MARK III Manometric Perfusion Pump

Vertical Deck

Dentsleeve International Ltd.
Manufactured by Mui Scientific

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Handbook
November, 2004
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### Notes on the use of this manual

- References within the manual are shown in brackets  
  eg (C – 4.2) = section C, part 4, instruction 2

- Part numbers (#) given in the text are unique for Dentsleeve

- The technical information and illustrations in this manual reflect specifications and operating procedures at the time of drafting. Some specifications and operating procedures differ from earlier manuals for Mark II perfusion pump models. Dentsleeve reserves the right to vary specifications and operating procedures as part of its continuous product improvement process.
Overview

Schematic of pump

Note: Schematic diagram of water perfusion circuit. Only critical components are shown.
Note: Pump length, channel numbers and spacings vary according to individual specifications. Standard deck version shown. Transducer types vary: Abbott Transpac 42582-10 transducers shown.
Overview

MKIII Pump Air – Water System

Max. Input Pressure: 240 kPa / 35 p.s.i.

110/220V

Optional Compact Resistor
- RO1-HRE/CO1
- RO1-HRE/CO2
- RO1-HRE/CO4
- RO1-HRE/CO8
- RO1-HRE/CO15
- RO1-HRE/CO30
- RO1-HRE/CO45
- RO1-HRE/CO60
**Precautions & Warnings**

- **Never drop.** Do not use if visible damage.
- **Water level never less than 2cm (C – 10).**
- **Air pressures never more than 300 kpa (45psi).**
- **Air perfusion channel. Only use for pharyngeal swallow monitoring (C – 9).**
- **Only pressurise reservoir with this line (C – 3.1).**
Assembly & filling of perfusate reservoir

1. Blow-off valve
2. ‘O’ ring
3. Always use diffusion float barrier
4. Always use water filter
   Part #: AP1FIL/WA/1
5. Fill with particle free, degassed, distilled $H_2O$
6. Add water, then place perfusion float barrier on top
7. Reservoir outflow control device
8. Tighten firmly to seal

Note: See E – 2 for Dentsleeve part #’s
Normal Use

For set-up and first use see E – 1 to E – 7

C – 2 Check, connect & set air supply

1

Click!

2

Air
Set to 100 kPa - 15 psi

To gas supply
Connection & flushing of water manifold

1. Air line from control box
   - Part # ZP1FIT/SW/B-QM2-B-200
   - Click!

2. Connect to water manifold
   - Filter

3. Open

4. Open, vent and close
Check flow values of each hydraulic resistor

1. Standard resistor shown: flow is colour coded

<table>
<thead>
<tr>
<th>Flow ml/min</th>
<th>Tube Colour</th>
<th>Screw Colour</th>
<th>Part #</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.01</td>
<td>Black</td>
<td>White</td>
<td>R01HRE/ST/1(3)</td>
</tr>
<tr>
<td>0.02</td>
<td>Black</td>
<td>Black</td>
<td>R01HRE/ST/2(3)</td>
</tr>
<tr>
<td>0.04</td>
<td>Red</td>
<td>Red</td>
<td>R01HRE/ST/4(3)</td>
</tr>
<tr>
<td>0.08</td>
<td>Red</td>
<td>White</td>
<td>R01HRE/ST/8(3)</td>
</tr>
<tr>
<td>0.15</td>
<td>Red</td>
<td>Black</td>
<td>R01HRE/ST/15(3)</td>
</tr>
<tr>
<td>0.3</td>
<td>Green</td>
<td>White</td>
<td>R01HRE/ST/30(3)</td>
</tr>
<tr>
<td>0.45</td>
<td>Green</td>
<td>Red</td>
<td>R01HRE/ST/45(3)</td>
</tr>
<tr>
<td>0.6</td>
<td>Green</td>
<td>Black</td>
<td>R01HRE/ST/60(3)</td>
</tr>
</tbody>
</table>

