# NRG-HeaRT (NRG-H)

## Device for shock wave therapy

# 1 Safety and Performance NRG-H

## 1.1 General description of the product

The NRG-H is an accessory for shock wave applicators approved by the manufacturer. It serves as a power supply as well as an operating unit for the control and monitoring of a shock wave applicator approved by the manufacturer.

The NRG-H is a tabletop device and is operated via a touch screen. All necessary settings, such as the number of shock wave pulses to be emitted and the pulse emission frequency, can be made on the device. The shock waves are triggered via a foot switch. The NRG-H device can deliver a high voltage of up to 25000 volts. This high voltage is generated by an internal charging circuit and a capacitor block. High voltage generation is only possible with a shock wave applicator plugged in.

The NRG-H device is located in the non-sterile area of the operating room and is operated by a non-sterile member of the surgical team. The NRG-H does not come into contact with the patient. The operator adjusts the NRG-H device and does not necessarily have surgical gloves on. The contact time of the operator and NRG-H device is less than 1 minute in intended use.

**Gebot!**
*Only shock wave applicators approved by the manufacturer may be plugged into the NRG-H device. The approved shock wave applicators are listed in chapter 0. In the course of this instructions for use, the term "shock wave applicators" refers to shock wave applicators approved by the manufacturer.*

## 1.2 List of approved shock wave applicators

- Cardiac Shockwave Probe 0200 (CSP0200) – Type CF

## 1.3 Intended purpose

The NRG-H device is used to provide high voltage, is control and trigger unit for electrohydraulic shock wave applicators.

The NRG-H is intended to be used together with a shock wave applicator approved by the manufacturer and is intended solely to enable its use in accordance with its intended purpose.

## 1.4 Indications

The NRG-H device is an accessory for a medical device and therefore has no independent indications of its own.
The indications can be found in the instructions for use of the inserted shock wave applicator.

**Gebot!**
*Shock waves do not replace the medically recognized standard procedures. It must be ensured that shock wave treatment is only used as an additional therapeutic procedure during surgery, supplementing the conventional, recognized standard procedures.*

## 1.5 Contraindications and exclusions

The NRG-H device is an accessory for a medical device and therefore has no contra-indications of its own.
The contra-indications can be found in the instructions for use of the inserted shock wave applicator.

## 1.6 Characterization of the Patients

The NRG-H device is an accessory of a medical device and therefore does not have a patient characterization. In addition, the NRG-H device has neither direct nor indirect contact to the patient.
The characterization of the patients can be taken from the instructions for use of the inserted shock wave applicator.

### 1.6.1 Vulnerable Population

As the NRG-H device has no patient characterization, please refer to the instructions for use of the plugged in shock wave applicator for information on the vulnerable patient population.

## 1.7 Performance characteristics

The performance characteristics of the device include serving as a power supply as well as an operating unit for approved shock wave applicators by the manufacturer.
Shock waves must be triggered by a deliberate action of the operator and the device has internal functions that prevent the uncontrolled triggering of shock waves and monitor the high voltage required for shock wave generation.

## 1.8 Safety instructions

You may only operate this device in accordance with the descriptions in this instructions for use and only use it for the purpose as specified in the intended use. This device may only be operated and used by persons who have the required medical expertise. Such persons are considered to be trained specialists to surgeons as well as clinic and practice personnel who have completed specialized training in the field of human medicine and medical training as operating room personnel.

**Mandatory action!**
*Before using the NRG-H device, the user must be initially instructed and trained by the manufacturer or already trained personnel.*

*Follow the instructions for use!*

This symbol is attached on the NRG-H device, it means that following the instructions for use is a mandatory action.
The operator of the device is responsible for compliance with local regulations of authorities and institutions that apply to the installation and operation of electrical medical equipment.

## 1.9 Warnings and precautions for safe use

### 1.9.1 General safety instructions

The safe operation of the device is only guaranteed if the following points are observed:

**Mandatory action!**
*In general, use only original accessories as specified or supplied by Avenns Medical GmbH*

**Prohibition!**
*In general, any modification of the device is not permitted unless described in this instructions for use.*

**Prohibition!**
*You must not use the device if it has electrical or mechanical defects. This also applies if error messages are displayed.*

**Mandatory action!**
*The device can be disconnected from the power supply by pulling out the power supply cord and is thus immediately safely out of operation. For this purpose, the device must be set up in such a way that the power supply cord is freely accessible.*

Additionally, the following points must be observed:

- The device requires regular inspections as well as professional service and maintenance
- If the operator uses the device in the wrong way or if the prescribed inspections and correct maintenance are not carried out, Avenns Medical GmbH cannot be held responsible for any resulting faults, damage or injuries.

### 1.9.2 Electrical Safety

This device has been tested according to harmonized standards for medical devices and may only be operated in medical rooms that comply with the local regulations of the respective country.

