Technical data

AUTOMATED INFUSIONS SYSTEMS

	Space^{plus} Perfusor®	Space^{plus} Infusomat®
Product specifications		
Type of device	Infusion syringe pump	Volumetric infusion pump
Classification [P+I]	According to IEC 60601-1 · Protection class II · Continuous operation · Defibrillation protection of type CF · Class IIb in compliance with Council Directive 93/42/EEC and (EU) 2017/745 According to FCC Rules part 15 · Classified as mobile device which typically operates at distances greater than 20 cm from the human body	
Moisture protection [P+I]	IP44 · Protected against solid objects with a diameter greater than 1.0 mm · Protected against water splashed from all directions	
EMC [P+I]	IEC 60601-1:2005 + A1:2012 IEC 60601-1-2:2014 IEC 60601-2-24:2012 DO-160G category M (Chapter 21) DO-160-G category T (Chapter 20)	
Operating conditions	+5 °C ... +40 °C (+41 °F ... +104 °F)	+10 °C ... +40 °C (+50 °F ... +104 °F)
	Relative humidity: 16% ... 95% (without condensation), atmospheric pressure: 500 ... 1,060 mbar [P+I]	
Size, weight	ca. 255 mm x 70 mm x 170 mm ca. 399 mm x 70 mm x 170 mm with drive fully extended ca. 1.9 kg	ca. 215 mm x 70 mm x 170 mm ca. 1.9 kg
Power Supply [P+I]	· 100 ... 240 V, 50 ... 60 Hz, connection via power cable or Space^{plus} Station · 11 ... 16 V DC via Connection Lead 12 V	
Battery type [P+I]	Rechargeable Lithium-Ion-battery	
Battery operating time	Approx. 11 h @ 25 mL/h with 50 mL Syringe @ 22°C with WiFi activated Approx. 13h @ 25 mL/h @ 22°C with WiFi deactivated	Approx. 8 h @ 100 mL/h @ 22°C with WiFi activated Approx. 13h @ 100 mL/h @ 22°C with WiFi deactivated
	During battery operation, display shows battery status in h and min [P+I]	
Battery recharging [P+I]	Internal battery charger recharges the battery when the pump is connected to mains power supply or 12 V connection lead; recharging time approx. 4 h	
Freeflow-protection	Integrated piston brake to prevent freeflow during syringe change	Device- and set-based anti-freeflow clamp for maximum security when pump door is opened or infusion line removed
Operator Interface		
User interface [P+I]	Standardized user interface for all infusion pumps in the Space^{plus} Family	
Display [P+I]	Resistive Color Touch TFT-LCD 5.1 Zoll (resolution: 800 [H] x 240 [V])	

