



Certificate

No. Q5 028817 0047 Rev. 00

Holder of Certificate: **MAQUET GmbH**

Kehler Straße 31
76437 Rastatt
GERMANY

Facility(ies):

MAQUET GmbH
Kehler Straße 31, 76437 Rastatt, GERMANY

Certification Mark:



Scope of Certificate:

Design and Development, Production, Sales and Service of Medical Devices including Patient Positioning Systems and associated accessories for Therapy and Diagnosis, Transport Devices, Operating Room Integration Systems (hardware / software), Sterilizers and associated accessories

Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems -
Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: 713126733

Valid from: 2018-10-16

Valid until: 2021-10-15

Stefan Preiß

Date, 2018-10-16

EU Declaration of Conformity for Medical Device

Document ID: 1067779 v01

Name and Address of the Manufacturer: MAQUET GmbH
Kehler Str. 31
D-76437 Rastatt

Single Registration Number: N/A

On our sole responsibility, we hereby declare that the product(s)

Product- / Trade Name: Mobile operating tables, see Annex I_EN

Description: The mobile operating tables are designed for the placement and positioning of the patient immediately before, during and after surgical interventions, as well as for examination and treatment.

Reference-No.: See Annex I_EN

Basic UDI-DI (acc. to Part C of Annex VI): 40467680119ABQ

Classification (acc. to Annex VIII): Class I

comply with the relevant provisions of the following Regulation(s) and Directive(s):

Regulation (EU) 2017/745 on Medical Devices

Conformity Assessment Procedure: Acc. to Annex II and Annex III of Regulation (EU) 2017/745

Common Specifications used: N/A

Directive 2011/65/EU on the restriction of the use of certain substances in electrical and electronic equipment

This declaration of conformity is valid from date of issue until 2025-05-29.

Rastatt, 2020-05-29



Holger Ullrich, Director Product Compliance SW
Signed on behalf of MAQUET GmbH



ANNEX I_EN

The products can be delivered in the following variants / with the following components:

Product-No.	Product Description	Basic UDI-DI
1133.22B4	ALPHAMAXX mobile operating table	40467680119ABQ
1133.22B5	ALPHAMAXX mobile operating table	40467680119ABQ
1133.22F4	ALPHAMAXX mobile operating table	40467680119ABQ
1133.22F5	ALPHAMAXX mobile operating table	40467680119ABQ
1433.02B0	YUNO II mobile operating table	40467680119ABQ
1433.02F0	YUNO II mobile operating table	40467680119ABQ
7100.01B0	MEERA ST mobile operating table	40467680119ABQ
7100.01B2	MEERA ST mobile operating table	40467680119ABQ
7100.01F0	MEERA ST mobile operating table	40467680119ABQ
7100.01F2	MEERA ST mobile operating table	40467680119ABQ
7200.01B0	MEERA mobile operating table	40467680119ABQ
7200.01B2	MEERA mobile operating table	40467680119ABQ
7200.01F0	MEERA mobile operating table	40467680119ABQ
7200.01F2	MEERA mobile operating table	40467680119ABQ



Maquet Meera Family Mobile Operating Tables

High performance, outstanding value

This document is intended to provide information to an international audience outside of the US.

GETINGE 





Premium features – affordable price

A universal mobile table for high-quality care

Hospitals of all sizes struggle with increasing cost pressures. With the Maquet Meera Mobile OR Table Family, your hospital can cost-effectively deliver premium patient care.

Modern medical centers are built on flexibility. In a major hospital, the same surgical theater can play host to five or six different surgical disciplines each day. A smaller outpatient surgery center may have higher throughput, but with less variation in procedure types. Yet for all of their differences, each facility needs a versatile, functional OR table that can meet the needs of every procedure.

For almost 180 years, Maquet OR Tables have been trusted to deliver an excellent quality and performance. The Maquet

Meera Table range was specifically developed to support a variety of procedures and now includes the high-performance allrounder Maquet Meera, the versatile Maquet Meera ST, and the highly maneuverable Maquet Meera CL.

Don't break your budget for capital equipment. Learn how the Maquet Meera Mobile OR Table range can deliver the flexibility you need to help you deliver the best patient care.

