Technical Data

Space System

Manufacturer	B. Braun Melsungen AG Carl-Braun-Straße 1, 34212 Melsungen, Germany www.bbraun.com
Quality Management	DIN EN ISO 9001 and DIN EN ISO 13485
MDD Class	IIb acc. to the Directive of the Council of Medical Products 93/42/EC
Classification	♥ Defibrillation-protected; typ CF protection class in accordance with IEC/EN 60601-1
Electromagnetic compatibility EMC	IEC EN 60601-1-2: 1993, IEC EN 60601-2-24: 1998
Technical Safety Check	Every 2 years
Manufacturer warranty	24 month counted from the delivery date. Excluded from the guarantee are batteries and repairs of defects that can be attributed to incorrect manipulations, improper use or normal wear. Space Smart Batteries come with 12 month warranty.

Infusomat® Space, Volumetric infusion pump

|	
Type of unit	Volumetric infusion pump
Dimensions	214 x 68 x 124 mm (WxHxD)
Weight	Approx. 1.4 kg
Moisture protection	IP 22, drip protected for horizontal usage
Display	Backlit graphic display, ~40° read angle from all sides
Keypad	Backlit keys , cell phone like cursor navigation
Flow Rates	0.1-1200 ml/h
Accuracy of set delivery rate	<< ±0,5 % mechanical accuracy ± 5 % according to IEC/EN 60601-2-24
Operating Temperature	+10° C ... + 40° C +50° F .... +105° F
Voltage	11-16 V DC supplied by external Space Power Supply or by SpaceStation
Battery operating time	Minimal power consumption of the devices and new battery technology ensure long operating times, e.g. 9.4 hrs. @ 80 ml/h, 8.5 hrs. @ 100 ml/h
Lifetime	Min. 10 years under continuous duty conditions

8713050 Infusmat® Space

Perfusor® Space

Type of unit	Infusion syringe pump, syringe driver
Dimensions	249 x 68 x 152 mm (WxHxD), drive parked
Weight	Approx. 1.4 kg
Moisture protection	IP 22, drip protected for horizontal usage
Display	Backlit graphic display, ~40° read angle from all sides
Keypad	Backlit keys, cell phone like cursor navigation
Flow Rates	0.01-1800 ml/h
Accuracy of set delivery rate	<< ± 0,5 % mechanical accuracy ± 2 % in compliance with IEC/EN 60601-2-24
Operating Temperature	+5° C ... + 40° C +41° F .... +105 °F
Voltage	11 - 16 V DC supplied by external Space Power Supply or by SpaceStation
Battery operating time	Minimal power consumption of the devices and new battery technology ensure long operating times, e.g. 16.8 hrs @ 1 ml/h, 16 hrs @ 5 ml/h, 14 hrs @ 20 ml/h
Lifetime	Min. 10 years under continuous duty conditions

8713030 Perfusor® Space

Technical Data

Space SmartBattery Packs

|	
Type of unit	High capacity SmartBattery Pack for Infusomat® Space, Perfusor® Space, SpaceCom and SpaceCover Comfort
Handling	Simple tool free replacement by opening the cover of the battery compartment
Cells	four 1.8 Ah NiMH cells
Electronics	Discreet processor / memory PCB that monitors and controls the charging / discharging cycle
Status	Visualization of the actual status as icon [ ] in the main screen (">10 %, ">50 %" or ">80 %" of the battery capacity) and as remaining time in hours and minutes
Recharging time	Approx. 3 hours for 80 % of the operation time Approx. 6 hours for 100 % of the capacity
Mechanism to extend battery lifetime	Processor PCB controls the temperature of the cells Embedded battery maintenance software
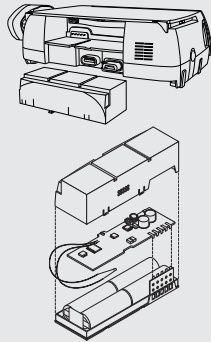
8713180 Space SmartBattery Pack

Space Power Supply and Space PoleClamp

Type of unit	High capacity SmartBattery Pack for Infusomat® Power Supply Space: Voltage supply for up to 3 Space pumps PoleClamp Space: Snap-in-Technique for fast fixation of stacks of up to 3 Space pumps
Fixation	PoleClamp can be attached to infusion poles and vertical tubes (diameter 16–40 mm) as well as horizontal wall rail systems accord. to EN1789
Moisture protection	Power Supply: protected for splash water, IP42
Voltage	100–240 V AC +/-10 % = 90–264 V AC, 50/60 Hz
Adapters	Euro, UK, USA, RSA, India, Korea, China, Australien
Cable length	2 m
Accessories	8713133 Combi Lead 12 V – to connect up to 3 Space pumps to one power supply 8713135 Short infusion stand for Space PoleClamp

