



P/N: 10095162
Rev: H
Title: PB560 Assembly procedure 2

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DOCUMENTATION ASSOCIATED TO THIS PROCEDURE

10038461 PB560 DHR

REV	ECO	PREPARED BY	APPROVED BY	DATE	SUMMARY
N/A	N/A	N/A	N/A	N/A	Refer to Agile, Rev C for previous revision history.
D	ECO-R230620		Refer to Agile	Refer to Agile	Update procedure to reflect changes to PHR 10038461
E	ECO-R242465		Refer to Agile	Refer to Agile	Update procedure to re-arrange the Assembly sequence outlined in section 'Expiratory Conical Block and Support'
F	ECO-R259799		Refer to Agile	Refer to Agile	Add instruction to record Assembly Part Revisions
G	EC048873		Refer to Agile	Refer to Agile	Removing G-AMFG-1771-00 from references and adding 10021625, Tube Cutting .Removing decimal point from balloon numbers.
H	EC114172		Refer to Agile	Refer to Agile	Add picture of new blower label which has scannable barcode. Add instruction to record blower lot code or serial number.

Appendices to this Procedure		
P/N	Description	Rev.
N/A	N/A	N/A



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1. PURPOSE

This assembly instruction details the steps required to assemble the PB560.

2. SCOPE

This procedure covers the PB560 ventilator product

3. DEFINITIONS

DHR – Device History Record

S/N – Serial Number

OP - Operation

4. REFERENCES

10038461	PB560 DHR
10095162	PB560 Assembly procedure 2
10095163	PB560 Assembly procedure 3
G-QAM001	Quality Manual
10021625	Tube Cutting – PB540/PB560/PB520
10009491	Mfg. Guidelines to Completion of Records
10021626	LOG - PB540/PB560/PB520 Tube Cutting
10021524	Preventative Maintenance PB540 / PB560 / PB520
G-AMFG-1814-00	Cosmetic Criteria, MONITORS / PB540 / PB560 / PB520
G-AMFG-1013-00	MRB Documentation
G-AMFG-2733-00	PB540 / PB560 / PB520 DHR & S/N Printing Procedure
G-AMFG-1817-00	Generic line clearance procedure
10037309	PB520/PB540/PB560 line clearance procedure
10039893	PB520/PB540/PB560 Line Clearance LOG
10021526	PB520/PB540/PB560 lot code and serial number assignment
10039975	PB560 child serial number assignment log

5. GENERAL REQUIREMENTS

- Ensure all relevant materials, tools, fixtures & jigs are available at the work station before commencing assembly/ manufacture.

DHR Notes:

- When completing PB560 DHR's – record all entries / data / dates per Galway Mfg. Guidelines for Completion of Records 10009491.
- When printing the DHR: ensure all pages are double sided, stapled at the top corner & all pages of DHR are present. Note: The manufacturing assembly sequence of the unit may alter/vary to accommodate manufacturing capability
- Record any components used for FRU in FRU Requirements section of DHR.



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General Notes:

- Before using any calibrated equipment, make sure that the calibration data (on calibration label) has not expired and there is no obvious damage to the equipment.
- If a torque tool is dropped on the floor during assembly, send for re-calibration.
- When connecting cables to connectors, check that male pins are straight. If not, place board into MRB.
- Torx screwdrivers to be used only for screw removal where required, and starting off / aligning screws into the holes. Do not use screwdrivers to tighten screws (there are specific torques for this)
- Hex wrenches to be used only for nut removal if required. Do not use to tighten nuts (there are specific calibrated angle torque tools for this)
- Ensure all tubing is inserted into connections fully
- Ensure all harnesses are fully pushed into mating connectors
- **Note:** Paint work can be scratched with sharp objects. To avoid scratching, ensure the Unit is not kept beside sharp objects. Use ESD safe foam to leave unit on during assembly.
- When printing serial numbers for production, record detail on log 10039975 – PB560 child serial number assignment log.
- When recording the requested component serial/lot numbers on the DHR, please refer to product BOM for corresponding part numbers.
- **Note:** If rework/repair is completed at any stage where dis-assembly is required, record all details on the last page of the DHR discrepancy log, 10038461. On the new DHR verify that s/ns and labelling revision are still correct, and that the appropriate final assembly checks are completed. If there is not sufficient space on the DHR, add a second DHR to include the additional information.
- **Note:** If a unit is being reworked / repaired, the battery must be removed to avoid potential shorting of the power supply in case of a screw dropping on the PCBA. Exceptions to this are when only an upper housing is being replaced (no risk screws causing shorts).
- **Note:** At the start of each week, it is the responsibility of the Line Leader / Production Supervisor to print out a copy of the BOM from Galway BPCS and sign & date it.
 - Compare revisions for any changes from previous week's build.
 - Prior to recording revisions on DHR, ensure that they match revisions on printout
 - Contact a quality engineer, line supervisor or manufacturing engineer when any discrepancies noted

Traceability:

- All component S/N and Lot Numbers as listed on the DHR LOG 10038461 must be recorded.



