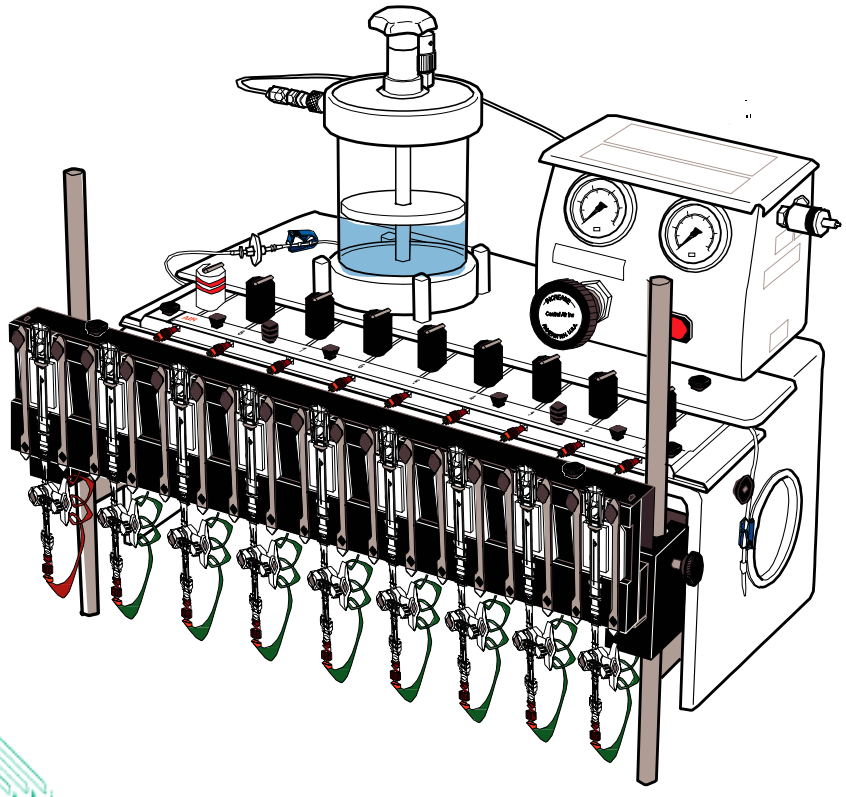
MARK II Manometric Perfusion Pump

Horizontal Deck



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Handbook

November, 2004

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In

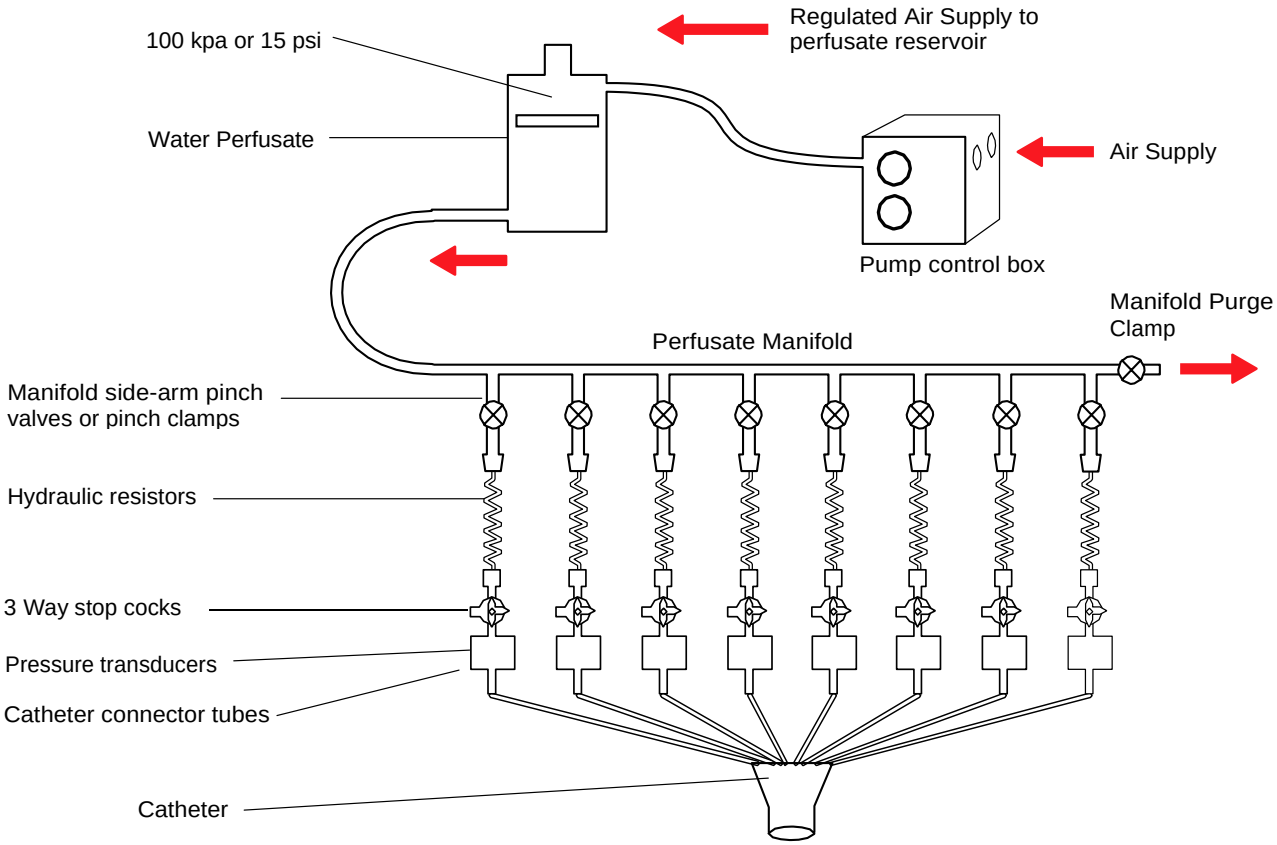
Notes on the use of this manual

- 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

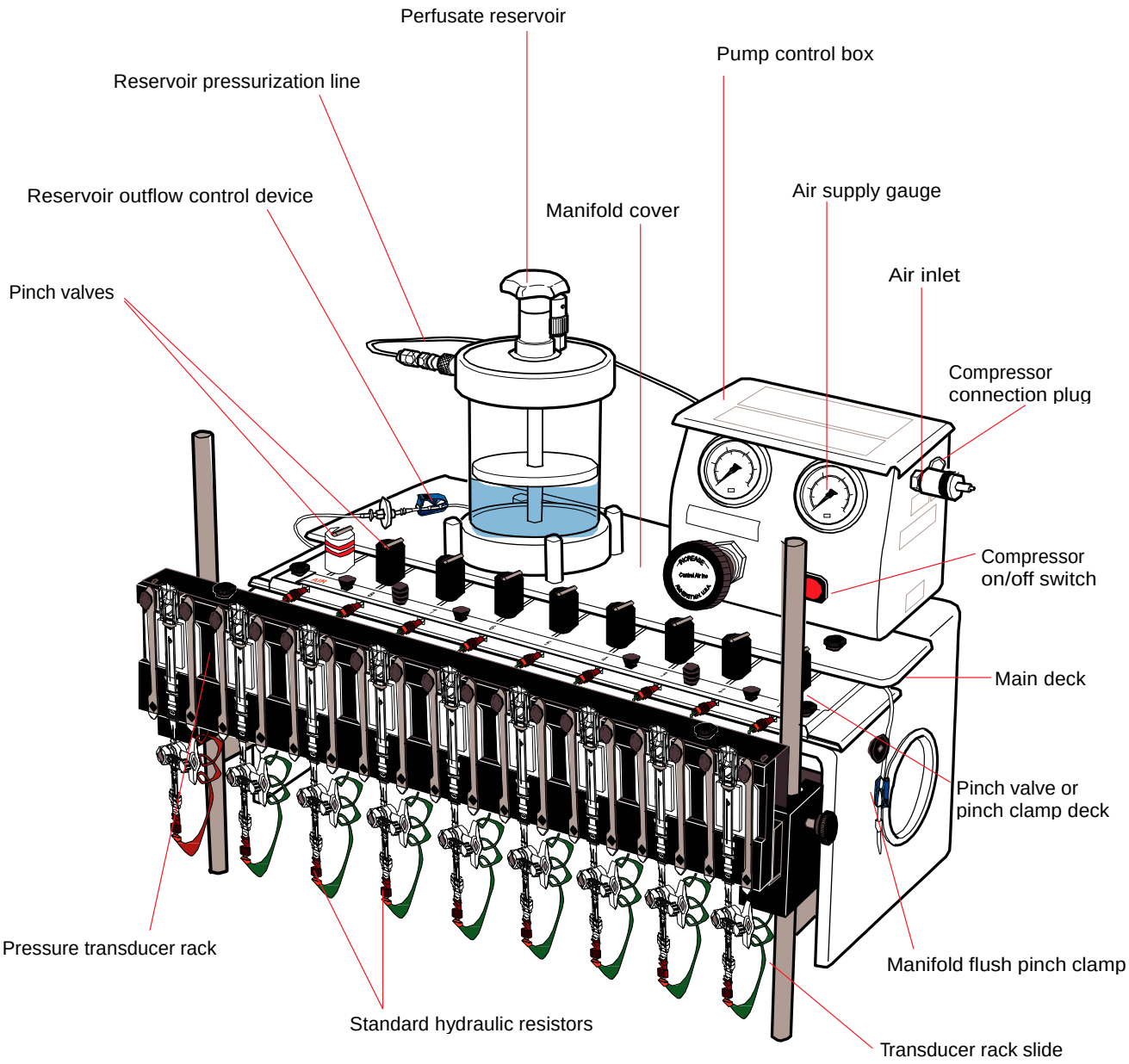
- The technical information and illustrations in this manual reflect specifications and operating procedures at the time of drafting. Some specifications and operating procedures differ from earlier manuals for Mark II perfusion pump models. Dentsleeve reserves the right to vary specifications and operating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

Schematic of pump A – 1



Note: Schematic diagram of water perfusion circuit. Only critical components are shown.

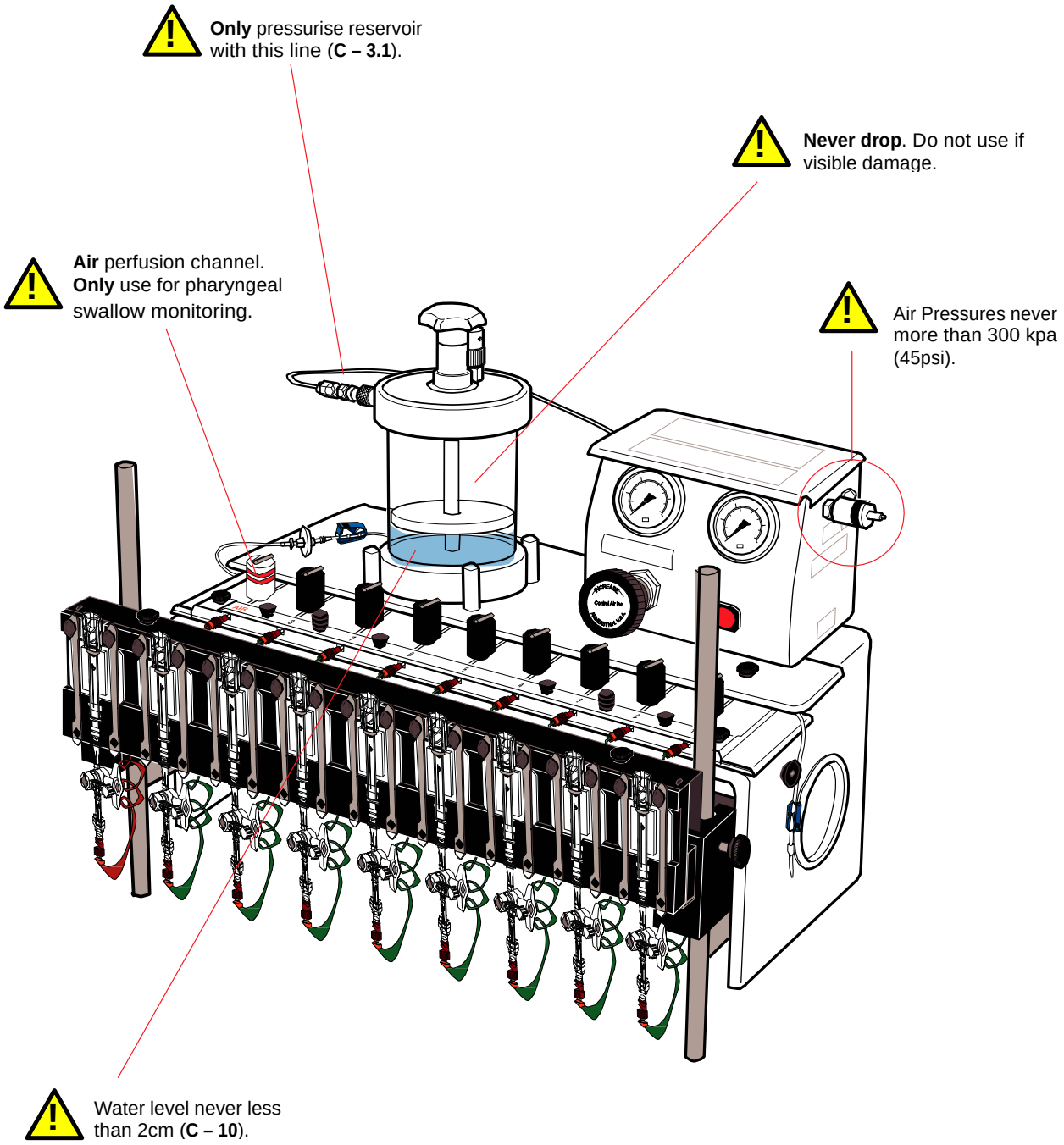
A – 2 Major pump components



Note: Pump length, channel numbers and spacings vary according to individual specifications. Compact deck version shown. Transducer types vary.

Precautions & Warnings

B



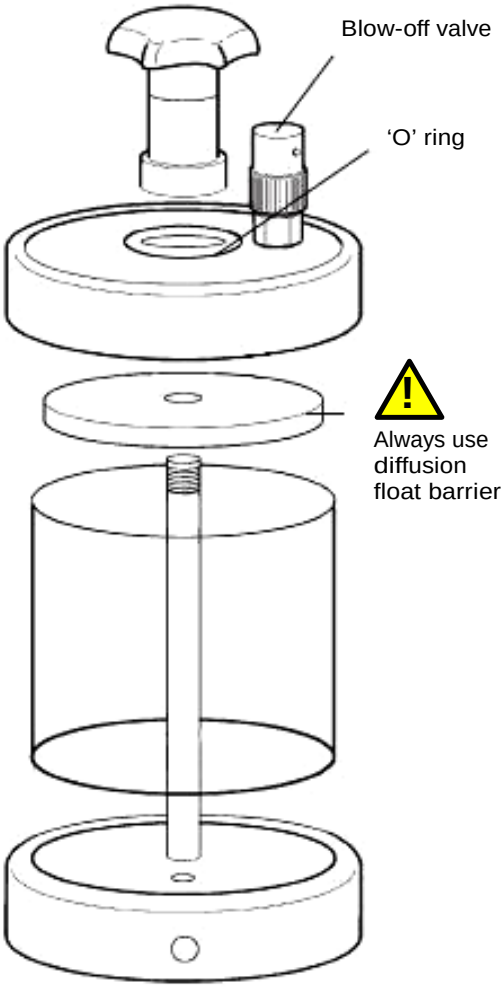
Normal Use

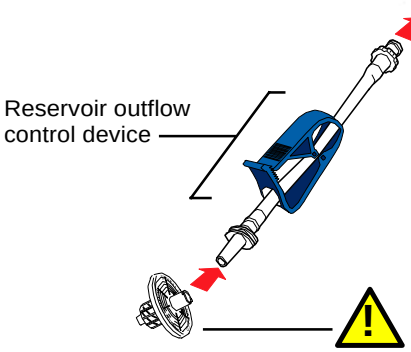
Assembly & filling of perfusate reservoir C – 1

Note: See E – 2 for Dentsleeve part #'s

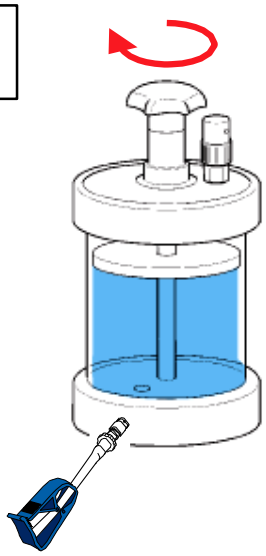
Fill with particle free, degassed, distilled H_20

