

# Technical data

## AUTOMATED INFUSIONS SYSTEMS

|                                    | Space <sup>plus</sup> Perfusor®   | Space <sup>plus</sup> Infusomat®   |
|------------------------------------|---|--|
| <b>Product specifications</b>      |   |  |
| Type of device                     | Infusion syringe pump   | Volumetric infusion pump   |
| Classification <sup>P+1</sup>      | According to IEC 60601-1<br>• Protection class II<br>• Continuous operation<br>• Defibrillation protection of type CF<br>• Class IIb in compliance with Council Directive 93/42/EEC and (EU) 2017/745<br>According to FCC Rules part 15<br>• Classified as mobile device which typically operates at distances greater than 20 cm from the human body |  |
| Moisture protection <sup>P+1</sup> | IP44<br>• Protected against solid objects with a diameter greater than 1.0 mm<br>• Protected against water splashed from all directions   |  |
| EMC <sup>P+1</sup>                 | IEC 60601-1:2005 + A1:2012<br>IEC 60601-1-2:2014<br>IEC 60601-2-24:2012<br>DO-160G category M (Chapter 21)<br>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)   |
| Size, weight                       | ca. 255 mm x 70 mm x 70 mm<br>ca. 399 mm x 70 mm x 170 mm with drive fully extended<br>ca. 1.9 kg   | ca. 215 mm x 70 mm x 170 mm<br>ca. 1.9 kg  |
| Power Supply <sup>P+1</sup>        | • 100 ... 240 V, 50 ... 60 Hz, connection via power cable or Space <sup>plus</sup> Station<br>• 11 ... 16 V DC via Connection Lead 12 V   |  |
| Battery type <sup>P+1</sup>        | Rechargeable Lithium-Ion-battery  |  |
| Battery operating time             | Approx. 11 h @ 100 mL/h with 50 mL Syringe @ 22°C with WiFi activated<br>Approx. 13h @ 100 mL/h @ 22°C with WiFi deactivated  | Approx. 8 h @ 100 mL/h @ 22°C with WiFi activated<br>Approx. 13h @ 100 mL/h @ 22°C with WiFi deactivated         |
| Battery recharging <sup>P+1</sup>  | During battery operation, display shows battery status in h and min <sup>P+1</sup><br>Internal battery charger recharges the battery when the pump is connected to mains power supply or 12 V connection lead; recharging time approx. 5 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 |
| <b>Operator Interface</b>          |   |  |
| User interface <sup>P+1</sup>      | Standardized user interface for all infusion pumps in the Space <sup>plus</sup> Family  |  |
| Display <sup>P+1</sup>             | Resistive Color Touch TFT-LCD 5.1 Zoll (resolution: 800 [H] x 240 [V])  |  |

<sup>P+1</sup> valid for both Space<sup>plus</sup> Perfusor® and Space<sup>plus</sup> Infusomat®

1.1.27; 2.1.29

1.1.26

2.1.28

1.1.16; 2.1.17

1.1.17

1.1.18; 2.1.20

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|---|--|--|
| <b>Performance Data</b>                   |  |  |
| Approved disposables                      | B. Braun OPS®/Omnifix®;<br>Becton Dickinson, Terumo, Monoject<br>Sizes: 2/3, 5, 10, 20, 30, 50/60 mL*  | Infusomat® Space-Lines* <span style="border: 1px solid red; padding: 2px;">2.1.3</span>  |
| 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<br>100.0 mL/h ... 999.9 mL/h in 0.1 mL/h increments<br>1,000 mL/h ... 1,800 mL/h in 1 mL/h increments   | 0.01 mL/h ... 99.99 mL/h in 0.01 mL/h increments<br>100.0 mL/h ... 999.9 mL/h in 0.1 mL/h increments<br>1,000 mL/h ... 1,200 mL/h in 1 mL/h increments           |
|   | Online rate modification without delivery interruption <sup>P+1</sup>  |  |
| Accuracy of set delivery rate             | ±2% in compliance with IEC 60601-2-24 <span style="border: 1px solid red; padding: 2px;">1.2.4</span>  | ±3% according to IEC 60601-2-24<br>Note: valid for 50 cm water column with Infusomat® Space-Line <span style="border: 1px solid red; padding: 2px;">2.1.5</span> |
| Bolus delivery                            | Delivery rate 1 - 1,800 mL/h   | Delivery rate 1 - 1,200 mL/h   |
|   | <ul style="list-style-type: none"> <li>• Bolus on demand<sup>P+1</sup></li> <li>• Bolus with volume/dose pre-selection<sup>P+1</sup></li> </ul>  |  |
| Volume pre-selection <sup>P+1</sup>       | 0.01 - 9,999 mL  |  |
|   | 0.01 mL/h ... 99.99 mL/h in 0.01 mL/h increments<br>100.0 mL/h ... 999.9 mL/h in 0.1 mL/h increments<br>1,000 mL/h ... 9,999 mL/h in 1 mL/h increments   |  |
| Time pre-selection <sup>P+1</sup>         | 00 h : 00 min : 00 s - 99 h : 59 min : 59 s  |  |
| Rate calculation <sup>P+1</sup>           | Automatic rate calculation by calculating volume over time or by dose  |  |
| Priming <sup>P+1</sup>                    | Customizable via Service Tool  |  |
| Brightness <sup>P+1</sup>                 | Sensor based or manually @ pump  |  |
| Dose calculation <sup>P+1</sup>           | Automatic calculation of the delivery rate based on <ul style="list-style-type: none"> <li>• 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),</li> <li>• bolus application in mg, µg, IU, mmol per kg and/or per time unit (min)</li> </ul> with automatic calculation of the bolus rate for one bolus infusion |  |
| KVO<br>Keep Vein Open Rate <sup>P+1</sup> | Default settings: <ul style="list-style-type: none"> <li>• Rate ≥ 10 mL/h: KVO Rate 3 mL/h</li> <li>• Rate &lt; 10 mL/h: KVO Rate 1 mL/h</li> <li>• Rate &lt; 1 mL/h: KVO Rate = set rate</li> </ul> User-defined configuration or deactivation of KVO rates possible  |  |
| Standby mode <sup>P+1</sup>               | Selectable by pressing one button (On/Off button)<br>Standby-time adjustable from 1 min up to 24 h in 1 min increments   |  |
| Drug Library <sup>P+1</sup>               | Drug selection in startup menu or options <ul style="list-style-type: none"> <li>• 10,000 drugs including all parameters in drug library</li> <li>• Up to 31 user-defined drug categories</li> <li>• Up to 32 user-defined patient-profiles</li> <li>• Medication errors are prevented by drug-specific limits defined in the drug library</li> </ul>                    |  |

