Automated External Defibrillator
Cardiolife
AED-3100

OPERATOR'S MANUAL

NIHON KOHDEN

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Cardiolife
AED-3100

NIHON KOHDEN

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About This Manual

Please read this manual before use so that you can use the AED-3100 Automated External Defibrillator safely and maximize its usefulness. Read the other attached documents as well.

Symbols Used in This Manual

	Indicates that the description continues to the next page.
	Indicates that you need to refer to the earlier pages.
	Indicates that you need to refer to the later pages.
	Indicates the number of a precaution in “General Handling Precautions”. A number is assigned to each precaution as shown in the left column. When you see a symbol that resembles  in this manual, refer to the precaution of the indicated number.

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CE 0086

About This AED

The AED-3100 automated external defibrillator is a compact automated external defibrillator. When you place the pads of the AED-3100 automated external defibrillator on the chest of a patient who is unconscious because of heart attack or other illness, the AED-3100 automated external defibrillator automatically checks (analyzes) the heart rhythm of the patient. When the AED-3100 automated external defibrillator determines that a defibrillation shock is required (the patient is shockable), the device tells the operator to deliver a shock through voice instructions and flashing of the shock button.*

* Essential performance in EMC standard

Analysis of the heart rhythm (heart rate) determines that defibrillation is required in the following cases:

- Ventricular fibrillation in which the average amplitude exceeds 0.1 mV
- Ventricular tachycardia in which the heart rhythm (heart rate) exceeds 180 bpm

Note that the AED-3100 automated external defibrillator does not deliver a shock when it cannot detect the heart rhythm (heart rate) of the patient (the patient is suffering asystole). In this case, the AED-3100 automated external defibrillator advises the operator to continue CPR.

Hereafter, the AED-3100 automated external defibrillator is referred to as “AED” in this manual.

About the Rescue Sequence

The rescue sequence employed in the AED conforms to the following guidelines based on the 2015 CoSTR*[1] recommended by the ILCOR*[2].

- American Heart Association (AHA) 2015 guidelines*[3]
- European Resuscitation Council (ERC) 2015 guidelines*[4]

The AED analyzes the heart rhythm and when it detects a heart rhythm (heart rate) that requires a defibrillation shock, it advises the operator to press the Shock Button. After a defibrillation shock is delivered, the AED advises the operator to perform CPR (cardiopulmonary resuscitation) for two minutes.

*[1] 2015 International Consensus on Cardiopulmonary Resuscitation and Emergency Cardiovascular Care Science with Treatment Recommendations. Circulation, 2015; 132: S1 to S311

*[2] International Liaison Committee on Resuscitation

*[3] 2015 American Heart Association Guidelines Update for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care. Circulation, 2015; 132: S313 to S589

*[4] European Resuscitation Council Guidelines for Resuscitation 2015. Resuscitation, 95 (2015) 1 to 132

What is an AED?

An automated external defibrillator (AED) determines the patient's heart condition. If needed, the AED delivers a defibrillation shock to the heart to return the activity of the heart to normal as much as possible.

The heart sends blood to the entire body. If heart stroke occurs, the heart cannot pump blood. After a few minutes of no blood flow, the brain might suffer damage. As more time elapses, the person might die.

However, the person does not die immediately after heart stroke. Death can be prevented by returning the heart activity to normal as quickly as possible so it can pump blood to the entire body.

There are several types of problems that might occur to the heart. For example, during cardiac arrest, which is quivering of the heart, ventricular fibrillation might occur. Only a doctor can determine the type of problem with the heart. An AED can determine the condition of the heart like a doctor, give voice instructions of what to do, and deliver a defibrillation shock if necessary to bring the heart activity to normal as much as possible.

Note to Medical Personnel

This manual was written so that the public can understand how to use the AED. Therefore, some expressions in this manual might differ from the medical terms used by medical personnels.

Giving the AED to Other People

Contact your Nihon Kohden representative when giving the AED to other people.

Contents

General Handling Precautions

Be sure to read the following and understand the contents well before you use the AED so you can use the AED safely.

Explanation of Warnings and Cautions

WARNING

A warning alerts the user to possible injury or death associated with the use or misuse of the AED.

CAUTION

A caution alerts the user to possible injury or problems with the AED associated with its use or misuse such as AED malfunction, AED failure, damage to the AED, or damage to other property.

Explanation of Symbols

Indicates the action is prohibited.

Indicates the action is mandatory.

General

WARNING ! 01

Never use the AED in the presence of any flammable anesthetic gas or high concentration oxygen atmosphere. Failure to follow this warning may cause explosion or fire.

WARNING ! 02

Never use the AED in a hyperbaric oxygen chamber. Failure to follow this warning may cause explosion or fire.

WARNING ! 03

Do not take the AED into an MRI test room. It AED is not designed to be used during MRI tests.

WARNING ! 04

To use the AED properly and effectively, it is recommended that first aid training including CPR and usage of this AED is performed.

WARNING ! 05

The effectiveness of defibrillation depends on the patient conditions such as height, weight, patient history, current medications, combination of symptoms, and how soon the CPR and defibrillation are performed after collapse.

WARNING ! 06

Do not disassemble or modify the AED. It might cause skin burn, fire, electrical shock or injury. The maximum performance from the AED cannot be guaranteed.

CAUTION ! 07

The AED may judge that defibrillation is not necessary even when it is necessary. Also in very rare cases, the AED may judge that defibrillation is necessary even when it is not necessary. When the AED judges that defibrillation is not necessary, it provides instructions for performing CPR.

CAUTION ! 08

Only use the specified accessories and options. Otherwise, the AED might not operate correctly and the maximum performance from the AED cannot be guaranteed.

CAUTION ! 09

Install the AED in a place which has the following conditions. Otherwise, the AED might not operate correctly.

- Temperature: –5 to +50°C (23 to 122°F)
- Humidity: 5 to 95% (noncondensing)
- Atmospheric pressure: 540 to 1060 hPa

General Handling Precautions

General

CAUTION ! 10

When disposing of the AED,

- Remove the battery pack from the AED.
- Follow your local laws.

During Resuscitation

WARNING ! 11

Before defibrillation, remove everything including electrodes, patches and gel from the site where the pads will be attached. If the disposable pads contact any gel or object on the patient's chest, the discharged energy may be insufficient and cause skin burn.

WARNING ! 12

Before you press the shock button to perform defibrillation, make sure that all electrodes, transducers and connection cords of all medical instruments other than this AED are connected to the instrument. If they are disconnected, the operator receives electrical shock.

WARNING ! 13

Before defibrillation, make sure that no one is in contact with either the patient or any metal part of any equipment or cables which supports or is connected to the patient. Failure to follow this warning causes serious electrical shock or injury.

WARNING ! 14

When performing defibrillation, do not touch the disposable pads and keep disposable pads away from the electrode or instrument connected to the patient and any other metal objects contacting the patient such as a bed frame or stretcher. Otherwise the discharged energy may be insufficient and cause skin burn.

WARNING ! 15

Before defibrillation, remove from the patient all electrodes, probes and transducers from connectors that do not have a  or  mark. Otherwise, the operator may receive electrical shock and the connected instrument may be damaged.

WARNING ! 16

When using an ESU, remove the defibrillation pads from the patient. High frequency energy from the ESU causes abnormal current to flow in the patient and unexpected discharge. This may cause burn or injury and damage the AED.

WARNING ! 17

If the AED gets wet, wipe it thoroughly before use. Otherwise, the operator may receive electrical shock.

WARNING ! 18

Do not use the AED when the patient's body is wet. If the patient's body is wet with water, sweat or oil, wipe the patient's body before defibrillation. If the patient body is wet, the discharged energy may be insufficient and the operator may receive electrical shock, or disposable pads cannot be attached to the patient.

WARNING ! 19

When the patient is age 8 or older, use the adult mode. If child mode is selected, the discharged energy may be insufficient.

WARNING ! 20

When the patient is a child age 0 to 7, use the child mode. If you perform defibrillation in the adult mode, the discharged energy may damage the patient's cardiac muscle.

WARNING ! 21

If the patient's body is small and the disposable pads contact each other, attach the disposable pads on the patient's chest and back instead of on the upper right and left side of the chest. If the disposable pads contact each other, discharged energy may be insufficient and cause skin burn.

WARNING ! 22

While the AED is analyzing the patient's ECG, stop CPR and do not move or shake the patient's body. If the patient is in a car, stop the car. Otherwise, the AED cannot analyze the patient's ECG correctly.

General Handling Precautions

During Resuscitation

CAUTION ! 23

Defibrillation is not performed when asystole occurs. Follow the voice instruction and perform CPR.

CAUTION ! 24

Before using the AED, check the following.

- The patient is unconscious.
- The patient is not breathing.
- No pulse (Only for medical personnel)

CAUTION ! 25

When turning the AED on, check that the proper mode (child or adult) is selected. Otherwise, the discharged energy may be insufficient or too much.

CAUTION ! 26

Make sure that there is more than 1 m of space between the mobile phones or small wireless devices and the AED.
For other wireless devices, make sure that there is more than the space of “Recommended separation distances: d*” in this manual.
Radio waves may affect the AED. Depending on the radio waves, noise superimposes on the ECG and analysis may be incorrect.

* The recommended separation distance is calculated from the equation in the “Recommended separation distances between portable and mobile RF communications equipment and the AED-3100” on p. 57.

CAUTION ! 27

Defibrillation might burn the patient skin where the disposable pads are attached.

CAUTION ! 28

If the disposable pads are not attached to the patient’s skin properly because of the patient’s chest hair, maximum performance from the AED cannot be guaranteed. In this case, firmly press the pads against the skin. If the pads placement indicators are still lit and there are spare pads, press the already attached pads to the chest skin, pull them off quickly to remove hair and then attach the spare pads for rescue. If there is a shaver, shave the chest hair.

CAUTION ! 29

Before defibrillation, make sure there is no contact between the patient including any fluid on the patient such as gel, blood or saline and any metal object such as a bed frame or stretcher. Contact between the patient and a metal object may provide unwanted pathways for the AED current and the operator may receive electrical shock.

When using the AED on a patient who has an implanted pacemaker or ICD

CAUTION ! 30

If a pacemaker or ICD* is implanted in the patient:

- Do not attach the disposable pads on top of or within 8 cm of the pacemaker or ICD bulge.
  - Do not wait to decide where to attach the disposable pads because rescue should be started without any hesitation.
  - If defibrillation was performed on a patient who has an implanted ICD or pacemaker, check the pacing system of the ICD or pacemaker at a medical facility.
- If the patient has an ICD that is delivering shocks, wait 30 to 60 seconds for the ICD to complete the treatment cycle before attaching the disposable pads. The analysis and shock cycles of the automatic ICD and the AED may conflict.
- When the width of the pacemaker pulse is wide, analysis might be incorrect.

* Implantable Cardioverter-Defibrillator

Battery Pack

WARNING ! 31

Never do the following. The following may cause leak, overheating, explosion and fire.

- Giving an impact to the battery pack by dropping or throwing.
- Charging, short-circuit, disassembly, deformation, overheating, dropping into fire, or immersing in water.

WARNING ! 32

Install the battery pack correctly. If there is no battery pack in the AED, self test is not performed and the AED condition is not maintained.

WARNING ! 33

If the battery pack is damaged and the substance inside the battery pack contacts the eyes or skin, wash immediately and thoroughly with water and see a physician. Never rub your eyes, because you may lose your eyesight.

WARNING ! 34

Do not expose the battery pack to direct sunlight or leave in a high temperature place such as in a car on a hot day or in front of a heater. The lifetime of the battery pack may be shortened, the performance of the battery pack may be degraded and the battery pack may leak.

General Handling Precautions

Battery Pack

WARNING ! 35

Do not use the battery pack if it is wet. Too much electricity might be discharged and the battery pack gets damaged.

WARNING ! 36

Do not use a broken or deformed battery pack. It may explode or cause fire.

CAUTION ! 37

Only use the specified battery pack. Otherwise, the performance of the AED is not guaranteed.

CAUTION ! 38

Check the remaining battery power periodically.

CAUTION ! 39

Store the battery pack in the following conditions. Otherwise, the battery pack might deteriorate.

- Temperature: –20 to +70°C (–4 to +158°F)
- Humidity: 5 to 95% (noncondensing)

CAUTION ! 40

When disposing of the battery pack, follow your local law.

CAUTION ! 41

In the following cases, the life of the battery pack may become shorter than 4 years.

- Turning the AED on and off too frequently for purposes other than rescue or inspection.
- Turning the AED power on for a long time, such as during training or inspection.
- Discharging energy too many times for testing.

Disposable Pads

WARNING ! 42

Do not use the pads if they are past the expiration date on the package. Failure to follow this warning may cause skin burn or insufficient energy discharge.

WARNING ! 43

If the package of the disposable pads is punctured, do not use the disposable pads. The discharged energy may be insufficient and it may cause skin burn to the patient.

WARNING ! 44

Open the package of the disposable pads only when you will immediately use them. Otherwise, the disposable pads deteriorate and cause burn to the skin. The disposable pads are disposable and single use only. If you use the disposable pads more than once, it may cause skin burn.

WARNING ! 45

Do not use the disposable pads if the gel is dark brown or dark brown gel is on the protection sheet. Failure to follow this warning may cause skin burn or insufficient energy discharge.

WARNING ! 46

Do not use the disposable pads if the gel has become dry or if the gel has become abnormal (the gel has become liquid or is coming off the edges of the pad, etc). Failure to follow this warning may cause skin burn or insufficient energy discharge.

WARNING ! 47

Do not use the disposable pads if the gel peels off while removing the protection sheet or if the foam is peeled off and the metal part is exposed. Failure to follow this warning may cause skin burn or insufficient energy discharge.

WARNING ! 48

When attaching the disposable pads, remove clothing and attach the disposable pads directly to the patient skin so that there is no space between the disposable pads and patient skin. If the disposable pads are not attached properly, the AED cannot analyze the ECG and the discharged energy may be insufficient and it may cause skin burn to the patient.

