VetOvation
Medical Electric Drill

HAS-E100 Instructions for Use

HAS-E100, Version A/0
Effective: 2018-8-25

VetOvation Medical Electric Drill

Contents

Warning

-The HAS-E100 Instructions for Use is written for users who are familiar with surgery principles and techniques. The systems are intended to be operated by a clinician qualified in the surgical operation.

- Don't use near active HF SURGICAL EQUIPMENT and the RF shielded room of an ME SYSTEM for magnetic resonance imaging, where the intensity of EM DISTURBANCES is high.

- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

- Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the **HAS-E100**, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Note: The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals(CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

Intended use

The VetOvation Medical Electric Drill is designed for drilling and to perform cutting of soft tissue and bone.

Medical Electric Drill:
A hand-held device intended to provide rotation for a rotary handpiece accessory during surgical procedures performed on bones and soft tissues (e.g., cartilage, ligaments). It typically has the capacity to be used with a variety of rotary instruments (e.g., drills, saw, etc...) and is not dedicated to a specific clinical procedure. It includes a built-in motor and an attachment for direct connection of accessories to the handpiece. It is powered by a detachable, rechargeable battery pack to directly provide low- voltage electricity to the motor of the hand piece.

External Battery Charger:
An electrically-powered device designed to supply an electrical charge, via a direct connection to rechargeable batteries to recharge it for operation in the Medical Electric Drill .

Cautions for Safe Operation and Safety Instructions

- You MUST read and understand this safety information before using the device.
- Before using the device, check the outer surfaces of the handpiece and any accessories to ensure safety.
- DO NOT use any component if the packaging is damaged.
- DO NOT use this device in conjunction with oxygen-rich environments. This unit is not intended for use with flammable anesthetics or flammable agents.
- When the unit is not in use, ensure that the device is turned OFF.
- No modification of this equipment is allowed.
- Please use the original packaging for storage and transport.
- DO NOT drop the device.
- The batteries may never be sterilized.
- To dispose of the unit or its components, follow the instructions in the user's guide.
- Remove the battery if not in use for an extended time.
- To prevent injury, the machine must be locked with the mode selector switch 'OFF' when coupling and removing accessories and tools, and before laying it down.
- Always check its functioning before use. DO NOT use with malfunction.
- Pay attention to all the instructions in the individual sections that are identified with.
- Improper use can result in serious injury. The user must be thoroughly familiar with the instructions and potential hazards involving surgery before attempting to use the device.

Contraindications:

-Patient who is not suitable for orthopedic surgery

-Any active infection

-Any allergic reaction to foreign bodies

-Do not use for surgeries other than those indications

Table for Label Icons:

 Consult the Instructions for Use before operating the device	 Indicates that the waste of electrical and electronic equipment must not be disposed as unsorted municipal waste and must be collected separately. Please contact an authorized representative of the manufacturer for information concerning the decommissioning of equipment. ◦
 The applied part of this tool is classified as type B applied	 Serial Number
IPX4 The applied part of this tool is classified as type B applied	 Manufacturer name and address
 Caution	 Date of manufacture
 Non Sterile	 Do Not Immerse

Product Overview

Main parts of HAS-E100 Medical Electric Drill

1. Hand piece
2. Drill chucks
3. Key
4. Charger
5. Rechargeable battery
6. Battery Sterile Case
7. Transfer Shield

Using the Device

How to use your HAS-E100 Medical Electric Drill

1. Mounting and Removing the Drill Chuck

Mounting: Insert the drill chuck into the connector port until it is in place with a "click". Pull the drill chuck to double check.

Removing: Twist the connector port and pull the drill chuck out of the handpiece.

2. Mounting and Removing the Drill Bit

Mounting: Insert the medical drill bit into the drill chuck. Use the key to lock in the drill bit. Pull the drill bit to double check.

Removing: Use the key to loosen the drill bit then pull the bit out of the chuck.

3. Operation of the Handpiece

First select the direction of rotation and then pull the trigger.

- Put the rotation direction switch to 'F' for clockwise.
- 'R' is for counterclockwise, and the center position is 'S' for Safety.
- Please put the switch in the 'S' position after every operation.

Precautions

Please remove the drill bit after use.