1 — **2** Add water, then place perfusion float barrier on top





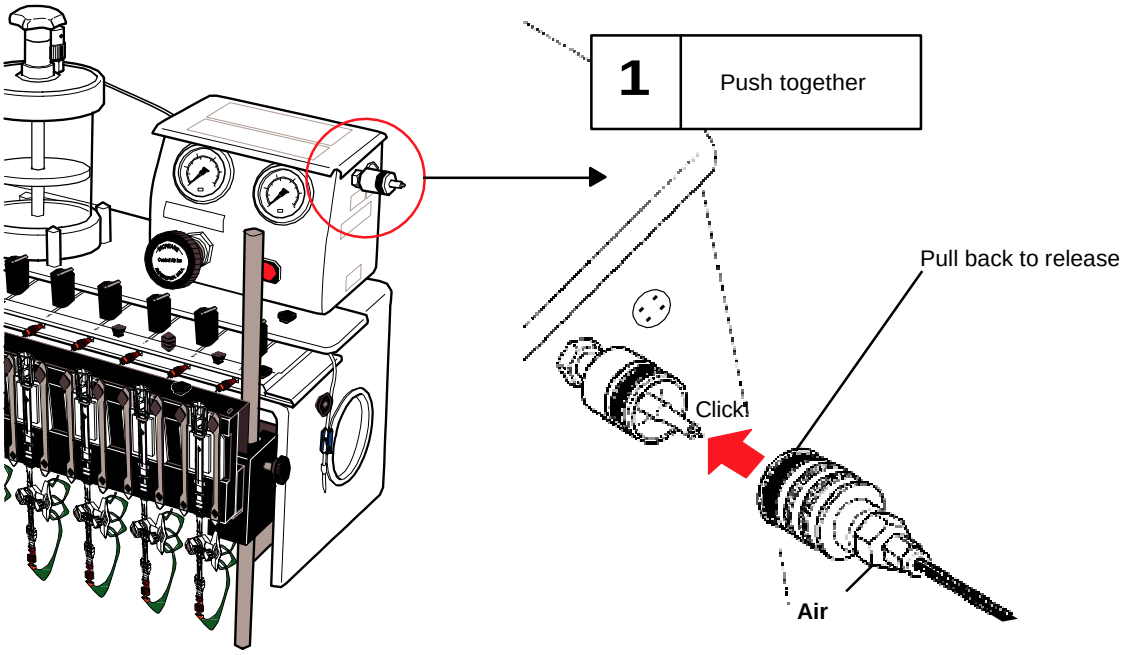
3 Tighten firmly to seal

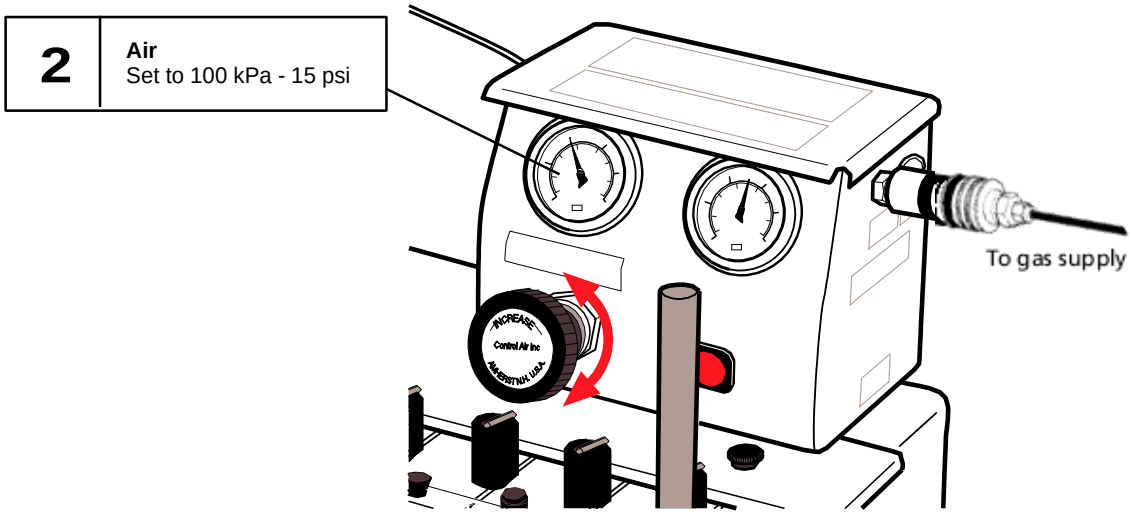


C Normal Use

For set-up and first use see E – 1 to E – 9

C – 2 Check, connect & set air supply



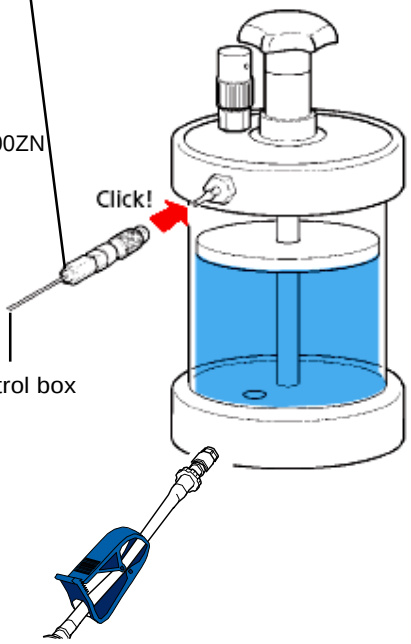


3	At least 1000 kpa (150 psi) in high pressure Air supply cylinder

Connection & flushing of water manifold C – 3

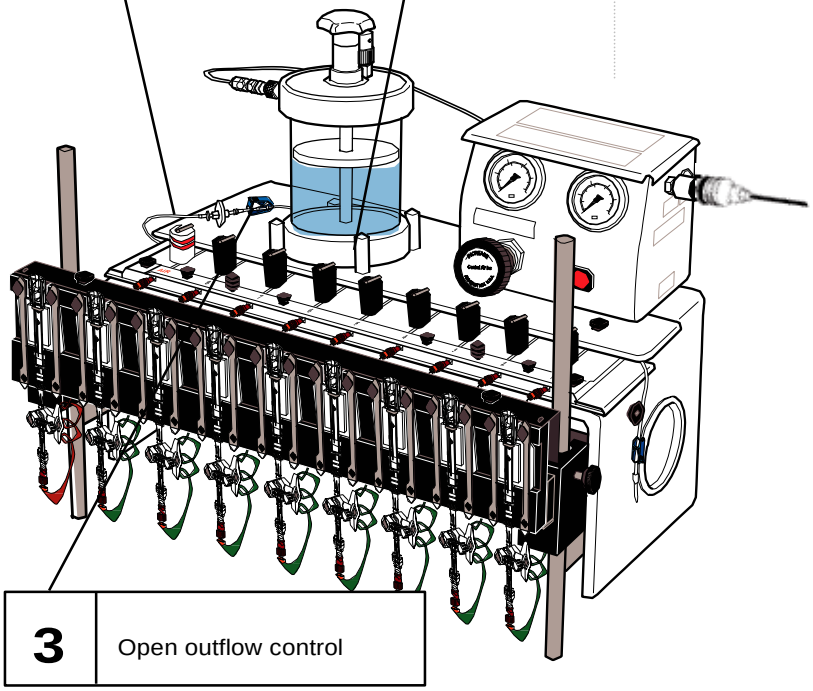
1 Push to seal onto reservoir

Part #:
ZP1FIT/SW/B-QM2-B-200ZN



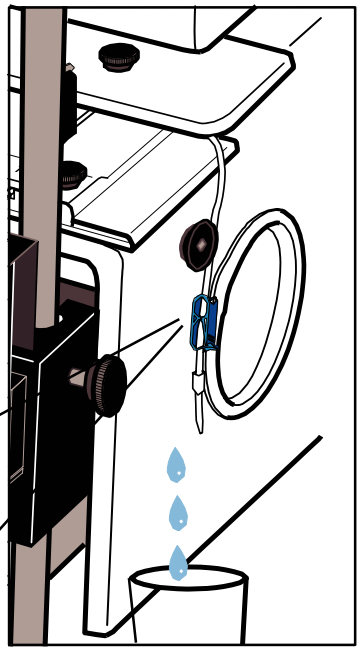
2 Connect to water manifold

Reservoir support posts



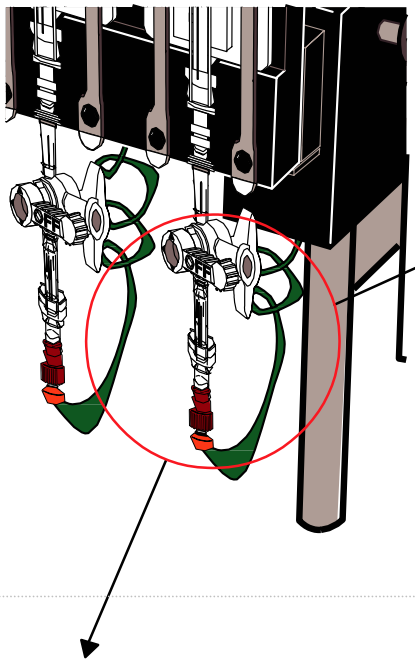
3 Open outflow control

4 Open to vent bubbles

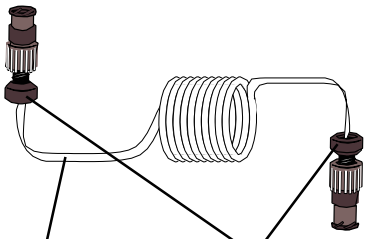


Manifold venting pinch clamp

C – 4 Check flow values of each hydraulic resistor

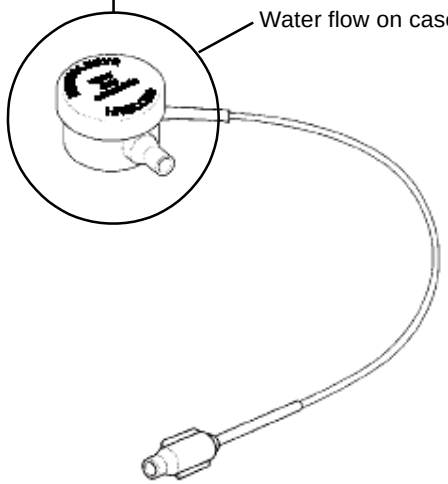


1 Standard resistor shown: flow is colour coded



Flow ml/min	Tube Colour	Screw Colour	Part #
0.01	Black	White	R01HRE/ST/1(2)
0.02	Black	Black	R01HRE/ST/2(2)
0.04	Red	Red	R01HRE/ST/4(2)
0.08	Red	White	R01HRE/ST/8(2)
0.15	Red	Black	R01HRE/ST/15(2)
0.3	Green	White	R01HRE/ST/30(2)
0.45	Green	Red	R01HRE/ST/45(2)
0.6	Green	Black	R01HRE/ST/60(2)

1 Alternative: Compact hydraulic resistor

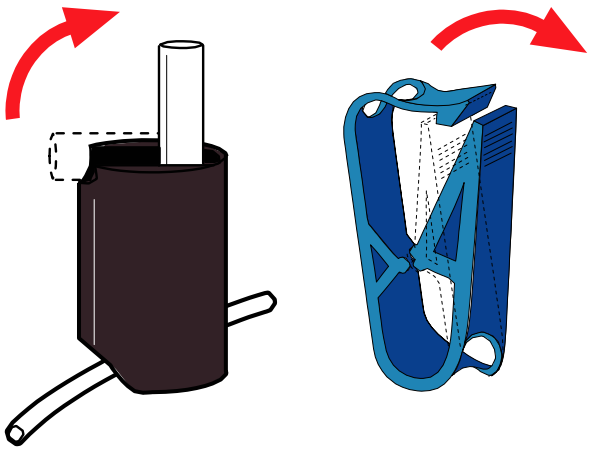


2 **The flow value is...**

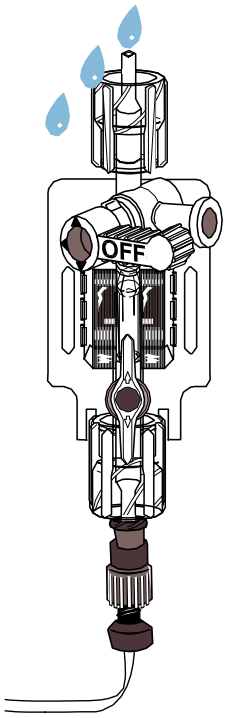
- **Correct**, go to ▶ **C – 5**
- **Changed**, go to ▶ **E – 5 or 6**

Turn on water perfusion to fill each transducer C – 5

1	Open pinch valve or clamp

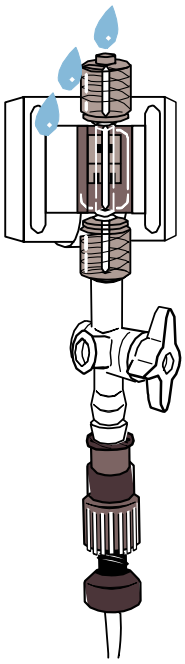


2	Fill transducers



Note: PVB DPT-6100 Transducer shown

2	Fill transducers



Prefered position for 3 way stopcock
- other than PVB DPT-6100

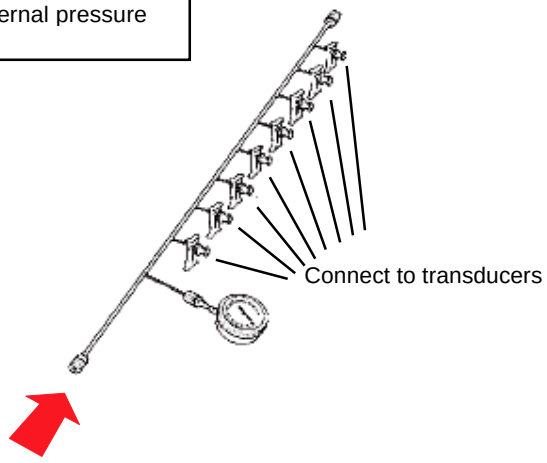
Note: Abbott Transpac 42582-10 Transducer Shown

C – 6 Transducer calibration (if required)

1	Turn perfusion off - (**C – 5**)

2	Set tranducer gain by applying standard external pressure

Shows AP1CMA/TR/2

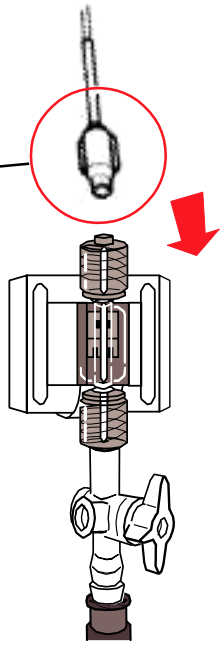


Note: Shows Dentsleeve calibration manifold; made according to channel numbers and spacings Part #'s AP1CMA/TR/1to5

C – 7 Connect catheter to transducers

1	Select correct channel

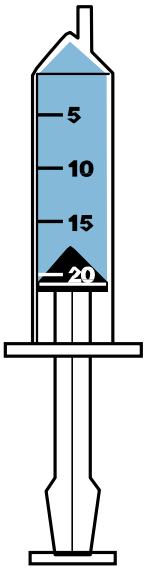
2	Twist & push on firmly



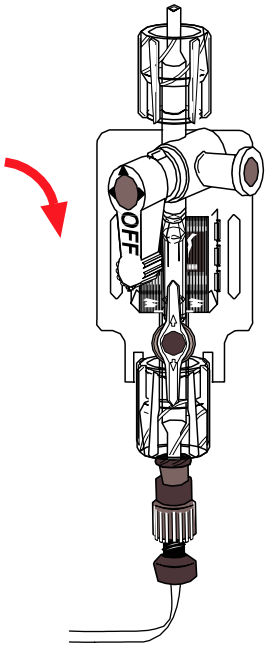
Note: Catheter detail is for Dentsleeve product