\* for more data, please refer to the IFU

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<sup>1</sup> profiles will be added later on via firmware/software update

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|---|---|--|
| <b>Performance Data</b>                         |   |  |
| Infusion profiles / therapy mode <sup>P+1</sup> | <ul style="list-style-type: none"> <li>• Continuous mode</li> <li>• Ramp/Taper mode</li> <li>• PC(E)A mode<sup>1</sup></li> <li>• TCI mode<sup>1</sup></li> <li>• TPN<sup>1</sup></li> <li>• Intermittent Mode<sup>1</sup></li> </ul> | <ul style="list-style-type: none"> <li>• Continuous mode</li> <li>• Ramp/Taper mode</li> <li>• PC(E)A mode<sup>1</sup></li> <li>• TCI mode<sup>1</sup></li> <li>• TPN<sup>1</sup></li> <li>• Intermittent Mode<sup>1</sup></li> <li>• Piggyback<sup>1</sup></li> </ul> |
| Occlusion alarm                                 | 9 occlusion pressure levels selectable <sup>P+1</sup><br>Perfusor 0.1 - 1.2 bar (75 - 900 mmHg)   | Infusomat 0.067 - 1.1 bar (50 - 825 mmHg)  |
| Bolus reduction <sup>P+1</sup>                  | Automatic bolus reduction triggered by occlusion alarm  |  |
| Upstream pressure detection                     |   | Upstream pressure sensor detects closed roller clamp   |
| Data lock <sup>P+1</sup>                        | 5RrR]`T\`_`UfX]VgM]`cWcUMUZTReUeZ`VaVz U  |  |
| Alarm indicators <sup>P+1</sup>                 | <ul style="list-style-type: none"> <li>• Optical and audible alarm signal with clear text in display and LED</li> <li>• Configurable alarm urgency per drug</li> </ul>  |  |
| Alarms  | Syringe empty, reminder alarm, pressure too high, battery empty, standby, syringe holder open, syringe not fixed properly, etc.   | Occlusion pressure alarm, upstream alarm, drop 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   |
| <b>History and interfaces</b>                   |   |  |
| History <sup>2 P+1</sup>                        | The last 1,000 events can be stored in real-time memory   |  |
| Interface type <sup>P+1</sup>                   | <ul style="list-style-type: none"> <li>• Cold connector for mains voltage (230V)</li> <li>• Accessory port for Connection lead 12V and staff call</li> <li>• Infrared for communication in the Station</li> </ul>                     |  |
| Staff call <sup>P+1</sup>                       | Max. 24 V/0.5 A / 24 VA   |  |
| <b>System configuration and update</b>          |   |  |
| Customizing <sup>P+1</sup>                      | User-specific configuration via Drug Library Manager Space <sup>plus</sup> or Service Tool  |  |
| Software updates <sup>P+1</sup>                 | Via WIFI connection to OnlineSuite <sup>plus</sup> , or connected to Space <sup>plus</sup> Station via Service Tool or via ServiceTool at each individual infusion pump   |  |
| <b>Technical Safety Check (TSC)</b>             |   |  |
| TSC Interval <sup>P+1</sup>                     | Pump displays next TSC Interval   |  |

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