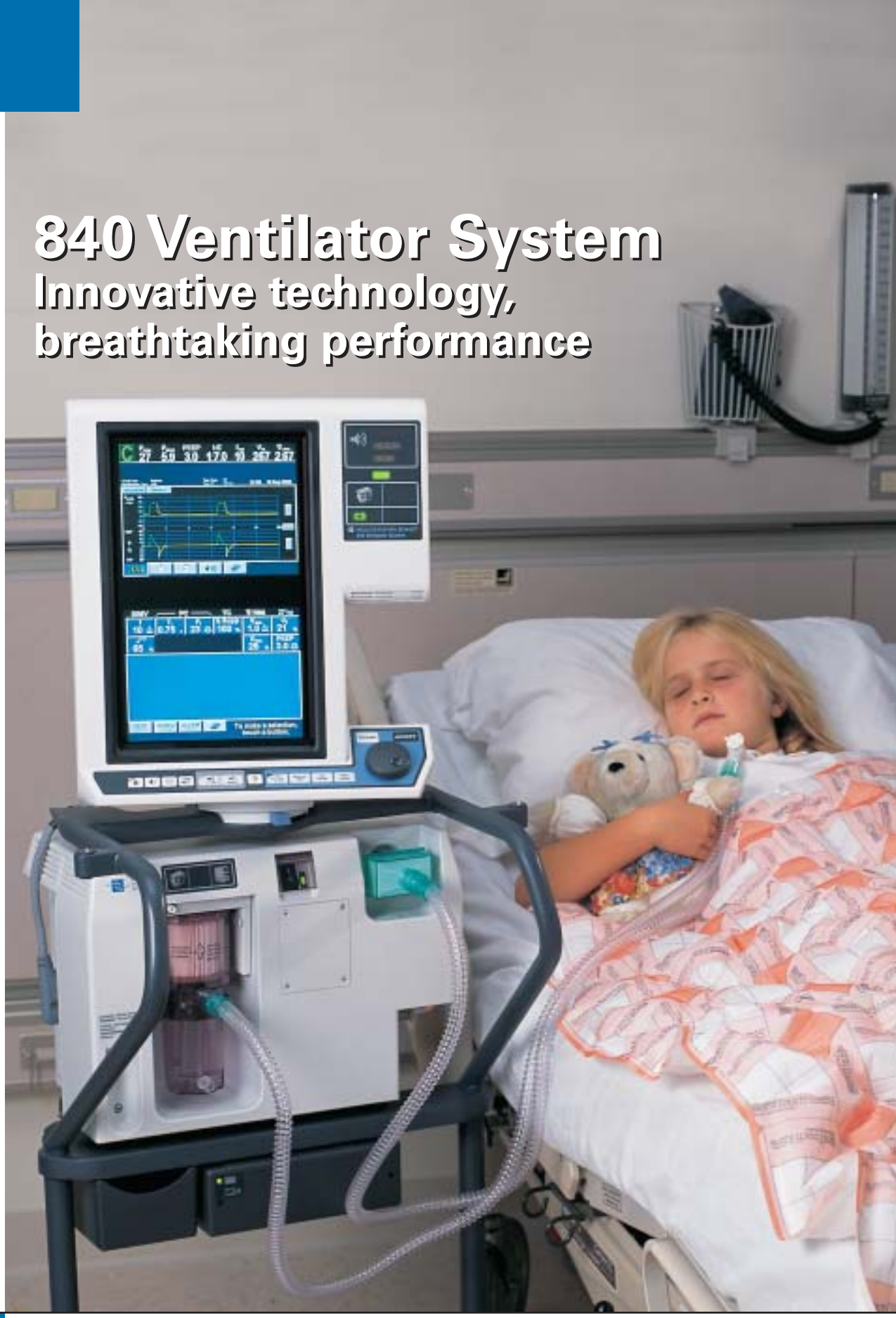
800 Series

840 Ventilator System

Innovative technology, breathtaking performance



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840 Ventilator System

The *840*™ Ventilator is an evolution in critical care ventilators. Compact and lightweight, it delivers sensitive, precise breaths to critically ill infant, Paediatric and adult patients. With its high-performance pneumatics and dual-microprocessor electronics, the 840 platform will accommodate technology updates well into the 21st century.