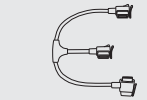8713130 Space PoleClamp
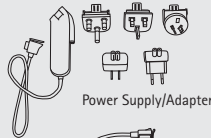
Power Supply/Adapter
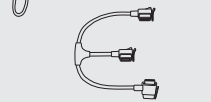
8713133 Combi Lead 12 V

Ambulance cars, helicopters and jets

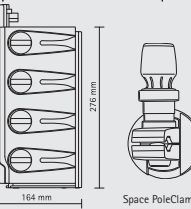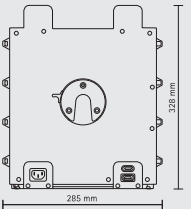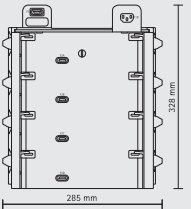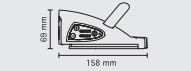|	
Type	12 V adapter cable to connect up to 3 Space pumps to the onboard supply system of ambulance cars, helicopters or jets
Certificates for pumps incl. accessories	EN 1789 Type B: Emergency Ambulance EN 1789 Type C: Mobile Intensive Care Unit EN 13718-1: Air, water and difficult terrain ambulance
Power consumption	max. 20 W for 3 pumps
Accessories	8713231 On-board 12 V supply 8713133 Combi Lead 12 V to connect up to 3 Space pumps

8713231 On-board 12 V supply

8713133 Combi Lead 12 V

SpaceStation, SpaceCover Standard, SpaceCover Comfort

Type of Device	Modular stackable rack (SpaceStation) for any combination of up to 4 Infusomat® Space or Perfusor® Space. SpaceCover Standard as roof of the upper SpaceStation. SpaceCover comfort with central optical and acoustic operation status indicator. Central adjustable volume of the alarm signals.
Components	8713147 SpaceCover Standard 8713145 SpaceCover Comfort 8713140 SpaceStation 8713142 SpaceStation incl. SpaceCom
Weights	SpaceCover Comfort: 0.9 kg SpaceCover Standard: 0.6 kg SpaceStation: 3.6 kg SpaceStation with SpaceCom: 4.1 kg
Expandability	Tool-free assembly of up to 6 Space Stations (6 x 4 slots) in one, two or three pillars
Fixation	Universal clamp can be attached to infusion poles (diameter 16-40 mm) as well as horizontal wall rail systes accord. to EN1789
Moisture protection	IP22, drip protected for horizontal usage
Power supply system	Built-in AC adapter. Standard mains cord for non-heating apparatus, rubber connector Primary: 100-120 V AC ~ 50/60 Hz, 200-240 V AC ~ 50/60 Hz, 110V 0.6 A/220 V 0.3 A; Secondary: 12V DC/35 W
Battery operating time	SpaceCoverComfort: ~ 26 hrs SpaceCom without WLAN: ~ 3 hrs @ one battery SpaceCom without WLAN: ~ 5 hrs @ two batteries SpaceCom with WLAN: ~ 2 hrs @ one battery SpaceCom with WLAN: ~ 3.5 hrs @ two batteries
Operating Temperature	+10° C ... + 40° C +50° F .... +105° F

82 mm
261 mm
69 mm
158 mm
328 mm
285 mm
328 mm
285 mm
276 mm
164 mm
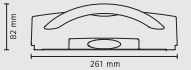
Space PoleClamp

SpaceStation, SpaceCover Standard, SpaceCover Comfort

Accessories	Cables to connect two or three pillars at one bed place - 8713210 Extension lead 60 cm - 8713215 Extension lead 120 cm - 8713315 Extension lead 10 m - 8713415 Extension lead 15 m Backup battery for SpaceCover Comfort or SpaceCom: - 8713180 Space SmartBattery Pack
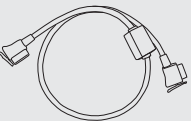
Technical Data