Three flexible table types

Choose the table that is tailored to your needs



Maquet Meera ST

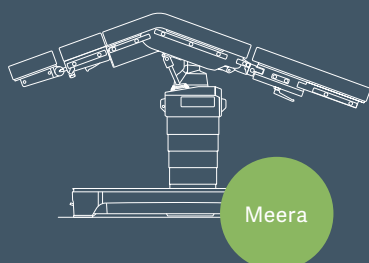


Maquet Meera CL



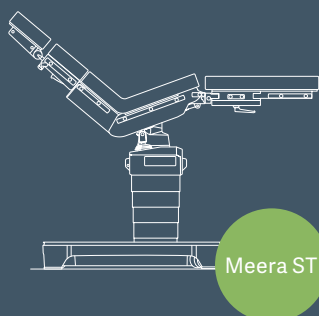
Maquet Meera

Maquet Meera family now consists of three OR tables that give you exactly the features you need – no more, no less. The tables offer premium features at an excellent price-performance ratio, helping your hospital to deliver excellent care without breaking your budget.



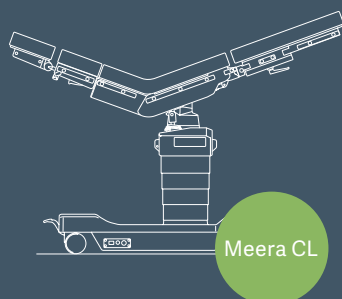
A universal mobile table for high-quality care

The mobile operating table Maquet Meera offers incredible flexibility to support a variety of procedures. The 310 mm motorized longitudinal shift delivers a large radiolucent area for gynecological or urological surgery, without an added seat plate extension. Maquet Meera is a stable table that meets the complex demands of bariatric surgery.



A multifunctional table for various types of procedures

Maquet Meera ST offers the same benefits as the Maquet Meera Table, without the longitudinal shift. It ensures that your OR will benefit from a solid, functional table, without features that your surgeons don't need.



Flexibility for many disciplines

Maquet Meera CL is built on the same stable components as the rest of the Meera range, but on a simplified base with a mechanical locking system. Specially designed castors enable smooth movement in all directions: intermediate operation, straight-line travel, and free-wheeling. Lateral movement capability is ideally suited for the needs of outpatient surgery centers.



The right features for every hospital

No matter which Maquet Meera Mobile OR Table you choose, you'll enjoy these important benefits.

For patients of all sizes

The complete Maquet Meera range can accommodate patients weighing up to 454 kg. An unrestricted capacity of 250 kg in any position ensures the safety and stability needed for the complex demands of bariatric surgery.

Ideal positioning with Trendelenburg / tilt combination

The range provides a great Trendelenburg / tilt combination that allows gravity to assist the surgeon, naturally moving organs out of the way in procedures like laparoscopic colon surgery.

Outstanding flexibility

The tables are capable of a broad range of angles and tilts for maximum procedural flexibility – just one table can accommodate nearly every surgical specialty, increasing cost-effectiveness.

Extend the value of your investment

Maquet Meera Tables are compatible with all existing Maquet Mobile OR Tables as well as Maquet Otesus accessories, extending the value of your existing investment.

Safety in an emergency

Even in the unlikely event of a table software blackout, the table can be controlled via the override panel that is hard-wired to a separate circuit, with no software in between.

Reduce the risk of hospital-acquired infections

Hospital-acquired infections (HAI) lead to costly complications and lengthy hospital stays. The Maquet Meera range has a stainless steel base and smooth surfaces for easy cleaning with traditional methods or new Getinge disinfectants.



Maquet Meera and Maquet Meera ST

Giving you the choice you need

Maquet Meera and Maquet Meera ST are built on the same advanced platform, providing all the features you need in a mobile table.

Excellent stability

The tables are capable of a broad range of angles and tilts for extraordinary cross-disciplinary flexibility. A stable three-point stance ensures the safety of patients of all sizes.

Comfort for patients and staff

From transport to in-procedure positioning, the Maquet Meera range has a variety of ergonomic benefits. The Smart Control* with graphic touchscreen makes it easy to precisely position the table for each procedure. A concave base and smart design ensure ideal access to the patient, reducing positional strain.

Safety and maneuverability

The Auto Drive function helps to safely move the table within the OR or corridor, without operator strain. Sensor Drive supports the precise controlling of the Auto Drive function. Together, they ensure that Maquet Meera Tables can be safely and efficiently repositioned.