Features & Specifications

Intelligent User Interface

- *DualView*™ liquid crystal display (LCD) Touch Screens display monitored data separately from ventilator settings for easy assessment of your patient's condition.
- The *SandBox*™ screen area lets you set up and review all proposed ventilator and alarm limit settings before you apply them to your patient. You can change any proposed setting or press the CLEAR key to cancel. No settings are applied to the patient until you press the ACCEPT key.
- The *SmartAlert*™ Alarm System prioritizes alarm annunciation. Primary alarms are distinguished from secondary, dependent alarms, which helps you to efficiently resolve root causes of alarms.
- The setting for ideal body weight (IBW) establishes boundaries that help prevent application of inappropriate ventilator settings.
- Entering Ideal Body Weight (IBW) automatically creates default settings and alarm limits which may either be quickly accepted for rapid setup or adjusted as needed.
- Once settings are applied, the ventilator offers an "undo" function that allows you to return to previous settings quickly and easily.

Ventilator Settings

Ideal body weight (IBW): 7.7 to 330.7 lb (3.5 to 149 kg)
Modes: Assist/Control (A/C), synchronous intermittent mandatory ventilation (SIMV), or spontaneous (SPONT). Optional *BiLevel*™.
Spontaneous breath types: Pressure supported (PS) or none
Pressure support (P_{SUPP}): 0 to 70 cmH_2O
Flow acceleration %: 1% to 100%
Expiratory sensitivity (E_{SENS}): 1% to 45%
Mandatory breath types: Volume control (VC) or pressure control (PC)
Tidal volume (V_T): 25 to 2,500 mL
Respiratory rate (f): 1.0 to 100 /min
Peak inspiratory flow ($\dot{V}_{MAX}$): 3 to 150 L/min for IBW > 24 kg; 3 to 60 L/min for IBW ≤ 24 kg
Flow pattern: Square or descending ramp
Plateau time (T_{PL}): 0.0 to 2.0 seconds
Inspiratory pressure (P_I): 5 to 90 cmH_2O
Constant during rate change: Inspiratory time (T_I), I:E ratio, or expiratory time (T_E)
Inspiratory time (T_I): 0.2 to 8.0 seconds
I:E ratio: ≤ 1:299-4.00:1
Expiratory time (T_E): $T_E \geq 0.2$ second
Trigger type: Pressure (P_{TRIG}) or flow ($\dot{V}_{TRIG}$, *Flow-by*® flow triggering)
Pressure sensitivity (P_{SENS}): 0.1 to 20 cmH_2O below PEEP
Flow sensitivity ($\dot{V}_{SENS}$): 0.5 to 20 L/min
O_2%: 21% to 100%
PEEP: 0 to 45 cmH_2O
Apnea ventilation: Apnea mandatory type: volume control (VC) or pressure control (PC)
Apnea flow pattern: Square or descending ramp
Apnea peak flow ($\dot{V}_{MAX}$): 3 to 150 L/min for IBW > 24 kg; 3 to 60 L/min for IBW ≤ 24 kg
Apnea inspiratory pressure (P_I): 5 to 90 cmH_2O
Apnea inspiratory time (T_I): 0.2 to 8.0 seconds
Apnea interval (T_A): 10 to 60 seconds
Apnea respiratory rate (f): 2.0 to 40 /min
Apnea O_2%: 21% to 100%
Apnea I:E ratio: ≤ 1.00:1
Apnea expiratory time (T_E): Te ≥ 0.2 second
Disconnect sensitivity (D_{SENS}): 20% to 95%
Humidification type: Heat-moisture exchanger (HME), non-heated expiratory tube, or heated expiratory tube
Patient circuit type: Pediatric or adult

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Alarm Limits

High circuit pressure ($\overline{\uparrow}P_{CIRC}$): 7 to 100 cmH_2O
High exhaled minute volume ($\overline{\uparrow}\dot{V}_{E\ TOT}$):
0.1 to 99.9 L or OFF
High exhaled tidal volume ($\overline{\uparrow}V_{TE}$):
50 to 3,000 mL or OFF
High respiratory rate ($\overline{\uparrow}f_{TOT}$): 10 to 110 /min or OFF
Low exhaled mandatory tidal volume ($\underline{\downarrow}V_{TE\ MAND}$):
5 to 2,500 mL or OFF
Low exhaled minute volume ($\downarrow\_\dot{V}_{E\ TOT}$): 0.01 to 60.0 L
Low exhaled spontaneous tidal volume ($\underline{\downarrow}V_{TE\ SPONT}$):
5 to 2,500 mL or OFF