WARNING ! 49

Do not use disposable pads which have already been used. The discharged energy may be insufficient and it may cause skin burn to the patient.

WARNING ! 50

Do not use training pads for defibrillation. The AED cannot analyze ECG and defibrillation cannot be performed if training pads are used.

CAUTION ! 51

When you connect the disposable pads to the AED, insert the disposable pad connector into the AED socket and make sure that it is locked. If the disposable pads are not connected properly, the AED cannot analyze the ECG and defibrillation is not performed.

CAUTION ! 52

The AED cannot analyze and perform defibrillation if disposable pads are put on the patient body with the disposable pads still in the package. To perform defibrillation, follow the instruction in this manual to attach the disposable pads.

CAUTION ! 53

Do not attach a disposable pad over another disposable pad. The discharged energy may be insufficient and it may cause skin burn to the patient.

General Handling Precautions

Disposable Pads

CAUTION ! 54

When you attach disposable pads to the patient skin, remove the backing sheets from the disposable pads.

CAUTION ! 55

Replace the disposable pads with new ones every 24 hours when you continuously use the AED for more than 24 hours. Otherwise, the discharged energy may be insufficient and it may cause skin burn to the patient.

CAUTION ! 56

Store the disposable pads in the conditions which are described on the package of the disposable pads. Otherwise, the disposable pads deteriorate and maximum performance cannot be guaranteed.

CAUTION ! 57

Do not put a heavy object on the disposable pads and do not bend the disposable pads. The metal foil of the disposable pads may break, the discharged energy may be insufficient and it may cause skin burn to the patient.

CAUTION ! 58

The used disposable pads are medical waste. Dispose of the disposable pads according to your local laws.

Installation, Replacement and Operation

CAUTION ! 59

This AED is medical equipment. For installation and usage of this AED, assign a manager.

CAUTION ! 60

Do not install the AED near equipment which emits strong electromagnetic waves such as microwave therapy instruments. The AED might not operate for resuscitation.

Communication

WARNING ! 61

Do not use the wireless communication function within 15 cm of an implanted pacemaker or ICD. The radio frequency energy from the AED might affect the pacemaker or ICD.

WARNING ! 62

Do not use the wireless communication function in an airplane. The radio frequency energy from the AED might affect critical instruments on the plane.

Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

GENERAL HANDLING PRECAUTIONS

Use only Nihon Kohden approved products with this device. Use of non-approved products or in a non-approved manner may affect the performance specifications of the device. This includes, but is not limited to, batteries.

Please read these precautions thoroughly before attempting to operate the AED.

1. **When installing or storing the AED, take the following precautions:**
   (1) Avoid moisture or contact with water, extreme atmospheric pressure, excessive humidity and temperatures, poorly ventilated areas, and dust, saline or sulphuric air.
   (2) Place the AED on an even, level floor. Avoid vibration and mechanical shock, even during transport.
   (3) Avoid placing the AED in an area where chemicals are stored or where there is danger of gas leakage.
   (4) Avoid placing the AED near equipment which generates heat.

2. **Before Operation**
   (1) Check that the AED is in perfect operating order.
   (2) Check that all disposable pads are connected properly.
   (3) Check that battery level is acceptable and battery condition is good.
   Never charge the battery pack.
   When replacing the battery pack, follow the instructions in this manual.
   (4) Pay extra attention when the AED is in combination with other instruments to avoid misdiagnosis or other problems.

3. **During Operation**
   (1) When using the AED, do not excess the specified time and value for diagnosis or treatment.
   (2) Both the AED and the patient must receive continual, careful attention.
   (3) To assure the patient's safety, turn the power off or remove the disposable pads if there is any abnormality in the AED.
   (4) Avoid direct contact between the AED and the patient.

4. **After Use**
   (1) Back the AED to its original position with all controls and its accessories in the condition described in this manual.
   (2) Remove the cords gently; do not use force to remove them.
   (3) Clean the AED together with all accessories for their next use.

5. **The AED must receive expert, professional attention for maintenance and repairs. When the AED is not functioning properly, it should be clearly marked to prevent use while it is out of order.**

6. **The AED must not be altered or modified in any way.**

7. **The AED and parts must undergo regular maintenance inspection as described in this manual.**

General Handling Precautions

WARRANTY POLICY

Nihon Kohden Corporation (NKC) shall warrant its products against all defects in materials and workmanship for eight years from the date of delivery. However, consumable materials such as battery pack and disposable pads are excluded from the warranty.

NKC or its authorized agents will repair or replace any products which prove to be defective during the warranty period, provided these products are used as prescribed by the operating instructions given in the operator's manual.

No other party is authorized to make any warranty or assume liability for NKC's products. NKC will not recognize any other warranty, either implied or in writing. In addition, service, technical modification or any other product change performed by someone other than NKC or its authorized agents without prior consent of NKC may be cause for voiding this warranty.

Defective products or parts must be returned to NKC or its authorized agents, along with an explanation of the failure. Shipping costs must be pre-paid.

This warranty does not apply to products that have been modified, disassembled, reinstalled or repaired without Nihon Kohden approval or which have been subjected to neglect or accident, damage due to accident, fire, lightning, vandalism, water or other casualty, improper installation or application, or on which the original identification marks have been removed.

EMC RELATED CAUTION

This equipment and/or system complies with IEC 60601-1-2 International Standard for electromagnetic compatibility for medical electrical equipment and/or system. However, an electromagnetic environment that exceeds the limits or levels stipulated in IEC 60601-1-2, can cause harmful interference to the equipment and/or system or cause the equipment and/or system to fail to perform its intended function or degrade its intended performance. Therefore, during the operation of the equipment and/or system, if there is any undesired deviation from its intended operational performance, you must avoid, identify and resolve the adverse electromagnetic effect before continuing to use the equipment and/or system.

The following describes some common interference sources and remedial actions:

1. Strong electromagnetic interference from a nearby emitter source such as a cellular phone:
   Turn off the cellular phone.

2. Effect of direct or indirect electrostatic discharge:
   Make sure all users and patients in contact with the equipment and/or system are free from direct or indirect electrostatic energy before using it. A humid room can help lessen this problem.

3. Electromagnetic interference with any radio wave receiver such as radio or television:
   If the equipment and/or system interferes with any radio wave receiver, locate the equipment and/or system as far as possible from the radio wave receiver.

4. Use with other equipment:
   When the equipment and/or system is adjacent to or stacked with other equipment, the equipment and/or system may affect the other equipment. Before use, check that the equipment and/or system operates normally with the other equipment.

5. Use of unspecified accessory, transducer and/or cable:
   When an unspecified accessory, transducer and/or cable is connected to this equipment and/or system, it may cause increased electromagnetic emission or decreased electromagnetic immunity. The specified configuration of this equipment and/or system complies with the electromagnetic requirements with the specified configuration. Only use this equipment and/or system with the specified configuration.

6. Use with radiation therapy equipment:
   When the equipment and/or system is used in a radiotherapy room, it may cause failure or malfunction due to electromagnetic radiation or corpuscular radiation. When you bring the equipment and/or system into a radiotherapy room, constantly observe the operation. Prepare countermeasures in case of failure or malfunction.

If the above suggested remedial actions do not solve the problem, consult your Nihon Kohden representative for additional suggestions.

For EMC compliance, refer to "Specifications - Electromagnetic Emissions/Immunity" in the Reference section.

The CE mark is a protected conformity mark of the European Community. Products with the CE mark comply with the requirements of the Medical Device Directive 93/42/EEC and Radio Equipment Directive 2014/53/EU.

NOTE about Waste Electrical and Electronic Equipment (WEEE) Directive 2012/19/EU

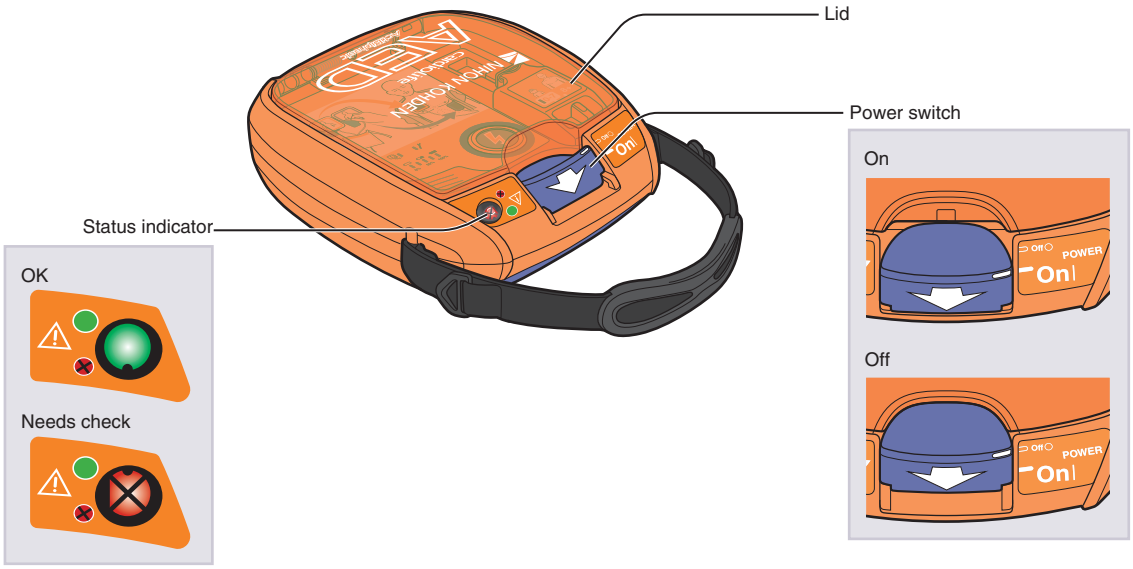
For the member states of the European Union only:
The purpose of WEEE directive 2012/19/EU is, as a first priority, the prevention of waste electrical and electronic equipment (WEEE), and in addition, the reuse, recycling and other forms of recovery of such wastes so as to reduce the disposal of waste.
Contact your Nihon Kohden representative for disposal.

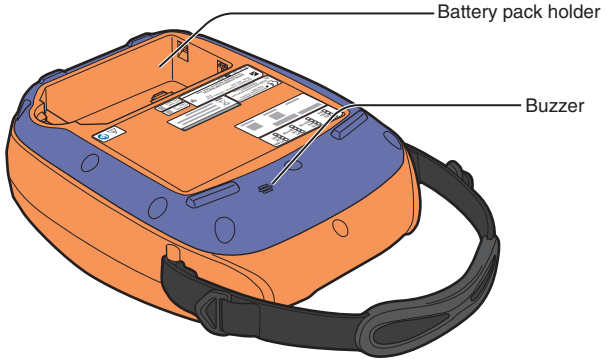
This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:
(1) this device may not cause harmful interference, and
(2) this device must accept any interference received, including interference that may cause undesired operation.

Introduction

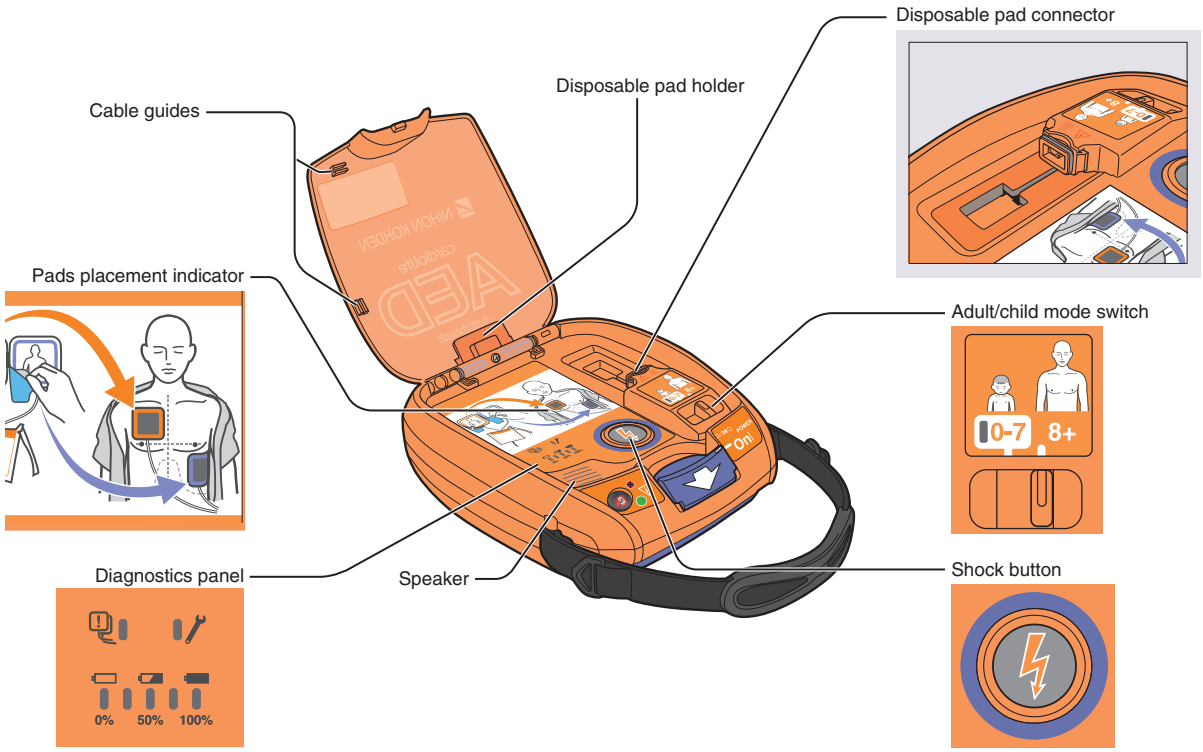
Explanation of Parts

When the lid is closed

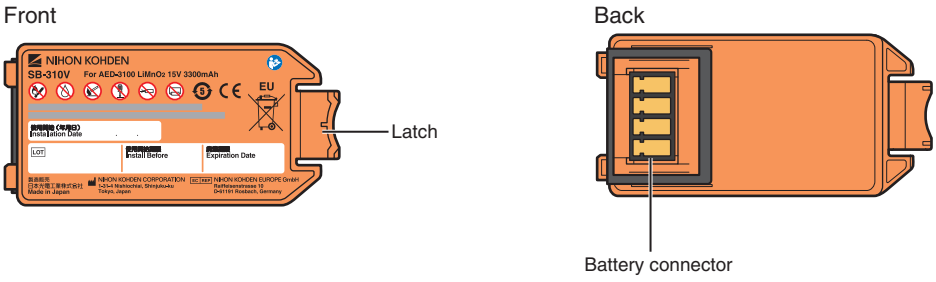




When the lid is open



Battery pack



Introduction

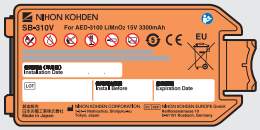
Items to be Checked

Make sure that the necessary items are ready.

