Hints Electromagnetic Compatibility
ASSKEA ped M and ASSKEA ped S

CE 0494

MEDICAL — GENERAL MEDICAL EQUIPMENT
AS TO ELECTRICAL SHOCK, FIRE AND MECHANICAL HAZARDS ONLY
IN ACCORDANCE WITH ANSI/AAMI ES60601-1 (2005) + AMD 1 (2012);
CAN/CSA C22.2 No. 60601-1:14;
IEC 60601-1-6 (2010) + AMD1(2013);
CAN/CSA-C22.2 No. 60601-1-6:11+ Am1: 2015;
ANSI/AAMI/IEC 60601-1- 8 (2006) + Am.1 (2012);
CAN/CSA-C22.2 No. 60601-1-8:08 + Am1:14;
ANSI/AAMI HA60601-1-11:15;
CAN/CSA-C22.2 No. 60601-1-11:15

EMV14-15 / Revision A / 2021-11

The safety of the **ASSKEA ped M resp. ASSKEA ped S** complies with the recognized rules of technology and meets the requirements of the **German Medical Devices Act**.
The **ASSKEA ped M resp. ASSKEA ped S** bears the **CE marking CE0494** in accordance with the EU Council Directive 93/42/EEC concerning medical devices and meets the essential requirements of Annex I of this directive, as well as with Article 120 of Regulation (EU) 2017/745 of the European Parliament and of the Council.
The **ASSKEA ped M resp. ASSKEA ped S** has been tested in accordance with IEC 62353.
The **quality management system** applied by ASSKEA GmbH is certified in compliance with the relevant international standards.
The **ASSKEA ped M resp. ASSKEA ped S** is a class IIa medical aspirator in accordance with EU Council Directive 93/42/EEC, Annex IX.

Errors and omissions excepted.

Contents

1 Safety instructions

WARNING: The **ASSKEA ped M or the ASSKEA ped S** may influence other devices, examinations and treatments electromagnetically. For this reason, special attention should always be paid to other devices as well as to examinations and treatments performed in parallel so that any influence is detected as soon as possible.

WARNING: Portable and mobile RF communication equipment (incl. peripheral devices such as antenna cables and external antennas) may influence medical electrical devices and therefore should not be used within a range of 30 cm of any part of the **ASSKEA ped M or the ASSKEA ped S** incl. their cables. Otherwise the performance of the device may be impaired.

WARNING: The use of accessories and spare parts, transformers and cables for the **ASSKEA ped M or the ASSKEA ped S** not indicated or provided by ASSKEA GmbH may increase the electromagnetic emissions or reduce the electromagnetic immunity of the **ASSKEA ped M or the ASSKEA ped S**, resulting in impermissible operation.

No warranty is provided for damages caused by using accessories and spare parts, transformers and cables not recommended or by improper use. Only use original **ASSKEA** accessories and spare parts!

WARNING: The use of the indicated or provided accessories and spare parts, transformers and cables for devices other than the **ASSKEA ped M or the ASSKEA ped S** may increase the electromagnetic emissions or reduce the electromagnetic immunity. No warranty is provided for damages caused by using the indicated or provided accessories and spare parts, transformers and cables with other devices or by improper use. Only use the accessories and spare parts, transformers and cables with the **ASSKEA ped M or the ASSKEA ped S**!

WARNING: The use of the **ASSKEA ped M or the ASSKEA ped S** directly adjacent to or stacked with other devices should be avoided, since this could lead to impermissible operation. If the use of the **ASSKEA ped M or ASSKEA ped S** adjacent to or stacked with other devices is required, the **ASSKEA ped M or ASSKEA ped S** and the other devices should be monitored in order to verify proper operation in this arrangement!