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6. PROCEDURE

TUBE CUTTING

1. Cut the tubes (bln # 11, 12 & 13), per below length as per 10021625 & record on log 10021626.
2. Silicone tube (bln#13) is cut to a length of 62mm with a tolerance of +/- 1mm, per page 10021625 Tube Cutting Procedure.
3. **Note:** It is permissible to complete batch cutting of ref bln#13
4. Ensure all tubes are stored in separate tote bins for each tube length

Materials:

Balloon Number	Part Number	Description	Size	Qty	Size	Qty	Size	Qty	Size	Qty
11	Refer to BOM	Silicone tubing 3.2x6.4	150mm	2	200mm	2	50mm	1	70mm	1
12	Refer to BOM	Silicone tubing 1.6x4.8	120mm	1					70mm	5
13	Refer to BOM	Silicone tubing diameter 15x21	62mm	1						

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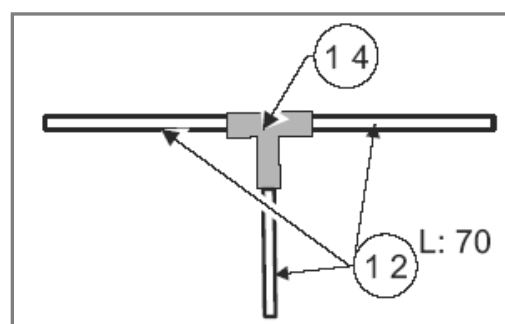
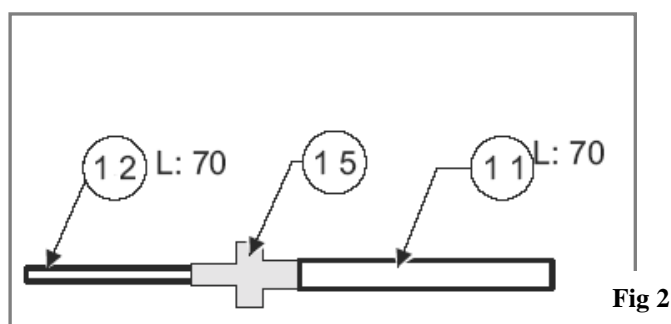
TUBE ASSEMBLY

Materials:

Balloon Number	Part Number	Description	Qty
14	Refer to BOM	Tee shape connector	1
15	Refer to BOM	Straight connector	1
11	Refer to BOM	Silicone tubing 3.2 x 6.4	1 x 70mm
12	Refer to BOM	Silicone tubing 1.6x4.8	4 x 70mm

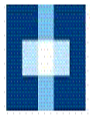
Note: Prior to commencing assembly, select the correct length tubing for the below assembly and place on assembly bench. Check each tube end for straightness; reject tubes that are not straight.

1. Assemble the straight and right angled connectors to the tubing as per fig 1 and fig 2.
2. Ensure that the tubes are fully sealing on the connector – see fig 3 and 4 for examples of correct and incorrect sealing.
3. Ensure that wider end of connector is connected to the 2969500 tube (bln #11) and the narrower end is connected to the 2969600 tube (bln #12)
4. Ensure tubing is cut a squarely as possible so as cut tubes can be pushed correctly into place ref fig 5 & 6.



Ensure that wider end of connector is connected to the 2969500 tube and the narrower end is connected to the 2969600 tube

Fig 1



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✓ Correct



Fig 4

✗ Incorrect



Note : Ensure tubing is cut a squarely as possible so as cut tubes can be pushed correctly into place ref fig 5 & 6.

✓ Correct



Fig 6

✗ Incorrect





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PREPARATION OF THE INSPIRATORY CONICAL BLOCK

Materials:

Balloon Number	Part Number	Description	Qty
21	Refer to BOM	Inspiratory Conical Fitting	1
22	Refer to BOM	Inspiratory Label	1
23	Refer to BOM	Label, Exhal. Valve, Prox Pressure, PB560	1
14/12	Refer to BOM	Tee shape connector with tubing	1
11	Refer to BOM	Silicone tubing 32x64	1 x 200mm 1 x 150mm
12	Refer to BOM	Silicone tubing 16x48	1 x 70mm 1 x 120mm
24	Refer to BOM	Internal FIO2 Cable	1
724	Refer to BOM	Wire Ferrite REF: 74271142	1
725	Refer to BOM	Double Sided Tape Adhesive 0.01M	A/R

Equipment:

- Straight tweezers
- Torque driver 4.4 in-lbs
- 10mm socket 10038462
- Inspiratory Block Labelling Fixture 10031632
- Isopropyl Alcohol - 901048
- Kim wipes - 901731

Note: Prior to commencing assembly, select the correct length tubing for the below assembly and place on assembly bench. Check each tube end for straightness; reject tubes which are not straight.

Process

1. Inspect the Inspiratory Conical Fitting for flash and blow out with air-gun. If any flash noted, contact Quality or Manufacturing Engineer.
2. Clean the Inspiratory Conical Fitting, fig 1 with alcohol and kimwipes (around the label application area).
3. Record the revision of the labels (blln #22 & #23) (this will either be on the label or on the label waste) on the DHR log P/N 10038461. Each individual label must be checked for revision.
4. Remove outer film from labels (blln #22 & #23) prior to affixing onto Inspiratory Conical Block.



Representation of Insp conical fitting
(blln #21)

Fig 1

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5. Position the labels (bln #22 & #23) with the tweezers and apply it as per fig 2.

Note: Picture does not represent hole for FIO2 fitting.

Fixture 10031632 may be used to aid affixing of labels, refer to fig 4.