Water injection procedure - each channel C – 8

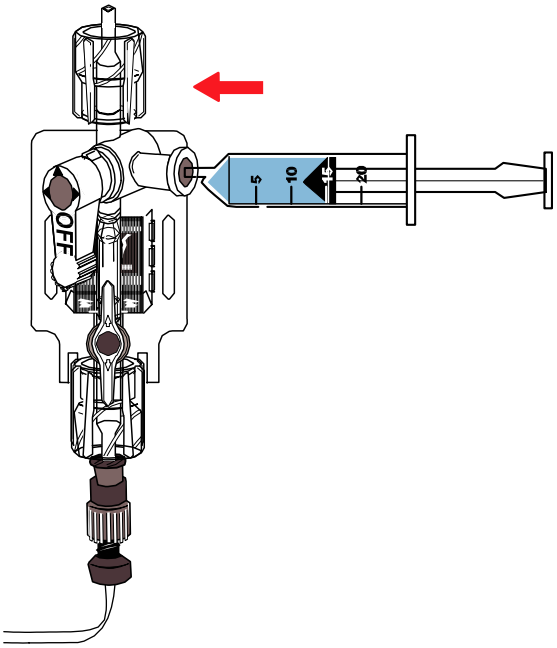
1	H_2O - no bubbles



2	Open side-port

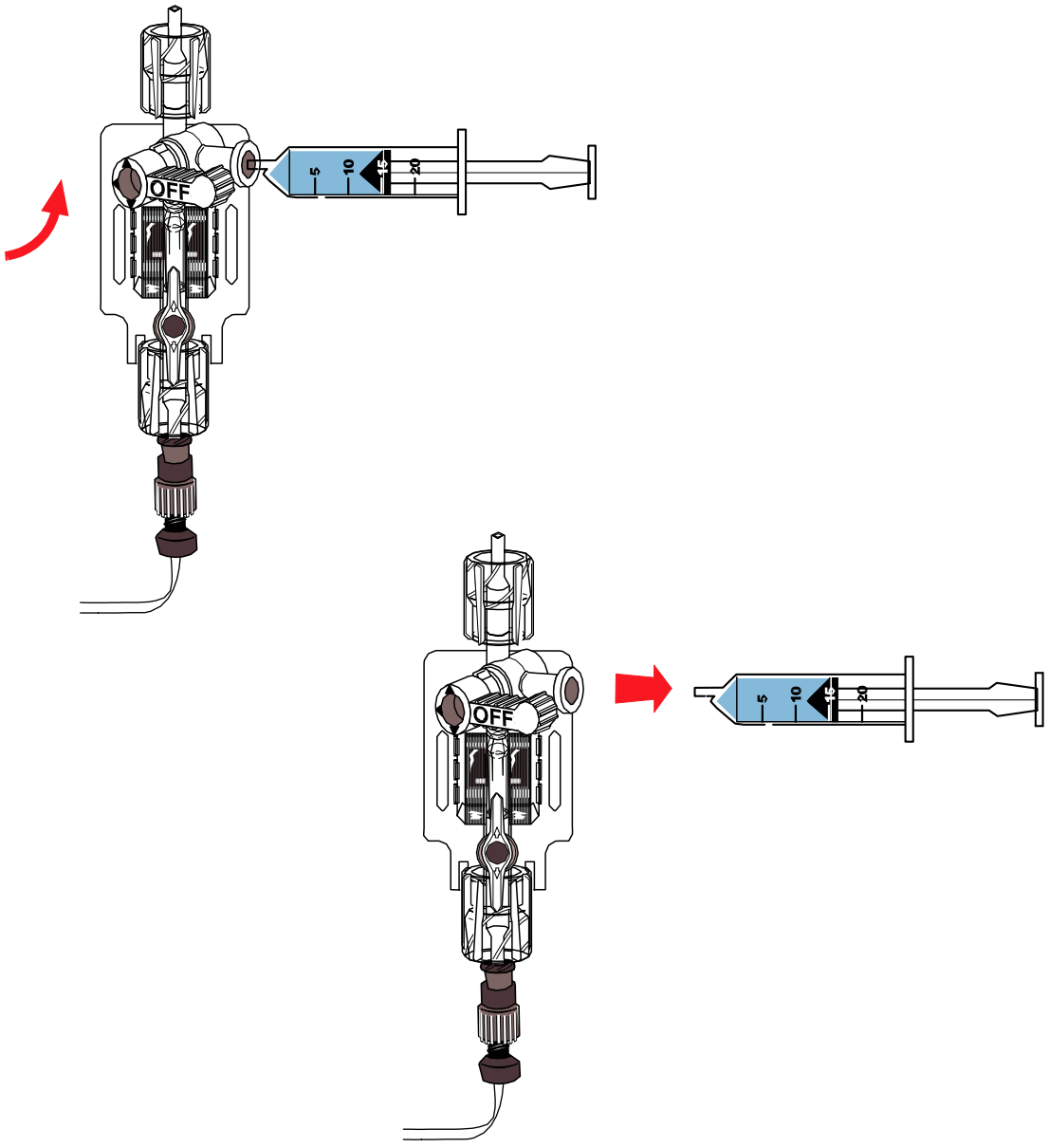


3	Inject **5ml** of H_2O



C – 8 Water injection procedure - each channel **(cont)**

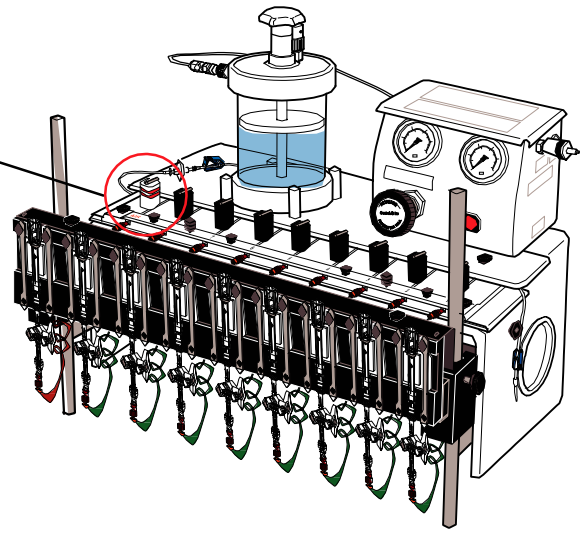
4	Close side-port then remove syringe

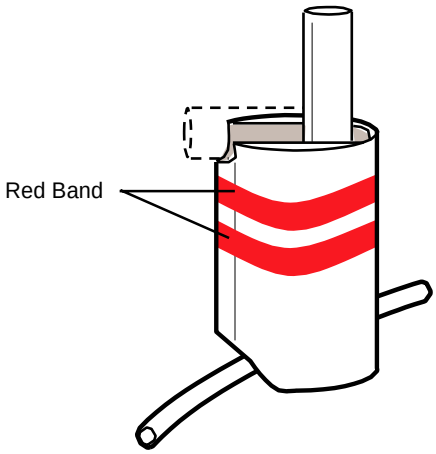


Note: Arrangement for PVB DPT-6100 transducer shown

Check flow value for air perfusion manometry C – 9

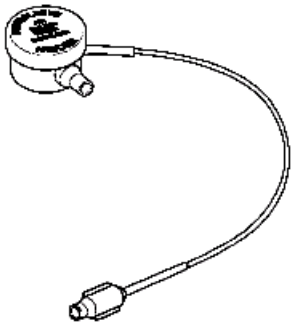
1 Identify air perfusion channel

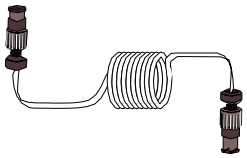




Only use air perfusion for detection of swallowing in pharynx

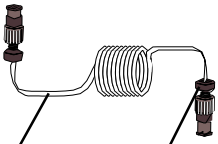
2 Ensure resistor for air perfusion channel is correct





Must be installed between manifold and transducer to limit air flow into catheter to **less than 10ml/min**

Air flow rate through hydraulic resistor is **x100 water flow rate.**



Water flow ml/min			Part #
0.02	Black	Black	R01HRE/ST/2(2)
0.04	Red	Red	R01HRE/ST/4(2)
0.08	Red	White	R01HRE/ST/8(2)

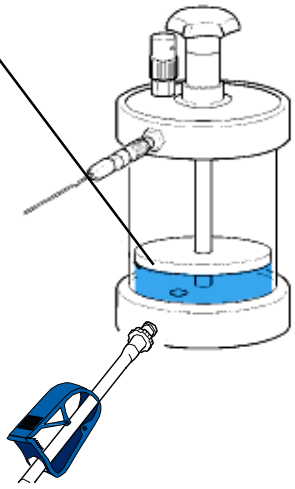
Suitable compact resistors give airflow on case

Air flow ml/min	Water Flow ml/min	Part #
2	0.02	R01HRE/CO/2
4	0.04	R01HRE/CO/4
8	0.0	R01HRE/CO/8

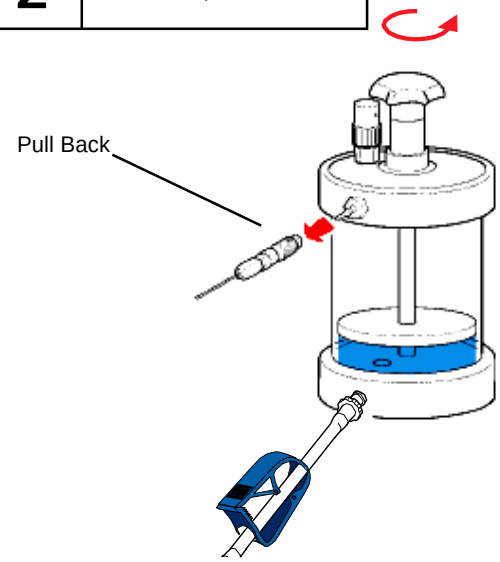
C – 10 Observation & refilling of perfusate reservoir

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

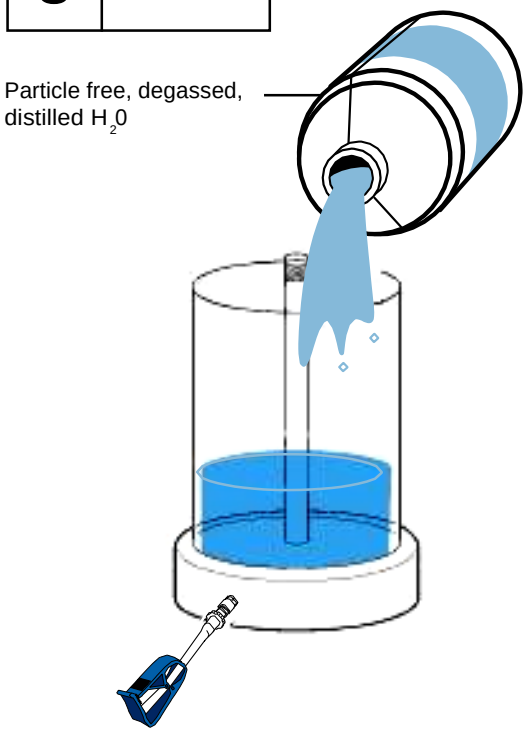
1 Refill when at 2cm



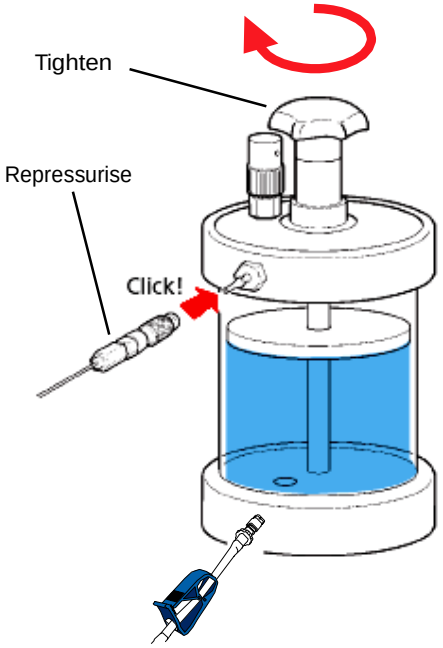
2 Release pressure



3 Refill

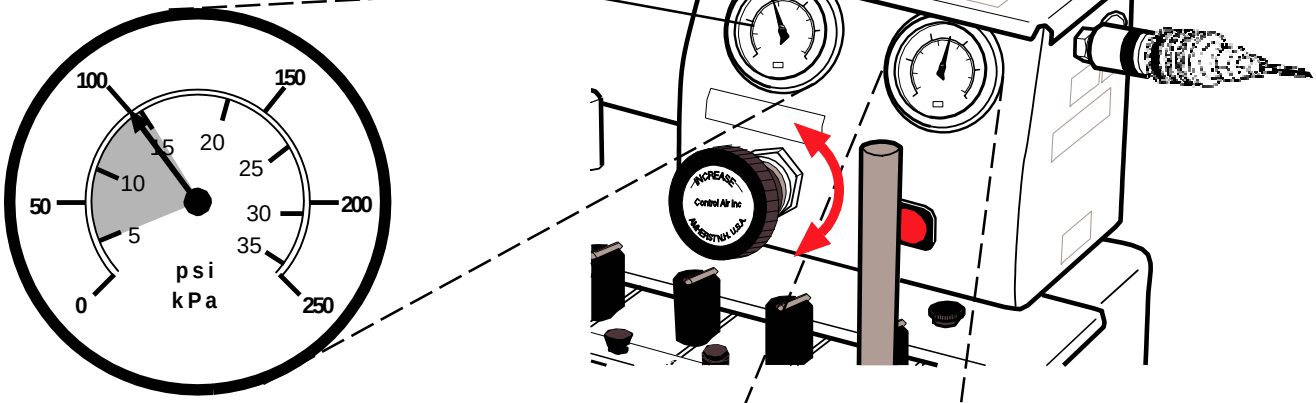


4 Restart perfusion

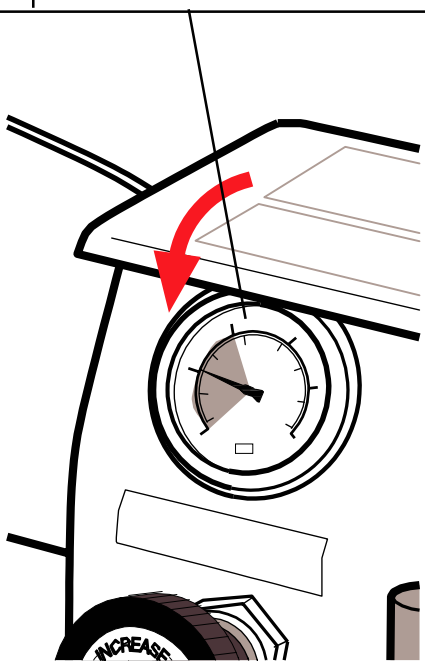


Maintain correct perfusate reservoir pressure C – 11

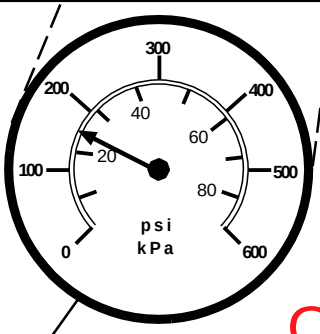
1 Monitor air pressure. Maintain at 100kPa/15psi.



2 Check if air pressure drops

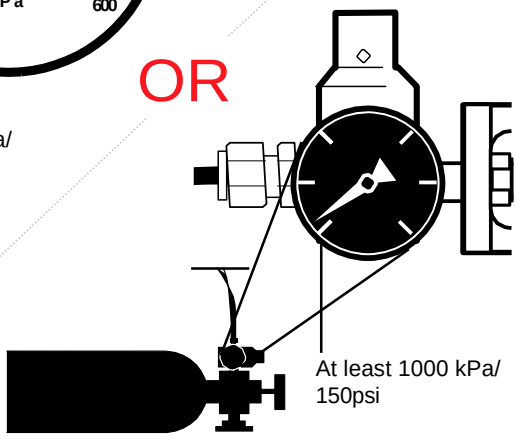


3 Check that air supply is adequate



At least 130 kPa/ 20psi

OR

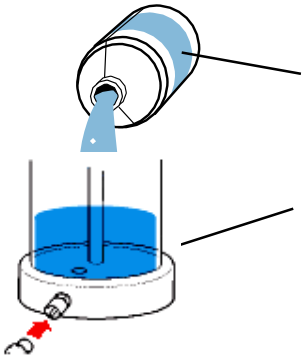


At least 1000 kPa/ 150psi

C – 12 Prevention, recognition and correction of hydraulic resistor blockage

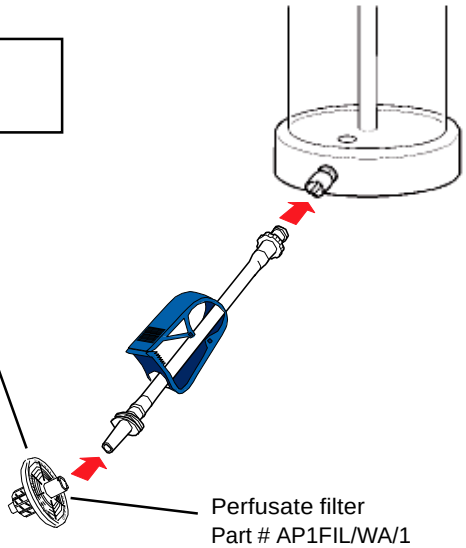
1 Prevention of blockages - **Always** use perfusate filter

2 Minimise perfusate particle load



Double-distilled or de-ionised water

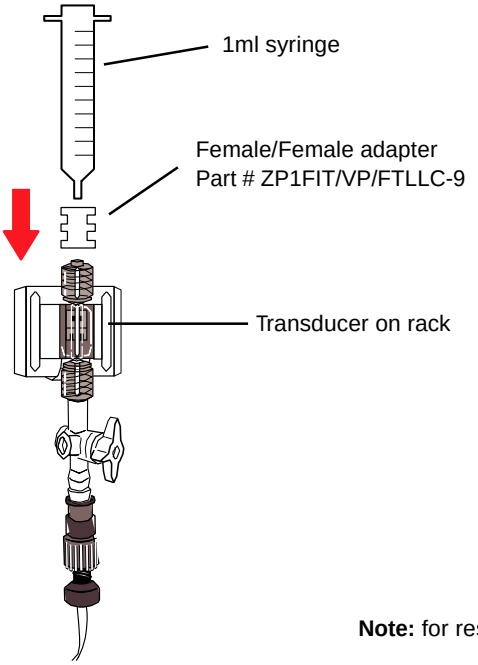
No particles in reservoir **(E-2)**



Perfusate filter
Part # AP1FIL/WA/1

3 Replace water perfusate filter regularly - **(G-1)**

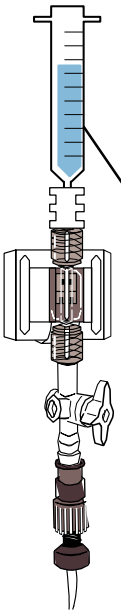
4 Check perfusate flow rates - assemble 1ml syringe barrel on transducer