The **ASSKEA ped M and the ASSKEA ped S** devices meet the requirements of IEC 60601-1-2/EN 60601-1-2 “Electromagnetic Compatibility – Medical Electrical Equipment”, without deviations or restrictions. Electromagnetic interference is therefore reduced to a minimum. Follow the indicated instructions and guidelines to sustain the basic safety and the essential functions of the **ASSKEA ped M and the ASSKEA ped S** over their entire expected service life.

2 Electromagnetic environment, in which the ASSKEA ped M and ASSKEA ped S may be operated

The **ASSKEA ped M and the ASSKEA ped S** are intended for operation in the electromagnetic environment specified below, in which RF disturbances are controlled. The customer or the user of the **ASSKEA ped M and the ASSKEA ped S** must ensure that it is operated in such an environment.
The environments for intended operation include professional healthcare institutions and the homecare environment. Special environments, such as close to RF surgery, MRI or environments in which the intensity of EMC disturbances is high are excluded.

Emission limits	
Conducted and radiated RF emissions	CISPR 11

Housing		
Phenomenon	**Test method**	**Immunity test levels**
Electrostatic discharge	IEC 61000-4-2	±8 kV contact ±15 kV air
Radiated RF disturbances	IEC 61000-4-3	10 V/m 80 MHz to 2,7 GHz 80 % AM at 1 kHz
Radiated RF disturbances	pursuant to frequencies and immunity test levels of EN 60601-1-2, table 9	see EN 60601-1-2, Table 9
Magnetic field at rated power frequency (50 Hz)	IEC 61000-4-8	30 A/m
Power supply AC		
Phenomenon	**Test method**	**Immunity test levels**
Fast transient electrical disturbances/bursts	IEC 61000-4-4	±2 kV 100 kHz repetition frequency
Impulse voltages/surges	IEC 61000-4-5	±1 kV line-to-line ±2 kV line-to-ground
Conducted RF disturbances	IEC 61000-4-6	3 V 0.15 MHz to 80 MHz 6 V in ISM bands and amateur radio bands between 0.15 MHz and 80 MHz 80 % AM at 1 kHz
Voltage dips	IEC 61000-4-11	0 % U_T for ½ period At 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315° 0 % U_T for 1 period 70 % U_T for 25 periods one-phase at 0°
Voltage interruptions	IEC 61000-4-11	0 % U_T for 250 cycles
Note: U_T is the AC mains voltage prior to the application of the test levels.		

3 Dealing with electromagnetic interactions

Although electromagnetic interference of the **ASSKEA ped M and the ASSKEA ped S** has been reduced to a minimum, electromagnetic disturbances between the **ASSKEA ped M and the ASSKEA ped S** and other devices cannot be excluded. You should therefore always comply with the specified requirements and instructions regarding the permissible electromagnetic environment and monitor the **ASSKEA ped M and the ASSKEA ped S** in order to ensure proper operation and to prevent adverse events for patients and users. Select another location for the **ASSKEA ped M and the ASSKEA ped S** if the permissible electromagnetic environment cannot be ensured or if you have observed functioning of the **ASSKEA ped M and the ASSKEA ped S** or of another device in the vicinity that is not intended.

Since electromagnetic propagation is affected by absorption and reflection from structures, objects and people and since the field strength from fixed transmitters cannot be predicted in advance with accuracy, a site survey of the electromagnetic phenomena at the location at which the **ASSKEA ped M and the ASSKEA ped S** are going to be operated should be considered to assess the existing electromagnetic environment at this location. If unusual performance is detected, additional measures may be required, for example a modified orientation or relocation of the **ASSKEA ped M and the ASSKEA ped S**. If the essential functions of the **ASSKEA ped M and the ASSKEA ped S** are impaired by electromagnetic disturbances, a reduced or non-existent flow rate and vacuum may be expected.

3.1 List of all cables and transformers replaceable by the user

Name	Specification	Maximum length
Power supply unit	Type: ATM024T-W120V Technical data: 100-240 V~, 50-60 Hz, 580 – 320 mA (in) 12 V DC, 2,0 A (out)	4.0 m

Impressum

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