EN

Infusion Dynamics

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www.infusiondynamics.com

POWER INFUSER®

Operating Instructions

Model M100B-3A

RESTRICTED DEVICE: Federal law (USA) restricts this device to sale by or on the order of a physician.

CE 0197

EC Authorized Representative: ZOLL International Holding BV, PO Box 52, 6669 ZH Dodewaard, The Netherlands. (+31) 6 51937017.

Contents

Power Infuser M100B-3A Operating Instructions
Re: Pump Part No. 0040-0013 (NSN 6515-01-499-5112)
Document No. 0080-0220 rev C 4/2005

Intended Use

The Power Infuser® Model M100B-3A is intended to support primary intravenous fluid resuscitation therapy to rapidly restore intravascular volume and blood pressure in patients with clinical shock, hypotension, and hypoperfusion states as a result of hemorrhagic blood loss, occult hemorrhage, neurogenic shock and septic shock.

The device is intended for use by medical, paramedical and EMT personnel in the field and in pre-hospital and hospital environments.

When used with the **Crystalloid/Colloid Cartridge** the device is intended to deliver crystalloid and colloid resuscitative fluids only. It is **not** intended to support the infusion of blood or blood products.

When used with the **Blood Cartridge** the device is intended to deliver crystalloid and colloid resuscitative fluids, whole blood and packed red blood cells.

The device is **not** intended to support the delivery of any pharmaceutical or other medications.

Features & Warnings

This is a unique infusion pump. Please make a note of these features, as you may need to change your infusion procedures.

High Flow Rates. The Power Infuser will infuse IV fluids at rates up to 6 liters per hour with no IV bag elevation. The pump has rate settings of 0.2, 1, 2, 4 and 6 liters per hour.

⚠ ***This pump is not designed for low flows. Do not use it to administer medications.***

Automated Bolus. When set to BOLUS the pump will infuse approximately 250 ccs in 2.5 minutes, then switch to standby.

⚠ ***Use a catheter that is large enough for these high flow rates. See chart on p19.***

Free Flow. Fluids can free flow through the pump cartridge at all times in the forward direction only. When the bag is elevated above the patient the flow rate due to gravity will be added to that generated by the pump.

The free flow rate is approximately 0.75 lph per foot of elevation when infusing saline through an 18ga peripheral IV

catheter. This feature can add flexibility in the way you use the pump. For example, use gravity to generate a low keep-vein-open rate or continue fluid delivery when the pump is disconnected. However,

⚠ ***be aware that free flow can cause the actual flow rate to be higher than the set rate, particularly at the low settings.***

⚠ ***In the event of a pump failure or unintended free flow, the maximum volume of fluid that can be infused will be determined by the volume remaining in the IV bag (typically 1 liter maximum).***

Air Elimination (crystalloid/colloid cartridge only). Filters in the crystalloid/colloid pump cartridge will vent air from the IV line once the cartridge has been primed.

⚠ ***Do not use blood or blood products with the Crystalloid/Colloid Cartridge—the 1.2 micron filter will clog.***

⚠ ***These membranes are not included in the Blood Cartridge. When using the Blood Cartridge, PURGE ALL AIR when priming and before starting the infusion.***

Air Detection. If the pump detects air exiting the cartridge it will stop pumping and signal the **air** alarm.

When using the Crystalloid/Colloid Cartridge this should only happen if the cartridge has not been fully primed. The air alarm can also be triggered if the cartridge becomes dislodged from the pump, if the IV solution does not have any saline content, or during the 10-20 second adjustment period when a primed cartridge is first attached to the pump or when switching from saline to blood through the same IV line.

Occlusion Detection. If the pump detects excessive resistance to flow on the patient side, the **occ** alarm will be triggered and the pump will stop.

⚠ ***An upstream occlusion or an empty IV bag will not trigger any alarms on the pump. The pump motor will continue to run but fluid flow will stop. Ensure that upstream roller clamps are wide open to achieve maximum flow rates, and monitor the bag level as needed.***

Long Battery Life. Six standard AAA size alkaline batteries will run the pump for approximately 8 hours at 6 liters per hour, longer at lower rates.