To order additional consumables, contact your Nihon Kohden representative.

AED

When you turn the AED power on and open the lid, the AED starts voice instructions. When the AED determines that a defibrillation shock is required, the AED starts charging. When charging is complete, the shock button flashes. When you press the shock button, the AED delivers a shock. The data collected during resuscitation, such as the heart rhythm, is recorded in the internal memory.

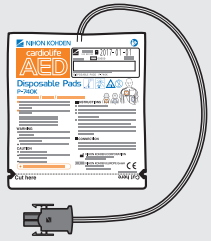


Battery pack (consumables)

The AED's dedicated battery pack stores important information, such as the total operation time and remaining battery power in the memory inside the battery pack. The battery condition is checked by the AED self test every day. If the AED is never used for resuscitation, the battery power lasts four years. Since the battery pack is not rechargeable, replace it with a new one when the battery power runs out.

p. 9 to 10 "Battery Pack" in the "General Handling Precautions" section, p. 29 "Consumables" in the "Checking the AED" section.

Note: Battery pack is sold separately. Also read the document attached to the Battery pack.



Disposable pads (consumables)

One package contains two pads to be placed on the patient. Connect the pads connector to the AED and put the package into the holder on the back of the lid. Since the pads are disposable, replace them with new ones after use. Replace the pads if they are past the expiration date, even if they have never been used. The expiration date is printed on the package.

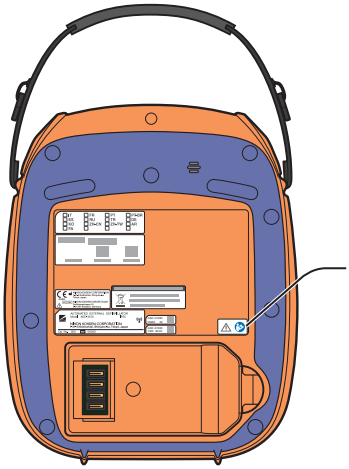
p. 10 to 12 "Disposable Pads" in the "General Handling Precautions" section, p. 29 "Consumables" in the "Checking the AED" section.

Note: Disposable pads are sold separately. Also read the document attached to the disposable pads.

Caution Labels and Caution Marks

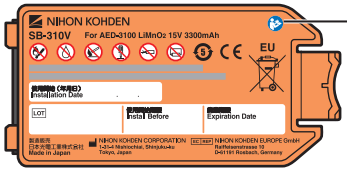
p. 21 “Connecting the Disposable Pads”

p. 26 “Daily Check”



Refer to the operator’s manual before you use the AED.

p. 4 “General Handling Precautions”



Refer to the operator’s manual before you use the battery pack.

Installation

Preparation

This section describes how to prepare the AED so it can be used any time.

p. 5 ! 08, p. 18 “Items to be Checked”, p.12 ! 59

1. Connect the disposable pads

Check that the disposable pads are not expired.

2. Set the adult/child mode switch and close the lid

3. Install the battery pack

- Check that today’s date is not past the date on the label.
- Write down the date (year, month and day) when you start using the battery pack on the label.

1. Connecting the Disposable Pads

Note 1: Check the expiration date indicated on the package of the disposable pads.

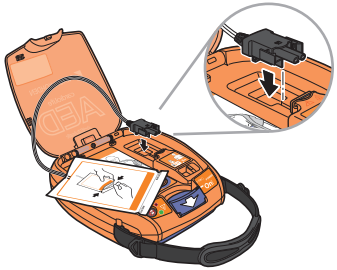
Note 2: Connect the disposable pads in a place where the disposable pads and AED cannot get wet.

1

Slide the power switch and open the lid

2

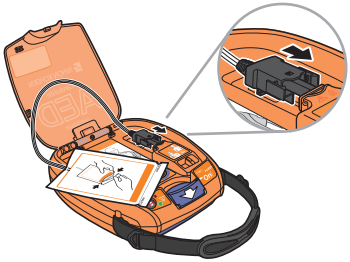
Insert the tab on the connector into the slot



3

Push the connector all the way in until it locks with a click

p. 11 ! 51



4

Store the pads on the back of the AED lid

Make sure that the illustration side of the disposable pad is facing toward you. Insert the package into the holders.

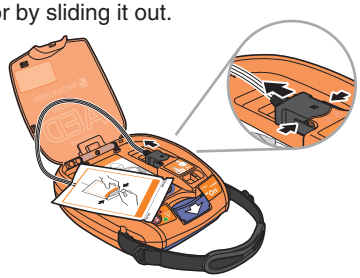
5

Run the cable through the cable guides

Run the cable through three cable guides on the back of the lid. (Indicated with arrows in the illustration)

How to remove the connector

Hold the sides of the connector and remove the connector by sliding it out.



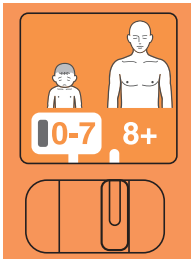
Installation

2. Setting the Adult/Child Mode Switch and Closing the Lid

1

Check the adult/child mode switch

Set the switch to “8+” which is the adult mode.



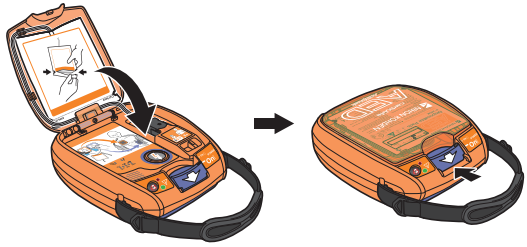
When you move the switch, make sure that it clicks into position.

If you expect that the AED might be used for children age 0 to 7, set the switch to “0-7”, which is the child mode.

2

Close and lock the lid

Close the lid and slide the power switch away from you until it clicks.



3. Installing the Battery Pack

- Check that today's date is not past the date on the label.
- Write down the date (year, month and day) when you start using the battery pack on the label.
- **When you install the battery pack, be sure to close the lid and set the power switch to Off.**
- Install the battery pack in a place where the battery pack and AED cannot get wet.

1

Insert the battery connector

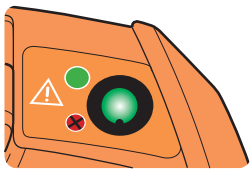
2

Firmly insert the battery pack until it clicks

Check that the battery pack is properly inserted.

3

Check whether the status indicator is green

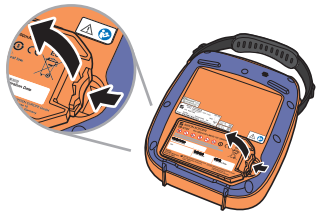


When you insert the battery pack into the AED, you hear a sound. Then after about 15 seconds, the status indicator turns green. If the status indicator remains red, open the lid and follow the voice instruction.

p. 30 "Voice instructions"

How to remove the battery pack

Push in the latch and slowly remove the battery pack.



Before removing the battery pack, make sure that the AED lid is closed, the AED power is off, and more than 5 seconds has passed after turning the AED power off.

Otherwise, the data might not be saved in the AED correctly.

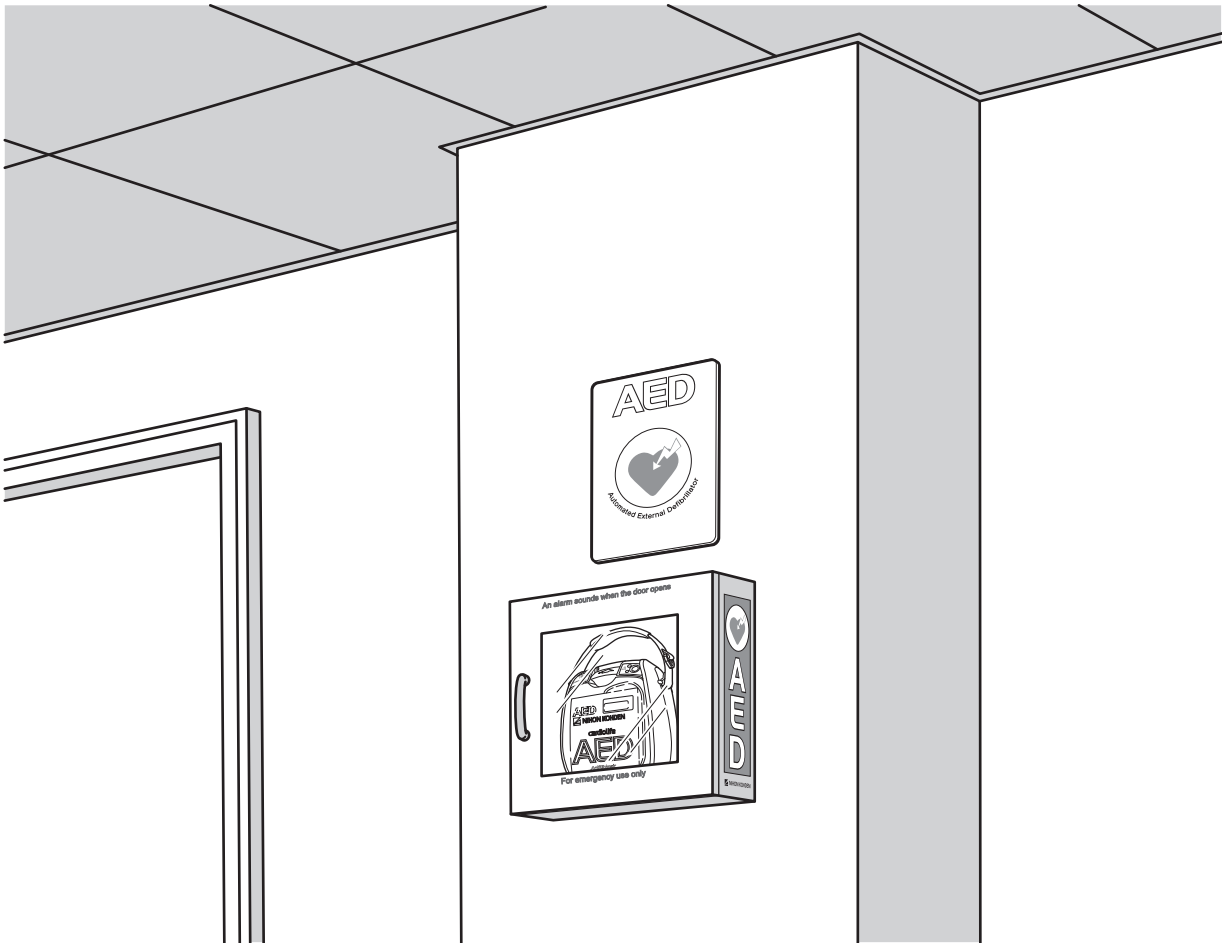
Installation

Location

Install the AED where it is easily accessible in an emergency. We also recommend that you put up a sign so people can easily find the AED.

For details about installing an AED, consult your facility manager.

Example



Precautions for Installation and Use

- Designate a manager for the AED before you install and operate it. p. 12 ! 59
- Install the AED so that you can see the expiration date of the disposable pads and the status indicator.
- Store the AED with the disposable pads connected and the adult/child mode switch set for the most likely patient type.
- The AED is a medical instrument. The installation location may be limited by your local laws or guidelines.
- Make sure that the AED is always ready for use and easy to find and access.
- Install the AED in an appropriate place where it can be kept in good condition and does not cause any danger to children.
- Avoid locations where the AED may get wet.
- Avoid excessive humidity and temperature, direct sunlight, dust, and saline or sulfuric air.
- Place the AED on a level surface. Avoid vibration and mechanical shock, even during transport.
- Avoid places where chemicals are stored or where there is possibility of gas leakage.
- Do not install the AED near equipment which emits strong electromagnetic waves such as microwave therapy instruments. The AED might not operate for resuscitation. p. 12 ! 60
- Keep the AED in the following conditions. The AED might not operate for resuscitation. p. 5 ! 09
  - Temperature: −5 to +50°C (23 to 122°F)
  - Humidity: 5 to 95% (noncondensing)
  - Atmospheric pressure: 540 to 1060 hPa
- The AED might not operate correctly in a cold environment such as when the temperature is below −5°C (23°F) because the output of the battery pack becomes low or the disposable pads freeze. Install the AED in an environment with an appropriate controlled temperature so that the AED can operate properly for resuscitation.
- Contact your Nihon Kohden representative when there is trouble or when transferring ownership of the AED.
- When disposing of the AED, remove the battery pack from the AED. Follow your local low. p. 6 ! 10

Installation Options

For purchasing options, contact your Nihon Kohden representative.
p. 66 “Option”

Checking the AED

Daily Check

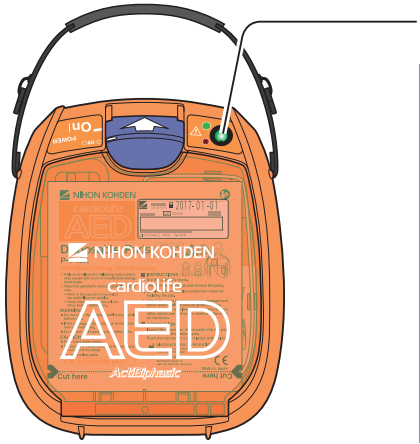
The AED performs a self test every day and displays the result on the status indicator.

