



P/N: 10095163
Rev: H
Title: PB560 Assembly procedure 3

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DOCUMENTATION ASSOCIATED TO THIS PROCEDURE:

REV	ECO	PREPARED BY	APPROVED BY	DATE	SUMMARY
N/A	N/A	N/A	N/A	N/A	For previous revision history see Rev C in Agile.
D	ECO-R223022		Refer to Agile	Refer to Agile	Update procedure to add additional check for any cosmetic anomalies to the LCD screen.
E	ECO-R230620		Refer to Agile	Refer to Agile	Update procedure to reflect changes to 560 PHR.
F	ECO-R259799		Refer to Agile	Refer to Agile	Add instruction to record Assembly Part Revisions
G	EC045535		Refer to Agile	Refer to Agile	Procedure updates as per QAP056 redlines, no change to process.
H	EC117495		Refer to Agile	Refer to Agile	Update to meet EMC 4 th edition standard requirements; apply foil tape to keyboard surround on inside of upper housing. Apply 10mm of EMI gasket as shown.



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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
10095161	PB560 Assembly Procedure 1
10095162	PB560 Assembly procedure 2
10095163	PB560 Assembly procedure 3
G-QAM001	Quality Manual
10009491	Mfg. Guidelines to Completion of Records
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

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.
- Record any components used for FRU in FRU Requirements section of DHR.

Traceability:

- All component s/n and lot numbers as listed on the DHR LOG 10038461 must be recorded.



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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).
- 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 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.
- **Note:** If rework/repair is completed at any stage where dis-assembly is required, record all details on the first 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.
- When recording the requested component serial/lot numbers on the DHR, please refer to product BOM for corresponding part numbers.
- **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. Operators must check all parts and Revs of product against that on the BOM.
 - 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.

6. Procedure



Note: Observe all ESD Precautions



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CPU INSTALLATION

Materials:

Balloon Number	Part Number	Description	Qty
85	Refer to BOM	Screw TCB 3.5x8	3
92	Refer to BOM	CPU card	1
64	Refer to BOM	Screw TFX M4x10	5
102	Refer to BOM	Foam Air filter, Electric	1
87	Refer to BOM	CPU/power supply harness	1
88	Refer to BOM	Buzzer PCBA	1

Equipment:

8.9in-lb torque driver
4.4 in-lb Torque Driver
Torx bit T10
Torx bit 15

Complete the following before starting this section:

- Tubing is correctly installed, ensuring ty-wraps are used and secured on each end of the silicon tubing between the solenoid valve and blower, and threaded caps in place and secured on each end of the polyamide tube at the solenoid valve and O2 connection valve.

Process:

1. Record Serial Number and revision of CPU on DHR LOG 10038461. See fig 1.

S/N on Middle line



Fig 1

Check [redacted] Valve Connectors,
ensure Finger Tight



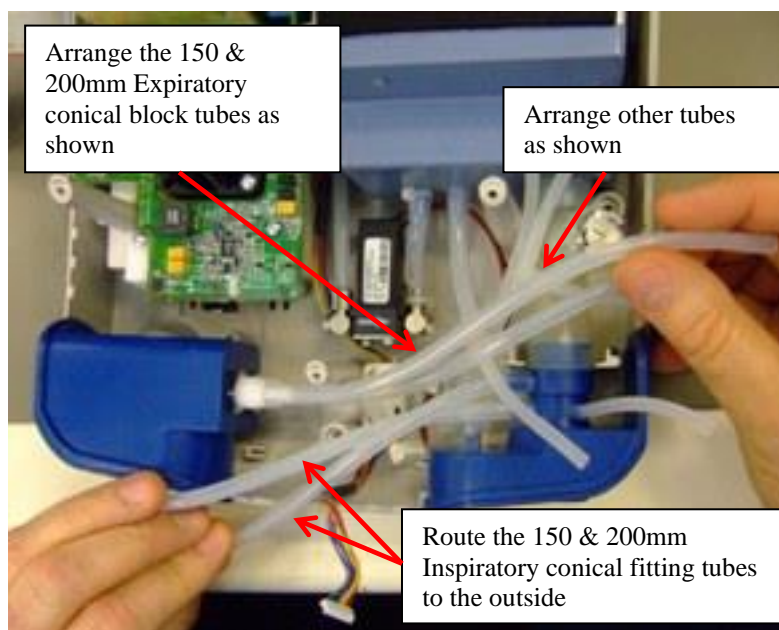
Fig 2

3.

2. Connect the tubing as per figures 3 to 16. Refer to 4097100.M01.000 also if necessary. Ensure that the tubing is pushed all the way in on all tubing connections.

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Arrange the tubing as shown to make tube connection easier to complete

Fig 3

3. Remove 4 red caps from flow sensor of CPU Card, (bln # 92). Ref Fig 4

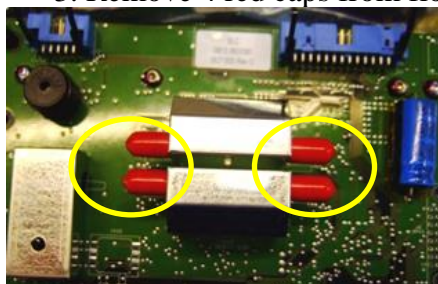
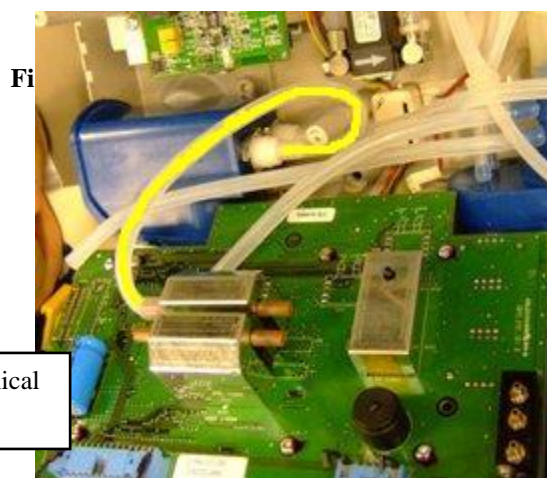
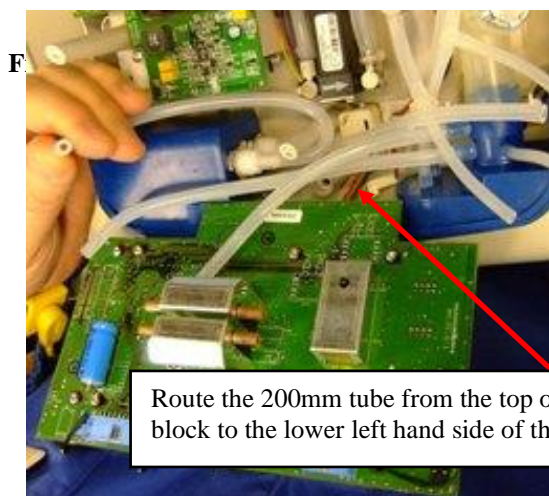


Fig 4

4. Hold the PCBA in the orientation as shown, Fig 5



5. Route the 200mm tube from the top of the EXP. conical block when looking in this direction to the lower left hand side of the PCBA. (tube highlighted in yellow for clarity), fig. 6.