Alternative:
Compact hydraulic resistor

2. The flow value is...
   - Correct, go to C – 5
   - Changed, go to E – 5 or 6
Normal Use

Turn on water perfusion to fill each transducer  C – 5

1  Open pinch valve or clamp

2  Fill transducers

Note: PVB DPT-6100 Transducer shown

Note: Abbott Transpac 42582-10 Transducer Shown
**Normal Use**

### C – 6 Transducer calibration (if required)

1. Turn perfusion off - (C – 5)

2. Set transducer gain by applying standard external pressure

   ![Diagram showing How to Connect to Transducers](image1.png)

   **Note:** Shows Dentsleeve calibration manifold; made according to channel numbers and spacings Part #’s AP1CMA/TR/1to5

3. or use gravity calibration

   ![Diagram showing 68cm H₂O, 50mm Hg](image2.png)

   **Note:** Catheter must be attached to transducers – (C – 7)

### C – 7 Connect catheter to transducers

1. Select correct channel

2. Twist & push on firmly

   ![Diagram showing Catheter Detail](image3.png)

   **Note:** Catheter detail is for Dentsleeve product
Water injection procedure - each channel

1. H₂O - no bubbles

2. Open side-port

3. Inject 5ml of H₂O
Normal Use

C – 8 Water injection procedure - each channel (continued)

4 Close side-port then remove syringe

Note: Arrangement for PVB DPT-6100 transducer shown
Check flow value for air perfusion manometry

1. Identify air perfusion channel pinch valve

2. Ensure resistor for air perfusion channel is correct

![Image](C.png)

- Only use air perfusion for detection of swallowing in pharynx
- Air flow rate through hydraulic resistor is \( \times 100 \) water flow rate.
- Suitable compact resistors give airflow on case

<table>
<thead>
<tr>
<th>Air flow ml/min</th>
<th>Water Flow ml/min</th>
<th>Part #</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>0.02</td>
<td>R01HRE/CO/2</td>
</tr>
<tr>
<td>4</td>
<td>0.04</td>
<td>R01HRE/CO/4</td>
</tr>
<tr>
<td>8</td>
<td>0.08</td>
<td>R01HRE/CO/8</td>
</tr>
</tbody>
</table>

![Image](C.png)

- Must be installed between manifold and transducer to limit air flow into manometric catheter to less than 10ml/min
C – 10  Observation & refilling of perfusate reservoir

If perfusate exhausted, large volumes of gas may be perfused down catheter

1  Refill when at 2cm

2  Release pressure

3  Refill

4  Restart perfusion

Particle free, degassed, distilled H₂O

Tighten

Repressurise

Click!
Maintain correct perfusate reservoir pressure

1. Monitor air pressure. Maintain at 100kPa/15psi.

2. Check if air pressure drops

3. Check that air supply is adequate

At least 130 kPa/20psi

OR

At least 1000 kPa/150psi

open
Prevention, recognition and correction of hydraulic resistor blockage

1. Prevention of blockages - Always use perfusate filter
2. Minimise perfusate particle load
   - Double-distilled or de-ionised water
   - No particles in reservoir (E-2)
3. Replace water perfusate filter regularly - (G-1)
4. Check perfusate flow rates - assemble 1ml syringe barrel on transducer
5. Start perfusion - (C-2)
6. Measure time to deliver water

Note: for resistor flow rates < 0.15ml/min use 0.25 - 0.50 ml syringe barrels
### Normal Use

#### Prevention, recognition and correction of hydraulic resistor blockage

<table>
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<th>Description</th>
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<td>Backflush forcibly</td>
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<td>Observe water flow</td>
</tr>
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<td>10</td>
<td>Re-install - (E – 5)</td>
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<tr>
<td><strong>OR</strong></td>
<td></td>
</tr>
<tr>
<td>11</td>
<td>Remove resistor from circuit</td>
</tr>
<tr>
<td>12</td>
<td>Insert flush support tool - (E – 6)</td>
</tr>
<tr>
<td>13</td>
<td>Same steps as C – 11.7 to 11.10 above</td>
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Normal Use