Good ergonomics

The Maquet Meera and Maquet Meera ST Tables are capable of a height range of 450 mm (17") which offers optimal ergonomic access. Whether seated or standing, tall or short, the 450 mm working height range can accommodate every individual and procedure type. Motorized joints on the reverse table side allow for superior surgical access to increase versatility and procedure types.





Maquet Meera

The Maquet Meera Table offers a motorized longitudinal shift that delivers a large radiolucent area for gynecological or urological surgery, without an added seat plate extension. Longitudinal shift increases the versatility of the table, accommodating a comprehensive range of procedures.

- ✓ Longitudinal shift
- ✓ High patient weight capacity
- ✓ Motorized leg plate adjustment
- ✓ Smart Control compatibility
- ✓ Auto / Sensor Drive availability

Maquet Meera ST

For hospitals performing few gynecological or urological surgeries, Maquet Meera ST ensures that your OR will benefit from a solid, functional table, without the longitudinal shift feature that your surgeons don't need.

- ✗ Longitudinal shift
- ✓ High patient weight capacity
- ✓ Motorized leg plate adjustment
- ✓ Smart Control compatibility
- ✓ Auto / Sensor Drive availability

More choices with Maquet Meera CL

Cost-effective flexibility in the OR

Maquet Meera CL offers similar functionality to the rest of the Maquet Meera Family, but at a price point that meets the needs of outpatient surgery centers or smaller facilities.

Improved throughput between procedures

The gas-spring assisted leg plates (1118.60X0) can fold around the column, remaining attached during gynecological procedures. This reduces reconfiguration time and helps to increase throughput.

Supporting intraoperative diagnostics and treatment

The 310 mm motorized longitudinal shift increases access for both the surgeon and the C-arm. The large radiolucent area is ideal for gynecological or urological surgery, and does not require an added seat plate extension. 360° imaging is possible when paired with carbon fiber accessories.

Ergonomic flexibility

With a height range of 622 to 1,072 mm, the Maquet Meera CL Table improves workplace ergonomics. It improves surgical site access, and helps to reduce fatigue for surgeons and staff.

Excellent maneuverability for small spaces

The special design of the castors enables intermediate operation, straight-line travel, and free-wheeling. The ability for lateral movement is ideal for outpatient surgery centers.



Maquet Meera CL

The newest member of the Maquet Meera family is the Maquet Meera CL, featuring a versatile and mobile design that is ideal for out-patient surgery centers.

- ✓ Longitudinal shift
- ✓ High patient weight capacity
- ✗ Motorized leg plate adjustment
- ✓ Smart Control compatibility
- ✗ Auto/Sensor Drive availability



Positioning possibilities

A flexible table can improve functionality and increase the cost-effectiveness of your OR

All members of the Maquet Meera Family offer various patient positioning possibilities by offering optimal reverse or normal positioning together with a wide range of angles and lateral tilt combinations. This may deliver increased access in surgical positions.



Struma position



Laparoscopic bariatric surgery



Femur treatment



Spinal surgery in prone position with optimum access for the C-arm

Technical description

and construction features

General construction features

- Battery and mains operation (see electrical data)
- Base made of robust cast steel, resistant to impact, fracture, and disinfectants, grey-dyed with scratch-resistant coat*
- Column casing and base cover made of CrNi steel
- Supporting bars for the seat section and back section, leg plate sockets, joint covers, and side rails made of CrNi steel
- Operating table top subdivided into five sections: head rest (optional), upper back plate (optional), lower back plate, seat plate (optional), leg plates (optional)
- Symmetrical accessory interfaces for Normal and Reverse positioning
- Entire table top is designed without crossbars to permit radiography during surgical interventions
- X-ray top for lateral insertion of X-ray cassettes (optional)
- Manually lower the base castors (unlock) using an integrated tool (if electronics or hydraulics fail)*
- Cover for the override panel made of GFR composite plastic, resistant to impact, breakage and disinfectants

Electrical data

- Specially designed batteries with capacity for two working days use in the operating room
- Electronic monitoring of the battery charge level with optical indicator and acoustic signal
- Batteries recharged from mains power supply 100–240 V AC (adjustable), 50–60 Hz, via power supply cord
- Safety class II type B; the enclosure leakage current meets the requirements of the patient leakage current for CF conditions as per EN 60601-1

