The Clinical Trial Service Company

B Braun Infusomat Space

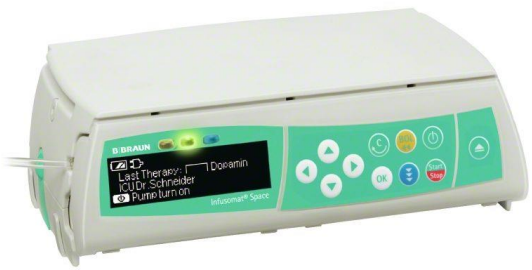
The Infusomat Space large volume infusion pump is designed for acute care adult and pediatric facilities. Weighing only 3 pounds, its smart, compact design allows for flexibility and easy transport within all care settings. The Infusomat Space packs state-of-the-art versatility that promotes efficiencies in the ICU, CCU, NICU, PICU, OR, Med Surg, Emergency Department, Infusion Centers, or Outpatient Care settings.

The Space pump design focuses on the needs of clinicians with an emphasis on intuitive workflow and navigation. To achieve this, B. Braun worked with Healthcare Human Factors, a global leader in developing best practices for human factors testing in healthcare.

During design and validation, the device underwent extensive usability testing with a total of 100 registered, practicing nurses and anesthesiologists participating in eight human factors tests – four formative evaluations and four summative usability tests. It was one of the first infusion pumps to be cleared by the FDA's new human factor and usability engineering process.

Key Features:

- Independent Modularity: Helps to prevent channel confusion and catastrophic pump failures.
- Efficient Design: Lightweight and compact design takes less space with vertical stacking for increased versatility in healthcare settings.
- Unique KeyGuard™: Non-numeric keypad with simple arrows designed to prevent manual programming errors by forcing user to observe the screen during programming and making it impossible for errors such as zero vs decimal to occur.
- Universal Interface: Same workflow as Perfusor and intuitive design help to reduce staff training time.
- Extensive Drug Library: Up to 1,200 drugs that can include customizable hard and soft limits and clinical advisories.
- Wireless Integration: Allows for complete interoperability.
- Alarm Display: Clearly visible with easily adjustable volume levels.
- MRI Environment: MR Conditional when used with the SpaceStation MRI to allow for the continuous delivery of medications to patients within the MRI suite.



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TECHNICAL DATA

Type of unit	Volumetric infusion pump
Classification (acc. to IEC/EN 60601-1)	defibrillator-proof; CF equipment Protective Class II; Protective Class I in combination with SpaceStation
Class (acc. to Directive 93/42 EEC)	IIb
Moisture protection	IP 22 (fluid protected for horizontal usage)
External power supply:	
■ Rated voltage	Via B. Braun SpaceStation or optional mains adaptor (rated voltage 100 ... 240 V AC~, 50/60 Hz) for stand alone operation
■ External low voltage	11 ... 16 V DC ⎓ via Connection Lead SP 12 V or via SpaceStation
Staff call	Max. 24 V / 0,5 A / 24 VA (VDE 0834)
EMC	IEC/EN 60601-1-2 / 60601-2-24
Time of operation	100 % (continuous operation)
Operating conditions:	
■ Relative humidity	30 % ... 90 % (without condensation)
■ Temperature	+5° C ... +40° C (+41° F ... +105° F)
■ Atmospheric pressure	500 ... 1060 mbar
Storage conditions:	
■ Relative humidity	20 % ... 90 % (without condensation)
■ Temperature	-20° C ... +55° C (-4° F ... +131° F)
■ Atmospheric pressure	500 ... 1060 mbar
Type of battery pack (rechargeable)	Li-Ion NiMH
Operating time of rechargeable battery	Li-Ion Wireless active Infusomat® at 100 ml/h typ. 4 hours Wireless active Infusomat® at 1200 ml/h typ. 2.5 hours Wireless active Infusomat® at 25 ml/h typ. 4 hours Wireless inactive Infusomat® at 100 ml/h typ. 12 hours Wireless inactive Infusomat® at 1200 ml/h 5 hours Wireless inactive Infusomat® at 25 ml/h 15 hours NiMH at 100 ml/h typ. 13 hours at 1200 ml/h typ. 5 hours at 25 ml/h typ. 16 hours

Recharging time	Approx. 6 hours
Weight	Approx. 1.4 kg
Dimensions (W x H x D)	214 x 68 x 124 mm
Volume preselection	0.1 - 99.99 ml in increments of 0.01 ml 100.0 – 999.0 ml in increments 0.1 ml 1000 – 99999 ml in increments 1 ml
Time preselection	00:01 – 99:59 h
Accuracy of set delivery rate	± 5 % according to IEC/EN 60601-2-24
Max. Volume in case of single fault condition	For incorrect dosages of 1,4 ml due to malfunctions of the device the pump will automatically shut off
Technical inspection (safety check)	Every 2 years
Administration Set Change Interval	Pumping accuracy is maintained for a minimum of 96 hours.
Multiple lines connected to one patient port	Connecting multiple infusion lines with different flow rates may affect the rate for all infusions past the point of connection.
Rate increments	0.1 - 99.99 ml/h in increments of 0.01 ml/h 100.0 - 999.9 ml/h in increments of 0.1 ml/h 1000.0 - 1200 ml/h in increments of 1 ml/H
Accuracy of bolus infusion	typ. ± 5 % as of a bolus volume > 1 ml
KVO-rate	Delivery rate ≥ 10 ml/h: KVO-rate 3 ml/h Delivery rate < 10 ml/h: KVO-rate 1 ml/h Delivery rate < 1 ml/h: KVO-rate = set rate (default setting 0.1 ml/h)
Computer connection	USB connection in combination with B. Braun interface lead CAN SP (8713230) including electrical insulation. Please pay attention to safety notices.
Air detector	Technical sensitivity: Detection of air bubbles ≥ 0.01 ml Alarm triggering: Single bubble alarm: 0.02 – 0.3 ml (default 0.3 ml) Cumulative air alarm: 0.5 – 3.8 ml/h (default 1.5 ml/h) Resolution: 0.01 ml
Sensitivity upstream sensor	9 levels from -120 mbar to -200 mbar (pressure reduction)
Occlusion alarm pressures	9 levels up to 1.2 bar

Occlusion pressure		Time to occlusion alarm [min] at rate		
	[bar]	[1 ml/h]	[25 ml/h]	[100 ml/h]
Level 1	typ. 0.3	09:07	00:33	00:07
Level 5	typ. 0.7	25:53	01:14	00:15
Level 9	typ. 1.2	46:50	02:06	00:24

Note: At a rate of 0,01ml/h, the time of occlusion alarm is > 3 hours.

Max. bolus after bolus reduction	≤ 0.2 ml
Alarm volume	9 levels from 1 (59dBA) to 9 (74dBA)
Mechanical occlusion pressure limit under fault conditions	Occlusion alarm pressure max. 2.1 bar (210 kPa). Maximum posts occlusion bolus volume 2ml.