For daily inspection, just check the status indicator once a day.

Note 1: Use the Inspection List on p. 67 if necessary.

Note 2: The manager must perform the periodic inspection to make sure that the AED is always in good condition.

p. 12 ! 59 Designate a manager for the AED before installing and operating it.



For Daily Inspection

Check whether the status indicator is green (the AED is enabled). If there is a problem, the status indicator becomes red (the AED needs to be checked) and an alarm sounds.

OK (green)

Needs check (red)

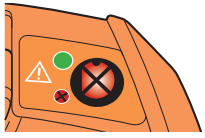
If the status indicator is red and an alarm sounds, turn on the AED and follow the voice instructions.

p. 30 “Voice Instructions”

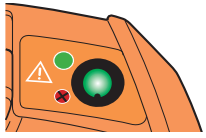
About self tests

The AED automatically performs a self test to check the disposable pads, battery and electric circuits. During a self test, the status indicator is red. If no problem is found, the status indicator becomes green. If a problem is detected, the status indicator remains red and an alarm sounds every 10 seconds.

Daily and monthly self tests are automatically performed. The time of self tests is 12:00 noon. When using the ARM-1000 AED remote monitoring system, the self test may not be performed at 12:00 noon.



The status indicator is red during a self test.



The status indicator becomes green when no problem is found.

Daily self test

A self test is performed every day.

The test checks whether the battery pack, disposable pads and circuits in the AED are normal. The same self test is also performed whenever the AED is turned on and off.

Monthly self test

A self test is performed on the 15th day of each month. The test checks whether the circuits in the AED are normal.

In addition to the items checked in the daily tests, the monthly self test also checks the high-voltage circuits by charging the AED with maximum energy and internally discharging the energy.

Saving the test results

The results of self tests are stored in internal memory. With the optional defibrillator report viewer software and the specified Bluetooth adapter, you can save the results of daily and monthly tests on a specified PC via Bluetooth communication.

Refer to the defibrillator report viewer software operator’s manual.

Monthly Check

To ensure that the AED operates correctly, monthly inspection is recommended.

Note 1: Use the Inspection List on p. 67 if necessary.

Note 2: The manager must perform inspection to keep the AED in good condition.

p. 12 ! 59 Designate a manager for the AED before installing and operating it.

Check the expiration date for disposable pads.

Check that the connected disposable pads are not expired.

If they are past the expiration date, replace them with new ones.

p. 20 “Installation”

Check the expiration date of the battery pack.

If more than four years have passed from the date written on the battery pack label, replace the battery pack with a new one.

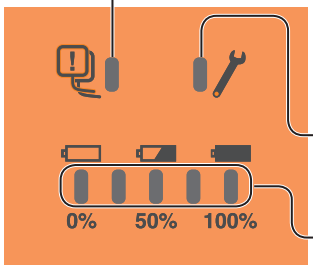
p. 20 “Installation”

Check the indicators, LEDs, speaker switch and buttons.

Check the indicators, switch and buttons by following the procedure on the next page.

p. 20 “Installation”

About the indicators on the diagnostics panel



Pads Check Indicator

This indicator lights when the disposable pads are disconnected from the AED or the pads are abnormal. If the indicator lights, check the connection of the disposable pads. If the indicator lights but the connection is normal, the pads are probably abnormal. Replace the pads with new ones.

How to replace disposable pads: p. 21 “Connecting the Disposable Pads”

Service Indicator

This indicator lights when the AED is faulty. Contact your Nihon Kohden representative.

Battery Status Indicators

Five LEDs indicate the amount of remaining battery power.

Replace the battery pack when the second indicator from the left is lit in green or the 0% indicator is red. When the 0% indicator is red, it indicates there is no remaining battery power, or an unspecified battery pack is used.

How to replace the battery pack: p. 23 “Installing the Battery Pack”

Checking the AED

Monthly Inspection Procedure

Inspecting the Status Indicator, LEDs, Speaker, Switch and Button

Check that each function is operating normally.

1	**Turn on the power switch and open the lid.**	• Check that there is a “pip” sound and all LEDs light. • Check that the status indicator is red and then about after two seconds, changes to green. • Check that there is a voice instruction “Adult mode. If patient has no response and is not breathing...”. • Check that at least two green battery status indicators are lit.
2	**Press the shock button.**	Check that there is a “pip” sound.
3	**Toggle the adult/child mode switch.**	• Set the adult/child mode switch to “0-7” and check that there is a voice message “Child mode. If patient is adult, set switch to “8+”.” • Set the adult/child mode switch back to “8+” and check that there is a voice message “Adult mode.” Make sure that the adult/child mode switch is set back to “8+” after the inspection. If it is assumed that the AED will be mainly used for children age 0 to 7, set the adult/child mode switch to “0-7” after inspection.
4	**Close the AED lid and turn the power off.**	Check that the status indicator is green.*

* The alarm does not sound even if the status indicator remains red after monthly inspection.

If You Hear “Check AED after use” When Opening the Lid

Even if you hear the “Continue using AED. Check AED after use. See operator’s manual.” voice instruction on AED power on, it does not mean AED malfunction. To use the AED, do the following.

1. Close the lid and turn the AED power off.
2. After 5 seconds, remove the battery pack and attach it again.
3. After 10 seconds, turn the AED power on and open the lid again.
4. Check whether the status indicator is green. If the status indicator remains red, contact your Nihon Kohden representative.

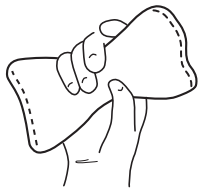
You hear this message when there is an abnormality in the internal clock of the AED, the AED was used outside the operating and installation temperature range, or unspecified pads are connected.

Other Checks

Appearance

Periodically check that the AED has no cracks, chips or loose parts and is not dirty.

If the AED is damaged, do not use it for rescue and contact your Nihon Kohden representative.



How to clean the AED

Immerse a cloth in water or diluted detergent, wring the cloth tightly, and wipe the surface.

Consumables

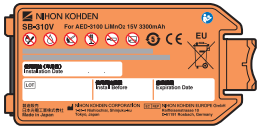
Note: For details about purchasing consumables, contact your Nihon Kohden representative.

Battery pack [SB-310V]

The life is four years after the start of its use.

The life of the battery pack may be shorter depending on installation conditions and frequency of use.

p.10 ! 41



Write down the date (year, month and day) on the label when you start using the battery pack.
Do not use the battery pack if the date on the label is past.

Prepare a spare battery in case of battery pack failure.

How to replace: p. 23 “Installing the Battery Pack”

How to discard: p. 10 ! 40

Disposable pads [P-740K]

When the expiration date on the package is past, replace the pads with new ones.

Be sure to prepare spare pads.

How to replace: p. 21 “Connecting the Disposable Pads”

How to discard: p. 12 ! 58

Stock period for repair parts

Nihon Kohden stocks the repair parts for the AED (components that are required to maintain the function of the AED) for eight years after the date of delivery. Your AED can receive repairs within this period.

Note 1: Depending on the date of purchase, the stock period may be shorter.

Note 2: Some parts of the AED can be repaired even after the stock period expires.

Voice Instructions

The AED tells the operator what to do by voice instructions.

This section lists the voice instructions you hear and the action to be taken. Note that some voice instructions are different for adult mode and child mode.

Open the package and remove pads.

When you hear voice instructions from the speaker, follow the instructions.

Voice Instructions

Voice instruction/Description and action	Refer to
Checking the mode	
Adult mode.	P. 34
Child mode. If patient is adult, set switch to “8+”.	P. 35
Placing the pads	
If patient has no response and is not breathing, remove all clothing from patient’s chest. Remove square package from AED.	P. 36
Open package and remove pads.	
Remove pads from blue liner and apply to right upper chest and left side as shown.	
Remove pads from blue liner and apply to patient as shown.	P. 42
Check pad cable connection to AED.	P. 38
Check skin contact and cable connection.	
Connect pads to AED. **Connect the disposable pads connector to the AED correctly.** You hear this instruction when the pad connector is disconnected from the AED.	—
Delivering a defibrillation shock	
Analyzing heart rhythm. Do not touch patient.	P. 38, 39, 41
Shock advised. Charging.	P. 39
Charging.	
Do not touch patient. Press flashing button.	P. 39, 40
Shock delivered.	P. 40
No shock advised.	P. 39
Heart rhythm changed. Shock cancelled. **Stay away from the patient and wait for the next voice instruction.** You hear this message when the patient’s heart rhythm has changed after the AED charged energy for a defibrillation shock and a shock is no longer necessary.	—
Could not analyze heart rhythm. **Stay away from the patient and wait for the next voice instruction.** You hear this message when the AED cannot analyze the heart rhythm since the patient is being touched or moved and noise occurs in the heart rhythm.	—

Voice Instructions

Voice instruction/Description and action	Refer to
Performing CPR	
It is safe to touch patient. Start CPR.	P. 41
Continue CPR.	
5 more times. Do not touch patient.	
Other voice instructions	
Pads are past expiration date. **Replace the disposable pads with new ones.** You hear this message when the AED detects that the disposable pads have exceeded the expiration date.	—
Battery low. **Prepare a new battery pack for replacement at any time.** After you hear this message, you can deliver about nine defibrillation shocks. Prepare a new battery pack before the remaining battery power runs out and replace the existing battery pack with a new one.	—
No battery power. Replace battery. **Immediately replace the existing battery pack with a new one.** You hear this instruction when the battery power is gone.	—
Battery is past expiration date. **Replace the existing battery pack with a new one.** You hear this message when the AED detects a battery pack that has exceeded the expiration date.	—
Wrong battery type. **Use the specified battery pack.** You hear this message when you use an unspecified battery pack.	—
Training pads are connected. Remove training pads and connect rescue pads. **Replace the existing pads with the disposable pads for rescue purposes.** You hear this instruction when the AED detects training pads.	—
Could not deliver shock. It is safe to touch patient. Attach pads and immediately start CPR. **Check that the pads are firmly attached.** **You hear this message when the pads are not attached to the patient firmly and defibrillation shock was not delivered correctly.**	—
AED not working. Do not use AED. Start CPR. AED not working. Call for service. **Contact your Nihon Kohden representative. If you are performing resuscitation, immediately start CPR.** The AED is broken and you cannot use it. The message stops when you close the lid.	—

Voice instruction/Description and action	Refer to
Other voice instructions	
Continue using AED. Check AED after use. See operator's manual. **After use, check the AED according to the following procedure.** 1. Close the lid and turn the AED power off. 2. After 5 seconds, remove the battery pack and attach it again. 3. After 10 seconds, turn the AED power on and open the lid again. 4. Check whether the status indicator is green. If the status indicator remains red, contact your Nihon Kohden representative. You hear this message when there is an abnormality in the internal clock of the AED, the AED was used outside the operating and installation temperature range, or unspecified pads are connected.	—
Communication mode You hear this message when you start wireless communications. p. 12 ! 61 ! 62	—

Using the AED

Checking the Patient's Condition and Placing the Pads

When you turn on the power switch and open the lid, you hear voice instructions.

Follow the instructions to place the disposable pads on the patient, and wait for the next voice instruction.

1

Open the lid

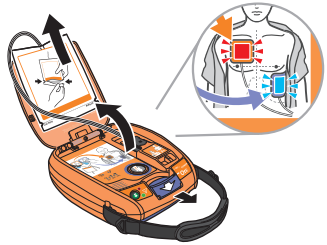
Check the safety in your surroundings before opening the lid.

Slide the power switch and open the lid

The pads placement indicators blink.

If you hear other voice instructions, refer to

p. 31 "Voice Instructions".



Adult mode. If patient has no response and is not breathing, remove all clothing from patient's chest.

Check that the selected mode is appropriate for the patient. Select the child mode for children age 0 to 7.

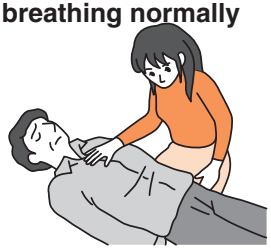
You hear either message when you open the lid or change the adult/child mode.

2

Check whether the patient shows all of the following signs

Unconscious

Not breathing normally



No pulse (for experienced personnel only)

Check whether the patient is adult or child

- If the patient is age 8 or older, confirm that the adult/child mode switch is set to “8+”.
- If the patient is age 0 to 7, set the adult/child mode switch to “0-7”. The voice instruction changes and the child mode indicator lights.

Child mode. If patient is adult, set switch to “8+”.

Select the child mode for children age 0 to 7.
You hear this message when you change the adult/child mode.

3

If the patient is younger than eight years old, refer to p. 7 ! 20.

When the patient is age 8 or older

When the patient is age 0-7

Place the disposable pads on the patient

Follow the voice instructions and place the disposable pads on the patient.

If the patient has an implanted pacemaker or ICD, refer to p. 9 ! 30.

4

If the patient is younger than eight years old, refer to p. 7 ! 19 ! 20 ! 21, p. 42 “Placing the Pads on a Child”.

From the moment you place the disposable pads on the patient, the internal memory of the AED starts recording data such as the heart rhythm and delivery of defibrillation shocks.

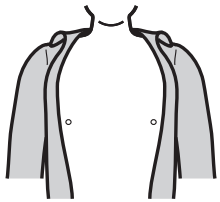
For details about other voice instructions, refer to p. 31 “Voice Instructions”.

Using the AED

Placing Disposable Pads on the Patient Chest

p. 10 ! 42 to p. 12 ! 57. For children, refer to p. 42 “Placing the Pads on a Child”.

1 Remove clothing from the chest of the patient

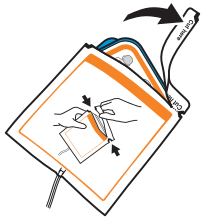


Remove all clothing from patient’s chest. Remove square package from AED.