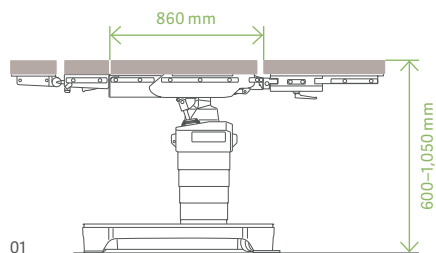
Smart Control features

- Display of table set up information
- Memory function for up to ten table top positions
- Charging status of column and hand control
- Service and error messages
- Pre-programmed positions: flex, reflex and back-horizontal
- Table lock for blocking movements
- Backlight function

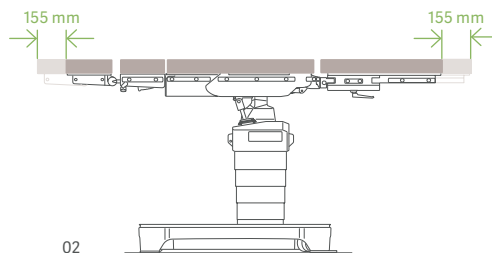
* applicable for Maquet Meera and Maquet Meera ST

Technical description

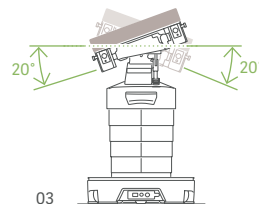
and construction features



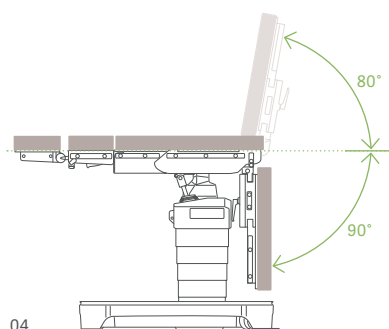
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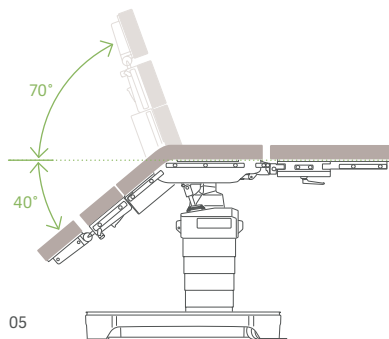
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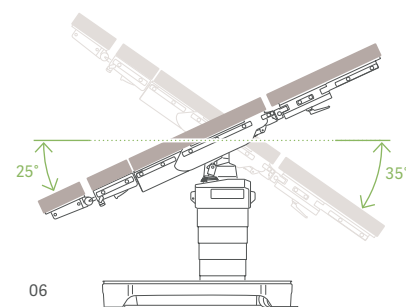
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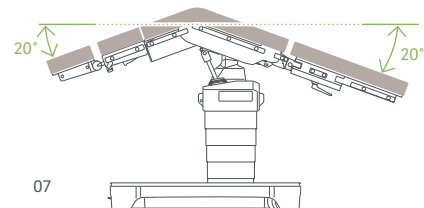
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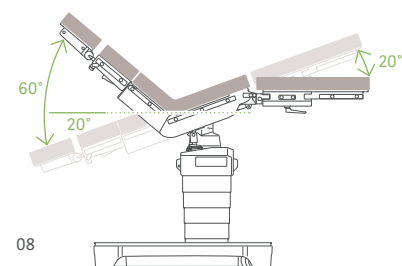
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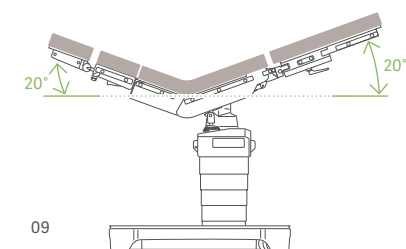
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07



08



09

02 not applicable for Maquet Meera ST

04 not applicable for Maquet Meera CL

01 and 05 dimensions/angles differ for Maquet Meera CL (see table)