Monitored Data

Breath type: Indicates the type (control, assist, or spontaneous) and phase (inspiration or exhalation) of the breath being delivered
Delivered O_2%
End expiratory pressure ($P_{E\ END}$)
End inspiratory pressure ($P_{I\ END}$)
Exhaled minute volume ($\dot{V}_{E\ TOT}$)
Exhaled tidal volume (V_{TE})
I:E ratio
Maximum circuit pressure ($P_{CIRC\ MAX}$)
Mean circuit pressure ($\overline{P}_{CIRC}$)
Spontaneous minute volume ($\dot{V}_{E\ SPONT}$)
Total respiratory rate (f_{TOT})
Integral waveforms function includes choice of:

- Pressure-time curve, flow-time curve, volume-time curve, or pressure-volume loop (one or two waveform curves or one pressure-volume loop can be displayed at the same time). Pressure-volume loop automatically calculates inspiratory area. All waveforms can be frozen.
- Adjustable baseline and vertical/horizontal axis scales
- Waveforms are automatically displayed and frozen when you press INSP PAUSE or EXP PAUSE. In INSP PAUSE, the calculated values for compliance and, when possible, resistance, are displayed after the inspiratory pause. In EXP PAUSE, the measured values for intrinsic and total PEEP are displayed during and after the expiratory pause.

Ventilator Status Indicators

High-urgency alarm: (blinking if active, steadily lit if autoreset)
Medium-urgency alarm: (blinking if active, turns off if autoreset)
Low-urgency alarm: (steadily lit if active, turns off if autoreset)
Normal operation
Normal BDU operation
Ventilator inoperative
Normal GUI operation
Loss of GUI
Safety valve open
Backup Power Source (BPS) ready
Ventilator operating on BPS
BPS charged/BPS charging
Compressor ready
Compressor supplying air to the ventilator

Other Keys and Indicators

Screen lock key: When lit, touching the screen or offscreen controls has no effect until you press screen lock again. New alarms automatically unlock the screen and controls.
Display contrast key: Adjusts screen contrast (monochrome only)
Display brightness key: Adjusts screen brightness (monochrome only)
Alarm volume key: Adjusts alarm volume (alarm volume cannot be turned off)
Alarm silence key: Turns off alarm sound for 2 minutes
Alarm reset key: Clears active alarms or autoresets high-urgency alarms, cancels an active alarm silence, and is recorded in the alarm log
? key: Displays basic operating information about the ventilator
100% O_2 / CAL 2 min key: Delivers 100% oxygen (if available) for 2 minutes and calibrates the oxygen sensor
MANUAL INSP key: Delivers one manual breath to the patient according to the current mandatory settings
EXP PAUSE key: Allows you to measure auto-PEEP (not functional in SPONT, and has no effect during the inspiratory phase of a breath)
INSP PAUSE key: Allows you to perform static mechanics maneuvers
Knob: Adjusts the value of a setting. A button that is highlighted means that the knob is linked to that setting.
CLEAR key: Cancels a proposed setting
ACCEPT key: Applies proposed settings

Software Options

BiLevel

Low PEEP ($PEEP_L$)
Range: 0 to 45 cmH_2O
High PEEP ($PEEP_H$)
Range: 5 to 90 cmH_2O
Low PEEP time (T_L)
Range: ≥ 0.2 second
High PEEP time (T_H)
Range: ≥ 0.2 to 30 seconds
Ratio of $PEEP_H$ time to $PEEP_L$ time (T_H:T_L)
Range: 1:299 - 149:1

Warranty

One year parts and labor

Environmental Specifications

Pneumatic Gas Sources

Air and oxygen: Must be supplied at 35-100 psi (241-690 kPa)*

Temperature

Operating: 50 to 104°F (10 to 40°C) at 10% to 95% relative humidity, noncondensing
Storage: -4 to 122°F (-20 to 50°C) at 10% to 95% relative humidity, noncondensing

Atmospheric pressure

Operating: 10.2 to 15.4 psi (700 to 1,060 hPa)
Storage: 7.3 to 15.4 psi (500 to 1,060 hPa)

Altitude

Operating: -1,350 to 10,000 ft (-443 to 3,280 m)
Storage: up to 20,000 ft (up to 6,560 m)

Physical Characteristics

Weight

Breath delivery unit (BDU): 40.1 lb (18.2 kg)
Graphic user interface (GUI): 12.6 lb (5.7 kg)
Backup power source (BPS): 14.6 lb (6.6 kg)
Cart: 34.2 lb (15.5 kg)
Compressor: 69.7 lb (31.6 kg)

Dimensions

BDU: 13" H x 18" W x 10" D
(330 mm H x 457 mm W x 254 mm D)
GUI: 18.1" H x 15.5" W x 6.7" D
(460 mm H x 394 mm W x 170 mm D)
BPS: 3.25" H x 9.6" W x 10" D
(83 mm H x 244 mm W x 254 mm D)
Cart: 39.3" H x 22.9" W x 23.7" D
(998 mm H x 582 mm W x 602 mm D)
Compressor: 16.4" H x 18" W x 14.25" D
(417 mm H x 458 mm W x 362 mm D)