SpaceCom	
Type	Central smart IT Interface for SpaceStations - 8713160 SpaceCom - 8713142 B. Braun Space Station with SpaceCom integrated
Connectors	Serial RS232 Interface with PS2 Adapter, Ethernet RJ45 , USB-master e.g. for memory sticks or Barcode reader, USB-slave
Wireless LAN	Compact flash slot for optional WLAN adapter 2.4 GHz, 100 mW, 54 Mbps, 802.11 b/g Modes: Infrastructure, AdHoc Encoding: WEP, WPA Encryption: WEP -128, TKIP Authentication: Open Sharded, WPA, WPA-PSK
Electrical isolation	Electrical isolation of 4 KV Devices that are conform to IEC950 or IEC1010
Accessories	8713237 RS232 cross over cable 8713238 RS232 connection cable 8713184 WLAN card for SpaceCom

SpaceStation MRI	
Type of unit	MR-conditional unit for taking up to four Space pumps incl. trolley
Certificates	Siemens MRI scanners: Trio 3 (Tesla) Trio A Tim System (3 Tesla) Verio (3 Tesla) Espree (1.5 Tesla) Avanto (1.5 Tesla) Sonata (1.5 Tesla) Symphony (1.5 Tesla) ESSENZA (1.5 Tesla)
Max. magnetic flux density	20 mT = 200 G Online vectorial measurement of the field components in three axes.
Radio interference suppression	IEC EN 60601-1-2:2001 IEC EN 60601-2-24:1998
Voltage	Primary: 100-120V AC / 200-240 VAC; max 80 VA Inlet connector for non-heating apparatus; rubber connector
Moisture protection	IP21, protection against water drops

Weight: app. 40 kg

1350 mm

600 mm

656 mm

SpaceStation MRI
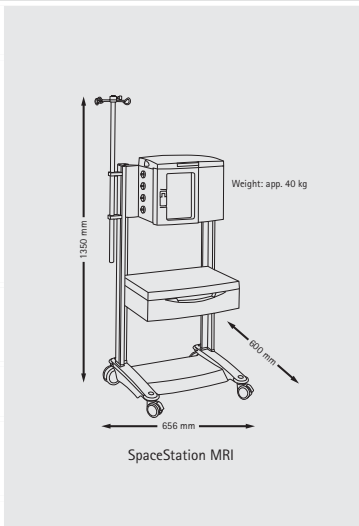
Technical Data

B. Braun Space Infusion Pumps

Performance data	Description
Accuracy	
- Infusomat® Space	± 5% over 96 h with Original Infusomat® Space Line
- Perfusor® Space	± 2% in compliance with IEC/EN 60601-2-24
Flow rate	Online rate modification without delivery interruption, predefined standard dosages via drug library
Dose rate calculation	Full-automatic via drug library or manually, integrated in start-up operation
Drug library	Integrated in the start-up procedure or via special functions
PCA profile	Via drug library, all parameters can be pre-configured
TCI profile*	Via drug library, all parameters can be pre-configured
Ramp/Taper profile*	Via drug library, all parameters can be pre-configured
Piggyback	Also supported by drug library
Take-Over-Mode*	Full automatic overlapping syringe change
Occlusion monitoring	9 occlusion pressure levels (0.1-1.2 bar), automatic bolus reduction to ≤ 0.2 ml
Keep vains open mode	Default settings: user-defined configuration or deactivation of KVO rates possible
Standby mode	1 min … 24 hrs, drug name also visible in standby mode
Datalock	Datalock on 3 safety levels, Datalock 3 also with drug specific hints

Disposables	Description
Infusomat® Space	PVC infusion lines with silicone pump element, optionally with:
	- injection port, needle-free access port
	- PrimeStop/AirStop
	PVC/DEHP free infusion lines also as Cyto-Set®
	Sets for blood transfusion, enteral nutrition
Perfusor® Space	B. Braun Original Perfusor® Syringe OPS: 20 ml, 50/60 ml
	B. Braun Omnifix®: 2/3 ml, 5 ml, 10 ml, 20 ml, 30 ml, 50/60 ml
	Becton Dickinson BD Plastipak: 3 ml, 5 ml, 10 ml, 20 ml, 30 ml, 50/60 ml
	Becton Dickinson BD Precise: 20 ml, 50/60 ml
	Fresenius Injectomat: 50 ml
	Terumo: 3 ml, 5 ml, 20 ml, 30 ml, 50/60 ml, 60 ml
	Tyco Monoject US: 3 ml, 6 ml, 12 ml, 20 ml, 35 ml, 50/60 ml
	Tyco Monoject EU: 3 ml, 6 ml, 12 ml, 20 ml, 35 ml, 50/60 ml