Technical data

	Maquet Meera 7200.01XX	Maquet Meera ST 7100.01XX	Maquet Meera CL 7000.01X0
Length of operating table top with standard back plate, head rest, and leg plate	2,040 mm / 80"	2,040 mm / 80"	2,040 mm / 80"
Length of operating table top without accessories	860 mm / 34"	860 mm / 34"	765 mm / 30"
Width without side rails	540 mm / 21"	540 mm / 21"	540 mm / 21"
Width across side rails	590 mm / 23"	590 mm / 23"	590 mm / 23"
Maximum radiolucent area	1,630 mm / 64"	1,630 mm / 64"	1,630 mm / 64"
Weight	ca. 291 kg / 642 lbs	ca. 291 kg / 642 lbs	218 kg / 481 lbs
Maximum overall load (patient and accessories)	454 kg / 1,000 lbs in Normal, 250 kg / 551 lbs in Reverse		

Electrohydraulic adjustments via corded hand control, IR hand control, and override panel

	Maquet Meera 7200.01XX	Maquet Meera ST 7100.01XX	Maquet Meera CL 7000.01X0
Height without padding	600–1,050 mm / 24–41"	600–1,050 mm / 24–41"	622–1,072mm / 24-42"
Trendelenburg / Reverse Trendelenburg	25° / 35°	25° / 35°	25° / 35°
Lateral tilt	20°	20°	20°
Lower back plate	+70° / -40°	+70° / -40°	+75° / -40°
Leg plate	+80° / -90°	+80° / -90°	-90° (manual)
Longitudinal shift	310 mm / 12"	–	310 mm / 12"
Base brake mechanism (lock / unlock)	Electric	Electric	Mechanic

Available control elements

Article no.	
1009.25A0	Smart Control*
1009.24B0	Mobile charging station for IR hand control
1009.24A0/C0	Stationary charging station for Smart Control

* Please see the accessory catalog for more accessories including leg plates, back plates, and head rests.



With a firm belief that every person and community should have access to the best possible care, Getinge provides hospitals and life science institutions with products and solutions aiming to improve clinical results and optimize workflows. The offering includes products and solutions for intensive care, cardiovascular procedures, operating rooms, sterile reprocessing and life science. Getinge employs over 10,000 people worldwide and the products are sold in more than 135 countries.

This document is intended to provide information to an international audience outside of the US.

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MEERA

Exceptional technology. Exceptional value.

MAQUET

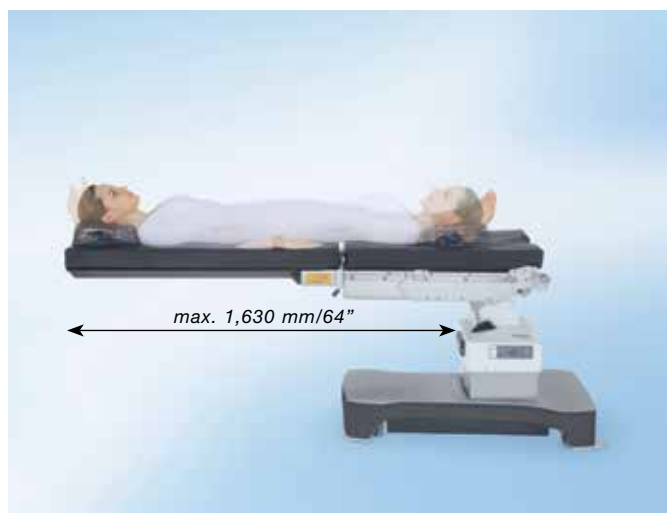
GETINGE GROUP



Greater flexibility,
enhanced workflows

Discover **MEERA**

High performance combined with exceptional flexibility and an attractive design. With features like motorized longitudinal shift, a min. height of 600 mm/24" and a max. height of 1,050 mm/41" MEERA perfectly meets the demands of daily work.



Features at a glance:

- **Motorized longitudinal shift** for large radiolucent area of up to 1,630 mm/64" and more possibilities for patient positioning
- **Improved adjustment ranges** for Reverse Trendelenburg, lateral tilt and height adjustment
- **Control units equipped with display**, showing status information, adjustment angle of table top and more
- **Small and flat table base construction** offers good access for the surgical team as well as for imaging equipment and is easy to clean
- **High stability** thanks to three-point stance
- **Autodrive function** for easy manoeuvring, can be controlled with SENSOR DRIVE
- **Lock function** for the complete table or only table top, preventing unintended movements