Compressor

1. Always ground

2. Turn on power switch. Power is on when switch is illuminated

3. Connect compressor air outlet to pump

4. Plug in compressor to pump control

5. Press compressor on/off switch. Functioning normally when switch is illuminated
Steps On Completion of Measurements

1. Depressurise

2. Close and disconnect from manifold

3. Remove lid

4. Drain Reservoir

5. Remove float & air dry

Do not transfer particles to internal surfaces of reservoir

Lint & particle free surface
Steps On Completion of Measurements

D – 2  Water manifold

1  Close

D – 3  Air supply

1  Turn off compressor

2  Close cylinder valve
Set Up Procedures & Connection of Components

Air supply  E – 1

⚠️ Installation only by an approved, qualified biomedical engineer

1. Use air

**Note:** Air chosen as:

1. Air dissolution in perfusate prevented by perfusate float barrier.
3. Usually more available and cheaper than N₂.
4. Available from wall supply and simple compressors.

2. Set up for compressor, wall or air bottle supply

- Compressor: E – 1.3
- Wall: E – 1.4
- Air bottle: E – 1.6 or 1.9
E – 1  Air supply (continued)

3  Install next to pump deck or place on bottom shelf of trolley

OR

4  Identify air line

Black  Part # ZP1TUB/NS/1  Part # ZP1FIT/SW/SS-400-7-2

Connects to pump Air inlet (C – 1.1) Part # ZP1FIT/SW/B-QC4-B-400KI

5  Ensure air source is suitable:
   • 130 - 240 kPa or 20 - 35 psi
   • no oil or moisture
   • filtered to 0.5 micron

6  Make appropriate connection to supply
Set Up Procedures & Connection of Components

Air supply (continued)

7. Identify air line with Dentsleeve supplied regulator

- Factory set by Dentsleeve to deliver 300 kPa or 45 psi
- Connect to pump air inlet (C – 1.1)
- Cylinder pressure gauge
- Part # ZP1REG/HP/1
- Medical international air pin index (Size C cylinders only)

8. Identify air line if no high pressure regulator supplied

- Black

9. Connect to suitable locally sourced high pressure regulator with lockable outlet pressure control

10. Adjust regulator to deliver outlet pressure of 300 kPa or 45 psi
E – 2  Perfusate reservoir prior to first use

1. Check correct assembly of perfusate reservoir
   - Blow-off valve
     Part # ZP1FIT/SW/SS-4CPA2-3
   - Closure Knob
   - 'O' ring
     Part # ZP1SEA/OR/1
   - Gasket under lid
     Part # ZP1SEA/GA/1
   - Reservoir outflow control device
   - Always use diffusion float barrier
   - Gasket in channel
     Part # ZP1SEA/GA/1
   - Outlet 'O' ring
     Part # ZP1SEA/OR/2
   - Always use water filter (C – 2.2)
     Part # AP1FIL/WA/1

2. Flush reservoir with water to remove any particles
Installation of pressure transducers

1

PVB DPT-6100

Abbott Transpac 42582-01

2

Mount bar removable
Installation of pressure transducers (continued)
Installation of pressure transducers (continued)
E – 4 Water perfusion manifold – removal

1.

Water perfusion manifold

Air perfusion (C – 9 and E – 7)
Water perfusion manifold – removal (continued)
Set Up Procedures & Connection of Components

E – 5 Standard hydraulic resistors

1. Identify standard resistor with correct flow value. (C – 4)

2. Prime resistor with water. Use 1 ml syringe for 0.6 - 0.15ml/min resistors
   0.5ml syringe for lower flow rates

3. Inject till water flows from other end

4. Fill resistor connector as syringe withdrawn

- Particle-free water
- No bubbles trapped in luer
Standard hydraulic resistors (continued)

5. Connect resistor to manifold side arm luer
   Ensure resistor connector remains water filled

6. Push and rotate resistor firmly onto manifold luer

7. Open
Set Up Procedures & Connection of Components

E – 5  Standard hydraulic resistors (continued)