Battery Replacement

1. To connect the battery pack to the handpiece:

(a) Align the contacts on the top of the battery pack with the handpiece connector

(b) Slide and pull the battery pack until it is in place with a“click”

2. To discharge the battery pack:

Press the release tab to pull the battery

System Specifications

Model	HAS-E100
Voltage	9.6V（±10%）
Temperature rising	≤50 ℃
Battery Capacity	2100mA（±10％）
No-load Rotation	0～1045r/min（±10％）
Rated	≥3.8 N·m
No load noise	＜75 dB (A)
Suited Drill	0-φ6.0mm

Conformance Standards

The device complied with the following standard：

- IEC/EN60601-1
- IEC/EN60601-1-2
- IEC/EN60601-1-6
- ISO10993-1

Environmental requirements and duty cycle

	Operational	Storage	Transport
Temperature	10°C – 30°C	-5 – 45°C	-5 – 45°C
Humidity	30% – 75 %	10% – 90 %	10% – 90 %
Pressure	700 – 1060 hPa	500 – 1060 hPa	500 – 1060 hPa

Duty Cycle:

Intermittent operation

Maximum Activation (On) Time	Minimum Deactivation (Off) Time	Cycles
30 seconds	180 seconds	50

Care and Maintenance

Inspection and Function Test

Visually inspect for damage and wear (e.g. unrecognizable markings, missing or removed part numbers, corrosion, etc.). Check the handpiece controls for smooth operation and function.

All movable parts should be operating smoothly . Ensure that the triggers do not remain stuck in the handpiece when pressing on them . Check that no residuals prevent the movable parts from moving smoothly.

The handpiece and connector port of base should operate smoothly, and should function well together with cutting tools and accessories.

CAUTION:

Examine instruments and cuttings tools for correct adjustment and functioning prior to every use.

Do not use damaged, worn or corroded components; send them instead to the manufacturer. Failing to follow these instructions will lead to damage and malfunction, increasing the risk of harm to the user and patient.

Recommended cleaning and sterilization procedure:

WARNINGS	• It is important that adequate cleaning be performed prior to sterilization. • The following maximum values SHALL NOT exceed 132°C over a maximum of 18 minutes. Higher values can damage the sterilized products. • Do not accelerate the cooling process. • Hot air, ethylene oxide, plasma and formaldehyde sterilization are not recommended.
Limitations on reprocessing	Repeated processing has minimal effect on these instruments. End of life is normally determined by wear and damage due to use. Inspection and function test instruction shall be followed prior to every use.
Point of use	Remove excess soil with disposable cloth/paper wipe
Containment and transportation	**PRECAUTION:** Products with accessories or parts that are detachable must be disassembled for individual cleaning and then reassembled prior to sterilization. Reprocessing must be performed immediately after each use. The interval shall be less than 10 minutes.
Preparation for Cleaning	**Preparation prior to cleaning:** **Disassembly:** Before cleaning, remove all instruments and attachments from the power tool. Make sure to remove the power battery from the handpiece and lock the lid of the sterile battery case.
	Precaution: Keep the device moist after use to prevent soil from drying, and removing gross soil from surfaces as soon as possible after use.

Instrument Washing

- Cleaners with a pH 7–9.5 are recommended. The use of cleaners with higher pH-values can (depending on the cleaner) causes a dissolution of the surface of aluminum and its alloys, plastics or compound materials. These cleaners should only be used according to the data regarding material compatibility referred to its data sheet. At pH values higher than 11 the surfaces of stainless steel can be affected. Avoid using any cleansers containing iodine or chlorine.
- The battery must not be washed, rinsed, disinfected or sterilized
- Do not immerse the handpiece, lid or attachments in aqueous solutions or in an ultrasonic bath as this could decrease the service life of the system.

3. When unloading, check cannulations, holes etc for complete removal of visible soil. If necessary repeat cycle or use manual cleaning.

- **Automatic Washing:** Dried-on soil is difficult and sometimes impossible to remove with automatic washing, especially at challenging design feature areas such as joints and crevices. The removal of gross soil from these areas prior to washing in automatic washer equipment is critical for achieving effective cleaning.

Recommended Cleaning Method

Cleaning: Automated

Equipment: Washer/disinfector, Enzymatic detergent

1. Twist the saw base to expose the connector port so it can drain.
2. Run the following cycle which has been validated for cleaning effectiveness.

Cleaning Step	Duration (In Minutes)	Cleaning Instructions
Pre-Wash	2:00	Tap Water ≥ 20˚C
Cleaning	5:00	Warm Water (50˚C); Use Detergent
Rinse	2:00	Warm Water (50˚C)
Cleaning	3:00	Warm Water (50˚C)
Rinse	5:00	Warm Water (≥ 95˚C)
Drying	35:00	Chamber Temperature (95˚C)