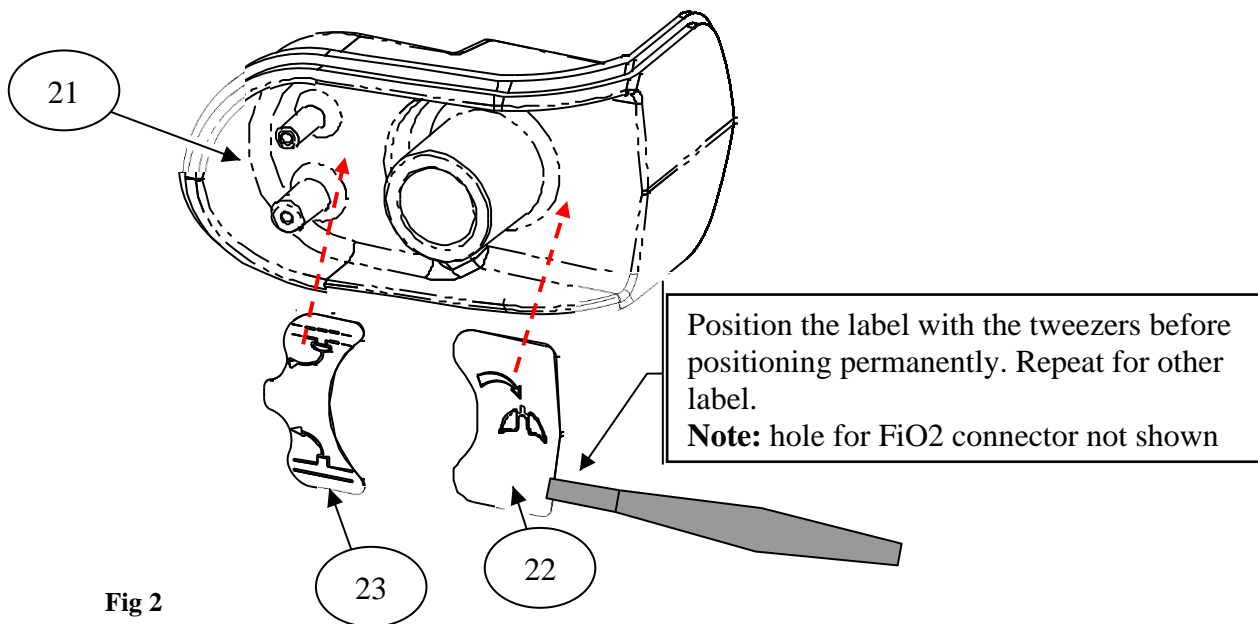


Fig 2

6. Once labels are applied, apply pressure to each label to ensure it is fully stuck to part. Check that there are no bubbles or cosmetic defects. Check with Quality Department if clarification required. Fig 3 shows the labels fully applied.



Note that labels are applied to match contours of inspiratory conical fitting

Fig 3



Inspiratory Conical Fitting (bln # 21) seated in Labelling Aid Fixture 10031632

Fig 4

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7. If it is fitted, remove the Hex nut from the Internal FIO2 Cable Assy (blln #24) taking care not to damage the J5 connector when removing and assemble to the Inspiratory Conical Fitting as shown in figure 5 and 6. Take care not to damage the J5 connector when refitting the hex nut.

Note: If a serrated washer is fitted this is not used as part of this assembly.



Arrow head

NOTE: Note: The connector is keyed and must be orientated with the white arrow head pointing away from the FiO2 symbol.

Fig 5

8. Refit the hex nut hand tighten as shown in figure 6.

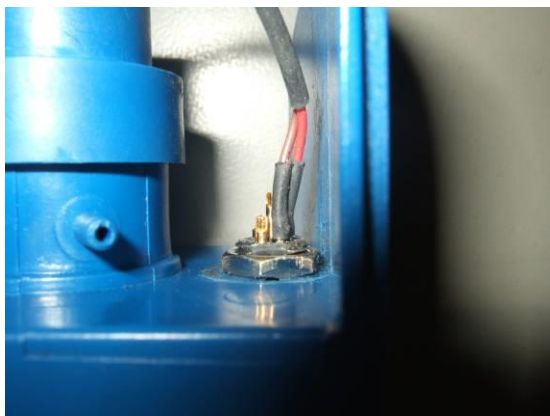


Fig 6

9. Using FiO2 socket (10038462) torque the nut to 4.4in lbs as shown in fig 7



NOTE: When tightening the FiO2 nut ensure the tool is not pushing against the Inspiratory Conical fitting.
Care must be taken that the tool is positioned correctly when tightening this nut.

Fig 7

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10. Using a calibrated rule and scissors, cut 25 mm of double sided tape (blln#725) as fig 8, and apply to Ferrite (blln#724) Note: 4 hole side up & 2 hole side down, as fig 9
11. Attach this ferrite to the FiO2 cable of the Inspiratory Conical Block. The FiO2 cable takes one loop around the ferrite and there is no more than 90mm of wire length between the ferrite and J5 connector on the cable (check with a calibrated steel ruler).
12. Assemble the tubing prepared in the tube cutting section.
13. Check that all tubing is assembled as per fig 10 of this section



Fig 8



Fig 9

Balloon Number	Description	Length (L)
14/12	Tee shape connector with tubing	3 x 70 mm
11	Tubing	1 x 200mm 1 x 150mm
12	Tubing	1 x 70mm 1 x 120mm