1ml syringe

Female/Female adapter
Part # ZP1FIT/VP/FTLLC-9

Transducer on rack



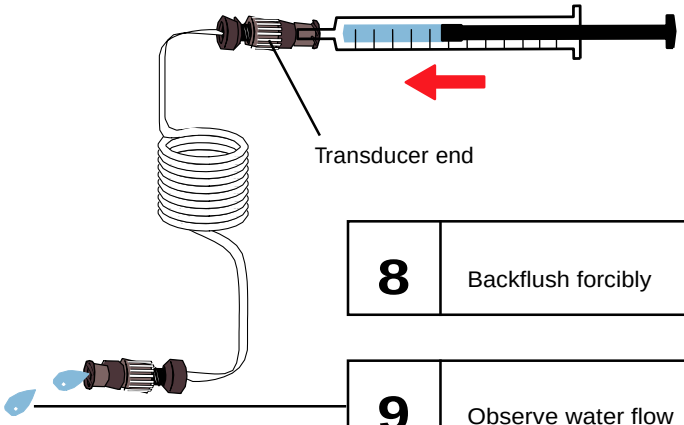
5 Start perfusion - **(C-5)**

6 Measure time to deliver water

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

Prevention, recognition & correction of hydraulic resistor blockage (cont.) **C – 12**

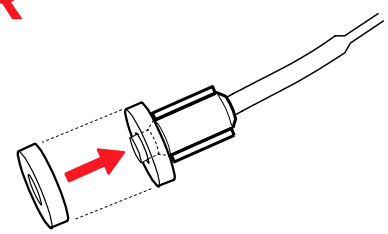
7	Flushing of blocked resistors - remove resistor from circuit

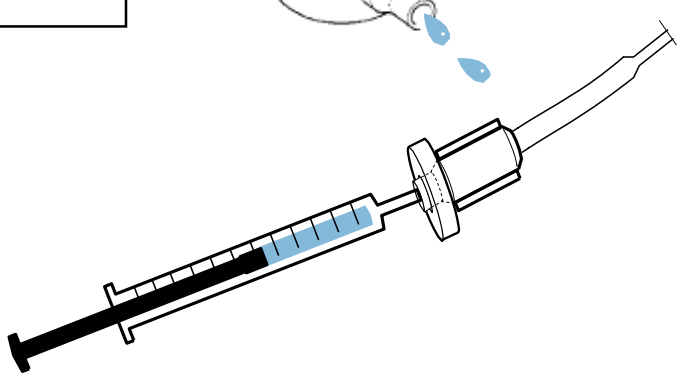


8	Backflush forcibly
9	Observe water flow
10	Re-install - **(E – 5)**

OR

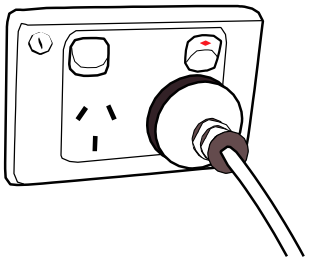
11	Remove resistor from circuit
12	Insert flush support tool - **(E – 6)**
13	Same steps as **C – 12.7 to 12.10 above**



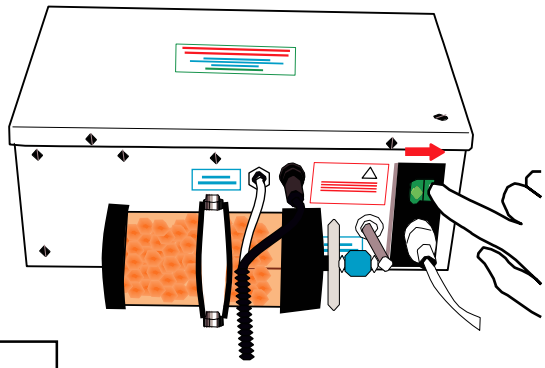


C – 13 Compressor

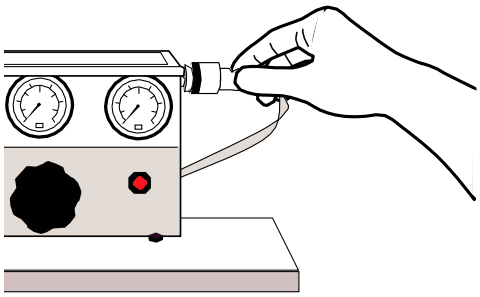
1	Always earth



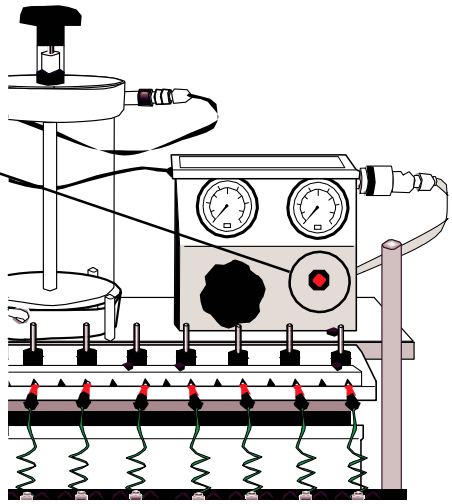
2	Turn on power switch. Power is on when switch is illuminated



3	Connect compressor air outlet to pump control box
4	Plug in compressor to pump control



5	Press compressor on/off switch. Functioning normally when switch is illuminated

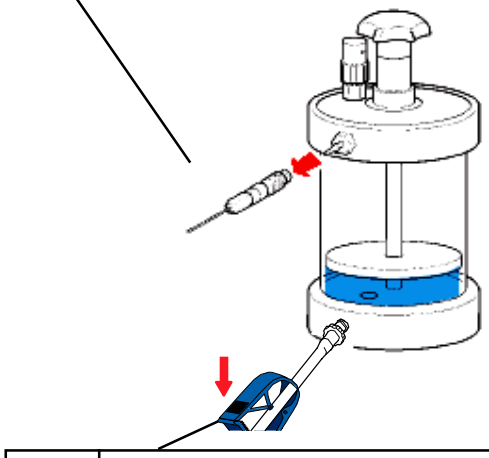


Steps On Completion of Measurements

D

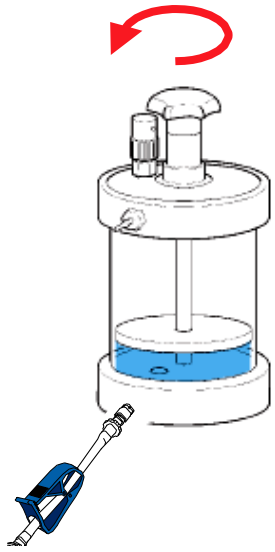
Perfusate reservoir D – 1

1	Depressurise



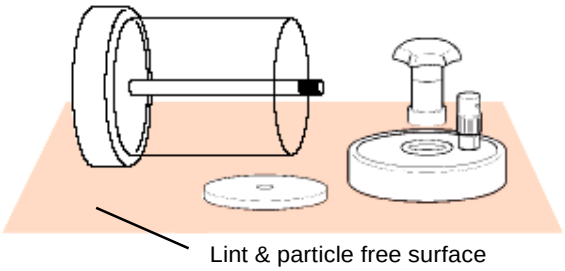
2	Close and disconnect from manifold

3	Remove lid



4	Drain Reservoir

5	Remove float & air dry



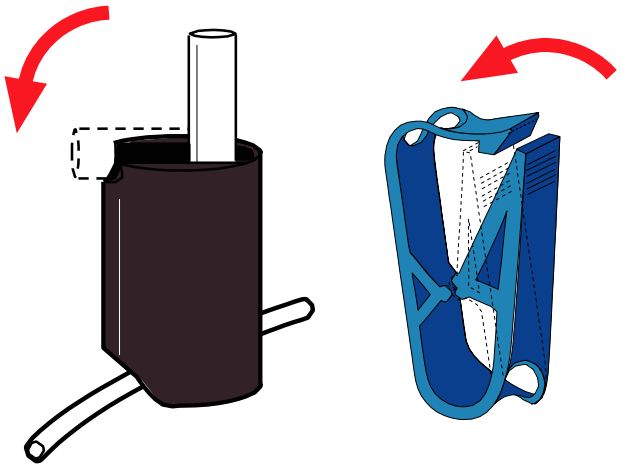
⚠ Do not transfer particles to internal surfaces of reservoir

D

Steps On Completion of Measurements

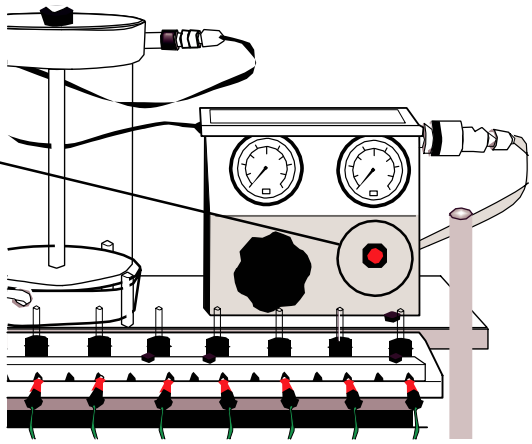
D – 2 Water manifold

1	Close

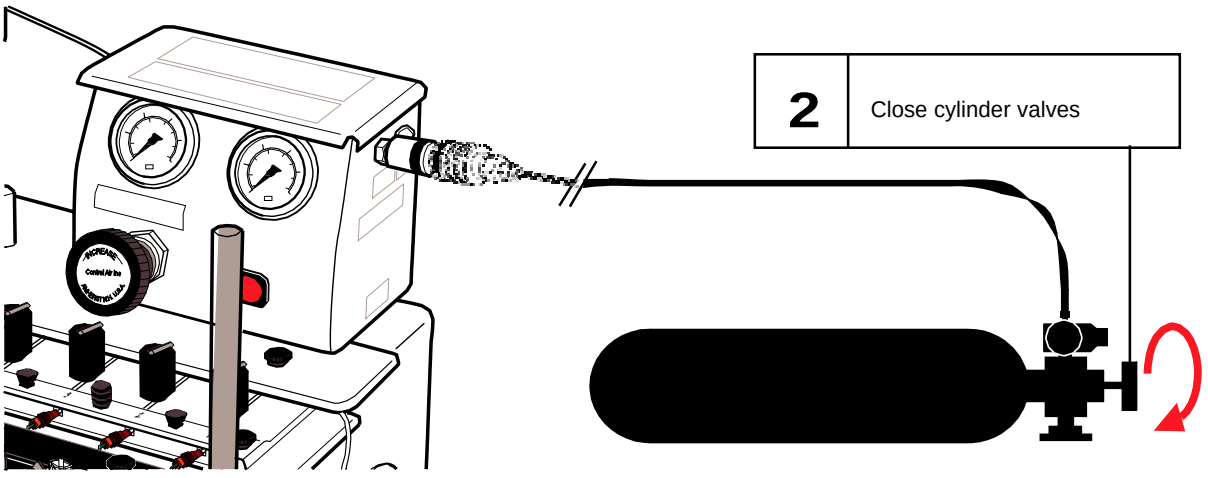


D – 3 Air supply

1	Turn off compressor



OR



2	Close cylinder valves

Air supply/Compressor 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.
2. More suitable for gas perfusion manometry than N_2 .
3. Usually more available and cheaper than N_2 .
4. Available from wall supply and simple compressors.

2	Set up for compressor, wall or air bottle supply

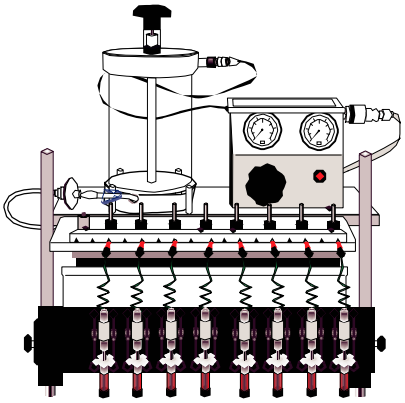
Compressor ▶ **E – 1.3**

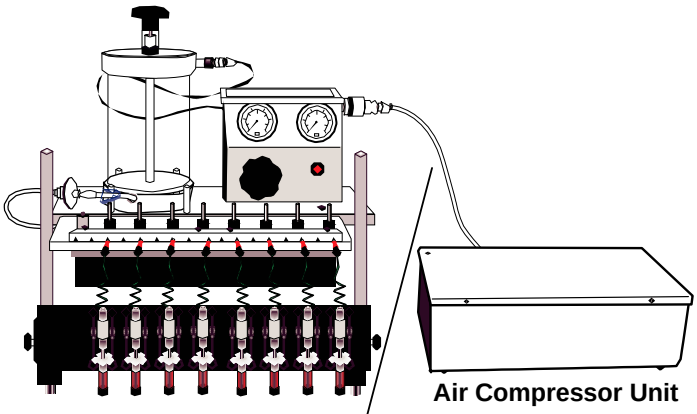
Wall ▶ **E – 1.4**

Air bottle ▶ **E – 1.6 or 1.9**

E – 1 Air supply/Compressor

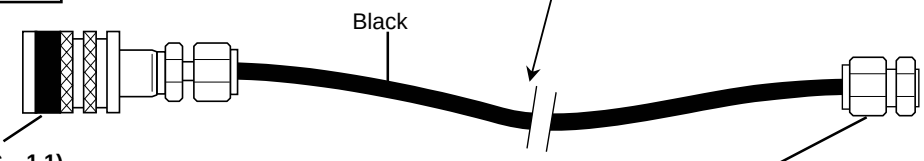
3	Install under pump deck





4	Identify air line

OR



Connects to pump Air/N2 inlet **(C – 1.1)**

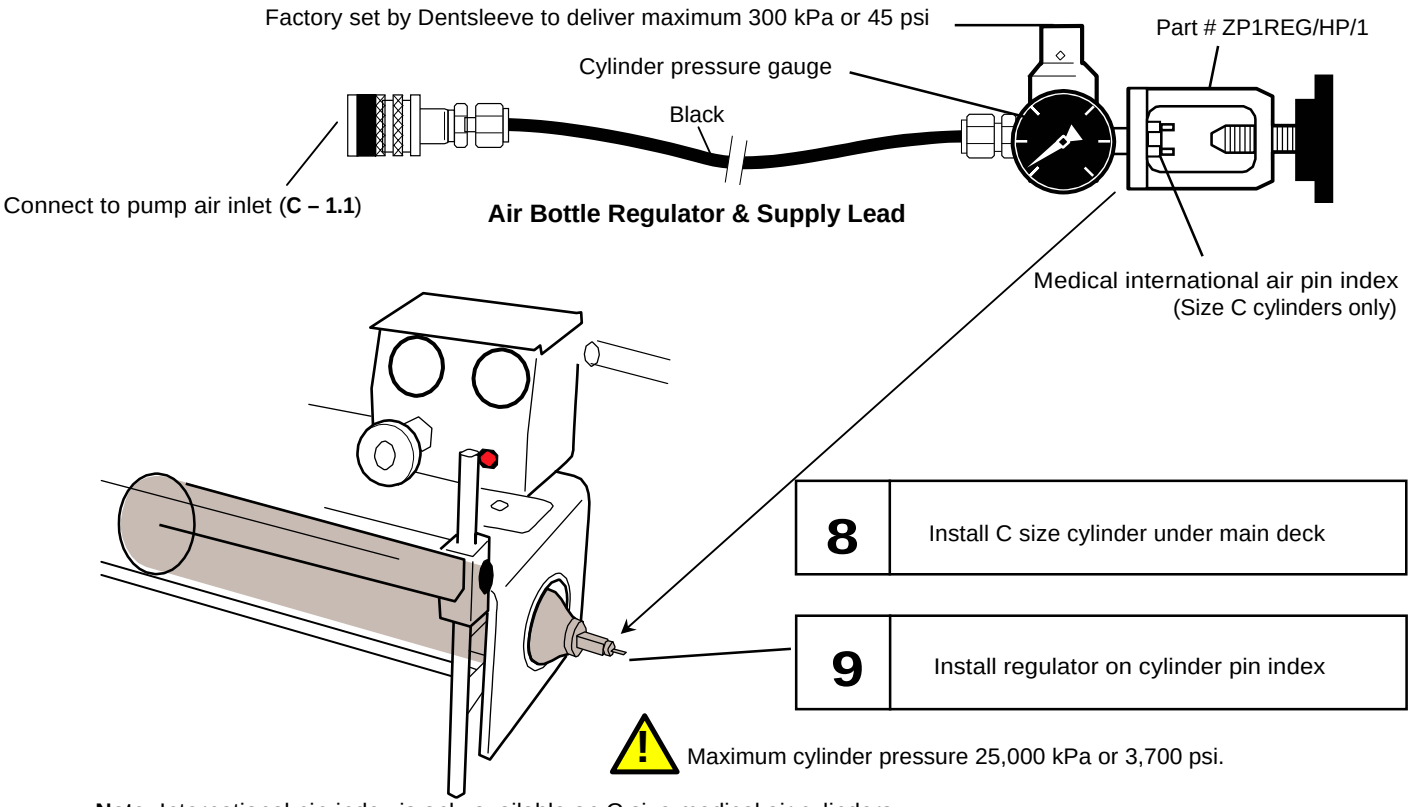
Short Air Link Lead – 65 cm

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

Air supply/Compressor E – 1

7	Identify air line with Dentsleeve supplied regulator

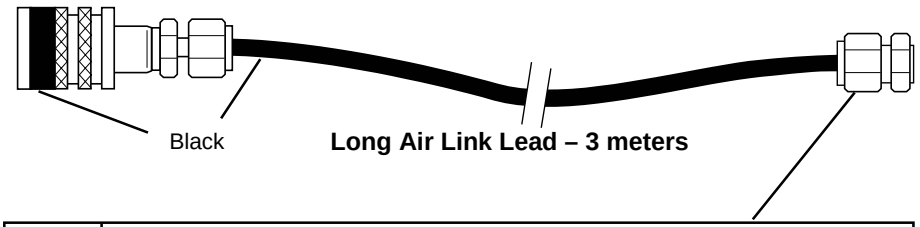


8	Install C size cylinder under main deck
9	Install regulator on cylinder pin index

⚠ Maximum cylinder pressure 25,000 kPa or 3,700 psi.

