

SECTION 2. GENERAL SPECIFICATIONS

Overall Size	9.5" wide × 3.95" high × 5.9" deep
Weight	4.99 Pounds
Accuracy	±3%, excluding syringe variations
Infusion Modes	<u>Body-Weight Modes</u> mcg/KG/min, mcg/KG/HR, MG/KG/min, MG/KG/HR <u>Mass Modes/Unit Modes</u> mcg/min, mcg/HR, MG/min, MG/HR mU/min, mU/HR, U/min, U/HR <u>Continuous Modes</u> ML/min, ML/HR <u>Volume/Time and Auto-Volume/Time Modes</u> dose volume / delivery time
Flow Rate	Dependent on syringe size selected (see Appendix II)
Bolus	In Body-Weight, Mass, Unit, and Continuous Modes
Power	AC Power or DC Internal rechargeable batteries
Recharge Time	No longer than 4 hours
Battery Capacity	At 25 degrees C, 4 hour charge will operate the pump for approximately 12 hours at 5.0 ML/HR with a 60 ML syringe
Alarms/Alerts	Audio Volume Alarm: LOW, NORM, HIGH, or VLOW Battery Depleted Bolusing Check Track Check Plunger Loading Syringe Empty Delivery Limit Exceed Max Rate / Try New Number Enter Access Lock Invalid Number / Try New Number Invalid Size / Check Syringe Low Battery Near Empty Occlusion (Plunger) Out of Soft Limit Plunger Disengaged Syringe Dislodged System Malfunction / Error Code ## Temporary Delay Alarm: 2 to 60 minutes
Status Alerts	Battery Charging Battery Depleted Battery in use Deliver Priming / Don't Prime To Patient Standby Mode Stop/Program

Syringe Manufacturer

Becton Dickinson (B-D)	1, 3, 5, 10, 20, 30, 50/60 ML
Monoject (Mono)	1, 3, 6, 12, 20, 35, 60, 140 ML
Terumo (Teru)	1, 3, 5, 10, 20, 30, 60 ML
B-D Glass (B-D G)	1, 2.5, 5, 10 ML
ABC	140 ML

Enteral Syringe Manufacturer

B-D with Enteral Tip (ETBD)	1, 3, 5, 10, 20, 30, 50/60 ML
Mono with Enteral Tip (ETMN)	1, 3, 6, 12, 20, 35, 60 ML
Baxa® NeoThrive (BAXA)	1, 3, 5, 10, 20, 35, 60ML
NeoMed® (NEOM)	1, 3, 6, 12, 20, 35, 60, 100 ML
Ameritus® (AMP)	1, 3, 5, 10, 20, 30, 60 ML
Vygon® C-Gon (VYGO)	1, 2.5, 5, 10, 20, 35, 60 ML
Acacia NuTrio Syr (ACAC) Medela	5, 10, 30, 60 ML
Medicina (MEDI)	5, 10, 20, 30, 60 ML

Total Delivered	
from 0.01	To 99999 ML
from 0.01	To 99999 MG
from 0.01	To 99999 U

Becton Dickinson (B-D) is a trade mark of Becton Dickinson and Co.

Monoject is a trade mark of Kendall Company/Tyco Healthcare

Terumo is a trade mark of Terumo Company

ABC stands for Atlanta BioMedical Corporation

ETBD/ETMN are the same luer-tip B-D/MONO syringes with added enteral tip.

Baxa® is a trade mark of Baxa Corporation


NeoMed® is a trade mark of NeoMed, Inc.

Ameritus® is a trade mark of Kentec Medical, Inc.

Vygon® is a trade mark of Vygon Corporation

Nutrio and Acacia are trade marks of Acacia Corporation

Power Rating: 120VAC, 115mA, 50/60Hz (240AC, 90mA, 50/60Hz available)

Safety Protection: Class I, Type BF  Equipment, IPX1 Protected against dripping water

⚠ WARNING: Accessories equipment connected to the communications port of this unit must be certified to the respective IEC/EN standards (i.e. IEC/EN 60950-1 for data processing equipment and IEC/EN 60601-1 for medical equipment.) Furthermore all configurations shall comply with the system standard IEC 60601-1-1.

⚠ WARNING: The maximum over-infusion which could occur in the event of a single-fault condition will not exceed 2 seconds of infusion at any infusion rate.

Operating Orientation: Pump is primarily designed for operating in horizontal position, but other orientations (e.g., 90° vertical) will not affect delivery accuracy.

Normal Operating Conditions

Temperature	5°C to 40°C (40°F to 104°F)
Relative Humidity	15 to 95% non-condensing
Ambient Pressure	70kPa to 106kPa (10.2 psi to 15.4 psi)
Infusion Back Pressure:	-100mmHg (-4.4ft H ₂ O) to +300mmHg (+13.4ft H ₂ O)

Storage Conditions:

Temperature:	0°C to 60°C (32°F to 140°F)
Relative Humidity:	5 to 95% non-condensing
Ambient Pressure:	70kPa to 106kPa (10.2 psi to 15.4 psi)

Guidance and manufacturer's declaration – electromagnetic emissions		
The ABC Model 4100 is intended for use in the electromagnetic environment specified below. The customer or the user of the ABC Model 4100 should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The ABC Model 4100 used RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The ABC Model 4100 is suitable for use in all establishments, other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class D	
Voltage fluctuations/ Flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration – electromagnetic immunity			
The ABC Model 4100 Syringe Infusion Pump is intended for use in the electromagnetic environment specified below. The customer or the user of the ABC Model 4100 Syringe Infusion Pump should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment guidance
Electrostatic Discharge (ESD) IEC 61000-4-2 IEC 60601-2-24	+/- 8 kV contact +/- 15 kV air	+/- 8 kV contact +/- 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast Transient/burst IEC 61000-4-4	+/- 2 kV or power Supply lines +/- 1 kV for input/output lines	+/- 2 kV for power supply lines Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	+/- 1 kV line(s) to line(s) +/- 2 kV line(s) to earth	+/- 1 kV differential mode +/- 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) For 0,5 cycle 40% U_T (60% dip in U_T) For 5 cycles 70% U_T (30% dip in U_T) For 25 cycles <5% U_T (>95% dip in U_T) For 5 s	<5% U_T (>95% dip in U_T) For 0,5 cycle 40% U_T (60% dip in U_T) For 5 cycles 70% U_T (30% dip in U_T) For 25 cycles <5% U_T (>95% dip in U_T) For 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the ABC Model 4100 requires continued operation during power mains interruptions, it is recommended the Model 4100 be powered from its battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8 IEC 60601-2-24	400 A/m	400 A/m	Power frequency magnetic fields should be at levels characteristics of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			