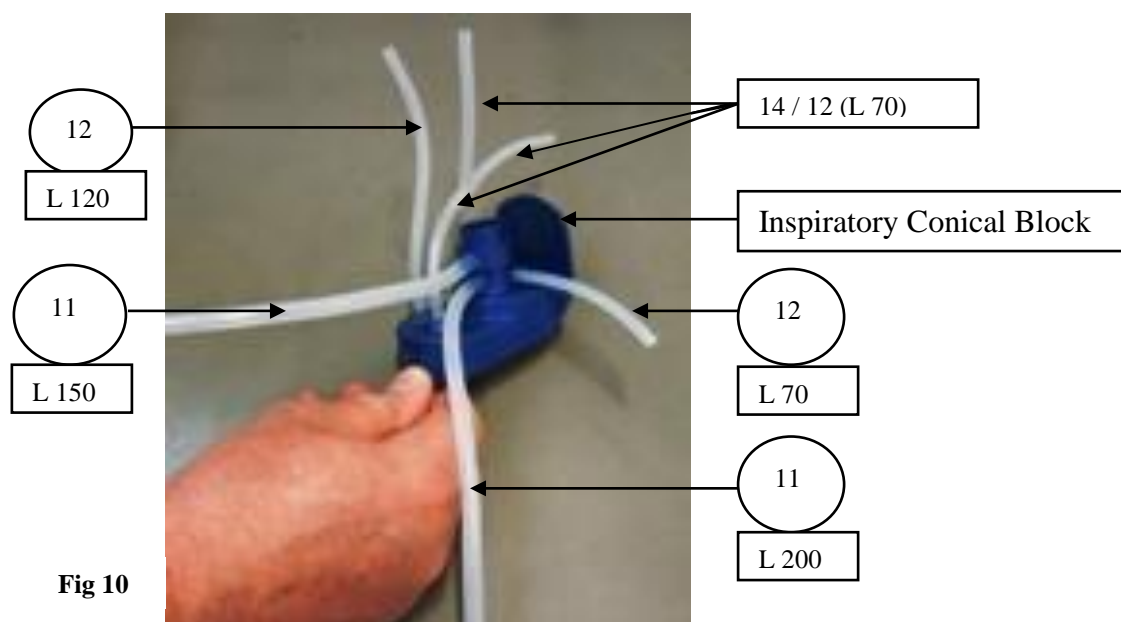


Fig 10

NOTE: All dimensions in mm



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EXPIRATORY CONICAL BLOCK AND SUPPORT

Materials:

Balloon Number	Part Number	Description	Qty
31	Refer to BOM	Expiratory Conical Block	1
32	Refer to BOM	Label, Expiratory Single Use, PB560	1
33	Refer to BOM	Expiratory Conical fitting support	1
34	Refer to BOM	Bulkhead connector (Baffle conduit fluted)	2
35	Refer to BOM	Label, Valve Connection, PB560	1
11	Refer to BOM	Silicone tubing 3.2 x 6.4	1 x 200mm 1 x 150mm

Equipment:

Isopropyl Alcohol, 901048
Kim wipes P/N 901731
4.4 in-lbs torque driver.
16mm socket 3834400
Straight tweezers

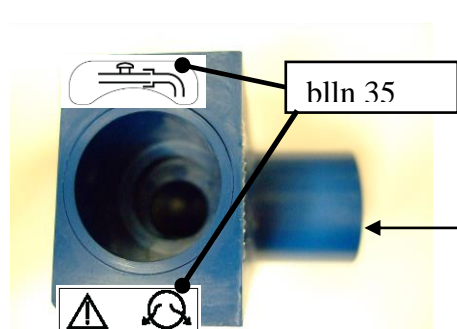
Note: Prior to commencing assembly, select the correct length tubing for the below assembly, refer to table above and procedure 10021625 and place on assembly bench. Visually check that each tube has been cut square. There should be no gap between the end of the tube and the barb when assembled later in this procedure, fig 7.

Process

1. Clean the Expiratory Block (blln #31) with alcohol and kimwipes around area where labels are being applied. Check for flash and MRB if required.
2. Record the revision of the labels (blln #32 & 35) (**this will either be on the label or on the label waste**) on the DHR log P/N 10038461. Each individual label must be checked for revision.
3. Remove outer film from labels (blln #32 & #35) prior to affixing onto Expiratory Conical Block.
4. Centre and affix the label (blln #32 and #35) with the tweezers (to avoid finger marks) on the expiratory return. See fig 1 and fig 2 of this section.
5. Once applied, apply pressure to label to ensure it is fully stuck to part. Check that there are no bubbles or cosmetic defects. Check with Quality Department if clarification required

Note:

Prior to commencing assembly, select the correct length tubing for the below assembly, ref table above and procedure 10021625 and place on assembly bench. Visually check that each tube has been cut square. There should be no gap between the end of the tube and the barb when assembled later in this procedure ref fig 5.



Template Fig 1

Rev B

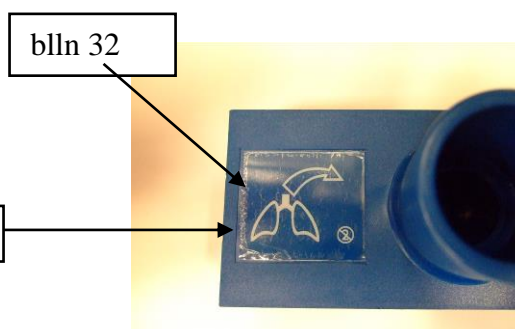


Fig 2

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6. Fit the bulk head connectors (blln # 34) directly into the Expiratory Conical Block (blln # 31), see fig 3 for reference.
7. Assemble both parts of Expiratory Conical support together, see fig 4 for reference. Ensure that the bulkhead connector's hex head sits correctly in the inset of the Expiratory Conical Fitting Support (blln # 33) - as outlined in fig 5.
8. Fit the 16mm hex socket tool, p/n 3834400 to the 4.4in-lb torque driver.
9. Hand tighten the nuts as outlined in fig 6, using the 16mm hex socket torque (p/n 3834400) to 4.4lbs, ensuring the block is placed on the workbench.
10. Connect the tubing prepared in procedure 10021626, see fig 7.

Note: ensure that the tubing is pushed all the way along the barb section until it is in all the way.

11. Figure 8 shows the diagrammatical assembly

Fig 3



Fig 4



Fig 5

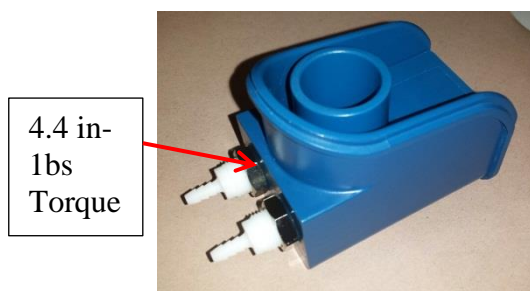
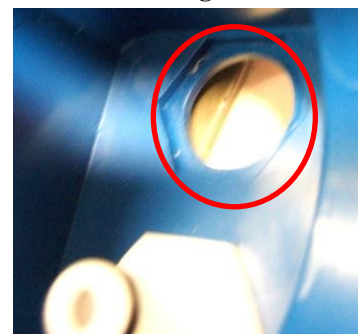