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6. Route the 150mm tube from the bottom of the EXP. conical block when looking in this direction to the lower right hand side of the PCBA (tube highlighted in yellow for clarity), fig. 7.



Fig 7

150mm tube from the bottom of the EXP. conical block to the lower right hand side of the PCBA



Fig 8

200mm tube from the outside port of the inspiratory conical fitting to the upper left hand side of the PCBA

7. Route the 200mm tube from the outside port of the inspiratory conical fitting when looking in this direction to the upper left hand side of the PCBA (highlighted in yellow for clarity), fig. 8.

8. Route the 150mm tube from the inside port of the inspiratory conical fitting when looking in this direction to the upper right hand side of the PCBA (tube highlighted in yellow for clarity), fig. 9.



Fig 9

150mm tube from the inside port of the inspiratory conical fitting to the upper right hand side of the PCBA



Fig 10

Two 70mm tubes connected by the straight connector, from the blower to the bottom sensor port of the PCBA

9. Route the tube assembly which has two 70mm tubes connected by the straight connector, from the blower to the bottom sensor port of the PCBA when looking in this direction (tube highlighted in yellow for clarity), fig 10

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10. Route the 70mm tube highlighted in yellow from the Tee-connector to the centre of the pilot valve.
 Fig 11

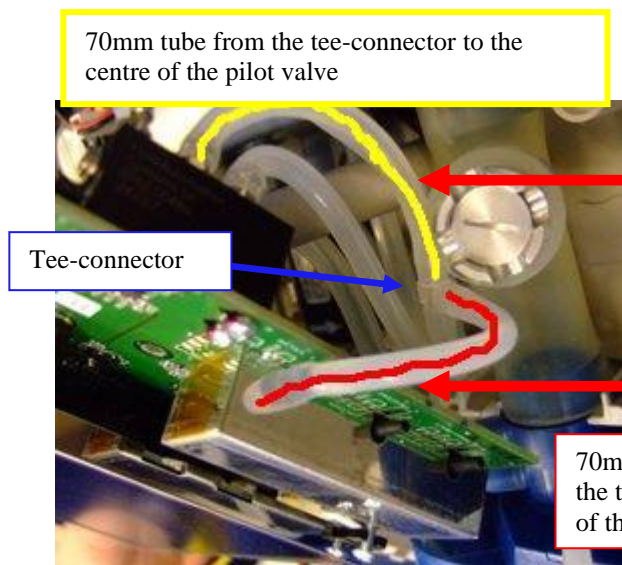


Fig 11

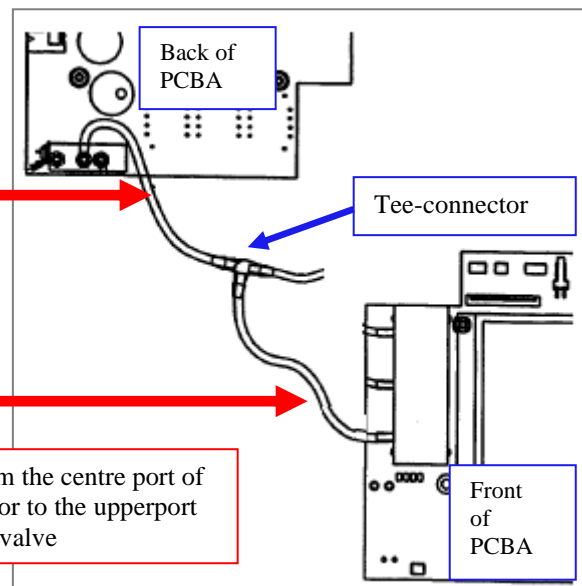
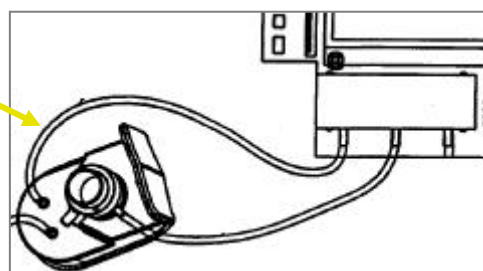
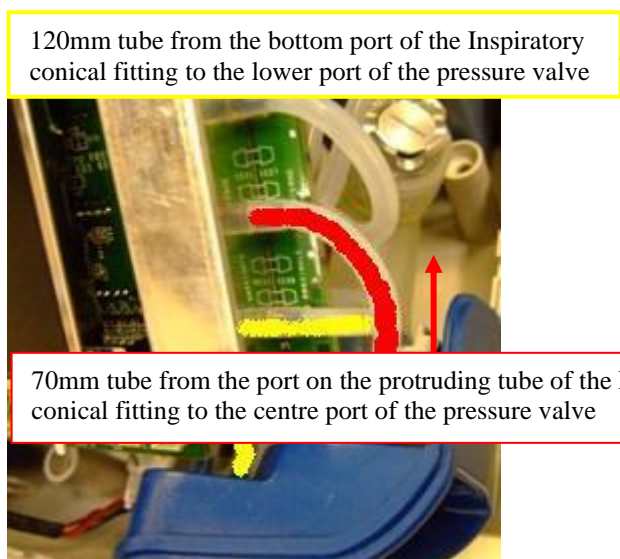


Fig 12

11. Route the 70mm tube from the centre port of the tee-connector to the upper port of the pressure valve (tube highlighted in red for clarity), Fig 11 & Fig.12