If the patient’s chest is sweaty or oily, clean the chest as much as possible.

p. 6 ! 11, p. 7 ! 18

2 Open the disposable pad package

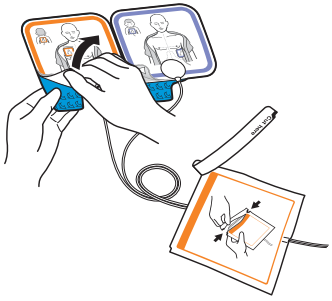


Open package and remove pads.

Tear the package containing disposable pads along the dotted lines and take out the pads. Leave the empty package attached to the cable.

p. 10 ! 44, p. 11 ! 49

3 Remove a pad from its protection sheet



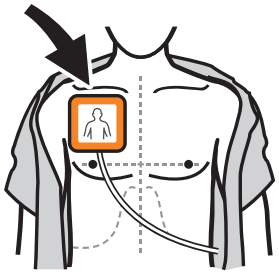
Remove pads from blue liner and apply to right upper chest and left side as shown.

You continuously hear this voice instruction until you correctly place the pads on the patient.

There are two disposable pads in the package. You can start removing the protection sheet from either pad. Hold the tab of a protection sheet and slowly peel away the protection sheet from the cable side.

p. 11 ! 45 ! 46 ! 47

4 Place the pad on the right upper chest



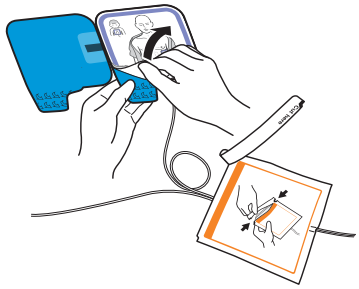
Remove pads from blue liner and apply to right upper chest and left side as shown.

You continuously hear this voice instruction until you correctly place the pads on the patient.

As shown in the illustration on the pad, place the pad on the right upper chest (under the collar bone, on the right of the sternum). Do not place the pad on the center of the chest.

p. 6 ! 11, p. 8 ! 28, p. 9 ! 30

5 Remove the other pad from its protection sheet



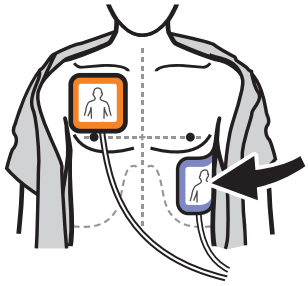
Remove pads from blue liner and apply to right upper chest and left side as shown.

You continuously hear this voice instruction until you correctly place the pads on the patient.

Hold the tab of a protection sheet and slowly peel away the protection sheet from the cable side.

p. 11 ! 45 ! 46 ! 47

6 Place the pad to the lower left chest



Remove pads from blue liner and apply to right upper chest and left side as shown.

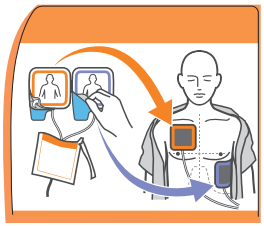
You continuously hear this voice instruction until you correctly place the pads on the patient.

As shown in the illustration on the pad, place the pad on the lower left chest (5 to 8 cm below the arm pit, below the left nipple slightly to the left).

p. 6 ! 11, p. 8 ! 28, p. 9 ! 30

Using the AED

7 Check whether the pads placement indicators are not blinking



When two pads are placed on the patient, the pads placement indicators stop blinking. The indicators continue to blink if the pads are not correctly placed or have fallen off. Check that the pads are firmly placed on the patient.

Follow the voice instructions

When the disposable pads are placed, the AED starts to analyze the heart rhythm.

Analyzing heart rhythm. Do not touch patient.

Stay away from the patient and wait for the next voice instruction.
You hear this message while the AED is analyzing the heart rhythm after you have placed the disposable pads on the patient.

Check pad cable connection to AED.

Check that the connector of the disposable pads is not disconnected. If disconnected, connect the connector correctly.
If you hear this instruction after you have placed the pads on the patient, check that the pad connector is correctly connected to the AED. The pads placement indicators on the AED blink. If the pad connector is disconnected from the AED, the pads check indicator is lit.
You continuously hear **"Check pad cable connection to AED."** until you correctly connect the pad connector to the AED and place the pads on the patient.

Check skin contact and cable connection.

Check that the disposable pads are correctly placed on the patient or that they are not fallen off. If the pads are not correctly placed, place them correctly.
You hear this instruction when the disposable pads are not correctly placed, the pads have fallen off, or the pad connector is disconnected from the AED. In these cases, the pads placement indicators on the AED blink. If the pad connector is disconnected from the AED, the pads check indicator is also lit.

Delivering a Defibrillation Shock

When the disposable pads are placed, the AED starts analyzing the heart rhythm.

The voice instructions change according to the condition of the patient.

Analyzing heart rhythm. Do not touch patient.

Stay away from the patient and wait for the next voice instruction.

You hear this message when the AED is analyzing the heart rhythm.

p. 7 ! 22, p. 8 ! 26

When a defibrillation shock is required

Shock advised. Charging.

Stay away from the patient and wait for the next voice instruction.

The AED has determined that a defibrillation shock is required by analyzing the heart rhythm. The AED is charging energy to deliver a defibrillation shock.

When a defibrillation shock is not required

No shock advised.
It is safe to touch patient.
Start CPR.

Leave the disposable pads attached and start CPR.

p. 41 “Performing CPR”

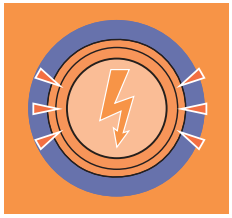
Do not touch patient. Press flashing button.

The shock button flashes.

Press the flashing shock button to deliver defibrillation shock to the patient. After a defibrillation shock is delivered, you hear **“Shock delivered.”**.

Note: Press the shock button within 30 seconds after you hear the above voice instruction. If 30 seconds passes without pressing the shock button, the shock button stops flashing and defibrillation shock is disabled.

p. 6 ! 12 ! 13 ! 14, p. 7 ! 15, p. 8 ! 29



Using the AED

Do not touch patient. Press flashing button.

When you hear the above instruction, confirm that no one touches the patient and press the flashing shock button.

The shock button flashes when the AED determines that a defibrillation shock is required.
Press the flashing shock button to deliver a defibrillation shock.

Note: If you press the shock button when it is not flashing, no defibrillation shock is delivered.

Shock delivered.

Stay away from the patient and wait for the next voice instruction.
You hear this message after a defibrillation shock is delivered to the patient.

Performing CPR

After defibrillation shock was delivered or the AED decided that defibrillation shock was not needed, start chest compressions and rescue breathing (CPR).

It is safe to touch patient. Start CPR.

Leave the disposable pads attached to the patient and start CPR.

You hear this voice instruction when the AED decides that no defibrillation shock is needed after the AED analyzes the patient's ECG or when the AED delivers defibrillation shock. Immediately start CPR.

Continue CPR.

Continue chest compressions and rescue breathing.

You hear this voice instruction every 30 seconds after you start chest compressions and rescue breathing.

5 more times. Do not touch patient.

Perform chest compression five times and then keep away from the patient.

You hear this voice instruction about two minutes after you start CPR.

Analyzing heart rhythm. Do not touch patient.

Stay away from the patient and wait for the next voice instruction.

You hear this voice instruction while the AED is analyzing the change in the patient's heart rhythm after CPR.

p. 8 ! 23 ! 27

Until the medical emergency team arrives, leave the disposable pads attached to the patient and follow the voice instructions from the AED.

Using the AED

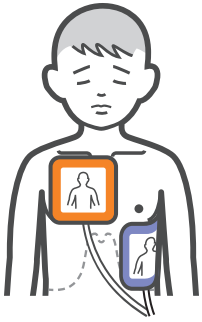
Placing the Pads on a Child

If the patient is a child age 0 to 7, switch to the child mode and perform resuscitation.

You need to place the pads on different locations on the patient depending on the size of the patient's body.

p. 7 ! 19 to ! 21

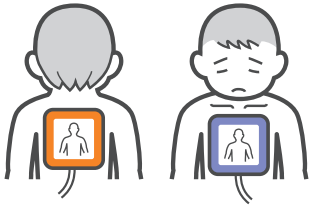
When the patient body is big



If the two pads do not touch each other, place the pads on the adult places.

p. 6 ! 11, p. 7 ! 18

When the patient body is small



If the patient's body is small and the two pads touch each other, place one pad on the center of the chest and the other pad on the back.

The two pads are interchangeable. You can attach either pad on either place.

p. 6 ! 11, p. 7 ! 18 ! 21

Remove pads from blue liner and apply to patient as shown.

You continuously hear this voice instruction until you correctly place the pads on the patient.

Until a Medical Emergency Team Arrives

Until a medical emergency team arrives, leave the disposable pads attached to the patient, do not turn off the AED and follow the voice instructions.

Until a medical emergency team arrives, follow the voice instructions of the AED and continue CPR and analysis of the patient's ECG. Even if the patient becomes conscious and starts to move, the condition of the patient might change at any time. Leave the AED turned on and do not remove the pads from the patient.

While the disposable pads are attached to the patient, the AED power does not turn off and continues giving voice instructions even if you close the AED lid and slide the power switch to the Off position.

Note to medical emergency teams

To turn off the AED with the pads attached to the patient for long transport or other reasons, close the lid and set the power switch to Off twice. When you turn the AED power on again, there are voice instruction **"Analyzing heart rhythm. Do not touch patient."** and the AED starts analyzing the patient's ECG.

Using the AED

Preparing for Next Use

After you use the AED for rescue, prepare the AED for the next use.

1	**Save the rescue file.** Connect the AED to a PC via *Bluetooth* and save the rescue file in the PC using the optional QP-551VK defibrillator report viewer software.	Refer to the QP-551VK defibrillator report viewer software operator's manual.

Note: When starting the next resuscitation, if there are three files in the AED internal memory, the oldest data will be overwritten. Three rescue files can be saved in the AED internal memory. One rescue file is up to 30 minutes.

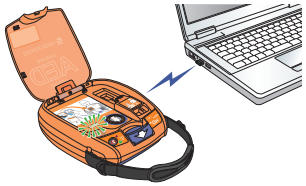
2	**Remove the used disposable pads.**	p. 21 "How to remove the connector" For discarding the used disposable pads, refer to p. 12 ! 58
3	**Connect the connector of the new disposable pads to the AED and store the disposable pads package in the holder on the back of the AED lid.**	p. 21 "Connecting the Disposable Pads"
4	**Check the remaining battery.**	p. 27 "About the indicators on the diagnostics panel"
5	**Check the position of the adult/child mode switch.**	p. 22 "Setting the Adult/Child Mode Switch and Closing the Lid"
6	**Close the lid and turn the AED power off.** Check whether the status indicator is green.	p. 22 "Setting the Adult/Child Mode Switch and Closing the Lid"

Displaying and saving rescue files using a PC

From the moment you place the disposable pads on the patient, the AED internal memory starts recording data such as the heart rhythm and delivery of defibrillation shocks.

The AED has *Bluetooth* wireless communication function. Use *Bluetooth* to connect the AED to a PC with the *Bluetooth* module or by using a *Bluetooth* adapter. Use the optional QP-551VK defibrillator report viewer software to copy the rescue files to the PC. You can display and print the rescue file once it is transferred to the PC.

Note: You cannot copy the rescue files in the AED to a PC while the disposable pads are attached to a patient.



QP-551VK Defibrillator Report Viewer Software

By using the QP-551VK defibrillator report viewer software, you can display and save the data stored in the AED during resuscitation. You can also use this software to set the internal clock in the AED and receive self-test results. To use this software, you have to install it on a PC.

For operation, refer to the QP-551VK defibrillator report viewer software operator's manual.

Adjusting the AED internal clock

The accuracy of the AED internal clock is ±20 s/month at an ambient temperature of 25°C (77°F).

The accuracy may be affected when strong impact is given to the AED, such as dropping the AED, or the AED is placed in a high- or low-temperature environment for a long period of time.

When you transfer the rescue files to the PC using the optional QP-551VK defibrillator report viewer software, you can also check and adjust the AED internal clock if necessary.

ARM-1000 AED Remote Monitoring System

The AED Linkage ARM-1000 AED remote monitoring system lets you monitor the status and manage remote AEDs and consumables.

A wireless modem beside the AED sends data to the server of the AED remote monitoring system.

You can check the AED status on the internet. If an abnormality is detected in an AED, or the expiration date of consumable items such as the disposable pads and battery pack is close or passed, an email is sent to the registered AED managers.

Also the AED inspection manager can enter daily inspection results in a log and the manager can view the inspection log of all AEDs.

Contact your Nihon Kohden representative for details on AED Linkage.

Reference

Notes for Using *Bluetooth* Wireless Communication

The AED has *Bluetooth* wireless communication so you can receive the rescue files from the AED, change the AED settings and automatically send the self-test results to a PC. For details, refer to the optional QP-551VK defibrillator report viewer software operator's manual.

To use the *Bluetooth* wireless communication, note the following.
The frequency band used by the AED is also used by microwave ovens and other industrial, scientific and medical devices, licensed private radio stations such as those for mobile identification in factory production lines, specified low power radio stations that do not require any licenses, and amateur radio stations. Hereafter, these are referred to as "Other Radio Stations".

1. Before using the AED wireless communication function, make sure that there are no Other Radio Stations operating nearby.
2. If radio interference occurs between the AED and Other Radio Stations, immediately move the AED to another place or stop wireless communication to avoid radio interference.
3. For any other radio interference of the AED, contact your Nihon Kohden representative.

For better communication:

- The distance between the AED and another *Bluetooth* device must be about 10 m or less under the line-of-sight conditions. The connectable distance becomes shorter depending on the surrounding environments (blocked by a wall or furniture) or structure of a building. If an obstruction is found between the AED and other *Bluetooth* devices, the connectable distance becomes shorter. Particularly, if there is a wall or floor of reinforced concrete between *Bluetooth* devices, they may be unable to connect with each other. Note that this does not warrant the above connection distance.
- During the connection, keep the *Bluetooth* device away from other electric devices (such as home electric appliance, AV devices, OA devices, digital cordless telephones and facsimiles) more than 2 m. (Particularly when using a microwave oven, keep *Bluetooth* devices away from it more than 3 m to prevent interference.)
- *Bluetooth* devices use the same frequency band (2.4 GHz) as wireless LAN (IEEE802.11b/g). Therefore, if a *Bluetooth* device is used near a wireless LAN device, radio interference may cause the communication to slow down, make noise or fail.