8  Debubble downstream resistor luer
   Inject particle-free water into bottom of luer

9  Ensure no bubbles are trapped

10 Connect to pressure transducer
    Preferred position for 3 way stopcock

11 Use special high pressure stopcock

12 Push and rotate resistor firmly onto
    3 way stopcock

Abbott transpac
42582-01 shown

Part # ZP1STO/HP/2

Water filled

Note  PVB DPT-6100 transducer has integral stop-cock at transducer outlet

13  Final setup: Follow instructions from (C – 7.2)
Compact resistors

1. Check flow values for each hydraulic resistor

2. Prime resistor with water - Use flush tool

   - Flush tool - Part # AP1FTO/CR/1
   - Adhesive tape
   - Flush tool holder on top of control box

3. Place flush tool on silicone rubber connector

4. Use 1 ml syringe for 0.6 – 0.15 ml/min resistors
   0.25 – 0.5 syringe for lower flow rates

5. Inject until water flows from other end

6. Fill resistor connector as syringe withdrawn

7. Remove flush tool
8 Connect as shown

Note: Connectors are self-debubbling. PVB DPT-6100 transducer shown.
9  Connect resistor to manifold sidearm

10  Open

11  Final set-up - follow from (C – 5.2).
E – 7  Air perfusion circuit

\[ \text{\footnotesize \textbf{Warning}} \]
\[ \text{\footnotesize \textbf{N}_2 \text{ perfusion into pharynx may dilute inspired oxygen - use only air for perfusate reservoir pressurisation in small children, as this gas is also used for gas perfusion circuit}} \]

1. Identify circuit

2. Locate air manifold and check correctly connected

3. Resistor must always be installed
Set Up Procedures & Connection of Components

Air perfusion circuit (continued)

4. Select resistor that controls airflow to less than 10ml/min

<table>
<thead>
<tr>
<th>Air flow ml/min</th>
<th>Waterflow ml/min</th>
<th>Part #</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>0.02</td>
<td>Black/Black</td>
</tr>
<tr>
<td>4</td>
<td>0.04</td>
<td>Red/Red</td>
</tr>
<tr>
<td>8</td>
<td>0.08</td>
<td>Red/White</td>
</tr>
</tbody>
</table>

5. Airflow is x100 waterflow

Appropriate compact resistors show airflow on case

6. Install air flow resistor between air manifold luer and transducer

7. No water prime required

Air perfusion to be used only for pharyngeal manometry
Cleaning & Disinfection

Cleaning of plastic parts

1. Clean with cloth and mild detergent
2. Wipe with isopropyl alcohol

Sterilization of perfusate reservoir

1. Gas sterilize only

Sterilization of manifolds

1. Autoclavable

Hydraulic resistors

1. Not autoclavable
2. Autoclavable

Cleaning of compressor

1. Wipe with a dry cloth
### Regular Maintenance

**G – 1**

Every 3 months (or as needed): perfusate water filter

<table>
<thead>
<tr>
<th></th>
<th>Replace</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td></td>
</tr>
</tbody>
</table>

Part # AP1FIL/WA/1
Every year or as needed: gas filters  G – 2

To be done only by an approved, qualified biomedical engineer

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Disconnect gas supply then open control box (G – 3.2)</td>
</tr>
<tr>
<td>2</td>
<td>Use correct filter</td>
</tr>
</tbody>
</table>

Part # AP1FIL/GA/1

Gas (Black)

3 Replace filter

4 Check for air-tightness

Note: Gas filter life depends on quality of air – always use medical grade
G – 3  Service of control box by Dentsleeve

1. Undo screw that holds control box
2. Send control box to Dentsleeve
Regular Maintenance

1. Check desiccant is orange. When it becomes colourless, replace.

- Spread granules evenly onto tray, one granule deep.
- Heat granules for approximately 15 mins. (or until it turns back to its original orange color) at 100°C (200°F) in a conventional oven.
- Cool desiccant before replacing back into canister.
Diagnosis of abnormal air consumption