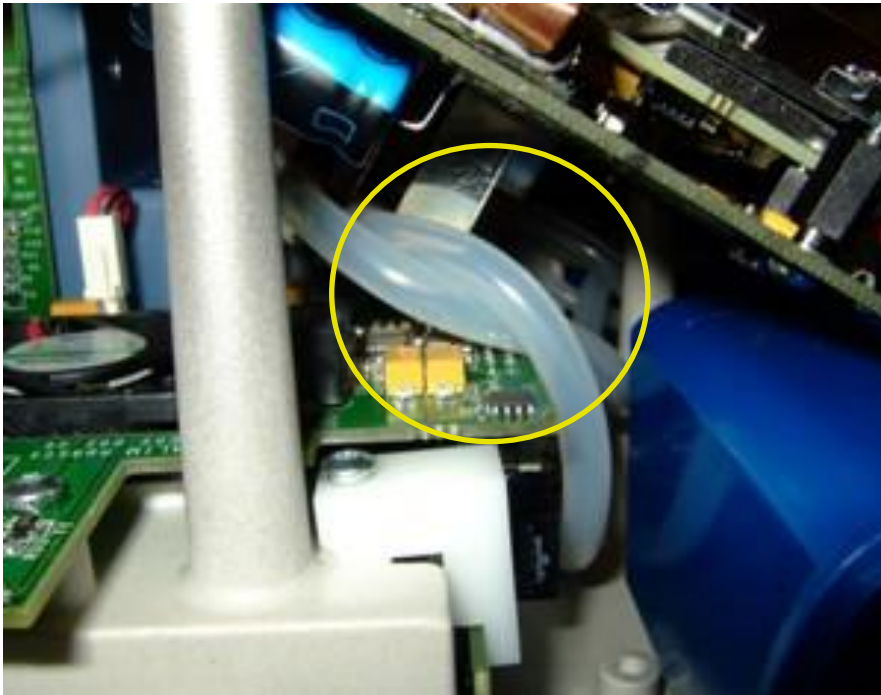
12. Route the 120mm tube from the bottom port of the Inspiratory conical fitting to the lower port of the pressure valve (tube highlighted in yellow for clarity, partially hidden under PCBA), fig 13a& Fig.13b



13. Finally, route the 70mm tube from the port on the protruding tube of the Inspiratory conical fitting to the centre port of the pressure valve (tube highlighted in red for clarity), fig 13

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**Fig 14**

Looking from the left hand side of the unit, make sure that the tubing is routed as shown, and that there are no sharp bends which could restrict flow as per Fig.14

**Fig 15**

Looking from the right hand side of the unit, make sure that the tubing is routed as shown, and that there are no sharp bends which could restrict flow as per Fig.15

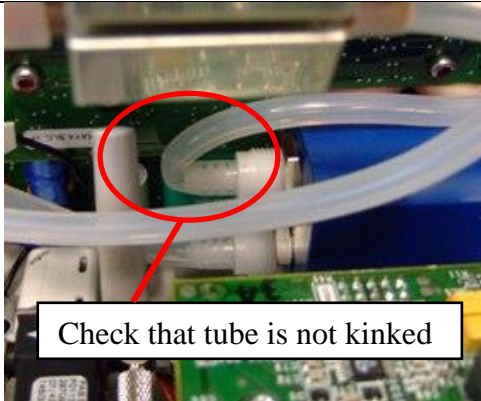
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2. Before completing this section, check that none of the following potential issues are present (ref fig 16-23):

Fig 16

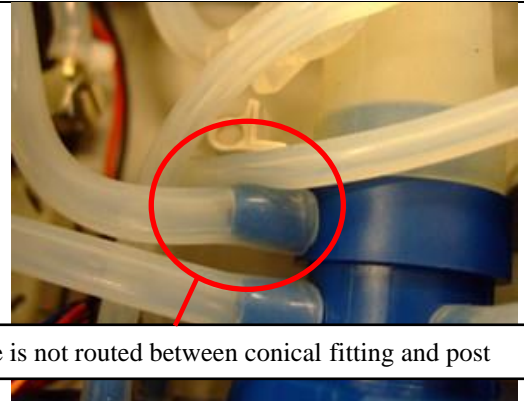
X



Check that tube is not kinked

Fig 17

X



Check that tube is not routed between conical fitting and post

Fig 18

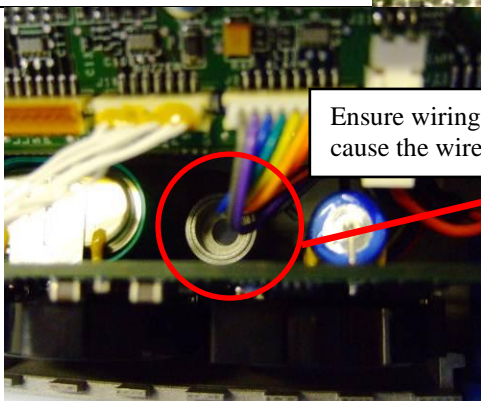
X

Ensure tubing to blower is connected and ty-wrap used to secure (completed at st.2)



Fig 19

X



Ensure wiring is not routed over hole. This can cause the wire to be pinched during final assembly

Fig 20

X

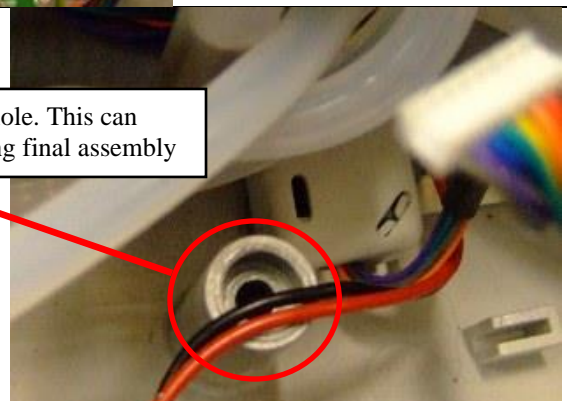
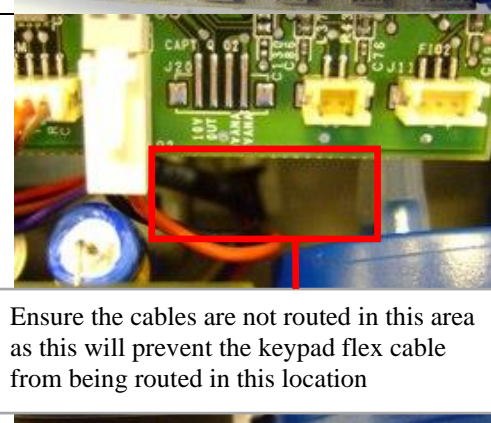


Fig 21

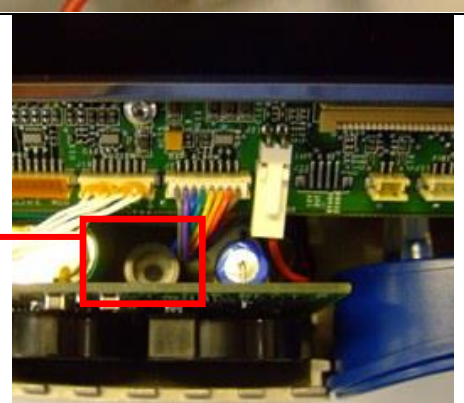
X



Ensure the cables are not routed in this area as this will prevent the keypad flex cable from being routed in this location

Fig 22

Sufficient space left for flex cable routing



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3. Align holes of CPU card (bln #92) with Lower Enclosure posts and using a torx screw driver loosely thread the three screws to lower enclosure, torque to 4.4 in-lb using torque bit 10 and check that no tubing is pinched. Refer to Fig 23.