FCC WARNING

Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

The wireless communication module in this AED complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:

1) The wireless communication module in the AED may not cause harmful interference.
2) The wireless communication module in the AED must accept any interference received, including interference that may cause undesired operation.

Reference

Frequently Asked Questions

During resuscitation

Q	When I do not know whether the child is older than 8, which mode should I select, adult mode or child mode?	A	**Select adult mode, immediately attach the disposable pads to the patient and follow the voice instructions.**
Q	What should I do when there is a voice message “No shock advised.”?	A	**Even if no defibrillation shock is advised, CPR is needed. Follow the voice instructions and start CPR immediately.** **The voice message means that the AED analyzed the patient’s ECG and decided that no defibrillation shock is needed or the patient’s condition will not change by delivering defibrillation shock. For example, the AED detected spontaneous pulse of the patient or asystole.**
Q	When do I hear “It is safe to touch patient. Start CPR.”?	A	**• When the AED analyzes the heart rhythm and determines that a defibrillation shock is not required.** **• After a defibrillation shock has been delivered.** p. 41 “Performing CPR”
Q	Is CPR necessary?	A	**Yes. CPR is necessary to save life.** **When you hear “It is safe to touch patient. Start CPR.” from the AED, perform CPR.**
Q	Can I perform CPR while the AED is analyzing the heart rhythm?	A	**No, you cannot.** **If you touch the patient while the AED is analyzing the patient’s heart rhythm, the AED might incorrectly analyze the heart rhythm.** **Do not touch the patient while the AED is analyzing the heart rhythm so that the AED can make correct decisions.**
Q	Can I transfer the patient by car while the AED is analyzing the patient’s heart rhythm?	A	**No, you cannot. If you need to start using the AED while you are transferring the patient by car, stop the car.** **When the car is moving, noise occurs and the AED might make incorrect decisions.** p. 7 ! 22
Q	Why do I hear the voice instruction to perform CPR while the AED is analyzing the patient’s heart rhythm?	A	**If the disposable pads are attached and removed 3 times or more, the AED stops analyzing the heart rhythm and urges you to perform CPR so that CPR interruption is minimized.**
Q	Before I place the pads on the patient, do I need to wipe the patient’s chest?	A	**No, you usually do not need to wipe the patient’s chest.** If the patient’s chest is sweaty or oily: p. 7 ! 18 If the patient’s chest is hairy: p. 8 ! 28
Q	Can I touch the pads placed on the patient?	A	**No. Do not touch the pads placed on the patient while the AED is working. If the operator touches the pads while the defibrillation shock is delivered, the operator receives an electrical shock.** p. 6 ! 13 ! 14
Q	I heard “Do not touch patient. Press flashing button.” from the AED and saw the shock button flashing then stop flashing. Why did it stop flashing?	A	**Because one of the following happened.** **- 30 seconds passed without pressing the shock button after the voice instruction.** **- the disposable pads came off the patient.** **- the disposable pad connector came off the AED.** **- the AED judged that a defibrillation shock was not necessary.**

Q	What should I do if the battery power runs short while I am using the AED?	**A**	**After you hear "Battery low." for the first time, you can deliver about nine defibrillation shocks.** **Prepare a new battery pack before the existing battery pack completely runs out and replace the existing battery pack with the new one.**
Q	The AED power does not turn on after opening the lid. What should I do?	**A**	**Perform CPR immediately. Use another AED.**
Q	The AED power turned off unexpectedly during resuscitation. What should I do?	**A**	**Perform CPR immediately. Use another AED.**

Regarding problems other than resuscitation

Q	The AED sounds continuously. How can I stop it?	**A**	**When the AED performs a self test and finds a problem, the status indicator becomes red and an alarm sounds. You need to check the AED.** p. 26 "Checking the AED" **If you open and close the lid, the alarm stops. However, the status indicator remains red and the AED becomes unavailable.**
Q	How can I set the internal clock of the AED?	**A**	**You can adjust the AED internal clock using the optional defibrillator report viewer software. Refer to the defibrillator report viewer software operator's manual.**
Q	When I removed the disposable pads and closed the lid, an alarm did not sound. Is the AED is broken?	**A**	**No. The AED performs a self test when its lid is opened and closed. However, in this case, no alarm sounds even if the status indicator becomes red.** **If the disposable pads are not connected when the AED performs a daily self test, an alarm sounds.**
Q	Status indicator was red but there were no voice instructions from the AED when I opened the AED lid. What should I do?	**A**	**The surrounding temperature might be below –5°C (23°F) or over 50°C (122°F) when the daily self test was performed. Do the following procedure.** **1. Put the AED in the place where the temperature is –5 to 50°C (23 to 122°F).** **2. Turn on the AED then turn it off.** **3. Confirm that the status indicator is green.** p. 26 "Daily Check"
Q	Is the monthly inspection necessary?	**A**	**Yes. The AED must always be kept in good condition so that it can be used in an emergency. To ensure that the AED operates correctly, we recommend you to perform the monthly check.** p. 27 to 28 "Monthly Check" and "Monthly Inspection Procedure"
Q	Can I open the lid when I am not using the AED?	**A**	**Yes. You can open the lid for monthly inspection.** p. 28 "Monthly Inspection Procedure"
Q	How can I tell that the remaining battery power is low?	**A**	**Remaining battery power is low when the leftmost battery status indicator is red or the second indicator from the left is green. After you see the first red indicator, you can deliver about nine defibrillation shocks.** p. 27 "About the indicators on the diagnostics panel"
Q	Can I change the volume of the voice instructions?	**A**	**Yes. You can change the volume of the voice instruction using the optional defibrillator report viewer software. Refer to the defibrillator report viewer software operator's manual.**

Reference

Terminology

AED

Automated external defibrillator

CPR

Cardiopulmonary resuscitation.
Refer to “Cardiopulmonary resuscitation”.

Pad

You use pads to deliver a defibrillation shock to patients.
A pad consists of a metal sheet and adhesive containing salt.
You place pads on a patient to induce electric activity of the heart from the body surface.

Defibrillation

Termination of ventricular fibrillation by applying electrical energy.

Heart rhythm

A waveform indicating the electric activity of the heart, which is induced by the pads placed on the patient’s chest. The AED records this waveform.

The shape of the waveform greatly changes due to the condition of the heart. The AED checks and analyzes the heart rhythm to determine whether the patient needs a defibrillation shock.

Cardiopulmonary resuscitation (CPR)

Chest compressions and rescue breathing which are given to a patient who has cardiopulmonary arrest in order to support blood circulation and breathing. If the patient is not responding and not breathing normally, immediately start CPR. It is important to continue CPR without pause as much as possible.

Heart rate

A contraction of the heart that pumps blood to the entire body is called a heartbeat. The heart rate is the number of heartbeats per minute.

Pulse

A pulse occurs when the heart contracts and the vibration of the artery wall goes to the peripheral vessels. Where an artery runs near skin, you can feel the pulse and it is almost identical to the heartbeat. Therefore, if you cannot feel the pulse, it means the heart is not beating.

Symbols

The names and meaning of the symbols on the AED, battery pack and disposable pads are as follows.

AED

Symbol	Description
	Dangerous voltage
 Background color: blue	Follow instructions for use
	Caution
	Defibrillation-proof type BF applied part
IP55	Complies with IEC 60529
	Battery check (Full)
	Battery check (Half)
	Battery check (Zero)
	Pad check indicator
	Service indicator
	Non-ionizing electromagnetic radiation
Bluetooth®	*Bluetooth* wireless communication device
CE 0086	The CE mark is a protected conformity mark of the European Community. Products marked with this symbol comply with the requirements of the Medical Device Directive 93/42/EEC and Radio Equipment Directive 2014/53/EU.
	Products marked with this symbol comply with the European WEEE directive 2012/19/EU and require separate waste collection. For Nihon Kohden products marked with this symbol, contact your Nihon Kohden representative for disposal.

Transport Package

Symbol	Description
	This way up
	Fragile
	Keep away from rain
	Stacking limit by number
CE 0086	The CE mark is a protected conformity mark of the European Community. Products marked with this symbol comply with the requirements of the Medical Device Directive 93/42/EEC and Radio Equipment Directive 2014/53/EU.
	Manufacturer
	Recycle

Reference

Battery pack

Symbol	Description
 Background color: blue	Follow instructions for use
 Circular band and slash: red	Keep away from fire.
 Circular band and slash: red	Keep away from water.
 Circular band and slash: red	Avoid strong impact or dropping.
 Circular band and slash: red	Never disassemble or modify.
 Circular band and slash: red	Do not recharge.
 Circular band and slash: red	Never short circuit the + and − terminals on the battery.
	Products marked with this symbol comply with an environmental protection use period of 5 years according to the SJ/T11364 “Marking for the Restricted Use of Hazardous Substances in Electronic and Electrical Products” of the People’s Republic of China Electronic Industry Standard.
	Manufacturer
EC REP	Authorized representative in a European Community
LOT	Lot number
CE	The CE mark is a protected conformity mark of the European Community. Products marked with this symbol comply with the requirements of the Medical Device Directive 93/42/EEC.
	Products marked with this symbol require separate waste collection according to EU battery directive 2006/66/EC.

Disposable pads

Symbol	Description
 Background color: blue	Follow instructions for use
	Temperature limits
	Expiration date
	Keep away from sunlight
	Do not reuse
LOT	Lot number
CE	The CE mark is a protected conformity mark of the European Community. Products marked with this symbol comply with the requirements of the Medical Device Directive 93/42/EEC.
	Non-sterile

Specifications

Defibrillator

Operation:	Semi-automatic (shock advisory)
Audible alerts:	Voice prompt, charging alert, maintenance alert
Visible indicators:	Status indicator, battery status indicator, service indicator, pads check indicator, pads placement indicator, shock button indicator, child mode indicator
Internal memory:	Maximum 3 records, up to 30 minutes ECG with annotations for one record
Dimensions and weight:	97 (H) × 206 (W) × 252 (D) (mm), 2.3 kg (including disposable pads and battery pack)
Environment	Operating and installation conditions
	Temperature: −5 to +50°C (23 to 122°F)
	Humidity: 5 to 95% (noncondensing)
	Atmospheric pressure: 540 to 1060 hPa
	Shipment, transport and storage conditions
	Temperature: −20 to +70°C (−4 to +158°F)
	Humidity: 5 to 95%
	Atmospheric pressure: 540 to 1060 hPa
	If the AED is stored at the upper limit temperature (70°C (158°F)) or lower limit temperature (−20°C (−4°F)) of the storage conditions and it is moved to an environment of 20°C (68°F), it may take up to 1 hour and 30 minutes before the specified performance is obtained from the AED.
Clock accuracy	At an ambient temperature of 25°C (77°F): ±20 s/month The accuracy may be affected when strong impact is given to the AED, such as dropping the AED, or the AED is placed in a high- or low- temperature environment for a long period of time.
Disposable pads:	IEC60601-2-4: 2010
	Adhesive, disposable pads
Battery pack	Battery type: Manganese dioxide lithium battery
	Rated voltage: 15.0 V
	Rated capacity: 3300 mAh
	Non-rechargeable
	Lithium contents: 6.40 g (max) (When transporting this battery pack by aircraft or ship, it should be treated as class-9 hazardous material.)
	Battery life when the AED is standing by:
	4 years (With the battery pack and disposable pads connected to the AED and the AED lid closed.)
	Install by date:
	2 years from the manufacturing date
	Expiration date: 6 years from the manufacturing date
	Time for ECG monitoring: more than 6 hours (minimum), or 7.5 hours (typical)
	(With the AED lid open, disposable pads attached to a patient, voice instruction operating, no defibrillation performed, with a fully charged new battery pack, at temperature 20°C (68°F).)
	Number of times for charging: more than 160 times (minimum), or 200 times (typical)
	(200J, with a fully charged new battery pack, at temperature 20°C (68°F))

	Charge times:	Up to 8 seconds (With a fully charged new battery pack, at temperature 20°C (68°F) From the start of analyzing to being ready to discharge 200 J energy) Up to 10 seconds (With a battery pack which has discharged energy 15 times, at temperature 20°C (68°F). From the start of analyzing to being ready to discharge 200 J energy) Up to 20 seconds (With a battery pack which has discharged energy 15 times, at temperature 20°C (68°F). From turning the AED power on to being ready to discharge 200 J energy)
Self test	Daily:	Battery, disposable pads, internal electronics, shock button, software
	Monthly:	Battery under load, disposable pads, internal electronics, full-energy charge cycle, shock button, and software
Communication	Communication method:	Bluetooth standard Ver.2.1+EDR
	Carrier frequency:	2.402 to 2.480 GHz
	Maximum RF output power:	4 dBm (Power Class 2)
	Maximum antenna gain:	2.0 dBi
	Communication distance:	10 m at maximum without any obstruction
	Standards:	Radio Act of Japan: 2.4-GHz wideband low-power data communication system EN 60950-1: 2006 EN 60950-1/A11: 2009.3 EN 60950-1/A1: 2010.3 EN 60950-1/A12: 2011.2 EN 60950-1/A2: 2013.8 EN 300 328 V2.1.1: 2016.11 EN 301 489-1 V2.1.1: 2017.2 EN 301 489-17 V3.1.1: 2017.2 EN 62479: 2010.9 FCC Part15
Lifetime	8 years, authenticated by Nihon Kohden, using in-house data	

Safety

Type of protection against electrical shock

INTERNALLY POWERED EQUIPMENT (Battery)

Degree of protection against electrical shock

DEFIBRILLATION-PROOF TYPE BF APPLIED PART: Disposable pads

Protection against harmful ingress of water or particulate matter

IP55

IPx5: When the AED is placed flat on the floor with the lid open and pads attached