Note: International pin-index is only available on C size medical air cylinders.
(3 Litres volume on hydrostatic test). Index must be specified for air.

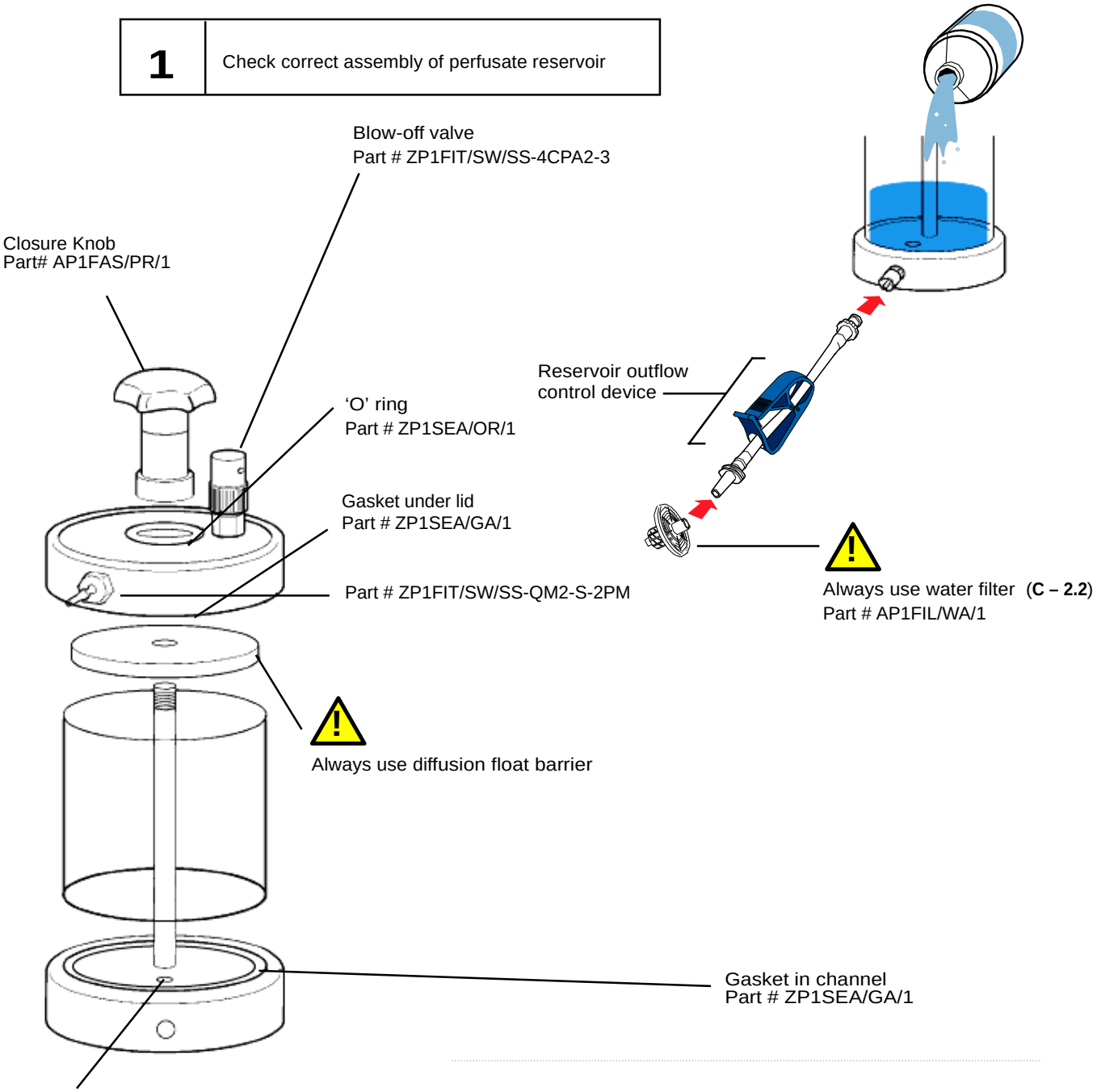
10	Identify air line if no high pressure regulator supplied



⚠ 11	Connect to suitable locally sourced high pressure regulator with lockable outlet pressure control
⚠ 12	Adjust regulator to deliver outlet pressure no greater than 300 kPa or 45 psi

E – 2 Perfusate reservoir prior to first use

1	Check correct assembly of perfusate reservoir

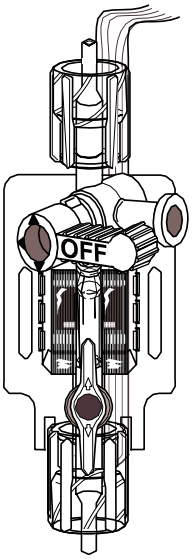


2	Flush reservoir with water to remove any particles

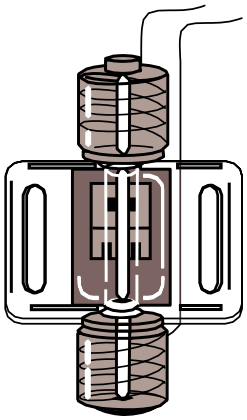
Installation of pressure transducers E – 3

1

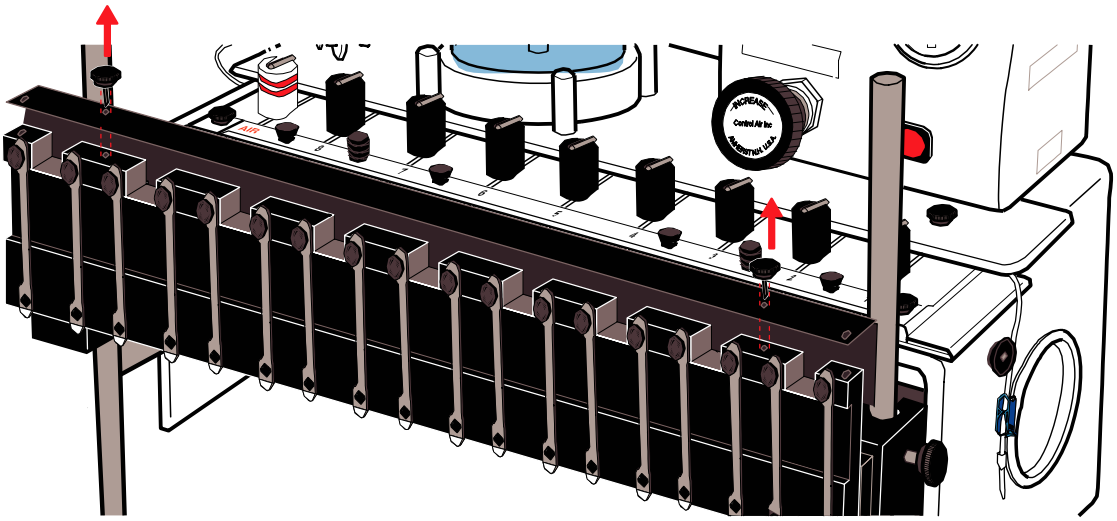
PVB DPT-6100



Abbott Transpac 42582-01

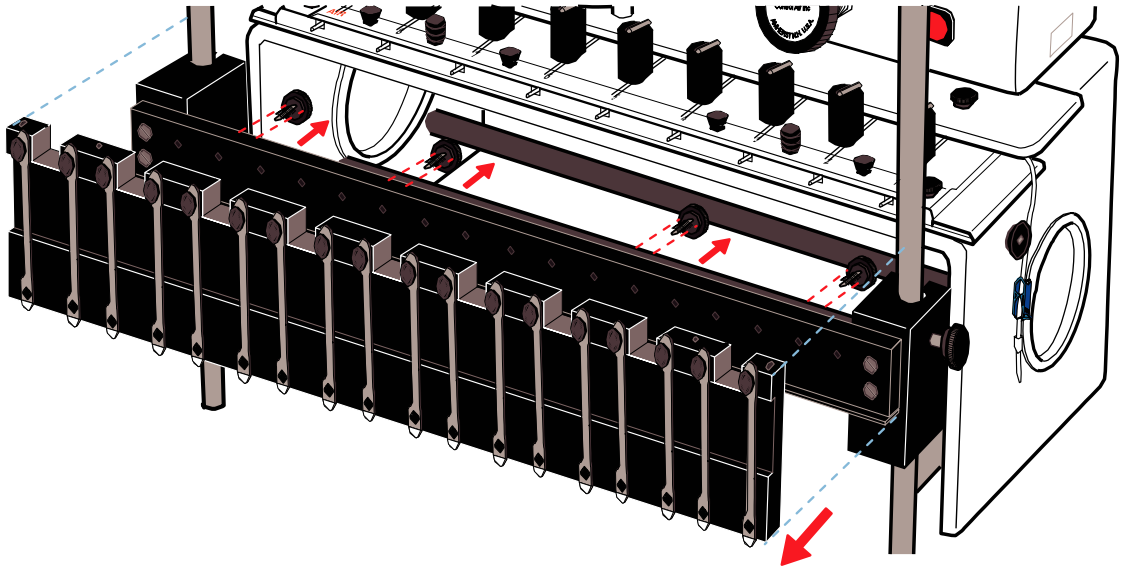


2 Remove cable cover

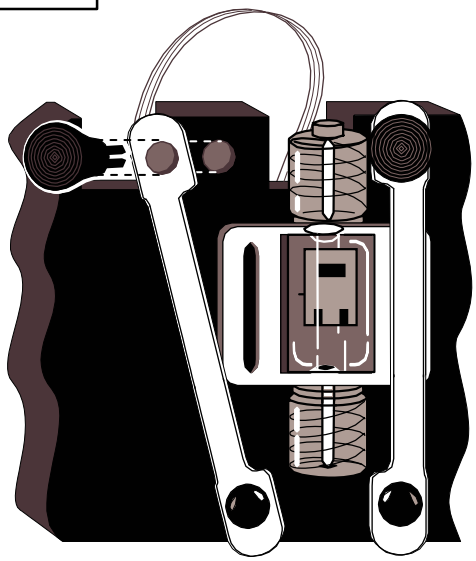


E – 3 Installation of pressure transducers (continued)

