CE

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- **the electrical installation of the relevant room complies with the applicable national and local requirements; and**
- **the product is used in accordance with the instructions for use.**

WARNING

□ This equipment must be operated by persons who have been trained in its operation. The operator should be trained in basic life support, advanced cardiac life support or other emergency medical response.

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- **Malfunction or damage caused by improper operation or repair by unqualified or unauthorized service people.**
- **Malfunction of the instrument or part whose serial number is not legible enough.**
- **Others not caused by instrument or part itself.**

Company Contact

Preface

Manual Purpose

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

This manual is based on the maximum configuration and therefore some contents may not apply to your product. If you have any question, please contact us.

Intended Audience

This manual is intended for persons who have been trained in equipment's operation. The operator should be

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1 Safety

1.1 Safety Information

DANGER

€ **Indicates an imminent hazard that, if not avoided, will result in death or serious injury.**

WARNING

€ **Indicates a potential hazard or unsafe practice that, if not avoided, could result in death or serious injury.**

CAUTION

€ **Indicates a potential hazard or unsafe practice that, if not avoided, could result in minor personal injury or product/property damage.**

NOTE

€ **Provides application tips or other useful information to ensure that you get the most from your product.**

1.1.1 Dangers

DANGER

€ **The equipment delivers up to 360 J of electrical energy. Unless properly used by following the prompts provided by the equipment, this electrical energy may cause serious injury or death. Do not attempt to operate this equipment unless thoroughly familiar with the operations and functions of all controls, indicators, connectors, and accessories.**

€ **To avoid explosion hazard, do not use the equipment in the presence of oxygen-rich atmospheres, flammable anesthetics, or other flammable agents (such as gasoline). Keep the equipment and the operating environment dry and clean.**

€ **Defibrillation current can cause operator or bystander severe injury or even death. Keep distance with the patient or metal devices connected to the patient during defibrillation.**

1.1.2 Warnings

WARNING

€ **Check for mechanical damages before each use. If case of any damage, do not apply it to patients.**

€ **Before putting the system into operation, the operator must verify that the equipment, connecting cables and accessories are in correct working order and operating condition.**

€ **The equipment is not intended to be used within the Magnetic Resonance (MR) environment.**

€ **Do not open the equipment housings. All servicing and future upgrades must be carried out by the service personnel.**

€ **This equipment is used for single patient at a time.**

€ **Medical electrical equipment which does not incorporate defibrillator protection should be disconnected during defibrillation.**

- € **Do not defibrillate a patient who lies on wet ground.**
- € **For the treatment of patients with implantable pacemakers, place the electrode pads away from internal pacemaker generator if possible to help prevent damage to the pacemaker.**
- € **To avoid inadvertent disconnection, route all cables in a way to prevent a stumbling hazard. Wrap and secure excess cabling to reduce risk of entanglement or strangulation by patients or personnel.**
- € **Do not touch device connectors or other live equipment if in contact with the patient; otherwise patient injury may result.**
- € **Do not touch the patient and live parts simultaneously. Otherwise patient injury may result.**
- € **Package material may contaminate the environment. Properly dispose of the package material according to applicable waste control regulations and keep it out of children's reach.**
- € **Keep a distance of at least 20cm away from the equipment when the wireless function is in use.**

1.1.3 Cautions

CAUTION

- € **At the end of its service life, the equipment, as well as its accessories, must be disposed of in compliance with the guidelines regulating the disposal of such products to avoid contaminating the environment.**
- € **Magnetic and electrical fields are capable of interfering with the proper performance of the equipment. For this reason make sure that all external devices operated in the vicinity of the equipment comply with the relevant EMC requirements. Mobile phones, X-ray equipment or MRI devices are a possible source of interference as they may emit higher levels of electromagnetic radiation.**
- € **Always install or carry the equipment properly to avoid damage caused by drop, impact, strong vibration or other mechanical force.**
- € **Dry the equipment immediately in case of rain.**

1.1.4 Notes

NOTE

- € **Put the equipment in a location where you can easily view and operate the equipment.**
- € **During normal use, the operator shall stand in a location where the equipment can be easily viewed and operated.**
- € **If the equipment has been dropped or mishandled, perform a user test. If any item fails, contact the authorized service personnel.**

2 Equipment Introduction

2.1 Intended Use

2.1.1 Intended Purpose Statement

The equipment is intended for semi-automated external defibrillation and automated external defibrillation.