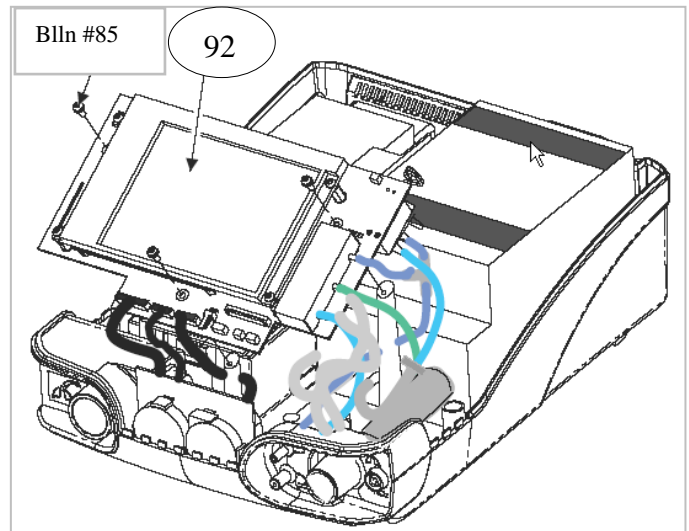


Fig 23

4. As a check that the CPU is fully secured, verify that there is no gap between the screw head and the CPU. Connect the harnesses (Alarm, O2 and FIO2 Cable) as highlighted in purple in Fig 24 below. Ribbon cable (bln # 87) is connected between J7 on power supply board (bln #84) and J7 on the CPU (bln #92) as per Fig.25

Note: Orientate cable such that ferrite on cable bln #87 is closest to CPU card. Connect Ribbon cable from blower driver assembly to J4 of CPU card (bln #92) see fig 26 below for specific routing. See fig 25 for pictorial representation of harness connection between PCBAs.

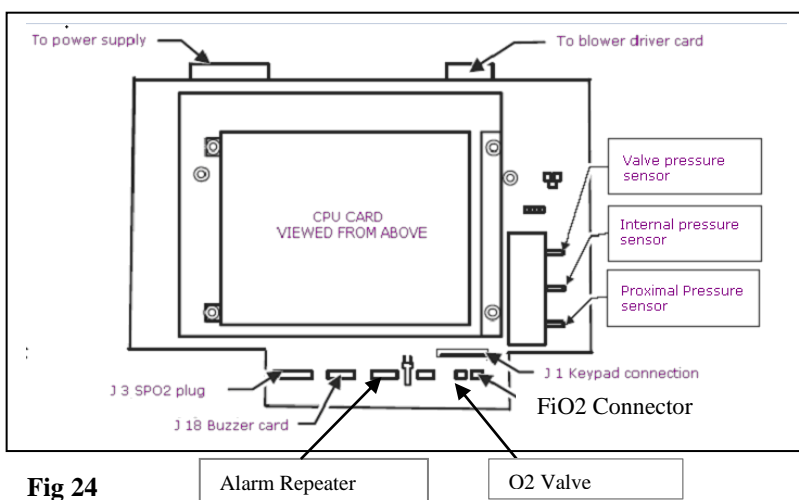


Fig 24

Blower PCB to CPU PCB



Fig 25

Power mgmt. PCB to CPU PCB

Note: J3 SPO2 plug in Fig.24 not used

5. Ensure that the harness connections are fully secured.

Notes:

Ensure all connectors are firmly pushed home and connectors are fully secured.

Note: ensure blower to CPU harness is routed as shown in Fig.26

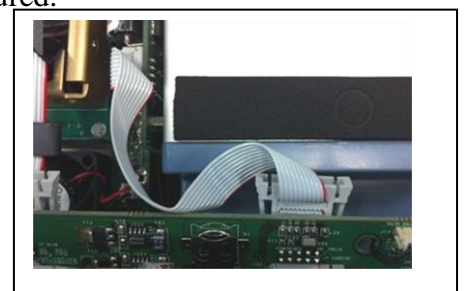


Fig 26

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BUZZER CARD INSTALLATION

1. Record the S/N and Revision of the buzzer card on DHR LOG 10038461
2. Set the switch in the buzzer board as shown in fig 1. Install Buzzer and connect up buzzer cable as per Fig.2.

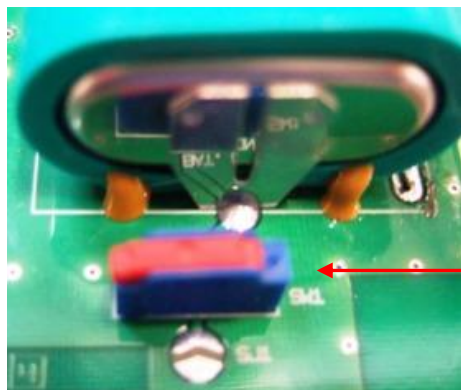


Fig 1

Set Switch as shown (push to left hand side with board in this orientation)

3. Check that the wiring is routed as per fig 2 below, ensure that there is no tension on the cables and that there are no wires routed at the centre of the buzzer PCBA. This is to allow for the upper enclosure post.