3	Remove transducer rack

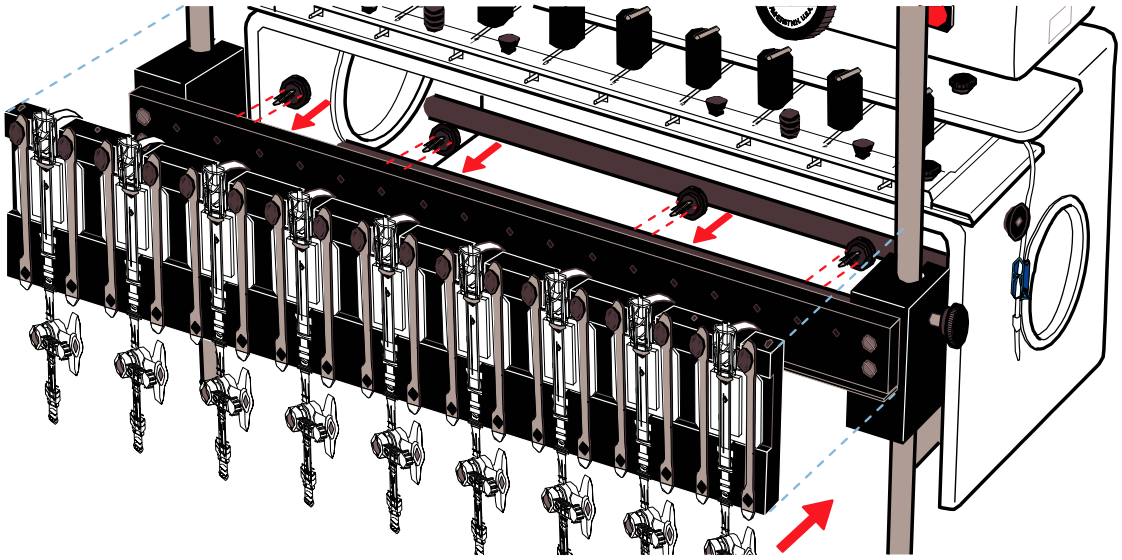


4	Attach transducers

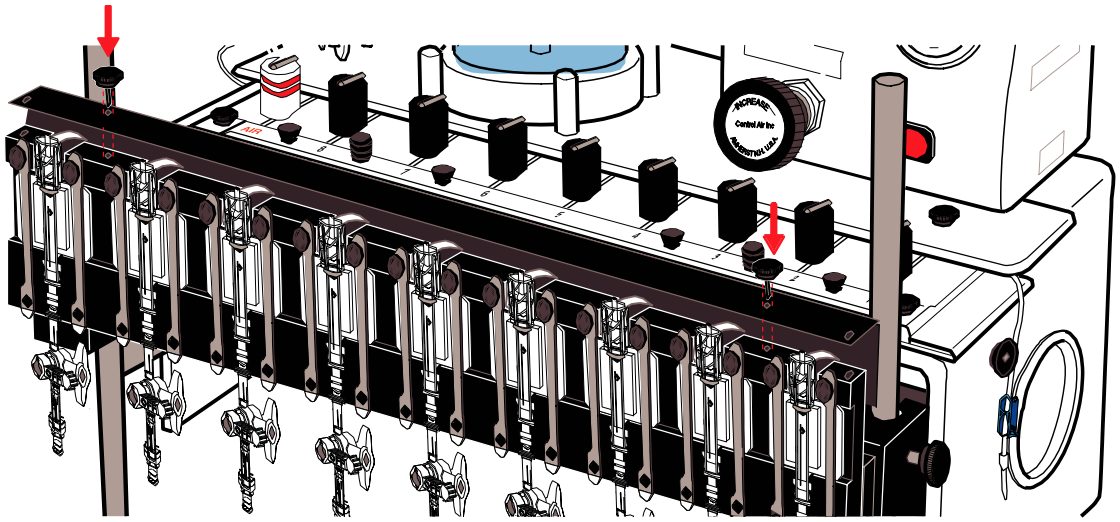


Installation of pressure transducers (continued) E – 3

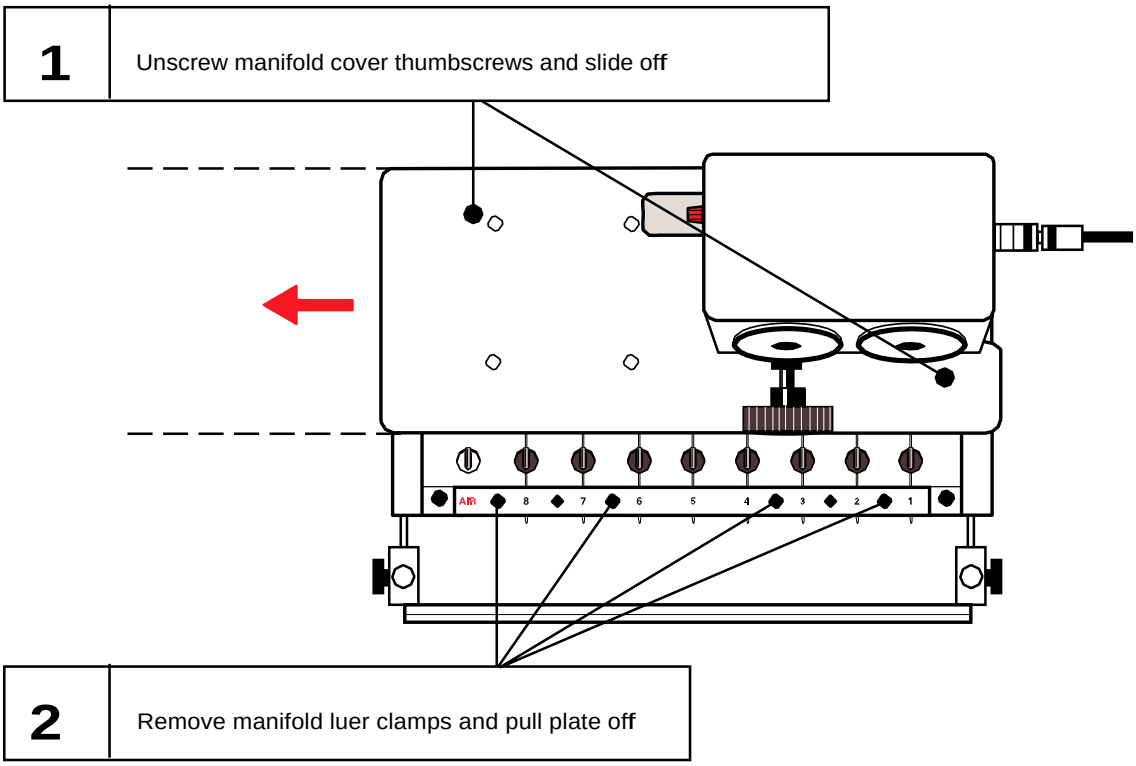
5	Replace transducer rack

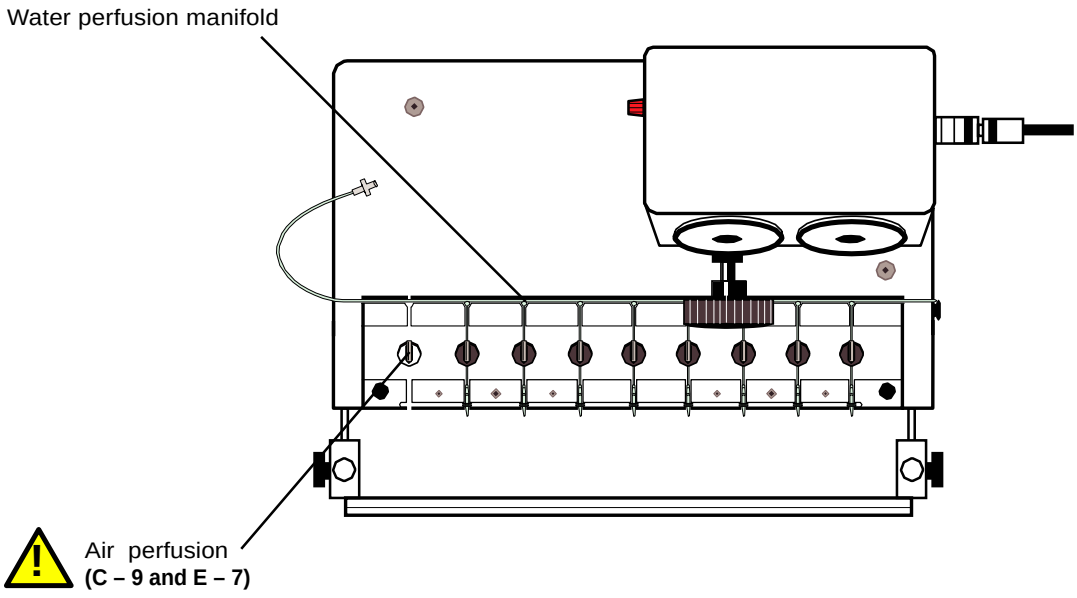


6	Replace cable cover



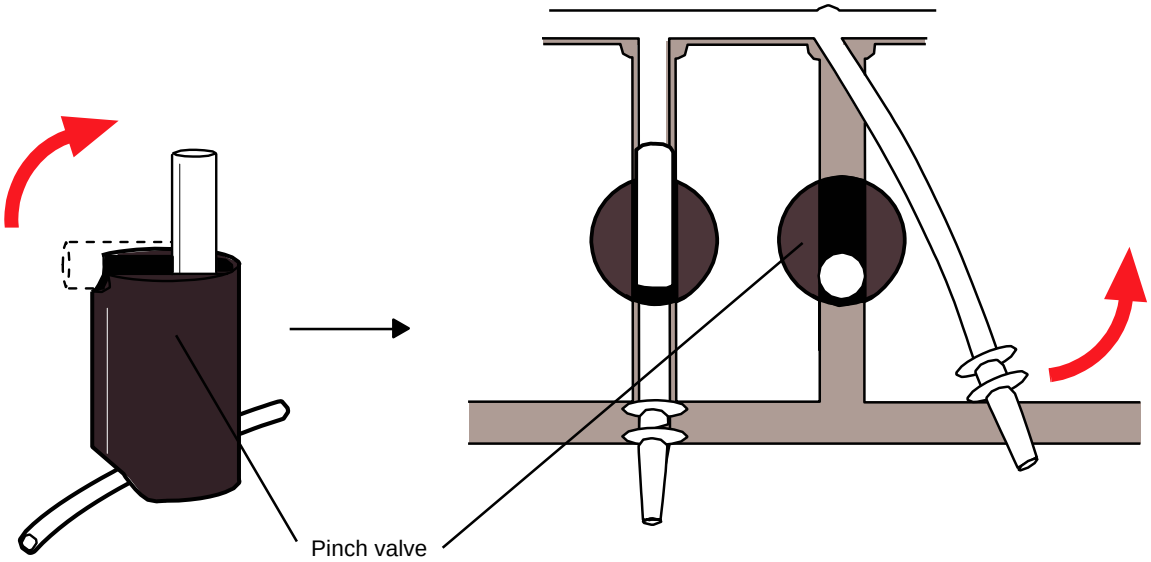
E – 4 Water perfusion manifold removal



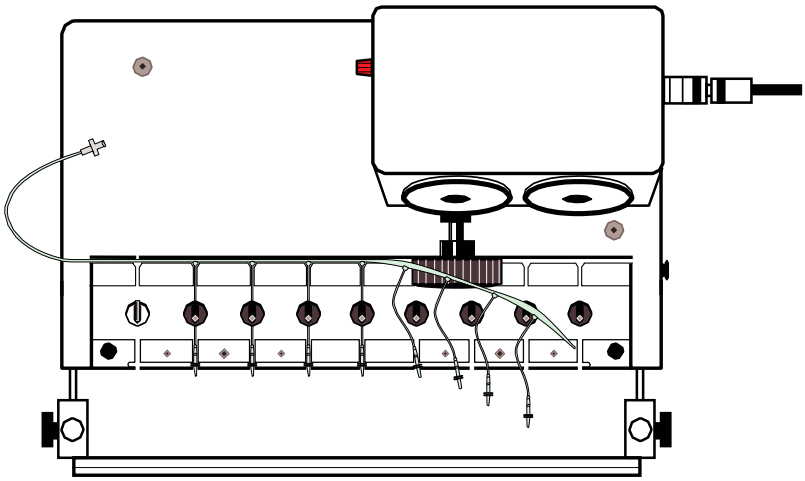


Water perfusion manifold removal (continued) E – 4

3



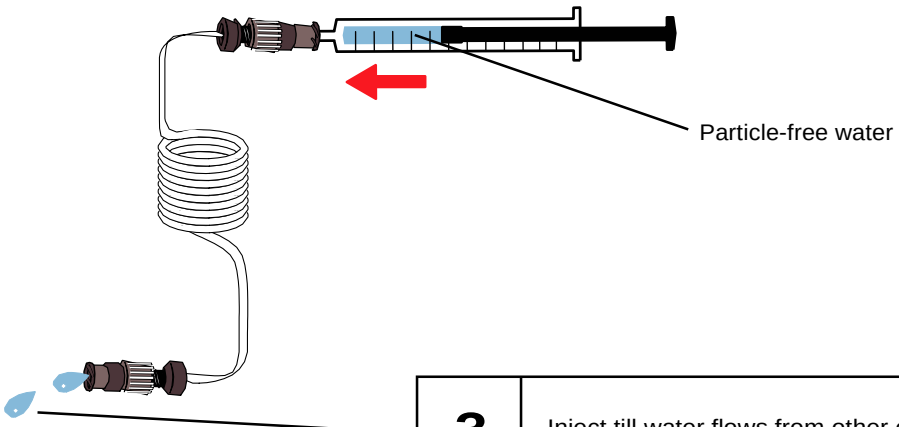
4



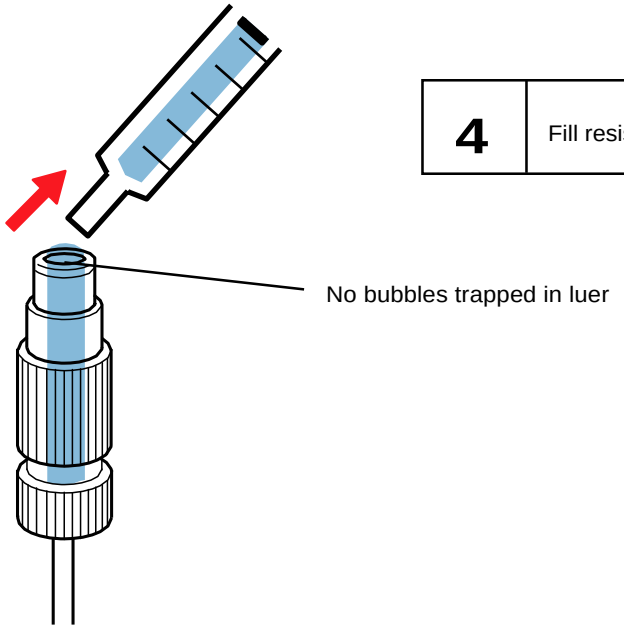
E – 5 Standard hydraulic resistors

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



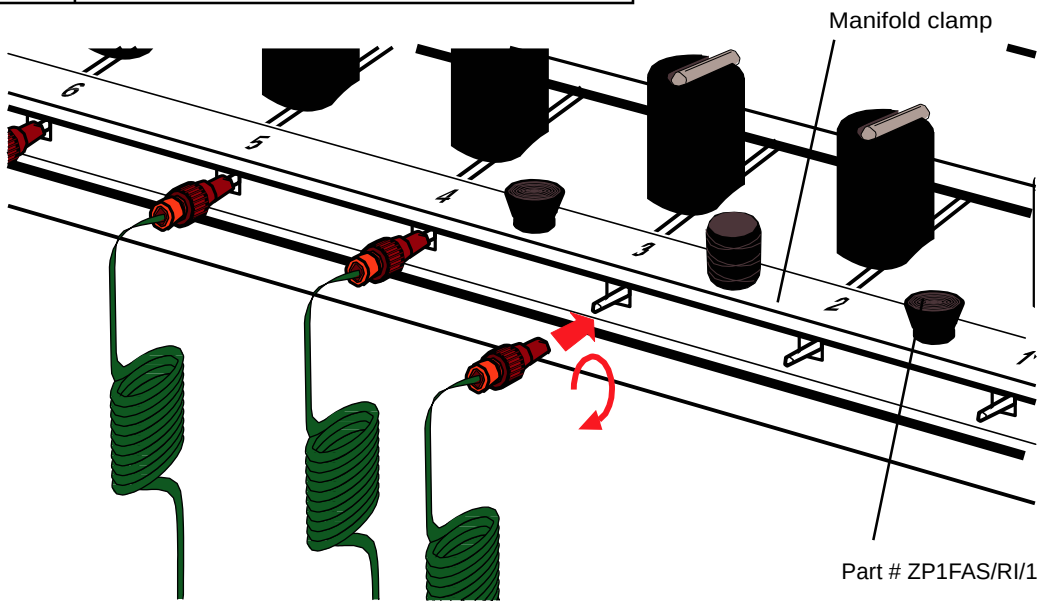
3	Inject till water flows from other end



4	Fill resistor connector as syringe withdrawn

Standard hydraulic resistors (continued) E – 5

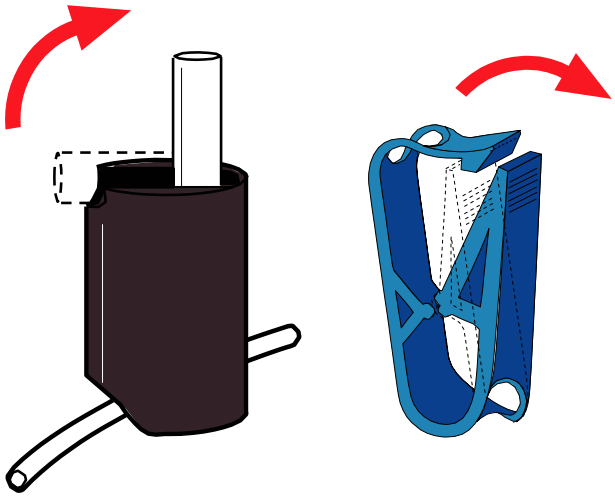
5	Connect resistor to manifold side arm luer Ensure resistor connector remains water filled



Part # ZP1FAS/RI/1

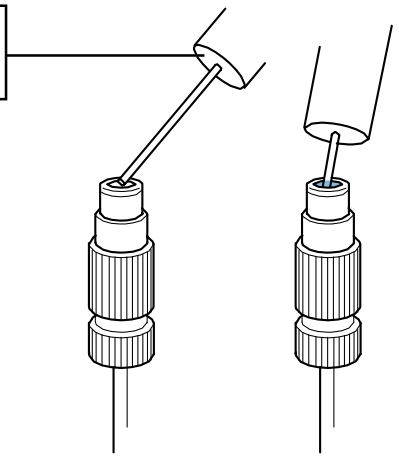
6	Push and rotate resistor firmly onto manifold luer

7	Open



E – 5 Standard hydraulic resistors (continued)

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

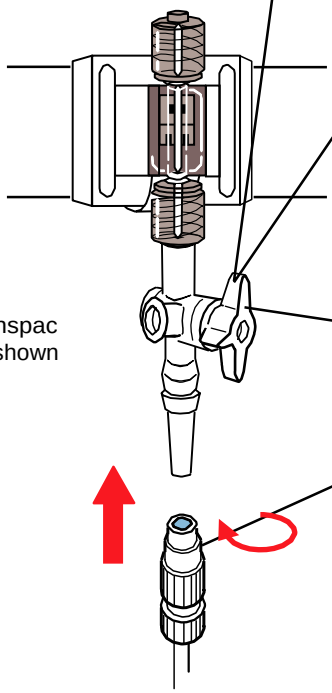


9	Ensure no bubbles are trapped

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

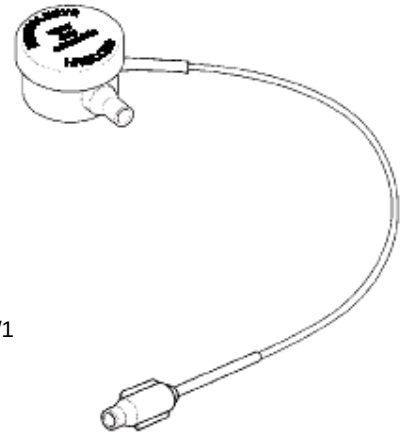


Note PVB DPT-6100 transducer has integral stop-cock at transducer outlet

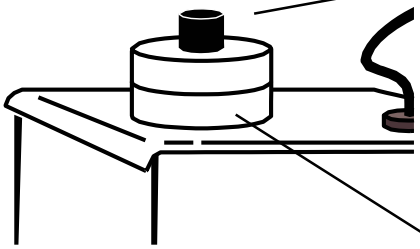
13	Final setup: Follow instructions from **(C – 7.1)**

Compact resistors E – 6

1	Check flow values for each hydraulic resistor



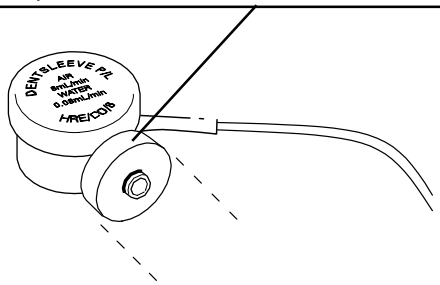
2	Prime resistor with water - Use flush tool

