulating coating
  - 4. Cracks in the paddle's overmolded plastic

If you observe any of the conditions above, remove the handle set from use.

- ZOLL Medical Corporation recommends that a backup set of Autoclavable Internal Handles with Integrated Paddles be available for use in the event of a failure.
- 1. Inspect the connector contact sockets for damage or corrosion. If you observe damage or corrosion in the connector contact sockets, remove the handle set from use.
- Connect the Autoclavable Internal Handles to the defibrillator and select **Defib.** Mode. Verify that the M Series defibrillator correctly identifies the Internal Handles with Integrated Paddles set by displaying *INT.PAD*.

- 3. Verify that the **Discharge** button (Style A Handles only) does not stick.
  - a) Before charging the defibrillator, press the discharge button and verify that there is an audible click and that the button springs back upon release
  - b) Charge the defibrillator to 2 Joules. Wait for the READY tone.
  - c) During the READY tone, hold both Internal Handles and Paddles out and away from any person or object, press and hold the **Discharge** button located on one of the handles to simulate delivery of energy to the patient.
  - d) Verify that the defibrillator *does not* discharge and displays the error message, *POOR PAD CONTACT*. Occurrence of this message verifies that the **Shock** button located on the right handle is operating correctly
- 4. **USER1** Press the up (▲) and down (▼) arrows of the Energy Select button located on the front panel of the M Series device and select 30 Joules.
- 5. **USER1** Press the **Charge** button on the defibrillator front panel to charge the unit to the selected energy level. Wait for the READY Tone.
- 6. USER2 Press the Paddle surfaces firmly together.
- 7. Discharge the energy.
  - a) **USER2** Style A Handles: Press and hold the **Discharge** button on the apex handle until the defibrillator delivers the selected energy to the patient (approximately 1-2 seconds).
  - b) USER1 Style B Handles: Press and hold the Shock button on the defibrillator front panel until the defibrillator delivers the selected energy to the patient (approximately 1-2 seconds).
  - c) The M Series device will discharge and display the messages *TEST OK* and *XX J DELIVERED* (*XX* = 28-30 Joules).
- WARNING: When performing pre-use checks, keep hands away from the paddles while pressing the Shock button.

See the figure on Page 10 for proper handling of the ZOLL Autoclavable Internal Handles with Integrated Paddles.

## **Defibrillation Procedure**

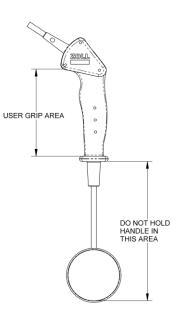
## WARNINGS

Before proceeding, CAREFULLY read the following:

- Only appropriately trained and skilled personnel who are familiar with equipment operation should attempt defibrillation.
- ZOLL Autoclavable Internal Handles require <u>two qualified persons</u> to operate, one person (USER1) to operate the controls on the defibrillator and a second person (USER2) to position the paddles on the patient.
- Do not use ZOLL Autoclavable Internal Handles in the presence of flammable agents, oxygen rich atmospheres, or flammable anesthetics. Using the paddles in the presence of such agents may cause an explosion.
- Verify that no one is in contact with monitoring cables, leads, bed rails, or any other potential current pathway prior to defibrillator discharge.
- Do not touch the bed, patient, or any equipment connected to the patient during defibrillation.
- All persons in attendance of the patient must be warned to *STAND CLEAR* prior to defibrillator discharge.
- Do not touch the paddles together during discharge into a patient.

Review the applicable ZOLL defibrillator's Operator's Guide to become familiar with the defibrillator's operation. Note the following special instructions for use of Autoclavable Internal Handles.

- Connect the Autoclavable Internal Handles set to the defibrillator and select **Defib. Mode**. Verify that the defibrillator correctly identifies the Internal Handle with Integrated Paddles by displaying *INT.PAD*.
- USER1 Press the up (▲) and down (▼) arrows of the Energy Select button located on the front panel of the defibrillator to select the desired energy. The maximum selected energy is limited to 50 Joules.
- 3. **USER1** Press the **Charge** button on the defibrillator front panel to charge the unit to the selected energy level. Wait for the READY tone.