Fig 2

4. By looking into the unit as per fig 3 and 4 and 5, check that there are no kinks in the tubing routing. Also verify that the tubing is fully connected, and that there are ty-wraps on both ends of the silicon tube from the solenoid valve to the blower. Verify Ribbon Cable is fully connected

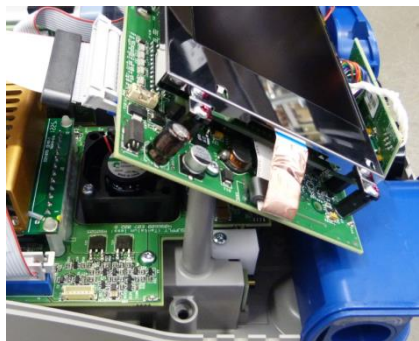


Fig 3

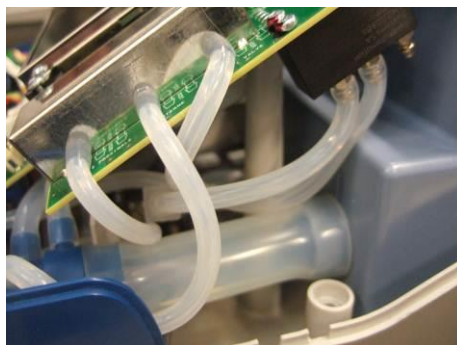


Fig 4



Fig 5



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BATTERY COVER ASSEMBLY

Materials:

Balloon Number	Part Number	Description	Qty
41	Refer to BOM	label PB540 Battery Assy	1
42	Refer to BOM	Adhesive stop	4
43	Refer to BOM	Battery Cover	1
44	Refer to BOM	Label, Product, 520, 540, 560, O2 RA	1
46	Refer to BOM	Silicon Stoper	2

Equipment:

Kim wipes P/N 901731
Isopropyl Alcohol, 901048
Fixture p/n 3835000

Process:

1. Clean the Battery Cover around areas where labels and stops are applied with alcohol and kimwipes, check for defects & MRB if required.
2. Record the revision of the label (bln #41)(**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. Affix the 4 adhesive stopers (bln #42) into the slots, and then affix battery assembly label as per fig 1 of this section

Fig 1



4. Affix 2 silicone stops (bln #46) as per fig 2 of this section. Use stop positioner battery cover fixture p/n 3835000 for placement

Silicone Stops bln #46

Fig. 2





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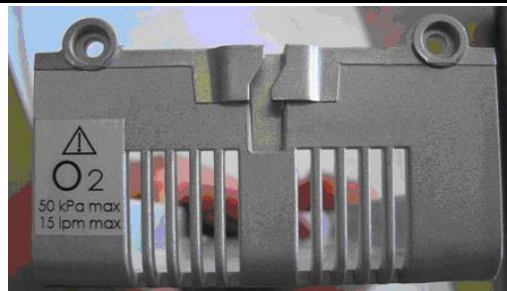
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5. Affix O2/RA label as per Fig 3.

Fig 3

Position the O2 piece of the O2/RA (bln #44) label as shown
Note: The alarm piece of the O2/RA label is affixed during the 'LOWER HOUSING' section of this procedure.





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UPPER HOUSING ASSEMBLY

Materials:

Balloon Number	Part Number	Description	Qty
61	Refer to BOM	Upper housing	1
62	Refer to BOM	Keypad PB560	1
63	Refer to BOM	Handle	1
64	Refer to BOM	Screw TFX M4x10	2
65	Refer to BOM	Label PB560 Tubing Diagram	1
66	Refer to BOM	Foil Tape	1
67	Refer to BOM	EMI Gasket	1

Equipment:

Torque Driver 8.9 in-lbs
Torx bit T15
Isopropyl Alcohol, 901048
Kim wipes P/N 901731
Foil tape P/N PT00096186
EMI Gasket P/N 4-076684-00

Process:

1. Prior to using upper housing, inspect for any defects. Place any non-confirming parts into MRB.
2. Using alcohol and a kimwipe, wipe the inside of the housing thoroughly for dust / debris, especially around where the tubing diagram label will be applied and the gates next to the housing window (per fig 1 below).
3. Record the revision of the label (blln #65) (**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. Attach the tubing diagram label (blln #65) inside the housing. Refer to Fig.1 below for positioning of label. When applying, remove back, align label and (optionally using cloth) apply pressure on one side at a time to avoid bubbles.

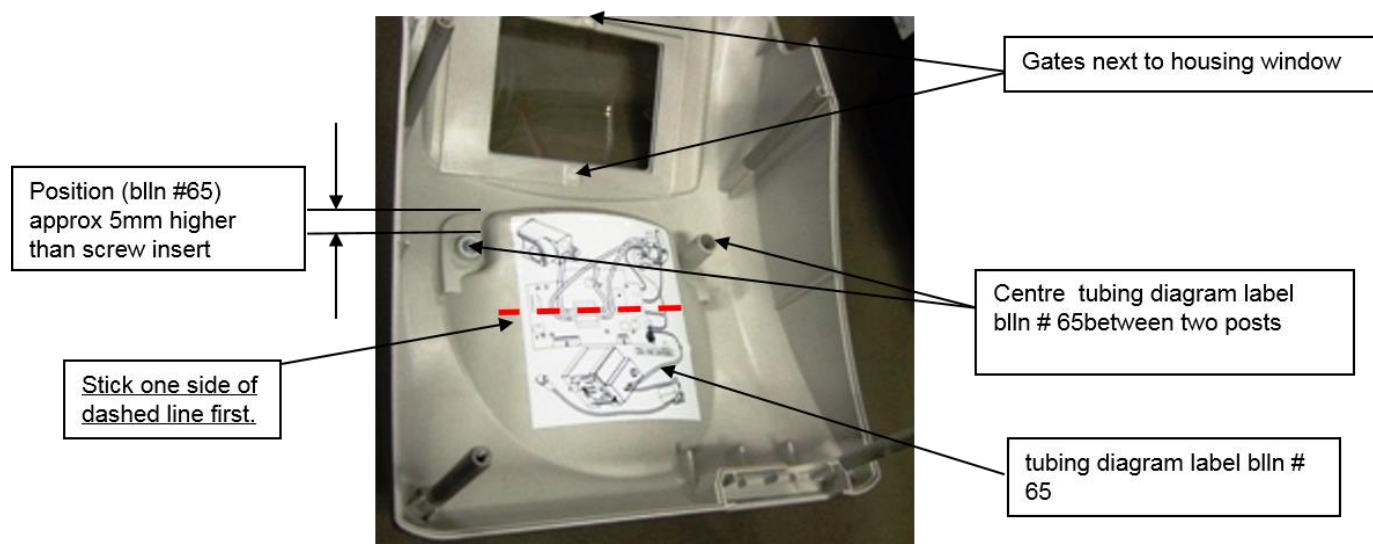


Fig. 1: Upper Housing (ref 6.1)

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Application of Handle

1. Mount the handle (bln #63). Using the 8.9 in-lbs torque, (torx bit 15) fix handle with two screws (bln #64) per Fig 4 of this section

Application of Keypad

1. Prior to application of Keypad (bln #62) to upper housing clean affected area with alcohol and kim wipes.
2. Cut foil tape (bln #66) to the following measurements:

Length (CM)	No. of lengths required	Apply to; (Interior of keyboard stage)
16.5 (+ 0.5)	1	Bottom
16.5 (+ 0.5)	2	Top
12.0 (+ 0.5)	4	Sides

3. Carefully apply foil tape to interior of keyboard stage as per table above and figs 2a and 2b below. The tape on top and sides of keyboard stage should overlap. Do not tape over flex tail slot.