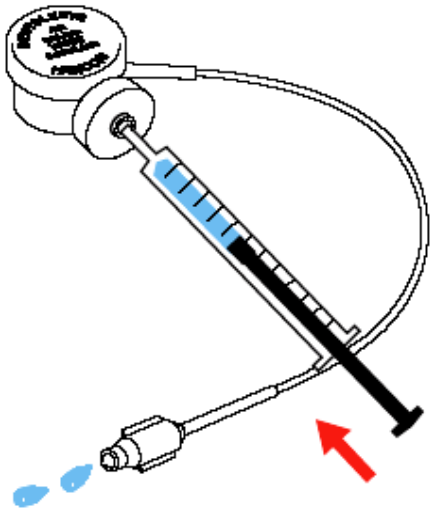


Flush tool - Part # AP1FTO/CR/1

Flush tool holder on top of control box – Part# AP1FTO/CR/2

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

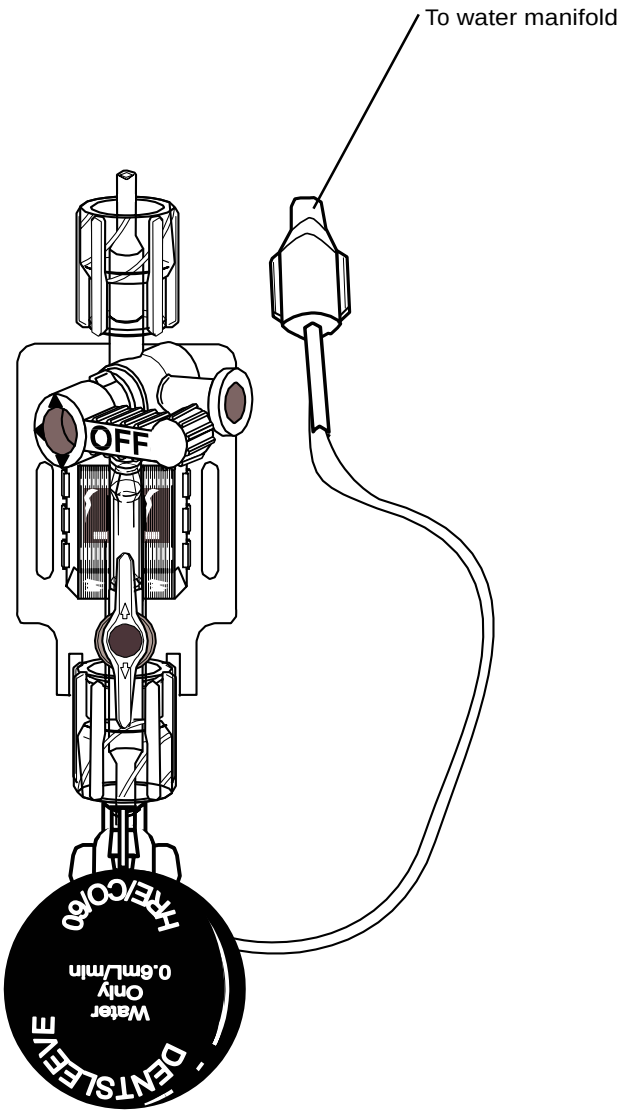
5	Inject until water flows from other end

6	Fill resistor connector as syringe withdrawn

7	Remove flush tool

E – 6 Compact resistor set-up (continued)

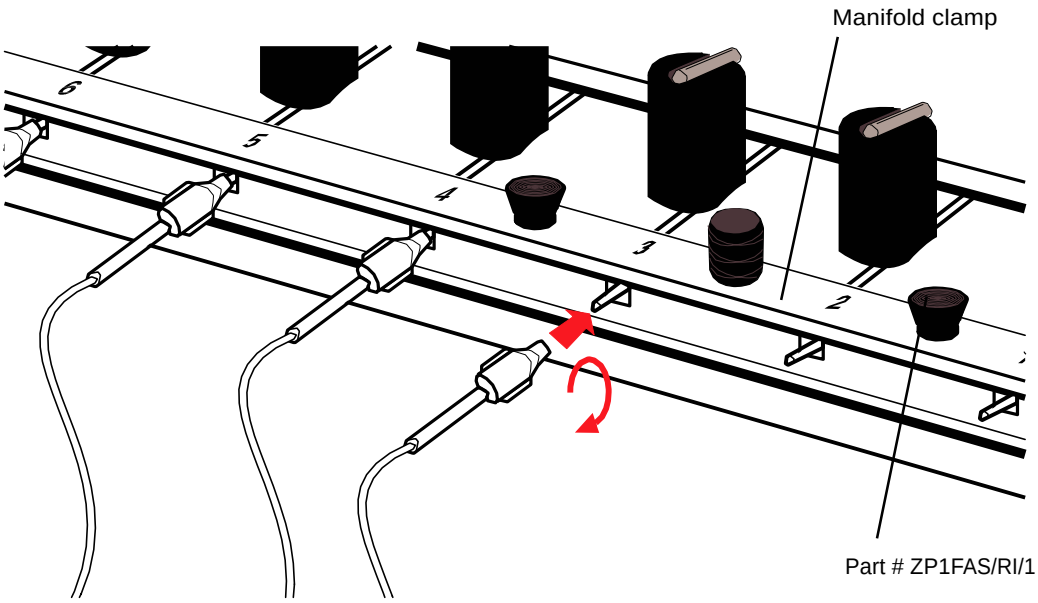
8	Connect as shown



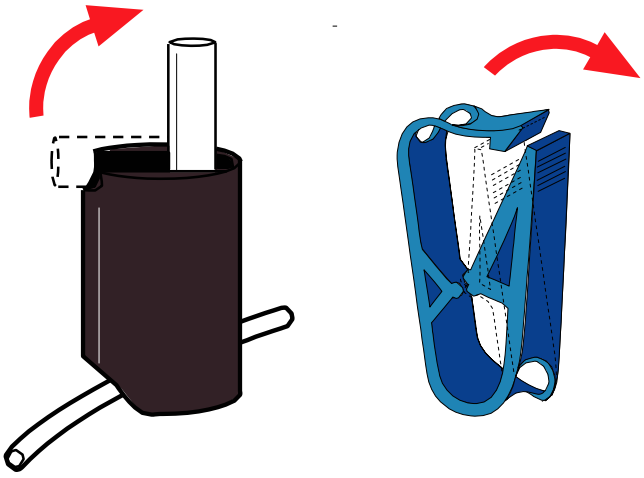
Note: Connectors are self-debubbling. PVB DPT-6100 transducer shown.

Compact resistors (continued) E – 6

9	Connect resistor to manifold sidearm



10	Open

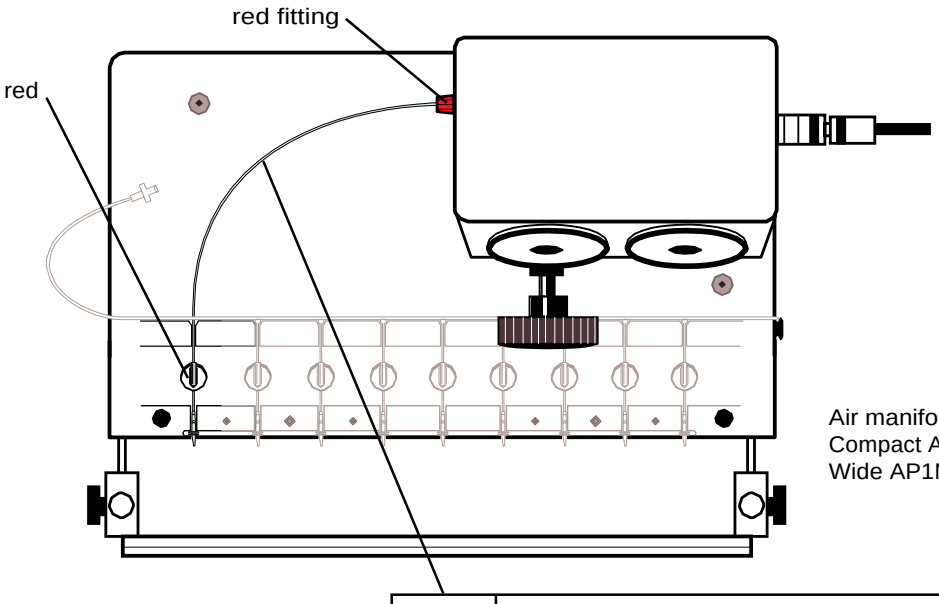


11	Final set-up - follow from **(C – 5.2)**.

E – 7 Air perfusion circuit

N_2 perfusion into pharynx may dilute inspired oxygen - use only Air for perfusate reservoir pressurisation in small children, as this gas also used for gas perfusion circuit

1	Identify circuit. To remove manifold cover see **E - 4.1 to 4.2**

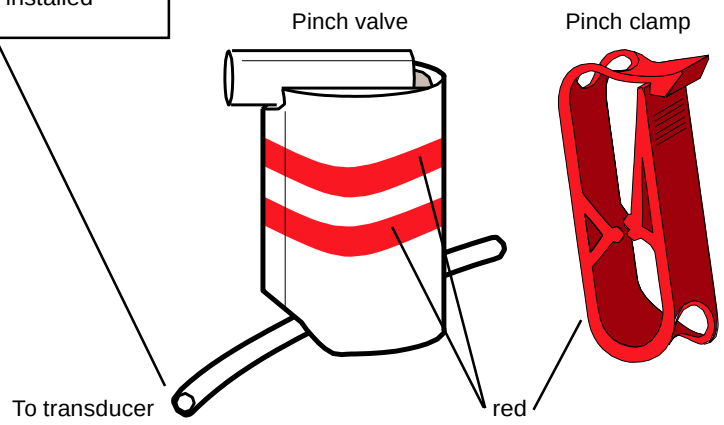


Air manifold Part #'s
Compact AP1MAN/AI/1
Wide AP1MAN/AI/2

Note: Shows Compact version
37mm channel spacings

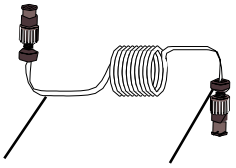
2	Locate air manifold and check correctly connected

3	Resistor must **always** be installed



Air perfusion circuit (continued) E – 7

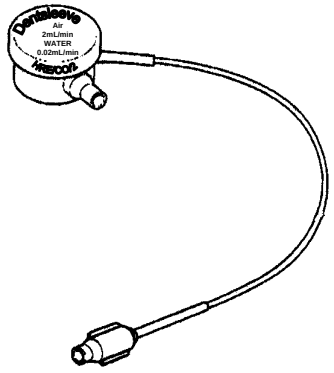
4	Select resistor that controls airflow to less than 10ml/min



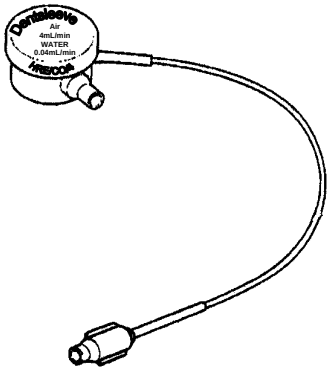
Air flow ml/min	Waterflow ml/min			Part #
2	0.02	Black	Black	R01HRE/ST/2(3)
4	0.04	Red	Red	R01HRE/ST/4(3)
8	0.08	Red	White	R01HRE/ST/8(3)

5	Airflow is x100 waterflow

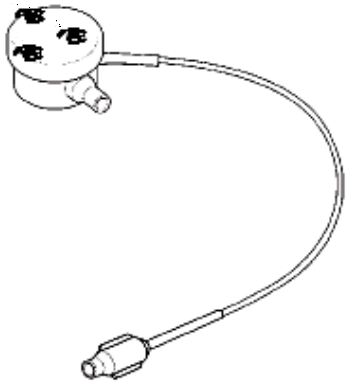
Appropriate compact resistors show airflow on case



Air = 2ml/min

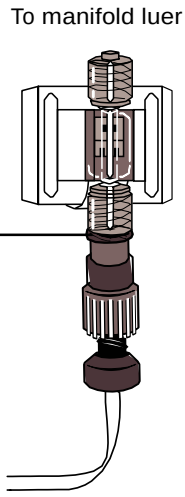


Air = 4ml/min



Air = 8ml/min

6	Install air flow resistor between air manifold luer and transducer



7	No water prime required

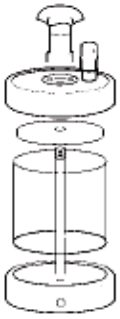
Air perfusion to be used only for pharyngeal manometry

Cleaning & Disinfection

Cleaning of plastic parts F – 1

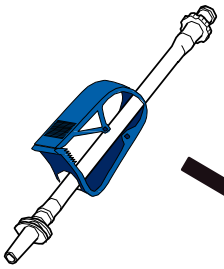
1	Clean with cloth and mild detergent
2	Wipe with isopropyl alcohol

Sterilization of perfusate reservoir F – 2



1	**Gas sterilize only**

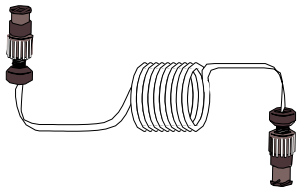
Sterilization of manifolds F – 3



Water manifold
Air manifold

1	Autoclavable

Hydraulic resistors F – 4



1	**Not** autoclavable
2	Autoclavable

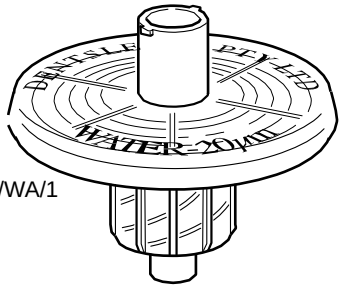
Cleaning of compressor F – 5

1	Wipe with a dry cloth

Regular Maintenance

G – 1 Every 3 months (or as needed): perfusate water filter

1	Replace

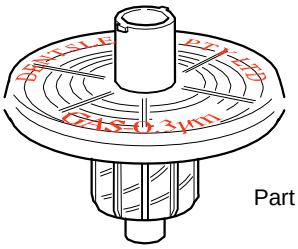


Part # AP1FIL/WA/1

Every year (or as needed): gas filters G – 2

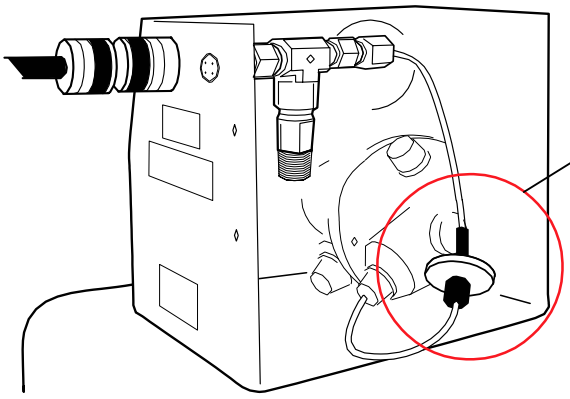
To be done only by an approved, qualified biomedical engineer

1	Disconnect gas supply then open control box (**G – 3.2**)
2	Use correct filter



Part # AP1FIL/GA/1

Gas (Black)



3	Replace each filter in turn

Do **not** cross connections

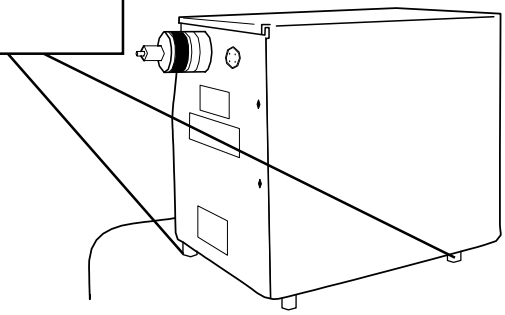
Air = Black ▶ Black

4	Check for air-tightness

Note: Gas filter life depends on quality of air – always use medical grade

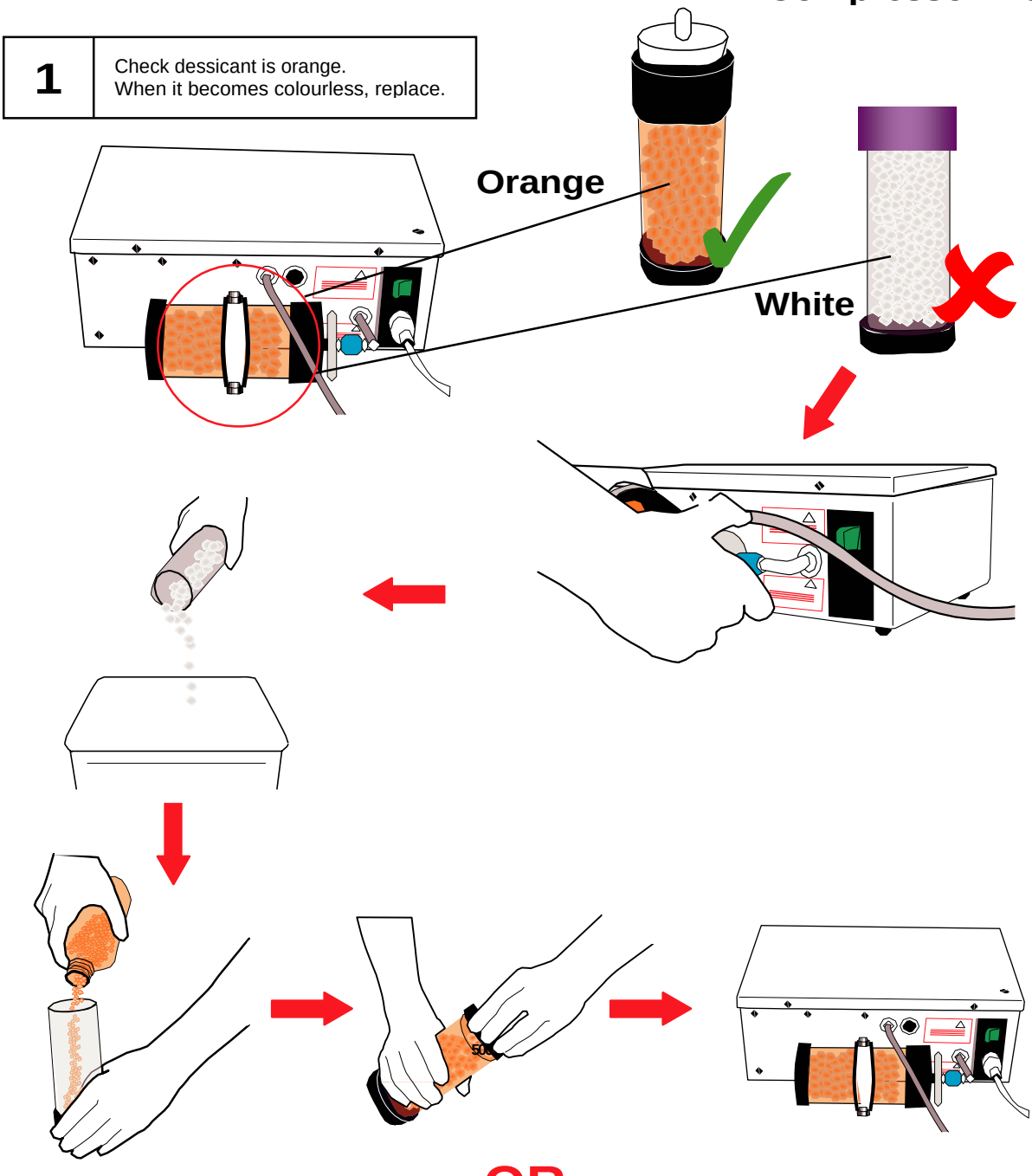
G – 3 Service of control box by Dentsleeve

1	Undo 4 screws under main deck that hold control box legs
2	Send control box to Dentsleeve



Compressor G – 4

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

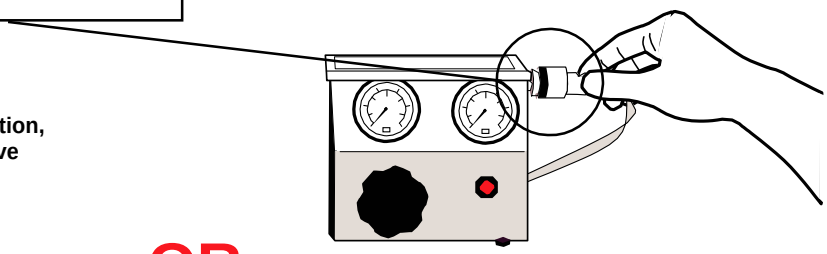


OR

- 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 dessicant before replacing back into canister.

