



Operio – Sterile air zone unit

*The innovative sterile air zone unit **Operio Mobile** ensures that both the surgical site and instruments near the wound remain sterile during entire surgical procedure.*

Operio Mobile is a sterile air zone unit, with an integrated foldable instrument tray, intended for use in the operating zone, which produces a directed, non-turbulent ultra-clean air flow over the surgical site and/or sterile instruments.

The ultraclean air flow is easily aimed over the surgical site or any other area where there is a need to keep the sterile integrity intact. The sterile air zone is clearly pointed out with the help of a smart visual indicator.

Operio Mobile has a unique sterile protective barrier in order for the unit to be placed close to the OR table. The unit circulates the ambient air through a HEPA filtration system, cleaning the air, which prevents dangerous, airborne bacteria-carrying particles from coming into contact with the surgical site, as well as surgical instruments near the surgical site. The unit is easy to use and transport between operation rooms and/or preparation rooms.



- ✓ **Operio Mobile** is easy to set up requiring no changes to the room.
- ✓ **Operio Mobile** can be used instead of an instrument table near the wound next to the patient, saving valuable space.
- ✓ **Operio Mobile** guarantees <5 cfu/m³ air inside the sterile air zone.



Toul Meditech's Quality Management System is conforming to the requirements of ISO 13485:2016. Operio complies with the Medical Device Regulation (EU) 2017/745.



Specification

Physical Data:

Air zone unit:	Overall size: 45 L x 60 W x 130 - 170 H cm Weight: 42 kg
Tray:	Tray size: 45 x 60 (optional 40 x 50) cm Load limitation: Tray may be loaded with max 5 kg Min-max height adjustment: 80 - 120 cm

Power Data:

Power supply:	230 VAC, 50 Hz
Power consumption:	290 VA (23 VA in standby-mode)

Airflow Data:

Airflow speed:	0.4 – 0.5 m/s
Air cleaning capacity/hr:	400 m ³ /hr
Clean air zone length:	120 cm / 47 inch
Cleanliness:	<5 cfu/m ³ air inside the sterile air zone.

HEPA Filter:

H14 Filter, High Efficiency Particles Filter	Filters 99.995% particles >0.3 µm
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Clinical Data:

Efficacy:	Studies have shown a reduction from 111 CFU to 2 Colony Forming Units in a clinical environment
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Regulatory compliance:

Europe	CE mark Class I according to Medical Device Regulation (EU) 2017/745.
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"Everything which is to come into contact with the wound has been made sterile, except the air, which is in contact with everything"

Whyte 1973

Manufactured by:
toul
meditech

Tunbytorpsgatan 31
SE 721 37 Västerås, Sweden
Ph: + 46 21 13 50 00
Fax: + 46 21 13 86 45
www.toulmeditech.com
info@toulmeditech.com