When the battery can no longer sustain the set rate, the batt ***alarm will flicker but the pump will continue to operate, often for another hour or more. When the battery is very low, the pump motor will stall and all the alarm lights will turn on and will not clear when the start/stop button is pressed. Battery lifetime decreases when cold.***

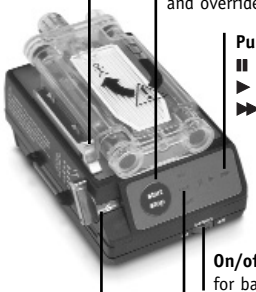
⚠ ***Discard used batteries properly. May explode or leak if recharged, inserted improperly, disposed of in fire or mixed with different battery types.***

⚠ ***To operate under AC power, first turn battery on/off switch to the off position. Use only power adapters supplied by Infusion Dynamics (p24)—use of an unregulated power supply, or any supply delivering >15VDC, may cause permanent damage to the Power Infuser.***

⚠ ***Under extreme circumstances (low humidity, synthetic-covered floors) electrostatic discharges to the Power Infuser may cause it to alarm and interrupt fluid delivery. Press* start/stop *to reset alarms and again to resume flow.***


Type BF (body floating) applied part complying with IEC 60601-1.

Controls



Start/stop button
Press to reset alarms and start or stop pump. Hold down to pump continuously and override alarms.

Cartridge release

Pump status
- ▮▮ standby
- ▶ on (0.2 lph)
- ▶▶ on (1-6 lph)

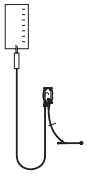
On/off switch
for battery power

Flow rate selector
liters/hour
BOL=250cc bolus

Alarms
- **air** air exiting cartridge
- **occ** patient-side occlusion
- **batt** low battery

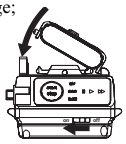
Normal Operation

Setup and Prime



Connect bag, cartridge and IV sets using standard IV bag spike with Luer connectors. When infusing blood products with the Blood cartridge, always use an IV set that is designed for blood products and contains an appropriate screen.

Install cartridge: hold at an angle and engage tab on the side of the cartridge; swing over rocker until the 2 pegs on the cartridge snap into the slots in the pump. Turn pump on for battery operation or connect optional power adapter.



Hold down **start/stop** to prime entire IV set. Tap cartridge to remove air bubbles. Stop pump.

⚠ ***Air elimination membranes in the Crystalloid/Colloid Cartridge will not function until the cartridge is primed and***

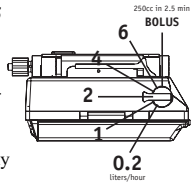
the filter is completely wet. Air that is trapped in the cartridge tubing may reduce flow rates. Air bubbles that are not cleared from the top of the filter during priming may release later, triggering the air alarm.

⚠ ***When using the Blood Cartridge, remove all air from the system. Note: There is no automatic air elimination system provided in the Blood Cartridge design.***

Attach IV set to patient catheter.

Recommended: 18ga 1-2in for crystalloid, 16ga 1-2in for colloid or whole blood; 14ga for warmed packed cells. See chart on p19.

Infuse IV Fluids



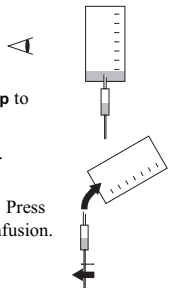
Set flow rate. Numbered settings (liters/hour) run continuously until stopped. BOLUS infuses approximately

250cc in 2.5 minutes and then stops automatically.

⚠ ***These settings are approximate and are based on IV bag level with patient, crystalloid infusate and an 18ga peripheral IV catheter. If IV bag is raised above patient, fluids will free flow and rate will be greater than setting. See p19 for catheter size and fluid viscosity effects on flow rates. Fully open all IV set clamps to achieve maximum flow rates.***

Press **start/stop** to begin infusion.

Change IV Bag



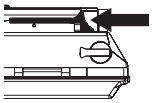
Monitor fluid level in IV bag. Press **start/stop** to pause pump.

Close clamp on IV set. Change IV bag.

Open clamp on IV set. Press **start/stop** to resume infusion.

End Infusion

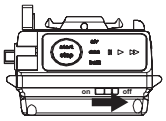
Push to release cartridge.



Gravity-driven infusion can continue with the cartridge in-line.