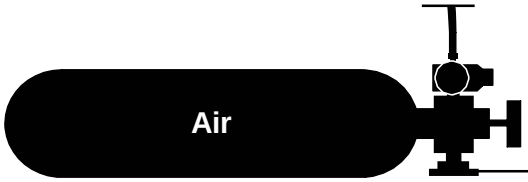
Diagnosis of abnormal air consumption H – 1

1 Check compressor connection



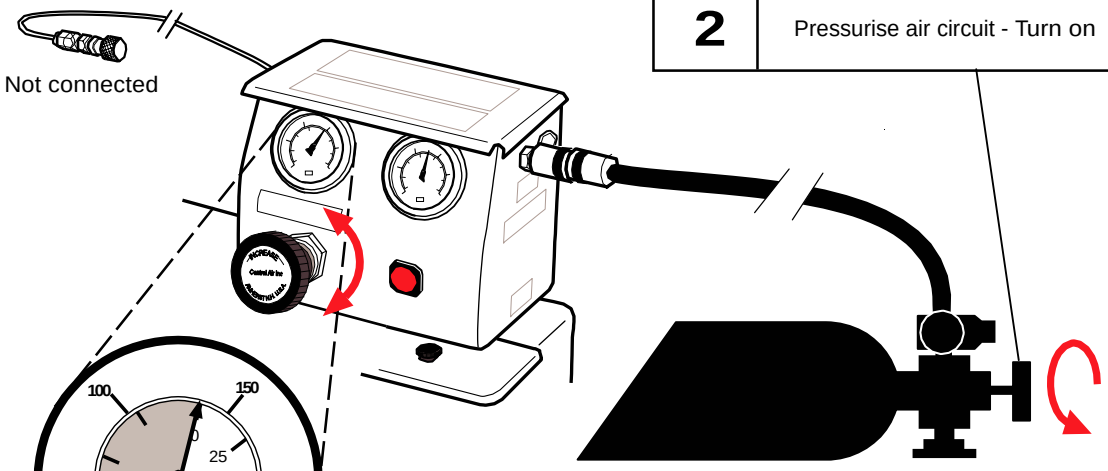
For compressor malfunction, please contact Dentsleeve

OR

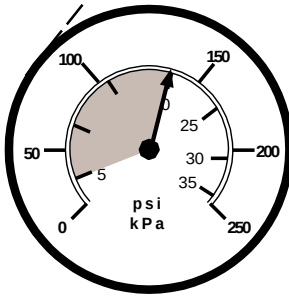


Check regulator/cylinder connection

Tighten



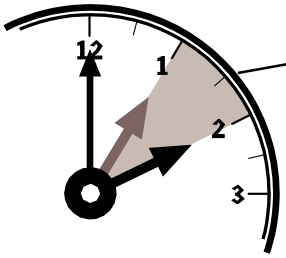
2 Pressurise air circuit - Turn on



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

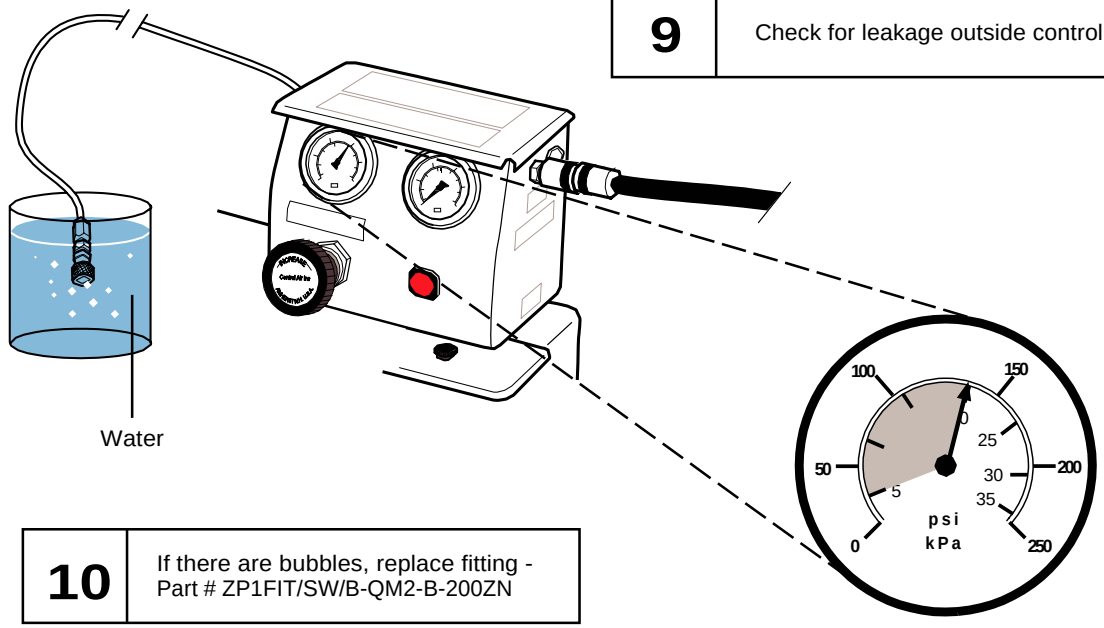
No significant leak

7 Drop more than 33 kPa/5psi

Significant leak

8 Follow **(H-1.9)** below

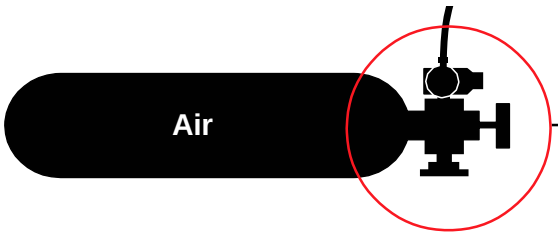
Diagnosis of abnormal air consumption (continued) H – 1



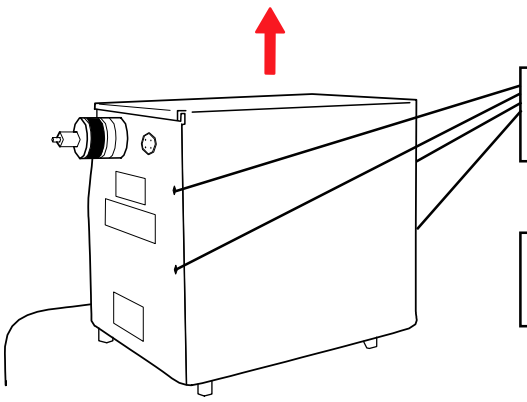
9	Check for leakage outside control box

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



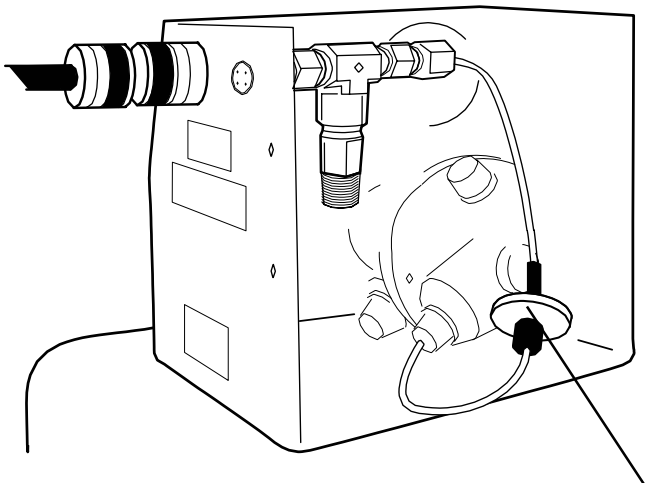
12	Leakage?



13	Open pump control box. Remove 2 screws on both sides

14	Remove control box lid/back

H – 1 Diagnosis of abnormal air consumption (continued)



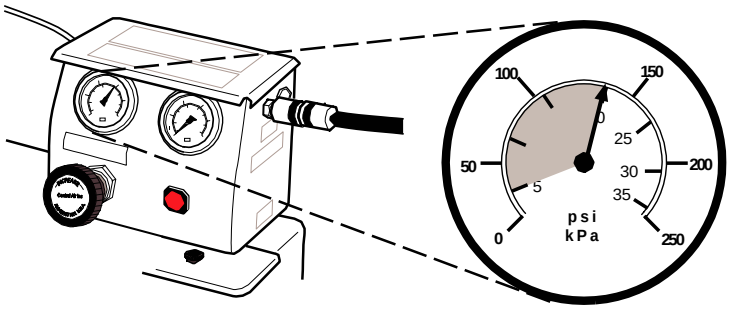
15	? Filter leakage - tighten or replace

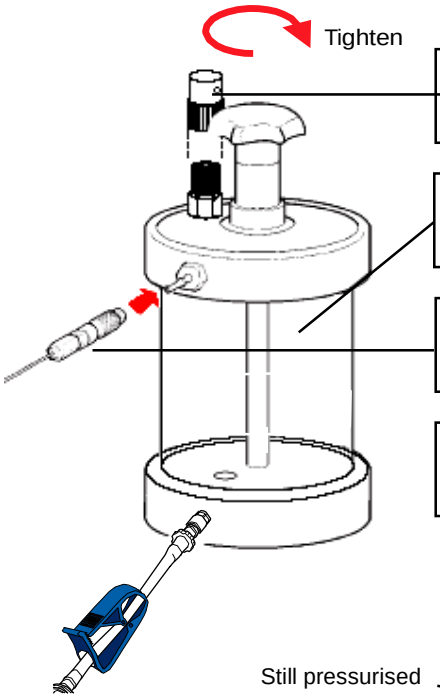
16	Check rest of air circuit

Abnormal air consumption - perfusate reservoir leakage H – 2

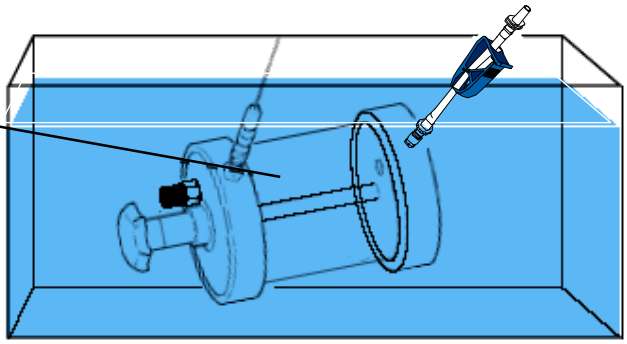
1	First exclude air circuit leakage - **(H – 1)**

2	Set pressure



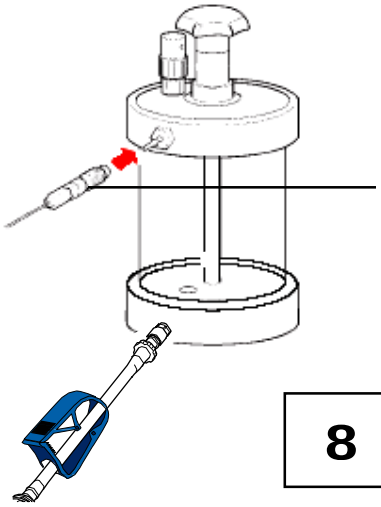


3	Set up reservoir. Remove blow-off valve cap
4	No water
5	Pressurise
6	Locate site of leakage - observe underwater

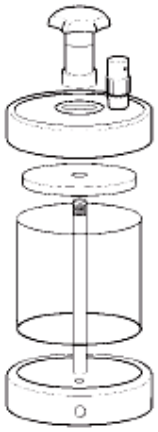


7	Locate site of bubbling

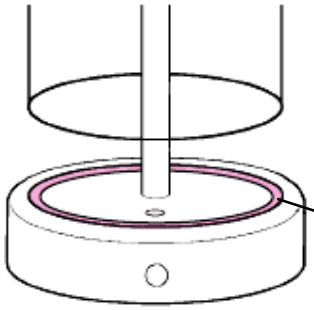
H – 2 Abnormal Air consumption - perfusate reservoir leakage (cont.)



ZP1FIT/SW/B-QM2-B-200ZN

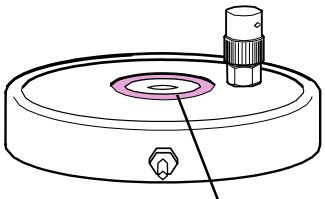


8	If leak elsewhere, dismantle reservoir



9	Identify cause of leakage at base
10	Gasket clean and intact?

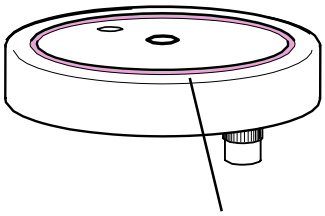
11	Identify cause of leakage at top



Check ‘O’ ring
Part # ZP1SEA/OR/1

Flip

Underside



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

Specifications, Support & Spare Parts

Specifications I – 1

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

Technical Support I – 2

1	Contact Dentsleeve for advice
2	See contact details on front cover

Spare Parts I – 3

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

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

Parts List I – 4

Part Number	Description
AP1-FIL/WA/1	Water Filters
AP1-FIL/GA/1	Gas Filters
AP1-STO/HP/2	Four (4) way Stopcock
AP1-STO/HP/1	Two Way Stopcock
AP1-CMA/TR/2	8 Channel Pressure Transducer Calibrator
AP1-CMA/TR/4	16 Channel Pressure Transducer Calibrator
AP1-CMA/TR/5	21 Channel Pressure Transducer Calibrator
ZP1-RES/PE/4	250ml Water Reservoir (with fitting)
ZP1-RES/PE/1	500ml Water Reservoir (with fitting)
ZP1-RES/PE/3	1000ml Water Reservoir (with fitting)
ZP1-OCD/PR/1	Outflow Control with Filter
AP1-FTO/CR/1	Compact Resistor Flush Tool, Kit of holder and 2 tools
AP1-DES/CO/1	Dessicant for air compressor
ZP1-FAS/RI/1	Large Push Pull Rivets for Luer Retaining Strip
ZP1-FAS/RI/7	Domed Rivets for Transducer Retaining Strip (Bottom)
ZP1-FAS/RI/8	Push Pull Rivets for Transducer Retaining Strip (Top)
ZP1-VDE/TR/1	Transducer Retaining Strip (Pair)
AP1-MAN/WA/PC4.2	Water Manifold 4-Ch. w/ Pinch Clamps MKII
AP1-MAN/WA/PC8.2	Water Manifold 8-Ch. w/ Pinch Clamps MKII
AP1-MAN/WA/PC12.2	Water Manifold 12-Ch. w/ Pinch Clamps MKII
ZP1-SEA/GA/1	Gasket (Silicone Seal)
ZP1-SEA/OR/2	Small O-Ring
ZP1-SEA/OR/3	Large O-Ring for old style Water Reservoir
ZP1-SEA/OR/5	Large O-Ring for new style Water Reservoir

Regulatory Information I – 5

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FRANCE

FDA Approved

CE Marked

IS013488:1996 Certified