Therapy Profiles

Space drug library	Description
DrugListEditor Space	Microsoft® Windows® based database application, user authentification by password
	One drug library file for Infusomat® Space and Perfusor® Space
	Minimal 720, typical 1500 drug profile settings per pump
Drug identification	Drug name with up to 24 characters
	Active agent ID* as identifier for PDMS and barcoding*, up to 20 alpha-numeric characters
	Drug ID as identifier for PDMS and barcoding*, up to 20 alpha-numeric characters
Drug content	Quantity of active agent in: µg, mg, g*, mEq, IU, mmol, kcal*, kJ*
	Volume in ml
	Container volume* for Infusomat® Space
	Concentration takeover from quantity of active agent/volume or patient specific concentration
Drug properties	Drug selectable on Infusomat® Space and/or Perfusor® Space
	Profiles (continuous infusion, PCA, TCI*) available for this drug
	Predefined start-up profile or user dialog
	Flow rate or dose rate as primary parameter selectable
	Alarm priority (low, medium and high) for alarm monitoring
	User notification text, 3 lines with 25 characters
	Automatic Datalock with start (off, Datalock level 1, Datalock level 2, Datalock level 3)
Navigation in the drug library	15 ward profiles/categories
	Index of all drugs, optionally disabled
	Fast navigation thanks to "ABC ➔ DEF ➔…" fast forward jump marks
	Barcoding for syringe and container identification
	XML data interface to receive the list of prescriptions from PDMS
Updating/uploading	Automatic drug library version management
	Uploading the drug database to up to 24 Space pumps in one work step
	Microsoft® Windows® based service software tool using the USB port

Adjustable range	Description	Units
Flow rate	0 … 99.99 in 0.01 increments	ml/h
	100 … 999.9 in 0.1 increments	ml/h
	1000 … 1800 in 1 increments	ml/h
Quantity of active agents	0 … 99,999 in 0.001 increments	ng*, mcg, mg, g*, mEq, IE, kIE*, mmol, kcal*
Volume	0.1 … 99.99 in 0.01 increments	ml
	100 … 999 in 0.1 increments	ml
	1000 … 9999 in 1 increments	ml
Dose rate	0 … 99,999 in 0.001 increments	unit (/patient weight) /min or /h or /24h
Patient weight	250 g - 250 kg	kg, g, lb

Technical Data

Continuous infusion	Description	Lower hard limit	Lower soft limit	Standard dose	Upper soft limit	Upper hard limit
Initial bolus	0/0.1 ... 99.99 ml, 0 ... 99,999 unit (/patient weight)	–	●	●	●	●
Flow rate						
- Infusomat® Space	0.1 ... 1200 ml/h	–	●	●	●	●
- Perfusor® Space	0.01 ... 999.9 ml/h	–	●	●	●	●
Volume to be infused VTBI	0 ... 99,999 ml	–	–	●	–	–
Time pre-selection	1 min ... 99 hrs 59 min	–	–	–	–	–
Dose rate	0 ... 99,999 unit (/patient weight) /min or /h or /24h	–	●	●	●	●
Quantity of bolus	0 ... 99,999 ml, units, units/patient weight	–	●	●	●	●
Bolus rate						
- Infusomat® Space	0.1 ... 1200 ml/h	–	●	●	●	●
- Perfusor® Space	0.01 ... 1800 ml/h	–	●	●	●	●

Patient Controlled Analgesia	Description	Lower hard limit	Lower soft limit	Standard dose	Upper soft limit	Upper hard limit
Observation time frame *	1 - 24 hrs	●	●	●	●	●
Dose limit	0.1 ... 99,999 ml, 0.001 ... 99,999 dose	–	●	●	●	●
Initial bolus	0/0.1 ... 99.99 ml, 0 ... 99,999 unit (/patient weight)	–	●	●	●	●
PCA bolus amount	0 ... 99.99 ml, 0 ... 99,999 unit (/patient weight)	–	●	●	●	●
Bolus rate						
- Infusomat® Space	0.1 ... 1200 ml/h	–	●	●	●	●
- Perfusor® Space	0.01 ... 1800 ml/h	–	●	●	●	●
Lockout time	1 - 240 min	●	●	●	●	●
Basal rate	optionally disabled					
- Infusomat® Space	0.1 ... 1200 ml/h	–	●	●	●	●
- Perfusor® Space	0.01 ... 999.9 ml/h	–	●	●	●	●