Note: Tape needs to be applied to the area marked within the red square. Particular attention should be taken so that the area marked with red arrowheads is taped (fig 2a, with exception of keyboard slot) as per fig 2b for unit to be protected from electrostatic discharge.

Note: Take care to place tape neatly surrounding the area for keyboard window so that the tape will not be visible from exterior of upper housing.

4. Apply 10 MM of EMI gasket (bln #67) to area circled (fig 2b).

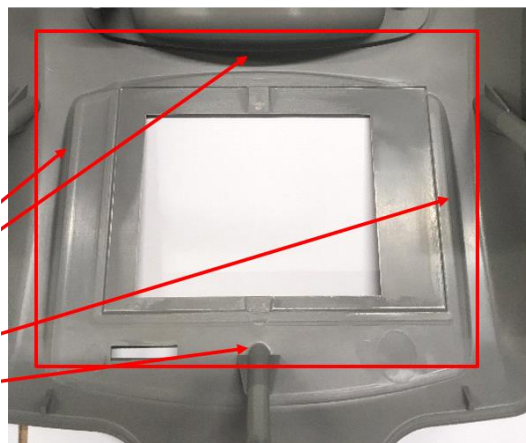


Fig 2a: Keyboard stage, interior of upper housing

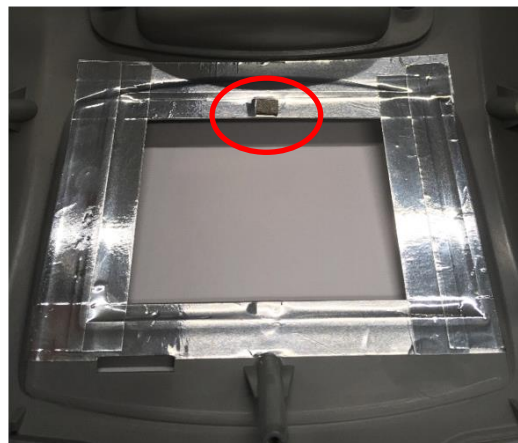


Fig 2b: Keyboard stage, with foil tape applied

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5. Record/Scan the Lot Code and revision of Keypad (62) on DHR LOG 10038461, for lot code see fig 3.

Record/Scan the Lot Code data from the Tag on the Keypad ribbon cable.

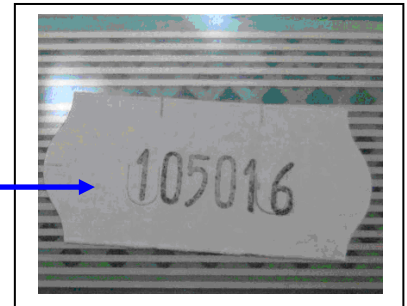


Fig 3

6. Remove protective backing from keypad adhesive area and push the ribbon-cable through the window before applying the keypad.

Remove inner protective film from clear window prior to proceeding any further.

7. Stick the keypad to the housing by applying even pressure around the membrane, starting at the top corners. Refer to fig 4 and 5 of this section.

Notes:

- Be careful to apply the membrane centred first time. Once the membrane is applied, it cannot be removed for re-adjustment as this may damage the buttons.
- Do not form or bend the flex tail at any stage during the assembly. This can damage the tracks. Ref to Fig 5 below.

NOTE: Flex Tail Tracks can be broken if Flex Tail is bent / creased.

If visible signs of Flex Tail damage: contact MFG / QA Engineer.

Use 8.9 in-lbs torque (torx bit 15) to secure the handle to the upper housing

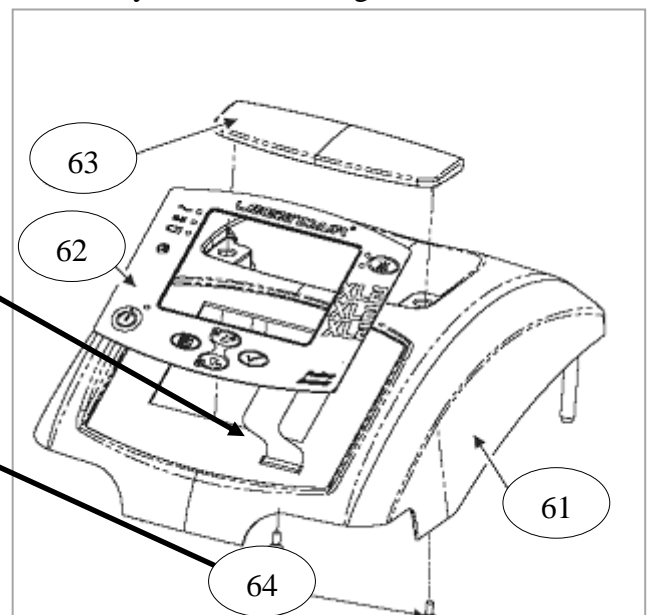


Fig 4

NOTE: Do not form or bend the flex tail at any stage during the assembly. This can damage the tracks.

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Fig 5: Upper Housing with installed Keypad



Note: Label not present on PB560 Keypad

Blln #61

Fig 6



Take care not to bend the flex cable in this area.

NOTE: Before installing the top housing, it is important to remove the protective film from the screen of the CPU.

Final Checks before closing the unit: (See Fig. 7 below)

- All wiring is connected and fully pushed in place with locking mechanism correctly in place where used.
- All tubing to CPU is installed and pushed in all the way.
- Verify that the Loctite is present on the blower (beside hex nut nearest to ferrite).