- 4. **USER2** Hold the Internal Handles in the USER GRIP AREA as shown in the figure. Position the Paddles appropriately on patient's heart.
- 5. Discharge the Energy to the patient.
  - a. **USER2** Style A Handles: Press and hold the **Discharge** button on the apex handle until the defibrillator delivers the selected energy to the patient (approximately 1-2 seconds).
  - b. **USER1** Style B Handles: Press and hold the **Shock** button on the defibrillator front panel to deliver the selected energy to the patient.

## **Three-Month Checkout Procedure**

To ensure quality operation of the Internal Handles perform this Checkout Procedure at least every 3 months.

### Continuity

Disconnect the handles from the defibrillator for this test. Using an electrical continuity tester, such as a volt/ohm meter (VOM) or a digital multimeter (DMM), verify the resistance between the test points shown in the table below.

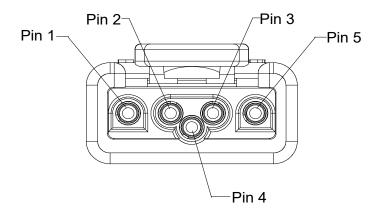
Be sure that good electrical contact is made between the test probes and the test points.

### Style A Internal Handles (Discharge Button on Handle)

Pin 5 (or Pin 1) to Right Paddle	< 1 ohm
Pin 1 (or Pin 5) to Left Paddle	< 1 ohm
Pin 2 to Pin 4 with shock button pressed (closed)	Between 2.72 and 2.88 K ohms
Pin 3 to Pin 2	Between 882 and 936 ohms

### Style B Internal Handles (No Discharge Button on Handle)

Pin 5 (or Pin 1) to Right Paddle < 1 ohm		
Pin 1 (or Pin 5) to Left Paddle	< 1 ohm	
Pin 2 to Pin 3	Between 1.42 and 1.52 K ohms	



#### Leakage Currents

Connect the internal handles set to the defibrillator. Perform a standard electrical safety leakage test. The system leakage current should not exceed 100  $\mu$ A at 110% of AC line voltage.

## **Six-Month Checkout Procedure**

When facilities are available, x-ray the cables to check for fractures or damage to the cable conductors and connectors.

# **Ordering Additional Parts**

Reorder numbers for the parts most frequently ordered are listed below:

REF	ITEM DESCRIPTION	ADULT	PEDIATRIC
8011-0139-01	Autoclavable Internal Handles with Switch, 100-120V Only, 1.0" [25mm] Spoon Diameter		•
8011-0139-02	Autoclavable Internal Handles with Switch, 100-120V Only, 1.6" [40mm] Spoon Diameter		•
8011-0139-03	Autoclavable Internal Handles with Switch, 100-120V Only, 2.7" [68mm] Spoon Diameter	٠	
8011-0139-04	Autoclavable Internal Handles with Switch, 100-120V Only, 3.0" [76mm] Spoon Diameter	٠	
8011-0139-05	Autoclavable Internal Handles with Switch, 100-120V Only, 2.0" [51mm] Spoon Diameter	•	
8011-0140-01	Autoclavable Internal Handles without Switch, 100- 240V, 1.0" [25mm] Spoon Diameter		•
8011-0140-02	Autoclavable Internal Handles without Switch, 100-240V 1.6" [40mm] Spoon Diameter		•
8011-0140-03	Autoclavable Internal Handles without Switch, 100-240V 2.7" [68mm] Spoon Diameter	٠	
8011-0140-04	Autoclavable Internal Handles without Switch, 100-240V 3.0" [76mm] Spoon Diameter	٠	
8011-0140-05	Autoclavable Internal Handles without Switch, 100-240V 2.0" [51mm] Spoon Diameter	•	
8011-0141-01	Autoclavable Internal Handles with Switch, 7ft cable, 100-240V, 1.0" [25mm] Spoon Diameter		•
8011-0141-02	Autoclavable Internal Handles with Switch, 7ft cable, 100-240V, 1.6" [40mm] Spoon Diameter		•
8011-0141-03	Autoclavable Internal Handles with Switch, 7ft cable, 100-240V, 2.7" [68mm] Spoon Diameter	٠	
8011-0141-04	Autoclavable Internal Handles with Switch, 7ft cable, 100-240V, 3.0" [76mm] Spoon Diameter	•	
8011-0141-05	Autoclavable Internal Handles with Switch, 7ft cable, 100-240V, 2.0" [51mm] Spoon Diameter	•	
9310-1006	Cap, Connector, Autoclavable		