Target Controlled Infusion*	Description	Lower hard limit	Lower soft limit	Standard dose	Upper soft limit	Upper hard limit
Algorithm	Propofol: Schnider, Marsh; Remifentanil: Minto	–	–	–	–	–
Mode	Plasma target, effect site target, navigation	–	–	–	–	–
	Additional manual bolus is always possible	–	–	–	–	–
Dilution	Change of drug concentration during syringe change possible	–	–	–	–	–
Initial bolus	0/0.1 ... 99.99 ml, 0 ... 99,999 unit (/patient weight)	–	●	●	●	●
Plasma Target	with Perfusor® Space drug specific	–	–	●	●	●
Effect site Target	with Perfusor® Space drug specific	–	–	●	●	●
Plasma Limit	100 % - 350 %	–	–	●	●	–
Max. Flowrate	1800 ml/h (Perfusor® Space); 1200 ml/h (Infusomat® Space)	–	–	●	–	–
TCI graphic	+5 min/-15 min timeframe	–	–	–	–	–

Parameter	Propofol		Remifentanil
	Marsh Plasma-Targeting	Schnider Plasma-/Effect Site Targeting	Minto Plasma-/Effect Site Targeting
V_1 [Litre]	0.0228 * Weight	4.27	5.1 - 0.0201 * (Age - 40) + 0.072 * (LBM -55)
k_{10} [min^{-1}]	0.119	0.443 + 0.0107 * (Weight - 77) - 0.0159 * (LBM - 59) + 0.0062 * (Height - 177)	[2.6 - 0.0162 * (Age - 40) + 0.0191 * (LBM - 55)]/ [5.1 - 0.0201 * (Age - 40) + 0.0072 * (LBM - 55)]
k_{12} [min^{-1}]	0.112	0.302 - 0.0056 * (Age - 53)	[2.05 - 0.0301 * (Age - 40)/ [5.1 - 0.0201 * (Age - 40) + 0.0072 * (LBM - 55)]
k_{13} [min^{-1}]	0.0419	0.196	[0.076 - 0.00113 * (Age - 40)/ [5.1 - 0.0201 * (Age - 40) + 0.0072 * (LBM - 55)]
k_{21} [min^{-1}]	0.055	[1.29 - 0.024 * (Age - 53)]/ [18.9 - 0.391 * (Age - 53)]	[2.05 - 0.0301 * (Age - 40)/ [9.82 - 0.0811 * (Age - 40) + 0.108 * (LBM - 55)]
k_{31} [min^{-1}]	0.0033	0.0035	0.01402 - 0.0002085 * (Age - 40)
k_{e0} [min^{-1}]	0.26	0.456	0.595 - 0.007 * (Age - 40)
Literature	Marsh et al., Br. J. Anaesthesia, Vol. 67, 1991 41 - 48	Schnider et al., Anesthesiology, Vol. 88, 1998, 1170 - 1182 Schnider et al., Anesthesiology, Vol. 90, 1999, 1502 - 1516	Minto et al., Anesthesiology, Vol. 86, 1997, 10 - 33

Patient data TCI	
Weight:	30 ... 200 kg
Height:	1.30 ... 2.20 m
Age:	16 ... 100 years
LBM ♂	[1.07 * (body weight in kg)] - [148 * (body weight in kg)^2] / (body height in cm)^2
LBM ♀	[1.10 * (body weight in kg)] - [128 * (body weight in kg)^2] / (body height in cm)^2

LBM according to: James WPT. Reserach on obesity, London, Her Majesty's Stationery Office. (ISBN 0-11-4500347). 1976.

