Technical Data

cardiolife

AED-3100

Automated External Defibrillator

Fighting Disease with Electronics

NIHON KOHDEN

TD. AED3100

SPECIFICATIONS

♦ Defibrillator

Waveform: Truncated exponential constant

power biphasic (Actibiphasic)

Output energy range: 50, 70,100,150,200J

(at 50 ohm)

Output energy sequence: 150J-200J-200J for adult mode 50J-70J-70J for child mode

Charging time to 200J from starting

analysis: less than 8 seconds (when using

new battery)

Charging time to 200J from end of CPR: less than 8 seconds (when using new battery) Automatic internal discharge: The charged energy is internally discharged in the following conditions;

-30 seconds passes after the SHOCK **BUTTON** starts blinking

- -A pad is disconnected from the AED or patient
- -The power is turned off
- -Non-shockable waveform appears

-Battery is removed

Impedance range: 15 to 175 ohm (for biphasic waveform)

Battery pack (SB-310V)

Output voltage: 15.0V Non-rechargeable

Operation life (standby): 4 years

Shelf life (storage out of devices): 6 years from

manufacturing date

Capacity:

With new battery at 20 °C ambient temperature; Time for monitoring: more than 6 hours (minimum), or 7.5 hours (typical)

Number of times for charging: more than 160 times (minimum), or 200 times (typical)

Self-test

Daily test: Battery (remaining amount, voltage, expiration date, type, memory) Pads (expiration date, type, connection to main unit, short circuit, cable disconnection), Temperature, Internal electronics, Shock button, Consumption current, Date and Software

Monthly test: High voltage capacitor checks by maximum energy charging and disarm, Speaker (cable disconnection), ECG circuit, Pad contact circuit, Status indicator, Buzzer and Daily test items

When the power is turned on : LED, History of self-test, Buzzer and Daily test items (except for Consumption current)

When the power is off: Battery (remaining amount, voltage) and Pads (expiration date, type, connection to main unit), History of self-test, Temperature, Date and Software

When the battery is set: High voltage capacitor checks by low energy charging and disarm, Buzzer, Daily test items

If abnormality is detected in self-test, status

indicator turns red with alarm.

Arrhythmia Analysis

Accuracy: IEC60601-2-4 2010 more than 90 % for VF (sensitivity) more than 75 % for VT (sensitivity)

more than 95 % for non-shockable waveform (specificity)

Analysis time:

4.5 seconds for shockable waveform 7.5 seconds for non-shockable waveform Under Continuous VF analysis 1.5 seconds for shockable waveform 4.5 seconds for non-shockable waveform

Data Storage

Total storage: 90 minutes

Up to 3 cases of rescue data (max. 30 minutes/data)

Indicators

Status indicator: Green (OK) or Red (Needs

check)

Shock button: Flashes when shock is available Pads placement indicator: Blinks when pads

are not attached on patient Pads check indicator:

Lights in following cases: when pads are not connected AED, when the term of pads expires,

when pads are not for AED-3100

Battery remaining lamp: 100 %: 4 green lamps light 75 %: 3 green lamps light 50 %: 2 green lamps light 25 %: 1 green lamp lights

0 %: red lamp lights

Child mode lamp: Lights when the adult/child

mode switch is set to child mode

Service indicator: Lights when AED is faulty

Dimensions and Weight

Dimensions: 97 H x 206 W x 252D (mm) Weiaht:

2.3 kg (including battery and pads)

Communication

Interface: Bluetooth (Ver. 2.1 + EDR) Carrier frequency: 2.402 to 2.480 GHz Maximum RF output power: 4dBm (Power

Class 2)

Communication distance: 10m at maximum without any obstruction

It is necessary to be registered by the Radio law to use Bluetooth in each country.

Standards:

-Radio Act of Japan: 2.4-GHz wideband low-power data communication system

-EN 301 489-1 V2.2.3: 2019.11 -EN 301 489-17 V3.1.1: 2017.2

-EN 300 328 V2.2.2: 2019.7

-EN 62479: 2010.9

-FCC Part15

Data transferred from an AED to a PC:

- -Device information (model name, serial number, version etc.)
- -Rescue data (ECG waveform and event etc.)

- -Self-test history
- -Battery information (model name, serial number, version, Number of charges completed, Time of operation, Days of standby operation, remaining battery capacity)
- -Operation history

Data transferred from a PC to an AED:

- -Time of day
- -Setting information
- -Version up program

Lifetime

8 years, authenticated by Nihon Kohden, using in-house data

♦ Environment

Operating and installation conditions (battery is installed and power off):

Temperature; -5 to +50 °C

Humidity; 5 to 95 % (Relative humidity,

non-condensing)

Atmospheric pressure; 540 hPa to 1060 hPa **Shipment, transport and storage conditions:**

Temperature; - 20 to +70 °C

Humidity; 5 to 95 % (Relative humidity) Atmospheric pressure; 540 hPa to 1060 hPa

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:

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 **Load** (withstand load closing the lid of the

device bottom down): 300 kg

♦ 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

Ingress protection: IP66 (Complies with

IEC60529)

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 a 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

IEC62366:2007 +Amendment 1:2014

ISO 14971: 2007 EN ISO 14971: 2012

EN 1789: 2007 + Amendment 1: 2010 Electromagnetic compatibility (EMC):

IEC 60601-1-2: 2014 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 (50Hz, 60Hz)

ESD:

IEC 61000-4-2: 2008

IEC 60601-2-4: 2010 202.6.2.2 Contact discharge: 2kV, 4kV, 6kV Air gap discharge: 2kV, 4kV, 8kV

Conductive RF: IEC 61000-4-6: 2013

IEC 60601-2-4: 2010 202.6.2.6

OPTIONAL ACCESSORIES

For AED

Non-rechargeable battery, SB-310V Defibrillation pads for adult/child, P-740K Defibrillator Report Viewer Software, QP-551VK Carrying bag, YC-310V AED Box, YZ-042H8 AED wall mount kit, KG-202V AED/CPR rescue kit, YZ-043H3

For Training

Training unit, TRN-3100K
Training unit remote controller, RY-310V
Training pads for adult/child, YZ-061H6
Y262B Spare stickers for training pad



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