IP5x: When the AED is placed flat on the floor with the lid open and pads attached, and when the AED is placed standing up on the floor with the lid closed and pads attached

Endurance (Classification on IEC 60601-2-4: 2010)

FREQUENT USE

Method of disinfecting or sterilization

Equipment not suitable for sterilization

Suitability for use in an OXYGEN RICH ENVIRONMENT

Equipment not suitable for use in an OXYGEN RICH ENVIRONMENT

Degree of safety of application in the presence of a FLAMMABLE ANAESTHETIC MIXTURE WITH AIR, OR WITH OXYGEN OR NITROUS OXIDE

EQUIPMENT not suitable for use in the presence of FLAMMABLE ANAESTHETIC MIXTURE WITH AIR, OR WITH OXYGEN OR NITROUS OXIDE

Mode of operation	CONTINUOUS OPERATION
ME EQUIPMENT type	PORTABLE EQUIPMENT
Safety standard	IEC 60601-1: 2005+Amendment 1: 2012
	IEC 60601-2-4: 2010
	IEC 60601-1-6: 2010+Amendment 1: 2013
	IEC 60601-1-9: 2007+Amendment 1: 2013
	IEC 60601-1-11: 2010
	IEC 60601-1-12: 2014
	IEC 62304: 2006
	ISO 14971: 2007
	EN ISO 14971: 2012
	EN 1789:2007+Amendment 1: 2010
Electromagnetic compatibility (EMC)	
	IEC 60601-1-2: 2007
	IEC 60601-2-4: 2010
Emissions	CISPR 11, Group 1, Class B
Immunity	IEC 61000-4-3: 2006+Amendment 1: 2007+Amendment 2: 2010
	IEC 60601-2-4: 2010 202.6.2.3
Magnetic	IEC 61000-4-8: 2009
	IEC 60601-2-4: 2010 202.6.2.8
	3 A/m (50 Hz, 60 Hz)
ESD	IEC 61000-4-2: 2008
	IEC 60601-2-4: 2010 202.6.2.2
	Contact discharge: 2 kV, 4 kV, 6 kV
	Air gap discharge: 2 kV, 4 kV, 8 kV
Conductive RF	IEC 61000-4-6: 2008
	IEC 60601-2-4: 2010 202.6.2.6

Electromagnetic Emissions/Immunity

The AED-3100's essential performances in EMC standard satisfy the following criteria.

AED-3100 is intended for use in the electromagnetic environment specified below.
The customer or the user of the AED-3100 should assure that it is used in such an environment.

Electromagnetic emissions		
The AED-3100 is intended for use in the electromagnetic environment specified below. The customer or the user of the AED-3100 should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The AED-3100 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The AED-3100 is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

Electromagnetic immunity			
The AED-3100 is intended for use in the electromagnetic environment specified below. The customer or the user of the AED-3100 should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	Not applicable Not applicable*	—
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	Not applicable	—
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% *Ut* (>95 % dip in *Ut*) for 0.5 cycles 40% *Ut* (60% dip in *Ut*) for 5 cycles 70% *Ut* (30% dip in *Ut*) for 25 cycles <5% *Ut* (>95 % dip in *Ut*) for 5 seconds	Not applicable	—
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: *Ut* is the AC mains voltage prior to application of the test level.			
* The instrument does not have a cable more than 3 m long.			

Electromagnetic immunity (1/2)			
The AED-3100 is intended for use in the electromagnetic environment specified below. The customer or the user of the AED-3100 should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	Requirement of IEC-60601-2-4: 3 Vrms 150 kHz to 80 MHz outside ISM bands [a] 10 Vrms 150 kHz to 80 MHz in ISM bands [a]	3 Vrms 10 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the AED-3100, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). [b] Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey [c], should be less than the compliance level in each frequency range. [d] Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2: These guidelines might not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
a: The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz. b: The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in these frequency ranges. c: Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the AED-3100 is used exceeds the applicable RF compliance level above, the AED-3100 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the AED-3100. d: Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

Electromagnetic immunity (2/2)

The AED-3100 is intended for use in the electromagnetic environment specified below. The customer or the user of the AED-3100 should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the AED-3100, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.5 GHz	10 V/m	Recommended separation distance $d = 1.2\sqrt{P}$ 80 to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz
	Requirement of IEC-60601-2-4:		Additional requirement of IEC 60601-2-4
	Correct operation of RRD: 10 V/m 80 MHz to 2.5 GHz	10 V/m	Correct operation of RRD: $d = 1.2\sqrt{P}$ 80 to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz
	No inadvertent energy delivery is allowed: 20 V/m 80 MHz to 2.5 GHz	20 V/m	No inadvertent energy delivery is allowed: $d = 0.6\sqrt{P}$ 80 to 800 MHz $d = 1.2\sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). [b] Field strengths from fixed RF transmitters, as deter mined by an electromagnetic site survey [c], should be less than the compliance level in each frequency range. [d] Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2: These guidelines might not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a: The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz.

b: The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in these frequency ranges.

c: Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the AED-3100 is used exceeds the applicable RF compliance level above, the AED-3100 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the AED-3100.

d: Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

• RRD is the abbreviation of Rhythm Recognition Detector.

Recommended separation distances between portable and mobile RF communications equipment and the AED-3100				
The AED-3100 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the AED-3100 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the AED-3100 as recommended below, according to the maximum output power of the communications equipment.				
Rated maximum output power of transmitter (W)	**Separation distance according to frequency of transmitter (m)**			
	150 kHz to 80 MHz outside ISM bands $d = 1.2\sqrt{P}$	**150 kHz to 80 MHz in ISM bands** $d = 1.2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.2\sqrt{P}$	**800 MHz to 2.5 GHz** $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.12	0.23
0.1	0.38	0.38	0.38	0.73
1	1.2	1.2	1.2	2.3
10	3.8	3.8	3.8	7.3
100	12	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2: The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz. NOTE 3: An additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. NOTE 4: These guidelines might not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.				

System Configuration for EMC Test

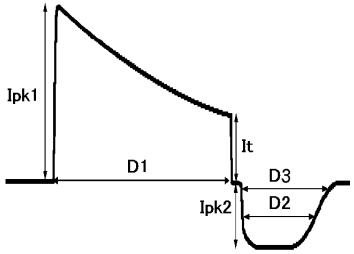
We tested that the AED complies with IEC 60601-1-2: 2007 and IEC 60601-2-4: 2010 with the following configuration. If other cables and equipments are used with the AED, the AED may not comply with these standards.

Configuration at testing	Cable length (m)
Automated external defibrillator, AED-3100	—
Disposable pad, P-740K	1.5 m

Mechanical Strength

Vibration	MIL-STD-810G 514.6 VIBRATION Category 4 (Secured Cargo)
	Exposure duration X: 20h Y: 20h Z: 20h
	MIL-STD-810G 514.6 VIBRATION Category 9 (Helicopter)
	Exposure duration X: 10h Y: 10h Z: 10h
	IEC 60601-1-11: 2010
	IEC 60601-1-12: 2014
	EN1789: 2007 +Amendment 1: 2010
Shock	IEC 60068-2-27: 2008 Shock peak value 50G
	IEC 60601-1-11: 2010
	IEC 60601-1-12: 2014
	EN1789: 2007 +Amendment 1: 2010
Drop	MIL-STD-810G 516.6 SHOCK Procedure IV Transit Drop 1.22 m
	IEC 60601-1-11: 2010
	IEC 60601-1-12: 2014
	EN1789: 2007 +Amendment 1: 2010

Waveform



Delivered energy: 200 J

Load resistance (Ω)	First phase			Duration between the 2 phases (ms)	Second phase		
	Ipk1 (A)	D1 (ms)	It (A)		Ipk2 (A)	D2 (ms)	D3 (ms)
25	58.10	3.85	22.6	≤ 0.5	13.00	3.62	< 6.5
50	35.40	6.36	13.3	≤ 0.5	10.90	3.62	< 6.5
75	25.40	8.86	9.45	≤ 0.5	9.45	3.62	< 6.5
100	19.80	11.40	7.32	≤ 0.5	8.45	3.62	< 6.5
125	16.20	13.90	5.97	≤ 0.5	7.71	3.62	< 6.5
150	13.70	16.40	5.05	≤ 0.5	7.14	3.62	< 6.5
175	11.90	18.90	4.37	≤ 0.5	6.67	3.62	< 6.5

Delivered energy: 150 J

Load resistance (Ω)	First phase			Duration between the 2 phases (ms)	Second phase		
	Ipk1 (A)	D1 (ms)	It (A)		Ipk2 (A)	D2 (ms)	D3 (ms)
25	50.4	3.85	19.6	≤ 0.5	11.3	3.62	< 6.5
50	30.8	6.36	11.5	≤ 0.5	9.42	3.62	< 6.5
75	22.1	8.86	8.19	≤ 0.5	8.19	3.62	< 6.5
100	17.2	11.40	6.34	≤ 0.5	7.32	3.62	< 6.5
125	14.1	13.90	5.18	≤ 0.5	6.69	3.62	< 6.5
150	11.9	16.40	4.37	≤ 0.5	6.18	3.62	< 6.5
175	10.3	18.90	3.79	≤ 0.5	5.78	3.62	< 6.5

Delivered energy: 100 J

Load resistance (Ω)	First phase			Duration between the 2 phases (ms)	Second phase		
	Ipk1 (A)	D1 (ms)	It (A)		Ipk2 (A)	D2 (ms)	D3 (ms)
25	41.3	3.86	16.0	≤ 0.5	9.21	3.62	< 6.5
50	25.1	6.36	9.42	≤ 0.5	7.69	3.62	< 6.5
75	18.0	8.87	6.68	≤ 0.5	6.68	3.62	< 6.5
100	14.0	11.4	5.18	≤ 0.5	5.98	3.62	< 6.5
125	11.5	13.9	4.22	≤ 0.5	5.45	3.62	< 6.5
150	9.75	16.4	3.57	≤ 0.5	5.05	3.62	< 6.5
175	8.45	18.9	3.09	≤ 0.5	4.72	3.62	< 6.5

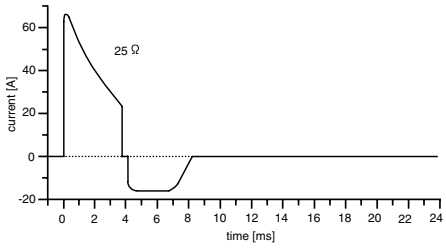
Delivered energy: 70 J

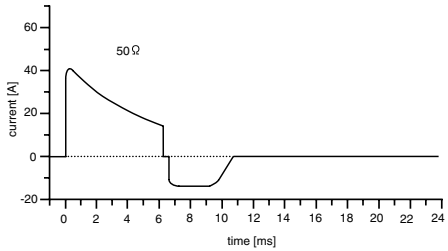
Load resistance (Ω)	First phase			Duration between the 2 phases (ms)	Second phase		
	Ipk1 (A)	D1 (ms)	It (A)		Ipk2 (A)	D2 (ms)	D3 (ms)
25	34.6	3.86	13.4	≤ 0.5	7.71	3.62	< 6.5
50	21.1	6.36	7.88	≤ 0.5	6.44	3.62	< 6.5
75	15.2	8.87	5.59	≤ 0.5	5.59	3.62	< 6.5
100	11.8	11.4	4.33	≤ 0.5	5.00	3.62	< 6.5
125	9.66	13.9	3.54	≤ 0.5	4.57	3.62	< 6.5
150	8.18	16.4	2.99	≤ 0.5	4.22	3.62	< 6.5
175	7.09	18.9	2.58	≤ 0.5	3.95	3.62	< 6.5

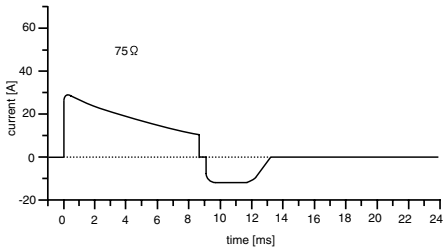
Delivered energy: 50 J

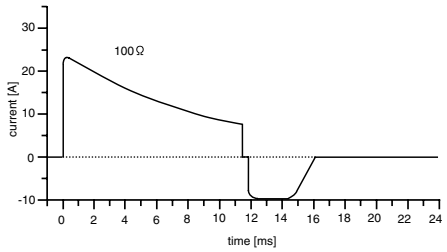
Load resistance (Ω)	First phase			Duration between the 2 phases (ms)	Second phase		
	Ipk1 (A)	D1 (ms)	It (A)		Ipk2 (A)	D2 (ms)	D3 (ms)
25	29.4	3.86	11.3	≤ 0.5	6.52	3.62	< 6.5
50	17.9	6.37	6.67	≤ 0.5	5.45	3.62	< 6.5
75	12.9	8.88	4.73	≤ 0.5	4.73	3.62	< 6.5
100	10.0	11.4	3.66	≤ 0.5	4.23	3.62	< 6.5
125	8.20	13.9	2.99	≤ 0.5	3.86	3.62	< 6.5
150	6.95	16.4	2.53	≤ 0.5	3.57	3.62	< 6.5
175	6.02	18.9	2.19	≤ 0.5	3.34	3.62	< 6.5

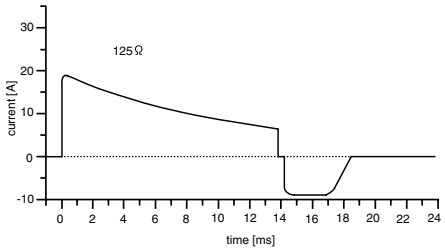
Output Waveforms: 200 J/25, 50, 75, 100, 125, 150, 175 Ω