Connectors

Inspiratory limb connector:
ISO 22-mm conical male
Expiratory limb connector (on expiratory filter):
ISO 22-mm conical male
Air and oxygen inlets: DISS, DISS female, NIST BOC, Air Liquide, or SIS fitting (depending on country and configuration)
Oxygen sensor life: Two years or 10,000 hours of use, nominal (actual life depends on operating environment; operation at higher temperature or FIO_2 levels will result in shorter sensor life)

Gas mixing system

Range of flow from the mixing system: Can be set to 150 L/min standard temperature and pressure, dry (STPD) for patients >24 kg and up to 60 L/min for patients ≤24 kg. Additional flow is available up to 200 L/min for compliance compensation.
Leakage from one gas system to another:
Meets standard EN 794-1
Operating pressure range: 35 to 100 psi (241 to 690 kPa)*

Alarm volume

Approximately 45 db(A) to 85 db(A)

* *Due to excessive restriction of Dräger, Air Liquide, and SIS hose assemblies, reduced ventilator performance may result when air or oxygen supply pressures <50 psi (345 kPa) are employed.*

Specifications subject to change without notice.

Power

Input power

Ventilator operation without compressor and with Fisher & Paykel MR730 Humidifier:

100 V ac, 50 Hz; 5.1 A
100 V ac, 60 Hz; 5.1 A
120 V ac, 60 Hz; 4.5 A
220-240 V ac, 50 Hz; 1.5 A
220-240 V ac, 60 Hz; 1.5 A

Ventilator operation with compressor and with Fisher & Paykel MR730 Humidifier:

100 V ac, 50 Hz; 10.7 A
100 V ac, 60 Hz; 10.7 A
120 V ac, 60 Hz; 10.1 A
220-240 V ac, 50 Hz; 4.1 A
220-240 V ac, 60 Hz; 4.1 A

Mains overcurrent release

Ventilator: 5 A, 100 and 120 V ac; 5 A, 220-240 V ac

Auxiliary mains: 10 A, 100 and 120 V ac; 5 A, 220-240 V ac

NOTE: Above values obtained using the following ventilator settings at 72°F (22°C) ambient temperature: mode, A/C; mandatory type, PC; IBW, 85 kg; f, 20/min; P_{SUPP}, 30 cmH_2O; T_I, 1 second; flow acceleration %, 50%; O_2%, 50%; $P_{CIRC\ MAX}$, 50 cmH_2O; P_{SENS}, 3 cmH_2O. Humidifier connection only available on 100 and 120 V ventilators.

Leakage current

Earth leakage current: 120 V ac operation: 300 µA max

Enclosure/patient leakage current:

120 V ac operation: 100 µA max

Patient auxiliary leakage current: Not applicable; no applied parts

Humidifier leakage current:

220 to 240 V ac operation: 100 µA max

802 Backup Power Source (BPS): 24 V dc, 6.5 Ah

Operating time (for a new, fully charged battery): At least 30 minutes (actual duration depends on ventilator settings, battery age, and level of battery charge)

Recharge time: Automatically recharges within 8 hours maximum while ventilator is connected to ac power

Shelf life: 24 months from date of manufacture

Storage conditions: Store at -4 to 122°F (-20 to 50°C), 25% to 85% humidity, avoid direct sunlight

Recharge requirements: Recharge every 6 months when storage temperature is 5 to 84°F (-15 to 29°C), every 3 months when storage temperature is 86 to 104°F (30 to 40°C), every 2 months when storage temperature is 105 to 122°F (41 to 50°C)

NOTE: BPS battery life specifications are approximate. To ensure maximum battery life, maintain full charge and minimize the number of complete discharges.

Compliance and Approvals

The *840* Ventilator System was developed in accordance with pertinent FDA guidances, and North American and international standards.

The ventilator's IEC 601-1/EN 60601-1 classification is Protection Class I, Type B, internally powered, drip-proof equipment, continuous operation.

The ventilator meets all requirements for Electromagnetic Compatibility (EMC) under the standard IEC 601-1-2, including CISPR II, Group I, Class B.

Certified by Canadian Standards Association (CSA) to the following international standards and requirements under the CB Scheme:

IEC 601-1 + Amendments 1 and 2
IEC 601-2-12

Approved to the type test requirements of Annex III of the Medical Device Directive (93/42/EEC) and bears the CE marking.