2.1.2 Indication for Use

The equipment is intended for patients with ventricular fibrillation, pulseless ventricular tachycardia and ventricular flutter.

2.1.3 Intended Users

The operator should be trained in basic life support or other emergency medical response.

2.1.4 Intended Patient Population

The equipment is intended to be used on adults and pediatric patients in a sudden cardiac arrest. The patients must be:

- **Unresponsive**
- **Not breathing or not breathing normally**

2.1.5 Intended Medical Conditions

The equipment is to be used in public places and facilities by persons who have been trained in its operation.

2.1.6 Contra-indications

The equipment is contraindicated in the treatment when the patient is showing any of the following:

- **Consciousness**
- **Breathing**
- **Detectable pulse or other signs of circulation**

2.1.7 Side-effects

Side-effects

Through clinical data from literature and clinical data from post-market surveillance activity of subject device, there is no side-effects identified.

After search the literature of similar device, the results of SOTA evaluation shown that undesirable effects may include myocardial damage.

2.2 Applied Parts

The applied parts of the equipment are:

- Electrode pads
- CPR sensor (if configured)

3 Getting Started

3.1 Preparation Safety Information

WARNING

- **The equipment shall be installed by personnel authorized by the manufacturer.**
- **The software copyright of the equipment is solely owned by the manufacturer. No organization or individual shall resort to altering, copying, or exchanging it or to any other infringement on it in any form or by any means without due permission.**
- **Devices connected to the equipment must meet the requirements of the applicable IEC standards (e.g. IEC 60950 safety standards for information technology equipment and IEC 60601-1 safety standards for medical electrical equipment). The system configuration must meet the requirements of the IEC 60601-1 medical electrical systems standard. Any personnel who connect devices to the equipment's signal input/output port is responsible for providing evidence that the safety certification of the devices has been performed in accordance to the IEC 60601-1. If you have any question, please contact the manufacturer.**
- **If it is not evident from the equipment specifications whether a particular combination is hazardous, for example, due to summation of leakage currents, consult the manufacturers or else an expert in the field, to ensure the necessary safety of all devices concerned will not be impaired by the proposed combination.**

CAUTION

- **Make sure that the operating environment of the equipment meets the specific requirements. Otherwise unexpected consequences, e.g. damage to the equipment, could result.**
- **The equipment might be contaminated during storage and transport. Before use, please verify whether the packages are intact, especially the packages of single use accessories. In case of any damage, do not apply it to patients.**

NOTE

- **Save the packing case and packaging material as they can be used if the equipment must be reshipped.**

3.2 Equipment Installation

WARNING

- **Keep the pads cable connected to the equipment at all times.**
- **Do not open sealed pads until immediately prior to use.**
- **Do not bend the electrode pads forcefully.**
- **Make sure the pads package is intact before use. Otherwise, replace it with a new one.**

3.3 Turning off the Equipment

WARNING

- **If the patient is not connected to the equipment, and no operation is found performed on the equipment within 30 minutes, the equipment will automatically shut down.**

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4 Using the Equipment

4.1 Operating Safety Information

DANGER

€ **Avoid contact between parts of the patient's body such as exposed skin of head or limbs, conductive fluids such as gel, blood, or saline, and metal objects such as a bed frame or a stretcher which may provide unwanted pathways for the defibrillating current.**

WARNING

€ **The equipment automatically removes the stored energy internally in following conditions.**

- Â **A rhythm change is detected and a shock is no longer appropriate.**
- Â **Electrode pads malfunction is detected.**
- Â **The Shock button is not pressed within the configured time on the semi-automatic models.**

€ **Performing CPR or otherwise handling or moving the patient during rhythm analysis can cause incorrect or delayed analysis.**

€ **For safety reasons, some low-amplitude or low-frequency heart rhythms as well as some VT rhythms may not be interpreted as shockable rhythms.**

€ **During defibrillation, air pockets between the skin and the electrode pads can cause patient skin burns. To help prevent air pockets, make sure the electrode pads are completely adhered to the skin.**

€ **During defibrillation, never press the Adult/Child mode switch to the Adult mode when using pediatric pads for children. Otherwise the electrode pads might be damaged and could result in delayed analysis.**

€ **Do not use dried-out electrode pads.**

CAUTION

€ **Prevent the electrode pads from contamination by dust or water before they are attached to the patient. Otherwise, incorrect or delayed analysis may result.**

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