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Performance Data		
Approved disposables	B. Braun OPS®/Omnifix®; Becton Dickinson, Terumo, Monoject Sizes: 2/3, 5, 10, 20, 30, 50/60 mL*	Infusomat® Space-Lines*
Delivery rate range	0.01- 1800 mL/h	0.1- 1,200 mL/h
	0.01 mL/h ... 99.99 mL/h in 0.01 mL/h increments 100.0 mL/h ... 999.9 mL/h in 0.1 mL/h increments 1,000 mL/h ... 1,800 mL/h in 1 mL/h increments	0.1 mL/h ... 99.99 mL/h in 0.01 mL/h increments 100.0 mL/h ... 999.9 mL/h in 0.1 mL/h increments 1,000 mL/h ... 1,200 mL/h in 1 mL/h increments
	Online rate modification without delivery interruption [P+I]	
Accuracy of set delivery rate	±2% in compliance with IEC 60601-2-24	±3% according to IEC 60601-2-24 Note: valid for 50 cm water column with Infusomat® Space-Line
Bolus delivery	Delivery rate 1 - 1,800 mL/h	Delivery rate 1 - 1,200 mL/h
	· Bolus on demand [P+I] · Bolus with volume/dose pre-selection [P+I]	
Volume pre-selection [P+I]	0.01 - 9,999 mL	
	0.01 mL/h ... 99.99 mL/h in 0.01 mL/h increments 100.0 mL/h ... 999.9 mL/h in 0.1 mL/h increments 1,000 mL/h ... 9,999 mL/h in 1 mL/h increments	
Time pre-selection [P+I]	00 h : 00 min : 00 s - 99 h : 59 min : 59 s	
Rate calculation [P+I]	Automatic rate calculation by calculating volume over time or by dose	
Priming [P+I]	Customizable via Service Tool	
Brightness [P+I]	Sensor based or manually @ pump	
Dose calculation [P+I]	Automatic calculation of the delivery rate based on · dose entries in mg, µg, IU or mmol, weight- and/or time-related (e.g. mg per kg/min; mg/kg/h; mg/kg/24h), · bolus application in mg, µg, IU, mmol per kg and/or per time unit (min) with automatic calculation of the bolus rate for one bolus infusion	
KVO Keep Vein Open Rate [P+I]	Default settings: · Rate ≥ 10 mL/h: KVO Rate 3 mL/h · Rate < 10 mL/h: KVO Rate 1 mL/h · Rate < 1 mL/h: KVO Rate = set rate User-defined configuration or deactivation of KVO rates possible	
Standby mode [P+I]	Selectable by pressing one button (On/Off button) Standby-time adjustable from 1 min up to 24 h in 1 min increments	
Drug Library [P+I]	Drug selection in startup menu or options · 10,000 drugs including all parameters in drug library · Up to 31 user-defined drug categories · Up to 32 user-defined patient-profiles · Medication errors are prevented by drug-specific limits defined in the drug library	

* for more data, please refer to the IFU

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[1] profiles will be added later on via firmware/software update

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AUTOMATED INFUSIONS SYSTEMS

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Performance Data		
Infusion profiles / therapy mode [P+I]	· Continuous mode · Ramp / Taper mode · PC(E)A mode[1] · TCI mode[1] · TPN[1] · Intermittent Mode[1]	· Continuous mode · Ramp / Taper mode · PC(E)A mode[1] · TCI mode[1] · TPN[1] · Intermittent Mode[1] · Piggyback[1]
Occlusion alarm	9 occlusion pressure levels selectable[P+I]	
	Perfusor 0.1 – 1.2 bar (75 – 900 mmHg)	Infusomat 0.067 – 1.1 bar (50 – 825 mmHg)
Bolus reduction [P+I]	Automatic bolus reduction triggered by occlusion alarm	
Upstream pressure detection		Upstream pressure sensor detects closed roller clamp
Data lock [P+I]	Data lock on drug level or for dedicated teams	
Alarm indicators [P+I]	· Optical and audible alarm signal with clear text in display and LED · Configurable alarm urgency per drug	
Alarms	Syringe empty, reminder alarm, pressure too high, battery empty, standby, syringe holder open, syringe not fixed properly, etc.	Occlusion pressure alarm, upstream alarm, air alarm, KVO alarm, reminder alarm, battery empty alarm, infusion line not or incorrectly inserted alarm, etc.
Pre-alarms	Pre-alarm when syringe almost empty, 3 min before preset target (VTBI / time) near-end, battery nearly empty	Pre-alarms for preselected volume and preselected time shortly before target (VTBI / time) near end, battery pre-alarm
History and interfaces		
History[2] [P+I]	The last 1,000 events can be stored in real-time memory	
Interface type [P+I]	· Cold connector for mains voltage (230 V) · Accessory port for Connection lead 12 V and staff call · Infrared for communication in the Station	
Staff call [P+I]	Max. 24 V / 0.5 A / 24 VA	
System configuration and update		
Customizing [P+I]	User-specific configuration via Drug Library Manager Space[plus] or Service Tool	
Software updates [P+I]	Via WIFI connection to OnlineSuite[plus], or connected to Space[plus] Station via Service Tool or via ServiceTool at each individual infusion pump	
Technical Safety Check (TSC)		
TSC Interval [P+I]	Pump displays next TSC Interval	

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