After use, dispose of cartridge and tubing sets in accordance with applicable regulations.

Turn off pump or unplug power adapter.



Troubleshooting

air

Problem: “air” indicator illuminated and unit continues to alarm.

Solution:

(a) Unit may have detected air as fluid exits the pump. If air bubble present extract air before resuming flow. Press **start/stop** to resume infusion.

(b) Check if cartridge has disconnected from pump. Re-insert cartridge as described on p9. Press **start/stop** to resume infusion.

(c) Fluid being delivered does not have adequate salinity. Fluid must have a salinity level greater than 0.15%. Press **start/stop** to resume infusion.

(d) Pump circuitry is adjusting to the IV fluid. This problem will correct itself 10-20 seconds after pump has been turned on and a primed

cartridge has been installed or when switching from IV fluid to blood products in the same IV line. Press **start/stop** to resume infusion.

When using the crystalloid/colloid cartridge, condition (a) should only occur if the IV set has not been properly primed (p8). Under normal operation the cartridge should vent air entering the pump.

occ

Problem: "occ" indicator illuminated and unit continues to alarm.

Solution:

(a) Flow has become restricted between pump and patient. Check that clamps are open and that lines are not kinked.

(b) Confirm that IV catheter is of adequate size (see p19) and properly positioned in vein.

When infusing saline or Ringer's Lactate, an 18ga peripheral IV catheter is

recommended. When infusing blood or blood products, use of a 14ga or 16ga peripheral catheter is recommended. See p19 for more information.

batt

Problem: "batt" indicator illuminated and unit continues to alarm.

Solution:

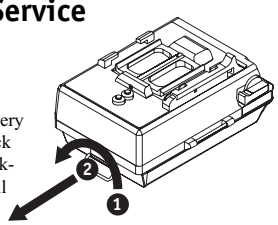
(a) Batteries are low. Replace batteries (p16) or connect optional power adapter.

Standard AAA alkaline batteries are recommended. Use only power adapters supplied by Infusion Dynamics.

Maintenance & Service

Change Batteries

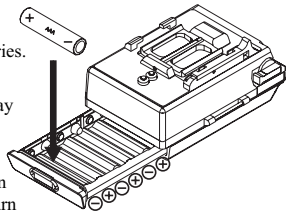
To open battery tray, turn lock counter-clock-wise and pull out.



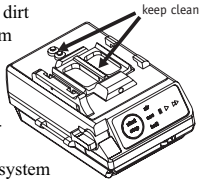
Insert six AAA batteries.

Orientation noted on tray rails.

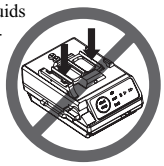
To close tray, push in fully and turn lock clockwise to secure.



Routine Maintenance



After each use, clean dirt and salt solutions from the top of the pump by flushing with water and drying thoroughly. Salt solutions can defeat the pump's air detection system and salt crystals can damage the pump's seals. Clean foreign matter from under the pump rocker to prevent jamming. Do not allow water or IV fluids to enter the battery compartment.



Do not manipulate the pump rocker with your finger—it can damage the mechanism.

Annual performance testing is recommended for organizations that wish to test the pump on a periodic basis to ensure that it is calibrated and functioning to specifications. Contact Infusion Dynamics for a copy of the End-User Performance Test Procedure (0080-0226).

Service

Please report any pump malfunctions to the company immediately. If a pump requires factory service, first contact Infusion Dynamics to receive a Returned Material Authorization number (RMA), then return the device to:

Infusion Dynamics
5209 Militia Hill Road
Plymouth Meeting PA 19462-1216
USA
TEL: 1 (800) 805-1246 or 1 (610) 941-0136