Fig 6

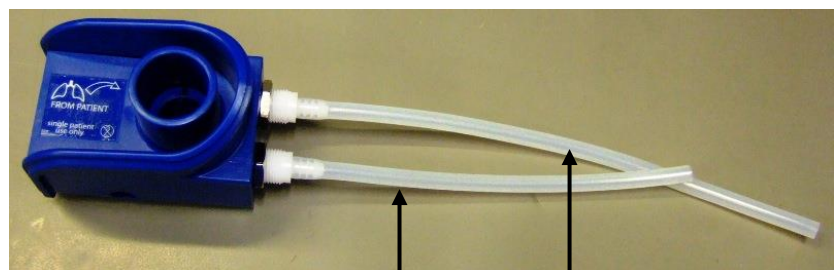


Fig 7

Length
150mm

Length
200mm

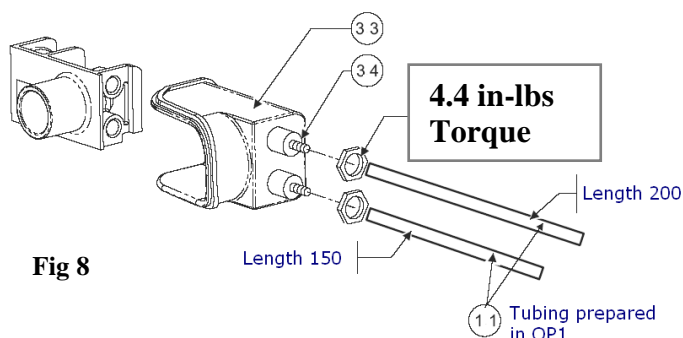


Fig 8

NOTE: All dimensions in mm



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BLOWER HOUSING



Note: Observe all ESD Precautions



Materials

Balloon Number	Part Number	Description	Qty
51	Refer to BOM	Screw TCBX M3x5	4
52	Refer to BOM	Shielding	1
53	Refer to BOM	Blower driver card	1
54	Refer to BOM	Hexagonal spacer M3xLength5	4
55	Refer to BOM	Adhesive foam strip,3x20,length 95 +/- 2mm	2
56	Refer to BOM	Blower	1
57	Refer to BOM	Plastic collar	1
13	Refer to BOM	Silicone tubing diameter 15x21	0.062
59	Refer to BOM	Power Supply Blower harness	1
511	Refer to BOM	Loctite 243	A/R
11/15/12	Refer to BOM	Straight connector with silicon tubing	1
720	Refer to BOM	Ty-wrap	1
111	Refer to BOM	Zinc-Plated Steel Tcb Screw Hexalobe D3x8	1
113	Refer to BOM	M3 Fender Washer	1

Equipment:

4.4 in-lb Torque Driver	Torx bit T10
Scissors	Isopropyl Alcohol, 901048
Kim wipes P/N 901731	6" or 12 "Calibrated steel ruler
5mm hex socket	8.9in-lb Hand Torque tool

Process

1. Record Lot number (from  label Fig 1A) **or** Serial number from  label 1B and revision of the Blower (bln #56) and serial number and revision of the Blower Driver Card (bln #53) on DHR LOG 10038461. Refer to fig 1 and 2 below:

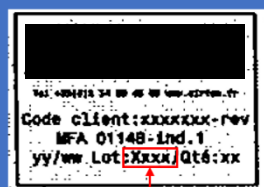


Fig 1A: Record Lot Number of this Label



Fig 1B: Record Serial Number of this Label

OR

Fig 1 Example of Blower Labels



Record Serial Number

Fig 2: Example of Blower Driver Card Label

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2. Using alcohol and kimwipe, wipe the blower housing where the strips (blln #55) and collar (blln #57) will be applied. See fig 3 below
3. Affix the 2 foam strips on the top of the blower as per fig 3 below
4. Screw the hexagonal spacers (blln #54) using a 4.4 in-lb Torque and 5mm hex socket in the location shown in fig 4 below

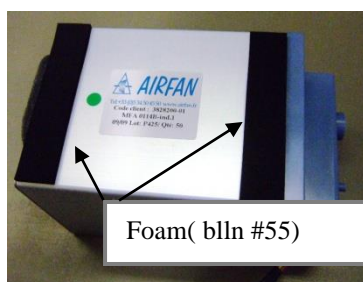


Fig 3

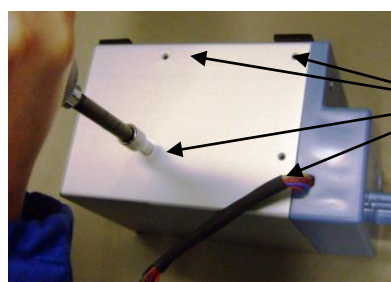
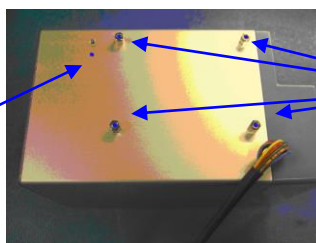


Fig 4

Torque hex spacers,
(blln #54 to 4.4lbs

5. Apply a drop of thread-lock glue LOCTITE 243 (blln #511) at the start of the tapping of each spacer as per fig 5 below. Add an additional drop of Loctite beside Hex nut closest to spacer (i.e. in a visible location) so presence of Loctite can be confirmed at a later stage. See fig 5

Add drop of adhesive approx
10mm directly below plastic
collar mounting hole



Add drop of adhesive into the
hex nut tapping as shown

Fig 5

6. Position the Blower Driver Card and install (but not torque) the top two M3x5 screws (blln #51). Add the shielding (blln #52) by positioning the harness under it, install two additional M3x5 (blln #51) screws and torque all four in a diagonal direction to 4.4in-lb, fig 6. Ensure that the cable is not pinched by the shielding by verifying that it can move freely under the shielding. Refer to Fig 7.
7. As a check that the Blower Driver Card is fully secured, verify that there is no gap between the screw head and the Blower Driver Card