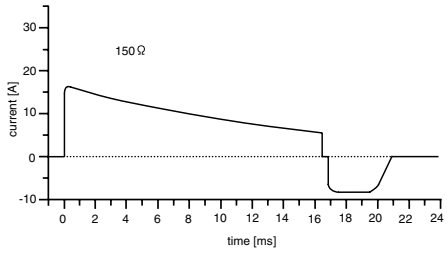


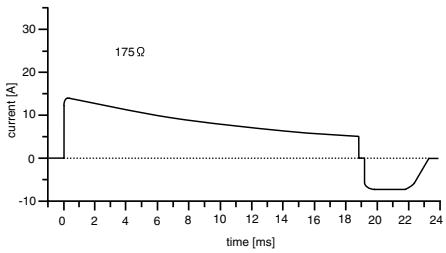












Discharged energy (these settings can be changed with the optional defibrillator report viewer software)
Adult mode: first time 150 J, second time 200 J, third time 200 J
Child mode: first time 50 J, second time 70 J, third time 70 J
Energy accuracy: ±10% (at 50 Ω impedance)

Reference

Member States This Equipment is Intended for Use In

cs Česky [Czech]	Tímto NIHON KOHDEN prohlašuje, že AED-3100 je v souladu se směrnicí 2014/53/EU. Úplné znění EU prohlášení o shodě je k dispozici na této internetové adrese: https://www.nihonkohden.com/
da Dansk [Danish]	Hermed erklærer NIHON KOHDEN, at AED-3100 er i overensstemmelse med direktiv 2014/53/EU. EU-overensstemmelseserklæringens fulde tekst kan findes på følgende internetadresse: https://www.nihonkohden.com/
de Deutsch [German]	Hiermit erklärt NIHON KOHDEN, dass der AED-3100 der Richtlinie 2014/53/EU entspricht. Der vollständige Text der EU-Konformitätserklärung ist unter der folgenden Internetadresse verfügbar: https://www.nihonkohden.com/
et Eesti [Estonian]	Käesolevaga deklareerib NIHON KOHDEN, et AED-3100 vastab direktiivi 2014/53/EL nõuetele. ELi vastavusdeklaratsiooni täielik tekst on kättesaadav järgmisel internetiaadressil: https://www.nihonkohden.com/
en English	Hereby, NIHON KOHDEN declares that the AED-3100 is in compliance with Directive 2014/53/EU. The full text of the EU declaration of conformity is available at the following internet address: https://www.nihonkohden.com/
es Español [Spanish]	Por la presente, NIHON KOHDEN declara que el AED-3100 es conforme con la Directiva 2014/53/UE. El texto completo de la declaración UE de conformidad está disponible en la dirección Internet siguiente: https://www.nihonkohden.com/
el Ελληνική [Greek]	Με την παρούσα ο/η NIHON KOHDEN, δηλώνει ότι ο AED-3100 πληροί την οδηγία 2014/53/ΕΕ. Το πλήρες κείμενο της δήλωσης συμμόρφωσης ΕΕ διατίθεται στην ακόλουθη ιστοσελίδα στο διαδίκτυο: https://www.nihonkohden.com/
fr Français [French]	Le soussigné, NIHON KOHDEN, déclare que le AED-3100 est conforme à la directive 2014/53/UE. Le texte complet de la déclaration UE de conformité est disponible à l'adresse internet suivante: https://www.nihonkohden.com/
it Italiano [Italian]	Il fabbricante, NIHON KOHDEN, dichiara che il AED-3100 è conforme alla direttiva 2014/53/UE. Il testo completo della dichiarazione di conformità UE è disponibile al seguente indirizzo Internet: https://www.nihonkohden.com/
lv Latviski [Latvian]	Ar šo NIHON KOHDEN deklarē, ka AED-3100 atbilst Direktīvai 2014/53/ES. Pilns ES atbilstības deklarācijas teksts ir pieejams šādā interneta vietnē: https://www.nihonkohden.com/
lt Lietuvių [Lithuanian]	Aš, NIHON KOHDEN, patvirtinu, kad AED-3100 atitinka Direktyvą 2014/53/ES. Visas ES atitikties deklaracijos tekstas prieinamas šiuo interneto adresu: https://www.nihonkohden.com/
nl Nederlands [Dutch]	Hierbij verklaar ik, NIHON KOHDEN, dat het AED-3100 conform is met Richtlijn 2014/53/EU. De volledige tekst van de EU-conformiteitsverklaring kan worden geraadpleegd op het volgende internetadres: https://www.nihonkohden.com/
mt Malti [Maltese]	B'dan, NIHON KOHDEN, niddikjara li dan it-tip ta' tagħmir tar-radju AED-3100 huwa konformi mad-Direttiva 2014/53/UE. It-test kollu tad-dikjarazzjoni ta' konformità tal-UE huwa disponibbli f'dan l-indirizz tal-Internet li ġej: https://www.nihonkohden.com/
hu Magyar [Hungarian]	NIHON KOHDEN igazolja, hogy a AED-3100 megfelel a 2014/53/EU irányelvnek. Az EU-megfelelőségi nyilatkozat teljes szövege elérhető a következő internetes címen: https://www.nihonkohden.com/
pl Polski [Polish]	NIHON KOHDEN niniejszym oświadcza, że typ urządzenia radiowego AED-3100 jest zgodny z dyrektywą 2014/53/UE. Pełny tekst deklaracji zgodności UE jest dostępny pod następującym adresem internetowym: https://www.nihonkohden.com/

pt Português [Portuguese]	O(a) abaixo assinado(a) NIHON KOHDEN declara que o presente AED-3100 está em conformidade com a Diretiva 2014/53/UE. O texto integral da declaração de conformidade está disponível no seguinte endereço de Internet: https://www.nihonkohden.com/
sl Slovensko [Slovenian]	NIHON KOHDEN potrjuje, da je AED-3100 skladen z Direktivo 2014/53/EU. Celotno besedilo izjave EU o skladnosti je na voljo na naslednjem spletnem naslovu: https://www.nihonkohden.com/
sk Slovenský [Slovak]	NIHON KOHDEN týmto vyhlasuje, že AED-3100 je v súlade so smernicou 2014/53/EÚ. Úplné EÚ vyhlásenie o zhode je k dispozícii na tejto internetovej adrese: https://www.nihonkohden.com/
fi Suomi [Finnish]	NIHON KOHDEN vakuuttaa, että AED-3100 on direktiivin 2014/53/EU mukainen. EU-vaatimustenmukaisuusvakuutuksen täysimittainen teksti on saatavilla seuraavassa internetosoitteessa: https://www.nihonkohden.com/
sv Svenska [Swedish]	Härmed försäkrar NIHON KOHDEN att denna typ av radioutrustning AED-3100 överensstämmer med direktiv 2014/53/EU. Den fullständiga texten till EU-försäkran om överensstämmelse finns på följande webbadress: https://www.nihonkohden.com/
is Íslenska [Icelandic]	Hér með lýsir NIHON KOHDEN því yfir að AED-3100 er í samræmi við tilskipun 2014/53/EU. Heildartexti EB-samræmisyfirlýsingarinnar er fáanlegur á eftirfarandi veffangi: https://www.nihonkohden.com/
no Norsk [Norwegian]	NIKON KOHDEN erklærer herved at AED-3100 er i samsvar med direktiv 2014/53/EU. Hele samsvarserklæringsteksten er tilgjengelig på følgende Internett-adresse: https://www.nihonkohden.com/
bg български език [Bulgarian]	С настоящото NIHON KOHDEN декларира, че този AED-3100 е в съответствие с Директива 2014/53/ЕС. Цялостният текст на ЕС декларацията за съответствие може да се намери на следния интернет адрес: https://www.nihonkohden.com/
ro Română [Romanian]	Prin prezenta, NIHON KOHDEN declară că AED-3100 este în conformitate cu Directiva 2014/53/UE. Textul integral al declarației UE de conformitate este disponibil la următoarea adresă internet: https://www.nihonkohden.com/
hr Hrvatski [Croatian]	NIHON KOHDEN ovime izjavljuje da je AED-3100 u skladu s Direktivom 2014/53/EU. Cjeloviti tekst EU izjave o sukladnosti dostupan je na sljedećoj internetskoj adresi: https://www.nihonkohden.com/

Specifications (continued from previous page)

Analysis Accuracy

Heart rhythm class	Specifications
Shockable rhythm – VF	The AED-3100 satisfies the requirements of IEC60601-2-4: 2010 (sensitivity > 90%).
Shockable rhythm – VT	The AED-3100 satisfies the requirements of IEC60601-2-4: 2010 (sensitivity > 75%).
Non-shockable rhythm	The AED-3100 satisfies the requirements of IEC60601-2-4: 2010 (specificity > 95%).

Validation was performed using data from the AHA (American Heart Association) official database, the MIT (Massachusetts Institute Technology) official database, and medical facilities in Japan.

The above analysis accuracy is ensured when the ECG contains a pacemaker pulse with amplitude less than 2 mV and width less than 1.3 ms.

ECG Analysis and Defibrillation Shock

Cases in which the AED judges that defibrillation is necessary

- Ventricular fibrillation in which the average amplitude exceeds 0.1 mV
- Ventricular tachycardia in which the heart rhythm (heart rate) exceeds 180 bpm

NOTE: The AED might judge that defibrillation shock is not necessary if a waveform such as QRS is mixed with VF, or if the QRS is sharp although the heart rhythm is VT.

Cases in which the AED judges that defibrillation is not necessary

The AED judges that defibrillation is not necessary for asystole, normal sinus rhythm and heart rhythm that does not meet the above criteria for VF and VT.

NOTE: For an asystole patient, the AED might judge that defibrillation is necessary if the ECG contains noise which is similar to VF, such as noise from static electricity or CPR.

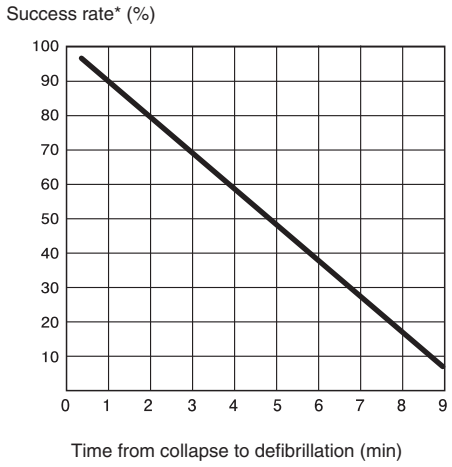
Continued Analysis after the AED Judges that Defibrillation is Necessary

The AED continues to analyze the heart rhythm after it determines that defibrillation is required. If the heart rhythm changes and the AED determines that defibrillation is no longer required, the shock button stops flashing and defibrillation shock is disabled.

Timely Defibrillation Shock and Survival Rate

As the graph shows, the probability of successful rescue decreases 7 to 10% each minute. If defibrillation is performed within 1 minute after heart attack occurs, 90% of the patients survive. The probability of survival decreases to 50% after 5 minutes, 30% after 7 minutes, 10% after 9 to 10 minutes, and 2 to 5% after 12 or more minutes.
(Guideline of the American Heart Association: 2000)

* Success rate: probability of survival to hospital discharge



Reference

Consumables and Options

For additional supplies, contact your Nihon Kohden representative.

[ ]: Model

Consumables

Battery Pack
[SB-310V]

Disposable Pads
[P-740K]

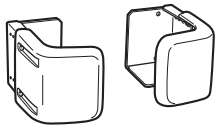
Option

AED Box
[YZ-042H8]

Defibrillator Report Viewer Software
[QP-551VK]

Carrying Bag
[YC-310V]

AED Wall Mount Kit
[KG-202V]



AED/CPR Rescue Kit
[YZ-043H3]

Inspection List

AED-3100

Daily inspection

Note: Copy this sheet for use.

Check that the status indicator is green.

Check the box for the displayed color.	Green ☑ Red ☐	Date (year and month): /

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
Green ☐ Red ☐	Green ☐ Red ☐	Green ☐ Red ☐	Green ☐ Red ☐	Green ☐ Red ☐	Green ☐ Red ☐	Green ☐ Red ☐
Green ☐ Red ☐	Green ☐ Red ☐	Green ☐ Red ☐	Green ☐ Red ☐	Green ☐ Red ☐	Green ☐ Red ☐	Green ☐ Red ☐
Green ☐ Red ☐	Green ☐ Red ☐	Green ☐ Red ☐	Green ☐ Red ☐	Green ☐ Red ☐	Green ☐ Red ☐	Green ☐ Red ☐
Green ☐ Red ☐	Green ☐ Red ☐	Green ☐ Red ☐	Green ☐ Red ☐	Green ☐ Red ☐	Green ☐ Red ☐	Green ☐ Red ☐
Green ☐ Red ☐	Green ☐ Red ☐	Green ☐ Red ☐	Green ☐ Red ☐	Green ☐ Red ☐	Green ☐ Red ☐	Green ☐ Red ☐

Monthly inspection

Previous inspection (month/day/year): / /

Next inspection (month/day/year): / /

Indicators, speaker, switch and buttons

☐ All LEDs light when you turn the AED on
☐ Status indicator changes from red to green
☐ Battery status indicators check
  ☐ No. of green indicators:__ ☐ Red indicator
☐ "Pip" sounds when you press the shock button
☐ Adult/child mode switch check

Disposable pads (replaced periodically)

☐ Disposable pads are connected

Expiration date (month/year): /

☐ Spare disposable pads ready

Expiration date (month/year): /

Battery pack (replaced periodically)

☐ Battery pack installed

Battery life (4 years):

Expiration date (month/year): /

Deadline for starting usage (month/year): /

Other inspection

Appearance

☐ No cracks, chips, loose parts

Last inspection date (month/day/year): / /

Next inspection date (month/day/year): / /

Option

☐ Necessary options are ready

Last inspection date (month/day/year): / /

Next inspection date (month/day/year): / /

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Contact information is accurate as of April 2018. Visit https://www.nihonkohden.com/ for the latest information.

The model and serial number of your device are identified on the rear or bottom of the unit.
Write the model and serial number in the spaces provided below. Whenever you call your representative concerning this device, mention these two pieces of information for quick and accurate service.

Model _____ Serial Number _____

Your Representative

AED-3100_0614-907464D