Effect of Catheter Size on Max Flow Rate

% difference, actual v. set flow rate @ 6*

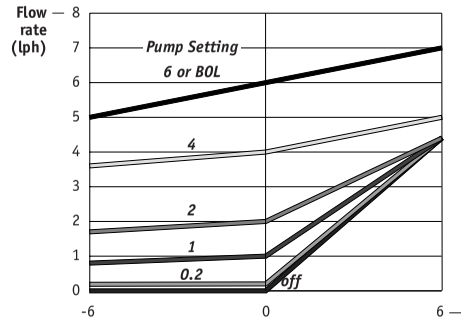
Cartridge	IV Fluid	Peripheral IV Catheter (Ga) 14 (12)	16 (14)	18 (16)	20 (18)	22 (20)
Crystalloid/ Colloid Cartridge (PN 0040-0050)	Crystalloid	+20%	+15%	**+0%**	-25%†	⊠
	Colloid	+0%	**-5%**	-20%†	⊠	⊠
Blood Cartridge (PN 0040-0051)	Crystalloid	+25%	+20%	**+10%**	-25%†	⊠
	Colloid	+15%	**+10%**	-15%†	⊠	⊠
	Whole blood	+10%	**-10%**	-35%†	⊠	⊠
	Packed RBCs	**-5%**	-25%†	⊠	⊠	⊠

Bold = Recommended; ⊠ = Do not use

*Effect of catheter size less at lower rates

†May trip occlusion alarm; use larger catheter if this occurs

Effect of IV Bag Elevation on Flow Rates



Using 18ga 1.5in catheter, saline and roller clamps wide open.

Specifications

Power Infuser Model M100B-3A (part no. 0040-0013)

Maximum flow rate	6 liters per hour
Minimum flow rate	0.2 liters per hour
BOLUS setting	250 cc in 2.5 minutes
Accuracy	±15%
Pump type	shuttle (patent no 5,577,891)
Flow profile (1-6, BOL)	pulsatile
Flow profile (0.2)	intermittent (on 4 sec at 1 lph, off 16 sec)
Free flow	yes, if fluid source above patient
Retrograde flow	prevented by valves
occ alarm triggering pressure	~20 PSIG (140kPa) peak, ~10 PSIG (70kPa) average
Typical occlusion detection time	~1 sec at 6 lph, ~5 sec at 1 lph, ~40 sec at 0.2 lph
Volume released when occ cleared	~1 cc
Air alarm (bubble size)	~20 µl
Power source	six AAA batteries or 12-15VDC power adapter
Typical battery life at 6 lph	8 hours
Power consumption	<1 W

Crystalloid / Colloid Pump Cartridge (part no. 0040-0050)

Compatible fluids	crystalloid or colloid IV fluids
Incompatible fluids	medications, blood products, non-ionic fluids
Priming volume	7cc (10cc including 18in segment)
Inlet connector	female Luer
Outlet connector	male locking Luer
Air elimination method	hydrophillic filter/hydrophobic vent
Filter pore size	1.2 microns
Maximum duration of use	24 hours, single patient
Weight	30 grams
Dimensions	4.6x9.7x1.3 cm

Blood Pump Cartridge (part no. 0040-0051)

Compatible fluids	whole blood, packed red blood cells, crystalloid or colloid IV fluids
Incompatible fluids	medications, non-ionic fluids
Priming volume	7cc (10cc including 18in segment)
Inlet connector	female Luer
Outlet connector	male locking Luer
Air elimination method	none (use IV set with drip chamber and blood filter)
Maximum duration of use	24 hours, single patient
Weight	30 grams
Dimensions	4.6x9.7x1.3 cm

These specifications hold under normal operating conditions, defined as: IV bag positioned at patient level, IV set and cartridge properly primed and cleared of air bubbles, 18in IV tubing (provided) the only segment between pump and catheter of size recommended on p19, compatible fluids used.

Components

The following Power Infuser components are available separately:

Crystalloid/colloid pump cartridges for the Power Infuser. Includes 18in pump-to-patient tubing set. Sterile, single use only. Box of 10.
Part No: 0040-0050
NSN: 6515-01-466-1488

Blood pump cartridges for the Power Infuser. Includes 18in pump-to-patient tubing set. Sterile, single use only. Box of 10.
Part No: 0040-0051
NSN: see www.infusiondynamics.com

AC/DC power adapter for the Power Infuser. Wall-mounted, US-type 120VAC plug.
Part No: 0040-0040
NSN: 6515-01-466-1481

IV pole clamp for the Power Infuser Includes IV bag holdeer and adjusts for horizontal or vertical mounting.
Part No: 0040-0070
NSN: 6515-01-470-9907

Visit www.infusiondynamics.com for the latest information on Power Infuser accessories.