**Mandatory action!**
*Any housing parts of the NRG-H device and all accessories may only be removed by the manufacturer.*

**Mandatory action!**
*To avoid the risk of electric shock, this device must be connected to a power supply with a protective earth conductor.*

### 1.9.3 Elektromagnetic Compatibility (EMC)

Generally, the device is intended for use in professional healthcare facilities.

**Warning!**
*Electromagnetic interactions!*
*During therapy operation, the device emits increased electromagnetic interference radiation. Patients who wear a pacemaker or implantable cardioverter-defibrillator (ICD) must have this device checked after treatment.*

**Warning!**
*Electromagnetic interactions!*
*Use of the NRG-H device immediately adjacent to other devices or with other devices in a stacked configuration should be avoided, as this could result in improper operation. If it is necessary to use the NRG-H described in this manner, the NRG-H and other equipment should be observed to ensure that they are operating properly.*

**Prohibition!**
*Do not use high-frequency surgical equipment at the same time!*
*During shock wave application with the applicator, do not operate with any HF surgical devices such as electrocautery or electroscalpel. This could lead to interference with the NRG-H device.*

**Warning!**
*Use of accessories!*
*The use of accessories, transducers, and wiring other than those specified or provided by the manufacturer may result in increased electromagnetic emissions or decreased electromagnetic immunity of the device and may result in improper operation.*

**Warning!**
*Interference!*
*Portable RF communications equipment (radios, including their accessories such as antenna cables and external antennas) should not be used within 30 cm of any part or wiring of the NRG-H device. Failure to do so may result in a reduction in the performance characteristics of the device.*

**Warning!**
*Re-boot of the device due to interference*
*Due to brief mains or electromagnetic interference, a system failure with subsequent restart of the device could occur during therapy operation. After the restart, the therapy settings must first be confirmed by pressing the Start key on the display, only then the shock wave output can be triggered again using the foot control.*

**Mandatory action!**
*If you observe a situation where the status of the device is not clear, turn the device off and on again at the power switch to restart the device..*

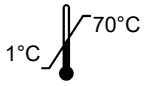
### 1.9.4 Patient positioning

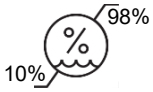
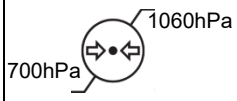
**Mandatory action!**
*Ensure that the patient is fixed in position in accordance with accepted standards of care.*

## 1.10 Residual Risk

The product NRG-H is designed in such a way that, when used under the intended conditions and for the intended purpose, all risks are acceptable when weighed against the benefits for the patient. The overall residual risk was classified as acceptable. Potential risks associated with the NRG-H device are following: Loss or reduction of the therapeutic regeneration effect, burning grade I, blast trauma, infection, irritation of the respiratory tract, tissue lesions, ventricular fibrillation and death.

## 1.11 Symbols

| Symbol | Description |
|---|---|
|  | General warning sign (ISO7010-W001) |
|  | General mandatory action sign (ISO7010-M001) |
|  | General prohibition sign (ISO7010-P001) |
|  | Refer to instruction manual/booklet!! (ISO 7010-M002) |
|  | Warning; Electricity (ISO7010-W012) |
|  | Operator's manual; operating instructions (ISO7000-1641) |
|  | Non-sterile (ISO 15223-1 5.2.7) |
|  | Temperature limit; a specified temperature range must be observed during storage and transport. (ISO 15223-1 5.3.7) |
|  | Date of manufacture; month and year of manufacture are indicated below the symbol. (ISO 15223-1 5.1.3, ISO7000-2497) |
|  | Manufacturer; indicates the manufacturer of the medical device. The name of the manufacturer including the address is indicated next to the symbol. (ISO 15223-1 5.1.1, ISO7000-3082) |
|  | Serial number of the manufacturer to identify an individual medical device. The serial number must be placed next to the symbol. (ISO 15223-1 5.1.7, ISO7000-2498) |

| Symbol | Description |
|---|---|
|  | Catalogue number of the product (ISO 15223-1 5.1.6, ISO7000-2493) |
|  | Protection class against ingress of water and solid substances. (IEC60529) |
|  | Medical device; Indication that it is a medical device (ISO 15223-1 5.7.7) |
|  | Type CF applied part, for heart application (EN 60601-1) |
|  | Connection to equipotential bonding (equipotential) |
|  | To identify a foot control device, connection or function. (IEC60417 - 6378, ISO7000) |
|  | RFID tag; indicates the presence of an RFID identification chip. (ISO7000 - 3010) |
|  | Humidity limitation; Indication of acceptable upper and lower limits of relative humidity. (ISO 15223-1 5.3.8, ISO7000-2620) |
|  | Atmospheric pressure limitation; Indication of acceptable upper and lower limits of atmospheric pressure. (ISO 15223-1 5.3.9, ISO7000-2621) |
|  | Separate collection of electrical and electronic equipment at disposal. (DIRECTIVE 2012/19/EU - WEEE) |
|  | CE mark with Notified Body number. (EU 2017/745 MDR) |