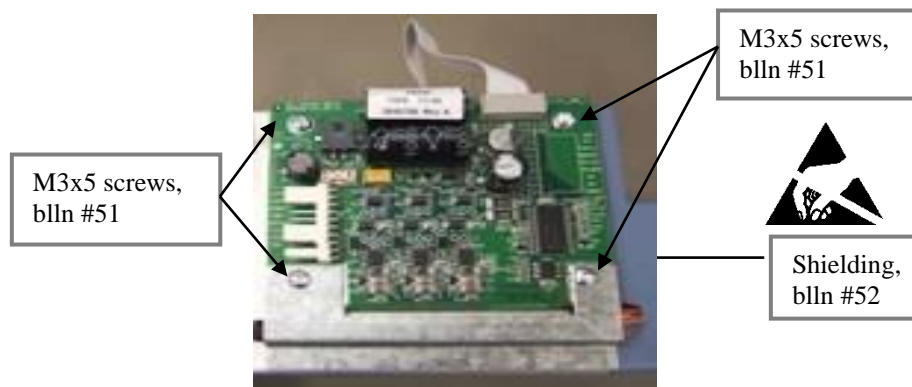


Fig 6

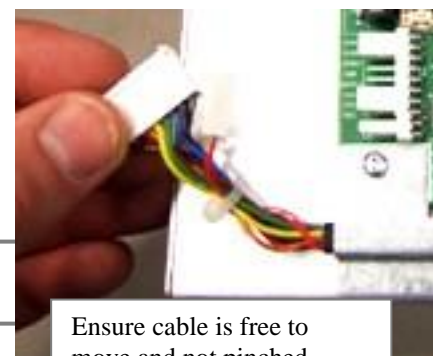


Fig 7

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Note: Observe all ESD Precautions

8. Twist the single strand and multi-strand blower harnesses together to shorten slack and connect the two blower harnesses to the J6 connector on the blower driver card. Ensure that the connection is fully secured.
9. Refer to Fig 8 of this section



Connect two
connectors

Fig 8

10. Refer to Fig 9 of this section for a diagrammatic representation of this assembly.

Apply drop of loctite (ref 511) in this location for visual indication only. Ensure that it is not located where the collar will be mounted.

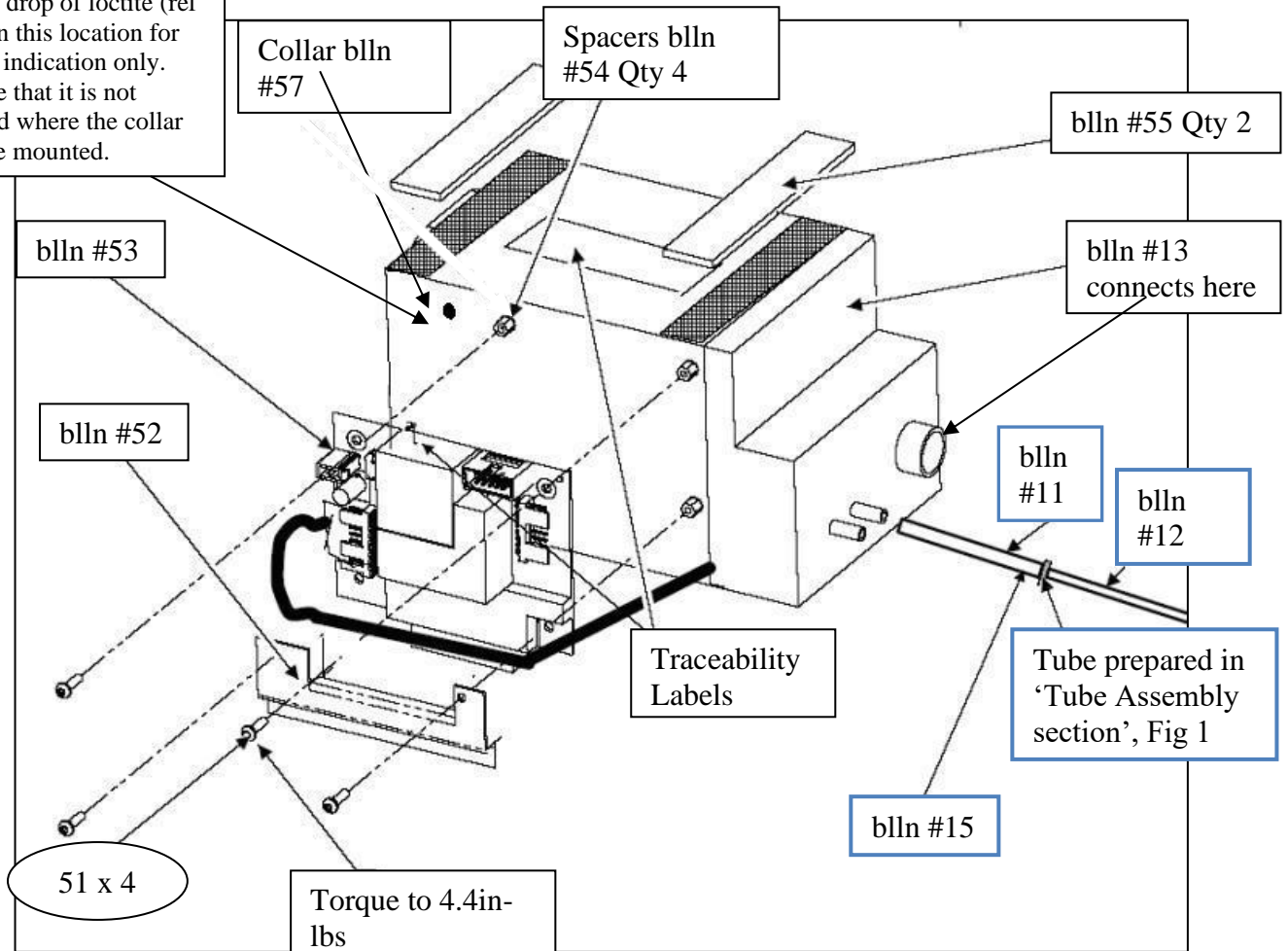


Fig 9

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11. Dress cabling using a ty-wrap as per fig 10 by, hand-tightening ty-wrap and cutting excess with pliers (do not use ty-wrap gun) as per fig 10. Verify that cabling is neat, i.e. no strands which are loose enough to come in contact with other components.