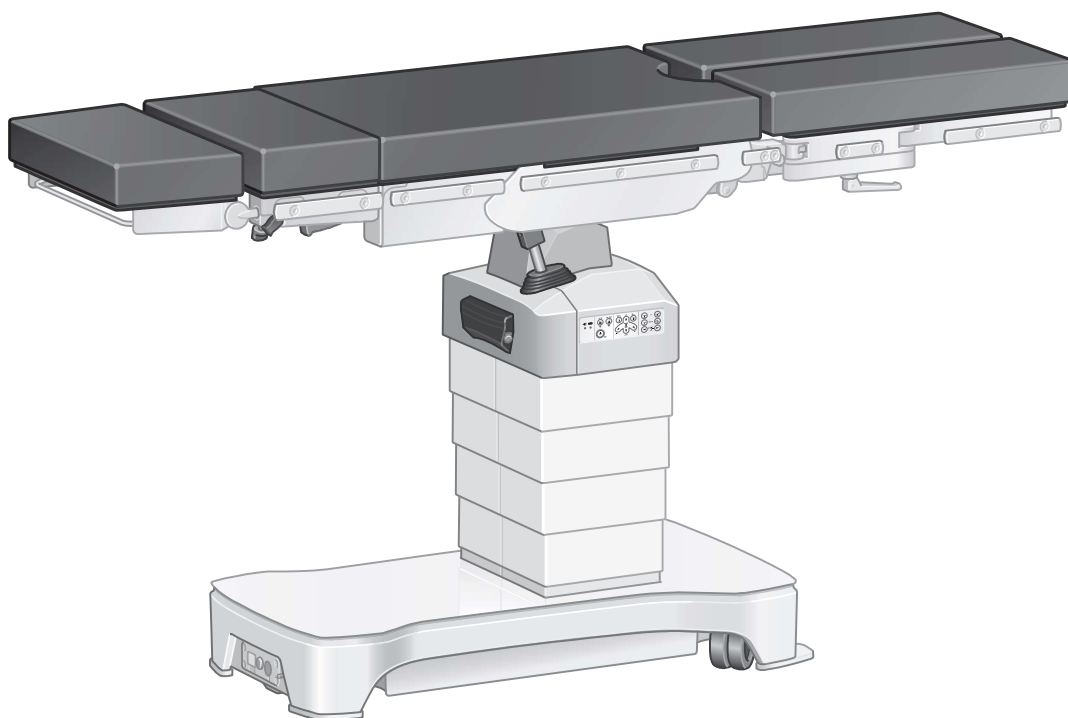
Technical Data

Min. height	600 mm/24"
Max. height	1,050 mm/41"
Trendelenburg/ Rev. Trendelenburg	-25° / +35°
Lateral tilt	20°
Lower back plate interface	+70° / -40°
Leg plate interface	+80° / -90°
Longitudinal shift	310 mm/12"
Max. overall load	454 kg/1,000 lbs
Length without accessories	860 mm/34"
Width without side rails	540 mm/21"
Width across side rails	590 mm/23"

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Instructions for use

7200.01XX **MEERA mobile operating table**

10 Technical specifications



NOTE

For dimensions, adjustment ranges and weight specifications, there is a tolerance of $\pm 5\%$, if no other tolerance is specified.

10.1 General specifications

Type of protection against electric shock	Protection class II
Level of protection against electrical shock	Table top: Type B (IEC 60601-1)
Risk of explosion	Class AP (for battery operation)
Protection against ingress of liquids	IP X4 (spray water protection)

10.2 Ambient conditions

Temperature: Shipping / storage	-20 °C to +50 °C
Temperature: Operation	+10 °C to +40 °C
Relative humidity: Shipping / storage	10 % to 95 %
Relative humidity: Operation	30 % to 75 % (non-condensing)
Atmospheric pressure: Shipping / storage	500 hPa to 1060 hPa
Atmospheric pressure: Operation	700 hPa to 1060 hPa

10.3 Surface temperature of application set

Maximum surface temperature of application set	45 °C
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10.4 Noise level

Noise level	approximately 53 dB (A)
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10.5 Electrical specifications

Nominal voltage	AC 127 / 200 / 120 / 240 / 100 / 220 V
Nominal frequency	50 / 60 Hz
Power consumption	maximum 230 VA
Internal operating voltage	IPS SELV DC 24 V
Operating mode	int 10 min on / 20 min off With an overall load as of 250 kg: int 2 min on / 120 min off
Rechargeable batteries	2 each with 12 V / 18 Ah



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