3. When unloading, check for complete removal of visible soil. If necessary repeat cycle or use manual cleaning.

	Cleaning: Manual
	Equipment: Enzymatic detergent, brush, running water Method: 1. **Remove debris.** Rinse device under running cold tap water for a minimum of 2 minutes. Use a sponge, soft lint-free cloth and/or soft-bristled brush to assist in the removal of gross soil and debris. Clean all cannulations with the cleaning brush. 2. **Manipulate moving parts.** Manipulate all moving parts such as the triggers, release sleeves for attachments, mode switch, etc. under running cold tap water to loosen and remove gross debris. 3. **Spray and wipe.** Spray and wipe device using a enzymatic cleaner or detergent solution or foam spay for a minimum of 2 minutes. Follow the enzymatic cleaner or detergent manufacturer's instructions for use for correct temperature, water quality and concentrations/ dilution. 4. **Clean with detergent.** Clean device manually under running water using an enzymatic cleaner or detergent for a minimum of 5 minutes . Manipulate all moving parts under running water. Use a soft-bristled brush and/or soft lint-free cloth to remove all visible soil and debris. Follow the enzymatic cleaner or detergent manufacturer's instructions for use for correct temperature, water quality and concentrations/dilution. 5. **Rinse with tap water.** Rinse device thoroughly using running cool to lukewarm water for a minimum of 2 minutes. Use a syringe or pipette to flush lumens and channels. Actuate joints, handles and other movable device feature in order to rinse thoroughly under running water. 6. **Wipe / Spray disinfection.** Wipe off or spray the surfaces of the devices with a minimum 70% alcohol based disinfectant. 7. **Visually inspect device.** Inspect the cannulations, coupling sleeves, etc. for visible soil. Repeat steps 1–7 until no visible soil remains. 8. **Rinse under clean running water** for 3 minutes. Ensure that running water passes through annulations, and that blind holes are repeatedly filled and emptied. 9. **Dry.** Dry device using a soft lint-free cloth or medical grade compressed air.
Cleaning Verification	1. After cleaning, visually inspect devices under normal lighting for the removal of visible soil. 2. For difficult-to-view design features, apply 3% hydrogen peroxide (bubbling is evidence of the presence of blood). Note: Rinse instruments thoroughly with warm water following hydrogen peroxide testing. 3. Repeat cleaning if not visibly clean and re-inspect.

Storage	Medical devices that will be stored between cleaning and sterilization should be dried with a low-linting, non-abrasive soft cloth to prevent microbial contamination that could result from wet instruments. Instruments should ALWAYS be thoroughly cleaned prior to storage.
Packaging	Use an appropriate sterilization wrap to package the product prior to sterilization, such as wrapping material which fulfills the requirements of EN ISO 11607-1 and suitable for steam sterilization.
Recommended Sterilization Parameters:	*High Temperature Vacuum Steam*
	• Exposure temperature 132–135° C (270–275° F • Exposure time: 4 minutes • Dry time: 8 minutes
	High Temperature Gravity Steam
	• Exposure temperature 132–135° C (270–275° F • Exposure time: 35 minutes • Dry time: 8 minutes
	World Health Organization (WHO) Steam Cycle
	• Exposure temperature 134–138° C (273–280° F • Exposure time 18 minutes • Dry time: 8 minutes
Storage	No particular requirements.
Additional Information:	When sterilizing multiple instruments in one autoclave cycle, ensure that the sterilizer's maximum load is not exceeded.

CAUTION: The instructions provided above have been validated by the manufacturer as being CAPABLE of preparing a medical device for re-use. Based on current testing by the manufacturer, the device can withstand at least 50 cycles of re-using and reprocessing. It remains the responsibility of the processor to ensure that the processing as actually performed using equipment, materials and personnel in the processing facility to achieve the desired result. This requires validation and routine monitoring of the process. Likewise any deviation by the processor from the instructions provided should be properly evaluated for effectiveness and potential adverse consequences.

Battery:

- The batteries should always be charged before use.
- Charge the batteries within an ambient temperature range of 0 °C to 40 °C.
- Refer to charger Instructions for Use for charging directions.
- Charge the batteries only when the ambient temperature is between 0 and 40 degrees C (32 and 104 degrees F) and discharge the batteries between 0 and 40degrees C (32 and 104 degrees F).
- Do not heat the battery or discard it in a fire.
- Do not expose the battery to temperature over 50 degrees C (122 degrees F). Keep it away from fire and other heat sources.
- Do not charge the battery near a heat source, such as a fire or heater.
- Do not leave the battery in direct sunlight.
- Do not pierce the battery with a sharp object, hit it, or step on it.
- Do not use a damaged battery.

Long term (3 months or more) storage of battery pack:

- Store the battery in a temperature range between -20 °C (-4 degrees F) and 45 °C (113 degrees F)
- Upon receipt of the product and before first time usage, it is highly recommended that the customer performs one full discharge/charge cycle. If the battery has not been used for >2 months, the customer is recommended to perform one full discharge/charge cycle. It is also recommended to store the battery in a shady and cool area.
- When storing packs for more than 6 months, charge the pack at least once during the 6 month timeframe to prevent leakage and deterioration in performance.
- Only use batteries for the indicated purpose.