Fig 7a

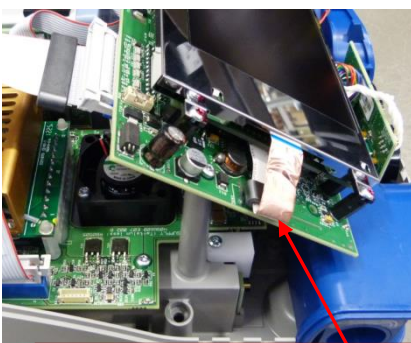


Fig.7b

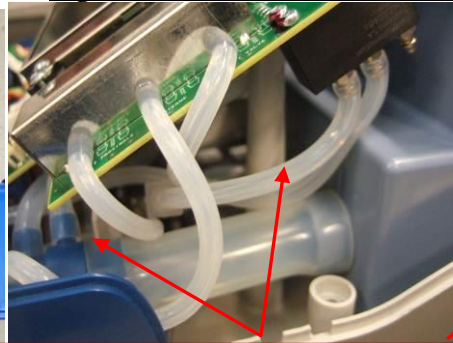
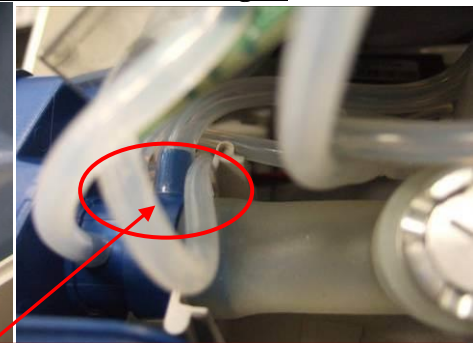


Fig.7c



Check Ribbon Cable fully seated. Check all tubing for NO kinks / NO pinches and that each tube is fully seated / connected.

FINAL ASSEMBLY – CLOSING THE UNIT

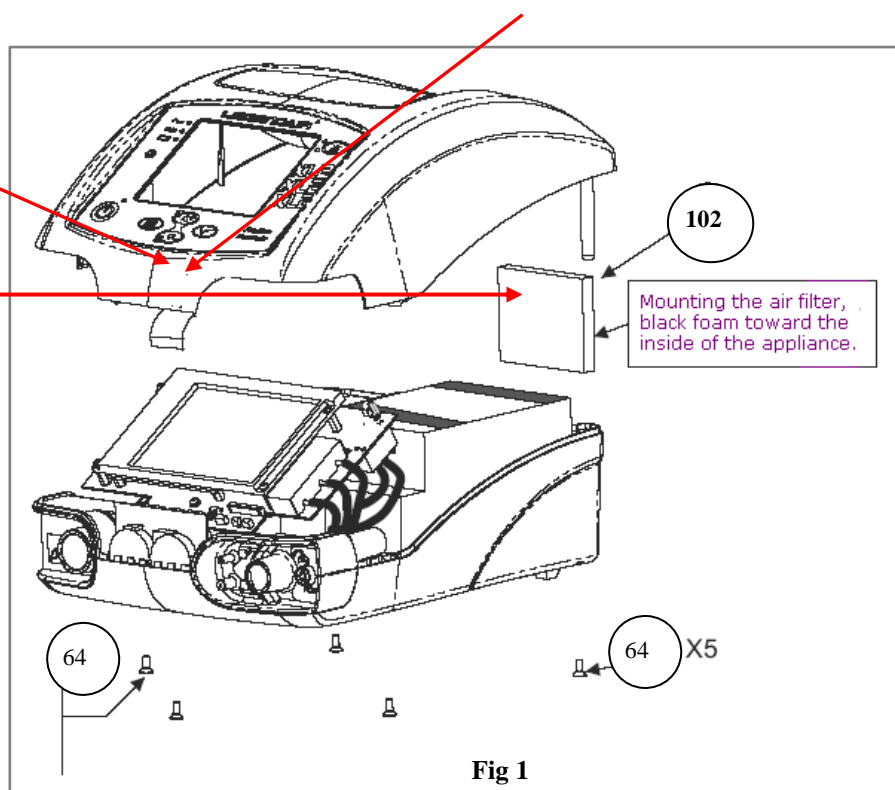
1. Connect the keypad ribbon cable, ensuring that the top enclosure does not make contact with the bottom enclosure unit and that the connection is fully pushed in.
2. Hold the Flex Tail in one hand, push down on connector alternatively on each side, until fully seated. Lock connector. Pull lightly on the ribbon-cable to check it is secure in place.
3. Place the air filter (bln #102) in position and close the appliance from back to front making sure the keypad's ribbon-cable does not get pinched. Ref to Fig 1 & 2.
4. **Using a torque set to 8.9 in-lbs,** secure unit using 5 screws (bln #64) using a Torx bit T15. See Fig.2 on next page

Note: Ensure tubing is not pinched between upper and lower enclosure.

Connect the keypad ribbon cable, ensuring that the top enclosure does not make contact with the bottom enclosure unit and that the connection is fully pushed in

NOTE: Flex Tail Tracks can be broken if Flex Tail is bent / creased. If visible signs of Flex Tail damage: contact MFG / QA Engineer.

Place the air filter (bln #102) in position and close the appliance from back to front making sure the keypad's ribbon-cable does not get pinched. Ref to Fig 2 & 3. Also ensure tubing is not pinched between upper and lower enclosure.



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Fig. 2 Location of 5 screws.
Torque to 89 in-lbs(15 bit)



Fig. 3



Fig 8

Fig. 4

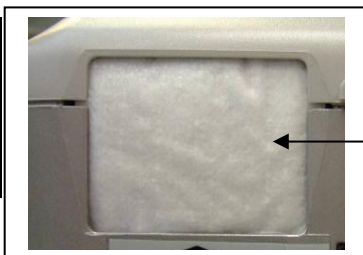
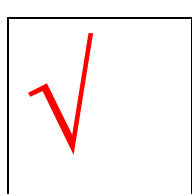


Fig. 5

Ensure that foam is centred in the slot and that there are no gaps around the edges

Fig. 6

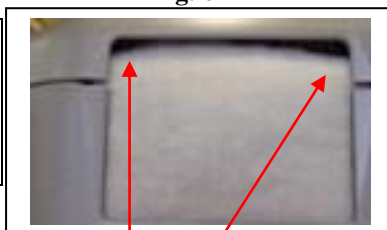


Fig. 7



X

X



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Ensure that foam is centred in the slot and that there are no gaps around the edges and the foam is not pinched by the housing

- Verify that the foam is correctly installed, ensure that foam is centred in the slot and that there are no gaps around the edges as per figs 5 - 7 of this section

MOUNT THE BATTERY

Materials:

Balloon Number	Part Number	Description	Qty
111	Refer to BOM	Screw TCB 3x8 hexalobe	3
43	Refer to BOM	Battery cover	1
112	Refer to BOM	Lithium 7S2P [REDACTED]	1
1121	Refer to BOM	Lithium 7S2P [REDACTED]	1

Equipment:

4.4in-lb Torque Driver

Torx bit T10

10025203 PB540 BATTERY INSERTION CRADLE

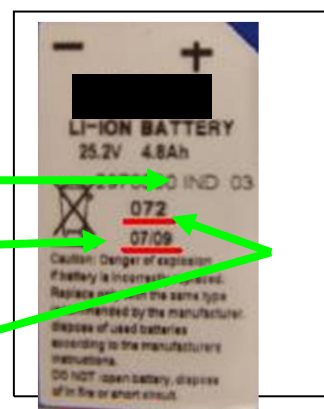
Note: it is acceptable to use either versions of battery (bln#112) or (bln#1121).