1. Check compressor connection

For compressor malfunction, please contact Dentsleeve

OR

Check regulator/cylinder connection

2. Pressurise air circuit - Turn on

3. Adjust air pressure

4. Turn off
H – 1  Diagnosis of abnormal air consumption (continued)

5  Recognise leakage - Wait 1 hour

either  or

6  Drop less than 33 kPa/5psi

- No significant leak

7  Drop more than 33 kPa/5psi

- Significant leak

8  Follow (H-1.9) below
Diagnosis of abnormal air consumption (continued)

9. Check for leakage outside control box

10. If there are bubbles, replace fitting - Part # ZP1FIT/SW-B-QM2-B-200ZN

11. Consult approved, qualified biomedical engineer to do check (H-1.12 to H-1.17) below

12. Leakage?

Air

13. Open pump control box.

14. Remove control box lid/back
H – 1 Diagnosis of abnormal air consumption (continued)

15 ? Filter leakage - tighten or replace

16 Check rest of air circuit
Abnormal air consumption - perfusate reservoir leakage

1. First exclude air circuit leakage - (H - 1)

2. Set pressure

3. Set up reservoir. Remove blow-off valve cap

4. No water

5. Pressurise

6. Locate site of leakage - observe underwater

7. Locate site of bubbling
H – 2 Abnormal Air consumption - perfusate reservoir leakage (cont.)

8 If leak elsewhere, dismantle reservoir

9 Identify cause of leakage at base

10 Gasket clean and intact?

11 Identify cause of leakage at top

Check ‘O’ ring
Part # ZP1SEA/OR/1

Flip

Gasket underneath clean and intact?
Part # ZP1SEA/GA/1
## Specifications

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<th>Details</th>
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<td>Medical grade only</td>
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<tr>
<td>High pressure regulators</td>
<td>CONCOA Medical Air (Air pin index)</td>
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<tr>
<td>Recommended first stage regulators (*if supplied)</td>
<td></td>
</tr>
<tr>
<td>Inlet pressure</td>
<td>Air 167 - 300kPa (25 - 45 psi)</td>
</tr>
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<td>Pump inlet pressure (from gas supply first stage regulator)</td>
<td>Compressor 130 - 240kPa (20 - 35 psi)</td>
</tr>
<tr>
<td>Supply lines (from gas bottles)</td>
<td>Supplied with Swagelok female quick connects</td>
</tr>
<tr>
<td>Air (black) line</td>
<td>Air Male Inlet</td>
</tr>
<tr>
<td></td>
<td>Swagelok Code ZP1FIT/SW/B-QC4-DI-400KI</td>
</tr>
<tr>
<td></td>
<td>Dentsleeve part #</td>
</tr>
<tr>
<td></td>
<td>Air female connector to perfusate reservoir</td>
</tr>
<tr>
<td></td>
<td>Swagelok Code ZP1FIT/SW/B-QM2-B-200ZN</td>
</tr>
<tr>
<td></td>
<td>Dentsleeve part #</td>
</tr>
<tr>
<td>Air supply on pump</td>
<td>Adjustable 0 - 250 kPa (0 - 36 psi)</td>
</tr>
<tr>
<td>Driving air supply (pump)</td>
<td>Flow restricted to 30ml/min at 100kPa (15 psi)</td>
</tr>
<tr>
<td>Air flow rate ± 20%</td>
<td></td>
</tr>
<tr>
<td>Pressure relief valves</td>
<td>Preset to 200 kPa (29 psi)</td>
</tr>
<tr>
<td>Perfusate reservoir relief valve</td>
<td>Preset to 300 kPa (45 psi)</td>
</tr>
<tr>
<td>Control box inlet overpressure relief valve</td>
<td></td>
</tr>
<tr>
<td>Filtration</td>
<td>0.5 micron male/female luer connection disposable disc filter</td>
</tr>
</tbody>
</table>

## Technical Support

1. Contact Dentsleeve for advice
2. See contact details on front cover
Spare Parts Kit

2x AP1FIL/GA/1 **Gas filters**, for installation within pump control box.

5x AP1FIL/WA/1 **Water filters**, for filtration of water perfusate

2x AP1SSA/PR/1 **Reservoir outflow control device**, for perfusate outflow.

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Regulatory Information

Authorised European Representative
SOLAL
2 Rue Du Travail
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FDA Approved

CE Marked

IS013488:1996 Certified