Waste Disposal:

After use, follow proper procedures for decontamination, cleaning, and waste disposal. The device must not be disposed of as unsorted municipal waste and must be collected separately. Please contact an authorized representative of the manufacturer for information concerning the decommissioning of your equipment.

The manufacturer is not responsible for an interference caused by using other than recommended accessories or by unauthorized changes or modifications to this equipment.

Troubleshooting

Problem	**Possible Cause**	**Potential Solution**
Handpiece does not function	- Battery Low	- Charge the battery or replace it with a charged battery
	- High temperature after sterilization	- Cool down the device to room temperature
	- Device protection	- Loosen the trigger switch and restart
Bone and tool heat up during surgery	Cutting edges of the drill bit/saw blade are blunt	Replace the drill bit/saw blade
The battery casing button is difficult to turn	The locking mechanism needs to be lubricated	Lubricate the locking mechanism

Contact the local Service Representative for other using problems.

Electromagnetic Compatibility

Accompanying Documents According to

IEC 60601-1-2, 2014, Clause 6
IEC60601-1-2，2014，

Table 1: Emission

Guidance and manufacturer's declaration – electromagnetic emissions		
The HAS-E100system is intended for use in the electromagnetic environment specified below. The customer or user of the HAS-E100system should ensure that it is used in such an environment.		
Emission test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The HAS-E100 system 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	HAS-E100system is suitable for use in all 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	

Table 2: Immunity (all devices)

Guidance and manufacturer's declaration – electromagnetic immunity			
The HAS-E100 system is intended for use in the electromagnetic environment specified below. The customer or user of the HAS-E100 system should ensure that it is used in such an environment.			
Immunity test standard	**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 the floors are covered with synthetic ma terial, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines	Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC61000-4-5	±1 kV line to line ±2 kV line to earth	Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Voltage Dips, short interruptions and voltage Variations on power supply lines IEC61000-4-11	< 5 % UT (0.5 cycle) 40 % UT (5 cycles) 70 % UT (25 cycles) < 5 % UT for 5 s	Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Note: UT is the AC mains voltage prior to the application of the test level.			
Power frequency (50/60Hz) magnetic field IEC61000-4-8	3 A/m	100 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital Environment.

Table 3: Immunity (not life-supporting devices)

Guidance and manufacturer's declaration – electromagnetic immunity
The HAS-E100 system is intended for use in the electromagnetic environment specified below. The customer or user of the HAS-E100 system should ensure that it is used in such an environment.

Precaution

Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

Electromagnetic environment – guidance

Portable and mobile RF communications equipment should be used no closer to any part of the

The HAS-E100 system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.

Immunity test standard	IEC 60601 test level	Compliance level	Recommended separation distance
Conducted RF IEC 61000-4-6	3 V/m 150 kHz to 80 MHz	Not applicable	d = 0.35 √ P 150 kHz to 80 MHz
Radiated RF IEC61000-4-3	3 V/m 80 MHz to 800 MHz	E1= 10 V/m (measured 20 V/m) 80 MHz to 800 MHz	d = 0.35 √ P 80 MHz to 800 MHz
Radiated RF IEC61000-4-3	3 V/m 800 MHz to 2.5 GHz	E2= 10 V/m (measured 20 V/m) 800 MHz to 2.5GHz	d = 0.35 √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).

Field strengths from fixed RF transmitters as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b]

Interference may occur in the vicinity of equipment marked with the following symbol:

Notes:

– At 80 MHz and 800 MHz, the higher frequency range applies.

– These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a) 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 HAS-E100 system is used exceeds the applicable RF compliance level above, the HAS-E100 system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the HAS-E100 system.

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

Table 4: Recommended separation distances

Recommended separation distances between portable and mobile RF communications equip ment and the HAS-E100 system

The HAS-E100 system is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or user of the HAS-E100 system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the HAS-E100 system as recommended below, according to the maximum output power of the communication equipment.

Rated maximum output power of transmitter	**Separation distance according to frequency of transmitter**		
W	m		
	150 kHz to 80 MHz $d = 0.35\ P\sqrt{}$	80 MHz to 800 MHz $d = 0.35\ P\sqrt{}$	800 MHz to 2.5 GHz $d = 0.35\ P\sqrt{}$
0.01	4 cm	4 cm	4 cm
0.1	11 cm	11 cm	44 cm
1	35 cm	35 cm	1.4 m
10	1.11 m	1.11 m	4.4 m
100	3.5 m	3.5 m	4 m

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated 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.

Notes:
– At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
– These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people
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