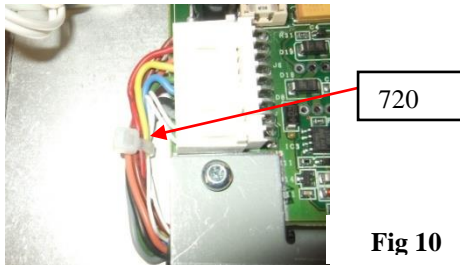


Fig 10

12. Attach the silicon tube (bln #13) to the blower, see fig.11 ensuring that the tubing is pushed all the way to the end.
13. Attach the tubing (bln #12/15/11) (ref fig 9 & 11 of this section), ensuring that the tubing is pushed all the way to the end of the barb / connection.

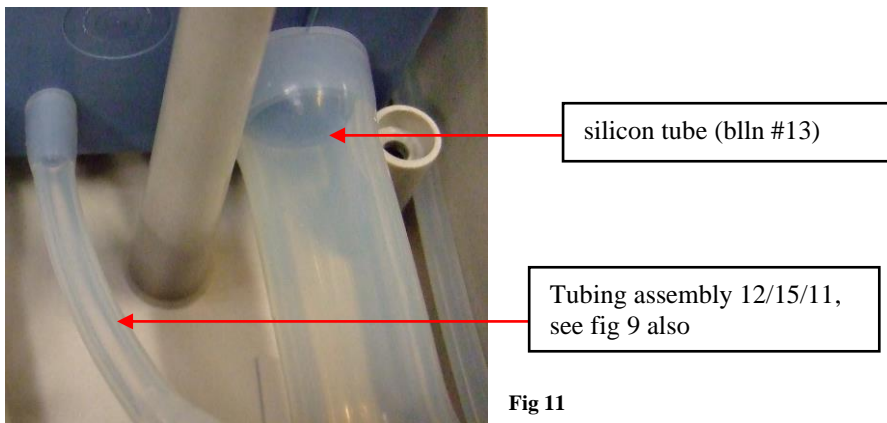


Fig 11

14. Connect the short end of the harness (bln #59) to the PCBA and fix the plastic collar (bln #57) around the ferrite so that it routes between the ferrite and the wire loop. See Fig 12 of this section. Ensure that the harness connection is fully secured.
15. Apply a drop of thread-lock glue LOCTITE 243 (bln #511) at the start of the tapping of the P-Clip mounting hole. Carefully mount the Plastic collar, now clipped onto the ferrite of harness (bln #59), to the Blower Housing using screw (bln #111) and washer (bln #113). Torque to 8.9 in-lbs. See fig 12 & 13 of this section. Ensure that the harness connection is fully secured.

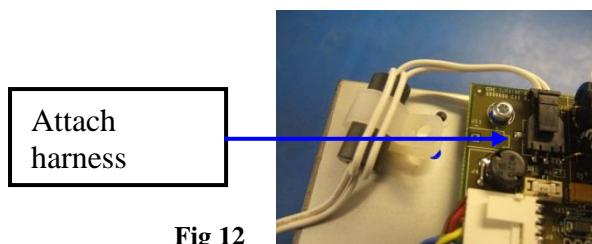


Fig 12

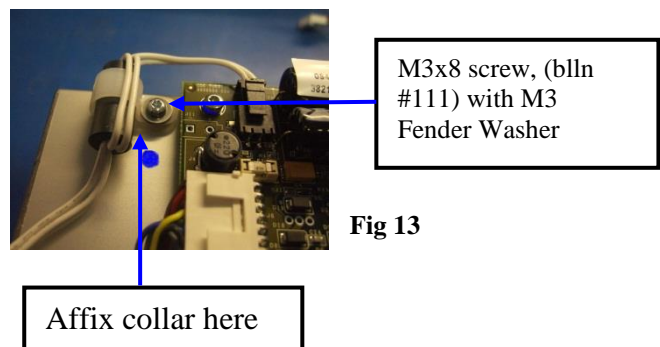


Fig 13



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POWER SUPPLY HARNESS, EXPIRATORY & INSP BLOC INSTALLATION

Materials:

Balloon Number	Part Number	Description	Qty
85	Refer to BOM	TCB Screw hexalobe D3 x 8	3
87	Refer to BOM	CPU/Power supply harness	1
88	Refer to BOM	Hardwired buzzer card	1
720	Refer to BOM	Ty-wrap	1
59	Refer to BOM	Power supply/Blower driver harness	1
725	Refer to BOM	Double sided tape	25mm
724	Refer to BOM	Ferrite	1

Process:

Note:



Note: Observe all ESD Precautions

Ensure that the fan is installed in the correct orientation, arrow pointing up and the connector is securely connected

Check that both foam strips (55 & 714) are in place.

