Hints Electromagnetic Compatibility
ASSKEA secretion aspirators M- and S-series

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

S20, S20K, S30, M20, M30^{Plus}

EMV01-02 / Revision A / 2021-06

The safety of the **ASSKEA secretion aspirators M- and S-series** complies with the acknowledged rules of technology and meets the requirements of the **German Medical Devices Act**.
The **ASSKEA secretion aspirators M- and S-series** bear the **CE marking CE0494** in accordance with EU Council Directive 93/42/EEC concerning medical devices and meet the essential requirements of Annex I of this directive.
The **ASSKEA secretion aspirators M- and S-series** have 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 device **ASSKEA secretion aspirators M- and S-series** are medical suction devices classified as class IIa in accordance with EU Council Directive 93/42/EEC, Annex IX.

Errors and omissions excepted.

Contents

1 Safety instructions

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 secretion aspirators M- and S-series** including the cables. Otherwise the performance of the device may be impaired.

WARNING: Use of accessories and spare parts, transformers and cables for the **ASSKEA secretion aspirators M- and S-series** not indicated or provided by ASSKEA GmbH may increase the electromagnetic emissions or reduce the electromagnetic immunity of the devices, resulting in impermissible operation. No warranty is provided for damage caused by using accessories and spare parts, transformers and cables not recommended or by improper use.
Use only original ASSKEA accessories and spare parts!

WARNING: Use of the indicated or provided accessories and spare parts, transformers and cables for other devices than the **ASSKEA secretion aspirators M- and S-series** may increase the electromagnetic emissions or reduce the electromagnetic immunity. No warranty is provided for damage caused by using the indicated or provided accessories and spare parts, transformers and cables with other devices or by improper use. Use only the accessories and spare parts, transformers and cables with the **ASSKEA secretion aspirators M- and S-series!**

WARNING: Use of the **ASSKEA secretion aspirators M- and S-series** directly adjacent to or stacked with other devices should be avoided, since this could lead to impermissible operation. If use of the **ASSKEA secretion aspirators M- and S-series** adjacent to or stacked with other devices is required, the **ASSKEA secretion aspirators M20 and S-series** and the other devices should be monitored in order to verify proper operation in this arrangement!

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

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

2 Electromagnetic environment, in which the ASSKEA secretion aspirators M- and S-series may be operated

The **ASSKEA secretion aspirators M- and S-series** are intended for operation in the electromagnetic environment specified below, in which RF disturbances are controlled. The customer or the user of the **ASSKEA secretion aspirators M- and S-series** must ensure that they are operated in such an environment.
The environments for intended operation include professional healthcare institutions and the home care environment. Special environments, such as close to RF surgery or 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 secretion aspirators M- and S-series** has been reduced to a minimum, electromagnetic disturbances between the **ASSKEA secretion aspirators M- and S-series** and other devices cannot be excluded. Therefore you should comply with the specified requirements and instructions regarding the permissible electromagnetic environment in any case and monitor the **ASSKEA secretion aspirators M- and S-series** in order to ensure proper operation and to prevent adverse events for patients and users. Select another location for the **ASSKEA secretion aspirators M- and S-series** if the permissible electromagnetic environment cannot be ensured or if you have observed functioning of the **ASSKEA secretion aspirators M- and S-series** or of other devices 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 secretion aspirators M- and S-series** shall 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 another location for the **ASSKEA secretion aspirators M- and S-series**. If the essential functions of the **ASSKEA secretion aspirators M- and S-series** 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

a) ASSKEA S-series

Name	Specification	Maximum length
Mains cable	Type: H05VV-F 2x1,0 mm² Technical data: 230 V~, 50 Hz	2.5 m

b) ASSKEA M-series

Name	Specification	Maximum length
Power supply unit incl. connecting cable	Type: GTM91099-6015-3.0-T2 Technical data: 100-240 V~, 50-60 Hz, 1.5 A (in) 12 V DC, 5 A (out)	1.20 m
Mains cable	Type: H03VVH2-F Technical data: 250 V~, 2.5 A	1.80 m

Impressum

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