Technical Data

Accuracy	Infusomat® Space	Perfusor® Space
Mechanism	Volumetric infusion pump	Syringe driver
Features	- Excellent smoothing of the pulsating drive typical for peristaltic pumps - Flow rates in the range between 0.1 ml/hr and 1200 ml/hr	- Supports all current syringe sizes from 2 ml to 50/60 ml - Fully automatic syringe load to achieve optimum start-up characteristics independent of the operator - Flow rates in the range between 0.01 ml/hr and 1800 ml/hr (999.9 ml/h)
Disposables permitted	Infusomat® Space Lines with silicon pump element for a wide range of applications	B. Braun Original Perfusor® Syringe OPS. B. Braun Omnifix®, Becton Dickinson BD Plastipak, Becton Dickinson BD Precise, Fresenius Injectomat, Terumo, Tyco Monoject US, Tyco Monoject EU
Measures to avoid boli during loading of the disposable	- Safety clip on the device occlusively seals the line	- Space PistonBrake secures the syringe plunger against unintended movement - automatic clamping of the syringe piston prevents unintentional boli caused by the user
Measures to avoid delays in drug application	- Peristalsis suppressed without delay	- Start-up ramp optimized by processor control regardless of syringe type - Spring-loaded axial fastener of syringe wings minimizes axial play - Special geometry of the claws permits form-fitting grip on syringes from 2 ml to 60 ml
Mechanisms for detection of stopped line	- Highly sensitive upstream pressure sensor - Optional drop sensor	./.
Sensitivity of the pressure sensor on the feed line	Detects even minimal pressure differences with a resolution of 10 mbar	./.
Time to detect a closed roller clamp, in seconds	Max. 20 sec	./.
Empty drip chamber can be detected by the pump	Yes, highly sensitive pressure sensor in the pump can detect B. Braun AirStop membrane	./.
Mechanical accuracy of the driving mechanism	<< ± 0.5 %	<< ± 0.5 %
Accuracy including disposable	± 5 % over 96 h with Infusomat® Space Line	± 2 % according to IEC/EN 60601-2-24
Measures to protect against free-flow according to ECRI (WHO) recommendations	- Safety clip on the device occlusively seals the line - Set based free-flow clamp stops the line automatically when removed from the device; passive safety system	- Space PistonBreak secures the syringe plunger when opening the syringe fastener

Mechanisms to protect against user error	Infusomat® Space	Perfusor® Space
Shift paddles instead of a numeric keypad	+	+
Incompatible IV set detected	+	./.
Exchanging flow direction ruled out	+	./.
Syringe size detected	./.	+

Air Sensor of the Infusomat® Space	
Type of sensor	Maintenance-free ultrasonic sensor
Features	- Sensor sensitivity 10µl ... 300µl air bubbles - No air entrapment between tube and sensor thanks to the smart sensor-tube coupling - Geometry of the sensor makes bypass of the sensor by a water droplet impossible - Acoustic lens technology minimizes signal divergence loss - Factory calibration reduces maintenance costs - Robust in terms of line geometry, no false alarms
Alarm triggering	Adjustable between 0.01 ml and 0.3 ml for single air bubble (standard 0.3 ml) and 0.1 - 3.8 m/1 hr for the accumulated air counter (1.5 ml/h)

Occlusion detection	Infusomat® Space	Perfusor® Space
Type of sensor	Maintenance-free piezo-resistant pressure sensor	Elongation measurement strips
Features	- Laser-calibrated pressure sensor - Factory calibration reduces maintenance costs	- Automatic calibration of sensor
Alarm triggering	Adjustable in 9 levels from 0.3 - 1.2 bar 225 - 900 mmHg 30 - 120 kPa 4.35 - 17.39 psi	Adjustable in 9 levels from 0.1 - 1.2 bar 75 - 900 mmHg 10 - 120 kPa ~ 1.45 - 17.39 psi
Max. bolus after bolus reduction	≤ 0.2 ml	≤ 0.2 ml

Information refers to the use of the Infusomat® Space Line AirStop (Code No. 8701148SP) or the B. Braun Omnifix 50/60ml syringe (Code No. 4617509F) and the device software Version F or newer.

Technical Data

SpaceOneView	
Space Equipment	- Beds are equipped with Space-Stations and the IT interface card (SpaceCom) - The SpaceStations are fix linked to the patient bed places - Optional two additional battery packs per bed as backup for power failure - SpaceOneView software license per bed, permanent license
Network Requirements	- TCP/IP based network - Ethernet network port available at each bed or reliable wireless LAN infrastructure
Hardware Requirements	- PC hardware: at least 650MHz processor, 128 MB RAM, 150 MB of free hard disk space - Monitor: resolution of 1024x768 or more, ideally touch screen - LAN: Ethernet RJ45 adapter or WLAN
Operation System Requirements	- Windows® 2000, XP or Vista - local administrator rights