1. Connect the power supply blower harness (bln #59) on blower assembly to power management card. See fig 1. Ensure that the harness connection is fully secured in place using clamp as per fig 1

Fig 1



Power supply/Blower driver harness

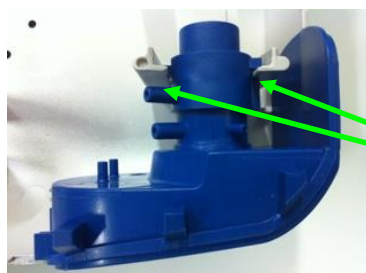
Connect harness to power management PCBA

2. Position the blower in its place, connect free end of the 50mm silicone tubing from the O2 solenoid valve to the blower making sure that the silicon tubing is pushed all the way in, and fasten it with the ty-wrap (bln #720) using ty-wrap gun. See fig 5.

Note: Be careful not to catch cables during this step.

3. Fig 2 below indicates how Silicon Tube 15x21 (bln #13) and O2 Valve should be connected (tubing on the Inspiratory Conical Block not shown for clarity). Ensure all tubing is fully seated on blower.

Note: this picture is for representation of insp block positioning



Insure insp block is installed as shown ie. the supports are correctly inserted into lower housing.

Fig 2

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4. Take the Inspiratory Block assembly, remove the backing strip from the double sided tape on the ferrite and attach the ferrite in the position shown in fig 3. Connect the Inspiratory Conical Block assembly to the Blower Housing via Silicon Tube 15x21. fig 4.

Note that the FiO₂ cable is routed under the Silicon Tube 15x21 and between lower housing features and conical block as indicated in Figure 5. See fig 2 for correct installation of insp block to lower housing

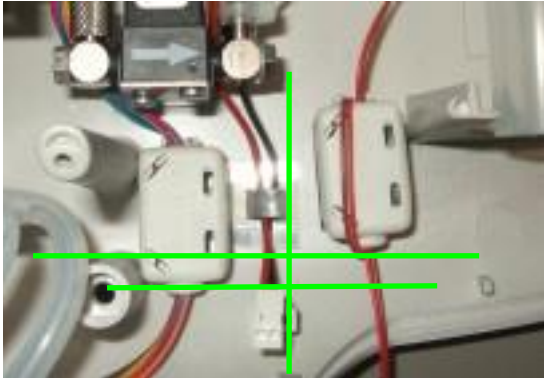


Fig 3

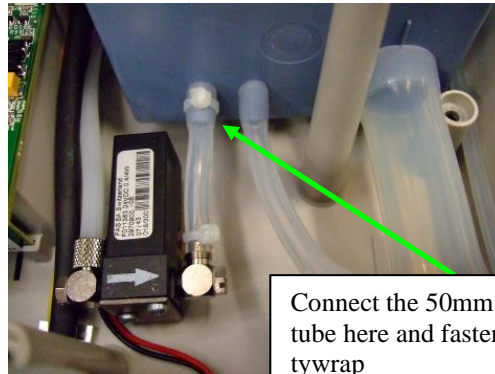
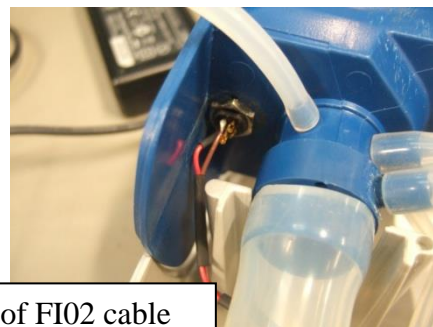


Fig 4

Connect the 50mm silicon tube here and fasten with tywrap



Fig 6



Note routing of FI02 cable

5. Fasten the expiratory conical block assembly by screwing (hand-tightened) the knurled knob under the appliance - Ref fig 7



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Note on routing of blower harness / DHR Check recording

Ensure that the harness is routed as shown in fig 8 of this section and that a ty-wrap is used to keep the single strand and multi-strand harnesses together. This will reduce risk of harness becoming caught between the PCBA and blower as in fig 9 of this section, which may lead to damage of the cable insulation.

Note correct routing of wires

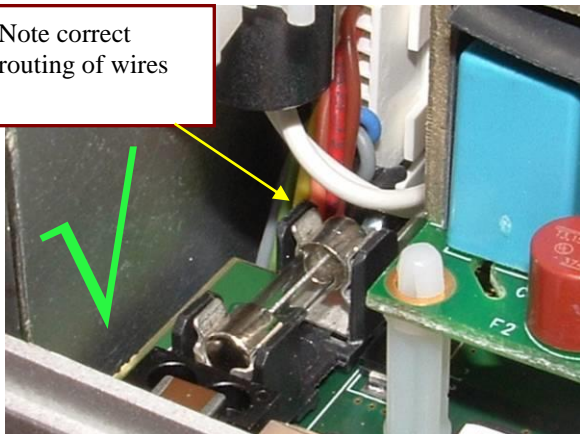


Fig 8 – correct routing

Note **incorrect** routing of wires (caught between PCBA and blower)

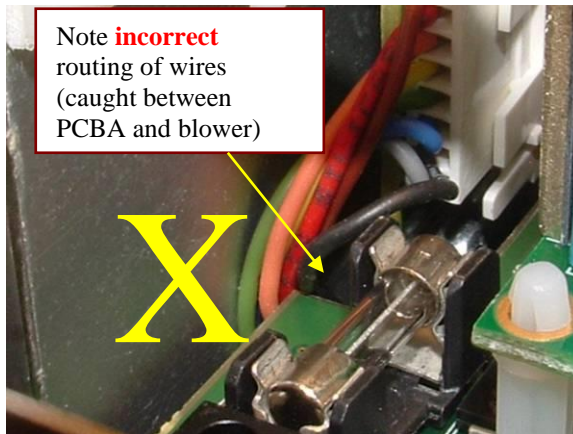


Fig 9 – **incorrect** routing

Note: verify collar is correctly secured to blower.

DHR LOG 10038461

1. Before moving unit to next stage, ensure that all applicable sections of DHR LOG 10038461 are completed.
2. Sign & Date DHR.