Certified by TU..V Rheinland to the following standards and requirements (220-240 V units):

EN 60601-1 + Amendments A1 and A2
EN 60601-1-1
EN 60601-1-2
EN 794-1

Also complies with the following standards:

EN 60601-1-4
IEC 601-1
IEC 601-1-1
IEC 601-1-2
IEC 601-1-4
ISO 10651-1

Ordering Information

***840* Ventilator**

(To order, call your local Mallinckrodt sales representative.)

Standard Accessories

REF	Description
4-032006-00	Flex arm
4-074600-00	Inspiratory bacteria filter Reusable (*Re/Flex*™, each)
4-070305-00	Expiratory bacteria filter and collector vial
	Reusable filter (*Re/X800*™, each)
4-074647-00	Reusable collector vial (*Re/X800*, each)
4-018506-00	Test hose
4-000612-00	Test lung
4-070520-00	802 Backup power source (BPS)

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Selection Required

REF	Description
Oxygen hose assembly	
4-001474-00	DISS (United States)
4-074697-00	Air Liquide (France)
4-074698-00	NIST/BOC (United Kingdom/Ireland)
4-074700-00	NIST (Netherlands)
4-074702-00	DISS (Israel, Japan, Saudi Arabia)
4-074705-00	DISS (Egypt, India, Italy, Kuwait, Poland, Portugal, South Africa)
4-074708-00	DISS (Switzerland)
4-074710-00	DISS (Canada)
4-074711-00	SIS (Australia, New Zealand)
4-074715-00	DISS/Dräger (Germany)
Air hose assembly	
4-006541-00	DISS (United States)
4-074696-00	Air Liquide (France)
4-074713-00	NIST/BOC (United Kingdom/Ireland)
4-074701-00	NIST (Netherlands)
4-074703-00	DISS (Israel, Japan, Kuwait, Poland, Portugal,South Africa)
4-074704-00	DISS (Saudi Arabia)
4-074706-00	DISS (Egypt, India, Italy)
4-074707-00	DISS (Switzerland)
4-074709-00	DISS (Canada)
4-074712-00	SIS (Australia, New Zealand)
4-074714-00	DISS/Dräger (Germany)
Power cord	
4-071420-00	North America
4-031322-00	United Kingdom
4-071424-00	Japan
4-031320-00	Australia
4-031321-00	Europe
4-071421-00	Denmark
4-031323-00	Italy
4-031325-00	Switzerland
4-071422-00	India/ South Africa
4-071423-00	Israel
4-031321-00	Russia
Operator's and technical reference manual	
4-070088-00	English (U.K.)
4-075609-00	English (U.S.)
4-070145-00	French
4-070144-00	German
4-070146-00	Italian
4-070151-00	Japanese
4-070148-00	Portuguese
4-070147-00	Spanish

Software options

BiLevel (For specific part numbers, call your local Mallinckrodt sales representative.)

Optional Accessories

REF	Description
4-070089-00	Service manual, English
4-075315-00	Wall air water trap kit
Patient breathing circuit	
G-061235-00	Reusable, adult, with heated wire, for Fisher & Paykel
G-061208-00	Reusable, adult, without heated wire
G-061237-00	Reusable, pediatric, with heated wire, for Fisher & Paykel
G-061223-00	Reusable, pediatric, without heated wire
Inspiratory bacteria filter	
4-074601-00	Disposable (*D/Flex*™, carton of 12)
Expiratory bacteria filter and collector vial	
4-070315-00	Disposable filter (*D/X800*™, carton of 12)
4-048491-00	Drain bag, disposable (package of 25)
4-048493-00	Drain bag tubing, disposable (package of 10)
4-048492-00	Clamp, reusable (package of 5)
4-074613-00	Drain cap
4-070311-00	Seal, expiratory filter
Mounting kit, humidifier	
4-075313-00	Fisher & Paykel 480/730
4-076102-00	Cart, ventilator
4-072214-00	Oxygen sensor*
4-070523-SP	Battery replacement kit
4-079046-00	10,000-hour preventive maintenance kit*, BDU/GUI
	10,000-hour preventive maintenance kit*, compressor (For specific part numbers, call your local Mallinckrodt sales representative.)
4-074374-00	Filter, compressor inlet

* *Oxygen sensor to be replaced every 2 years or as necessary by a qualified service technician. Preventive maintenance kits must be installed by a qualified service technician.*

CE 0123

CE marked, indicating compliance to the European Medical Device Directive (93/42/EEC).

M-840TECH/GB

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