Note: Prior to assembly, check that the power switch at the back of the unit is set to '0' i.e. **off**

Fig. 1a



Fig.1b



Revision

Date code

Serial no.

- Record Serial Number and revision of the Battery on DHR LOG 10038461. See Fig.1a & 1b above.
- Carefully place the unit into the battery insertion cradle. Avoid touching the unit against the fixture to minimise the risk of scratching. See fig 2.



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Fig 2

3. Verify that all the 8 silicon stops are in place on the lower enclosure and battery cover is well bonded and that the battery label is attached as per fig 3 and fig 4 below.

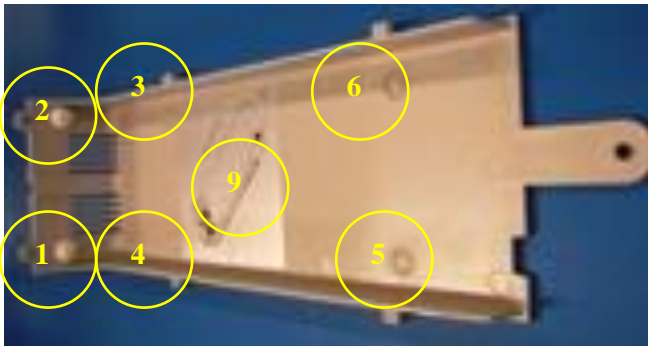


Fig 3

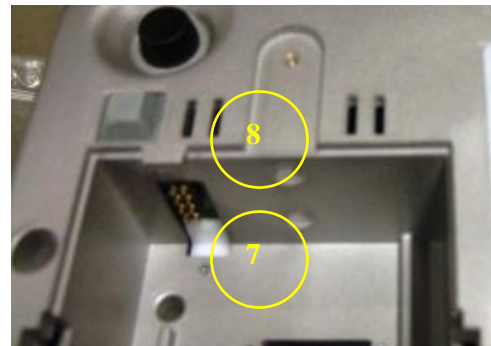


Fig 4

4. Line up the battery (bln#112) making sure it's in the right direction (see fig 5) and add the cover (bln #43) by pressing manually towards the rear of the cover.

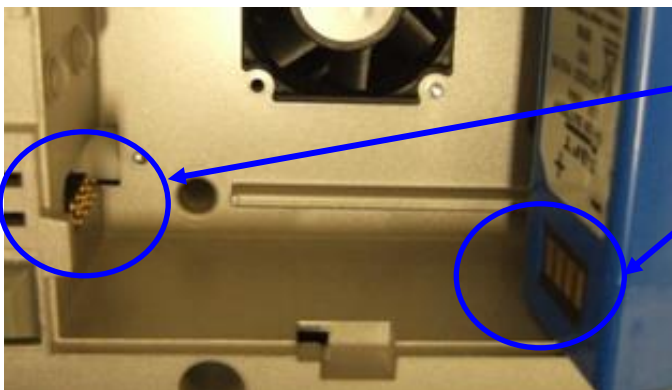


Fig 5

Make sure pins line up with pads.

Note: This is for representation purposes only and battery types will vary

HANDLING:

- Do not handle or contact battery pads by hand.
- Do not wear jewellery when handling the battery

Note: Do Not allow the battery to make contact with the pins until the battery door is in place.

5. Slide both battery and battery door in together and slowly clamp the battery door so that the screw holes line up as per fig 6 of this section

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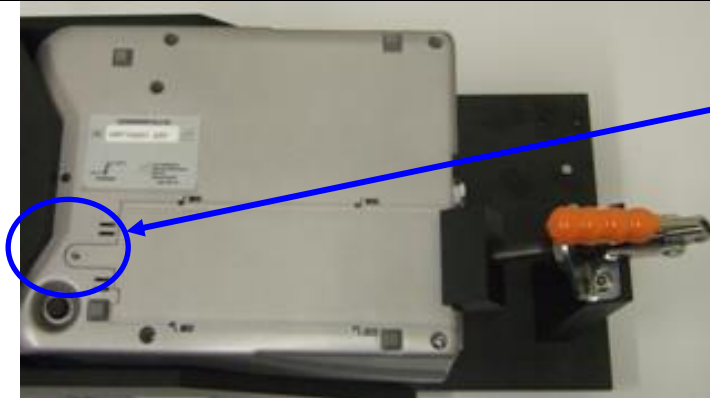


Fig 6

Tighten this screw using 4.4lbs torque (Torx bit 10)

6. Tighten the base screw (bln #111), torqued to 4.4 in-lbs as per fig 6.
7. Stand the fixture up on its end and tighten the two screws (bln #111), torqued to 4.4 in-lbs as per Fig 7 & 8.

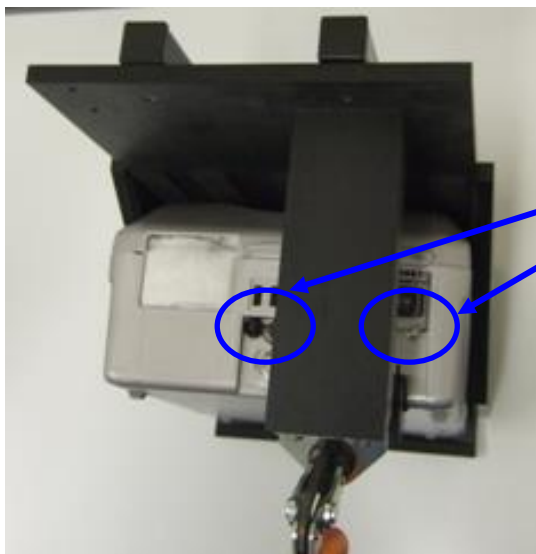


Fig 7

Screw location shown for clarity

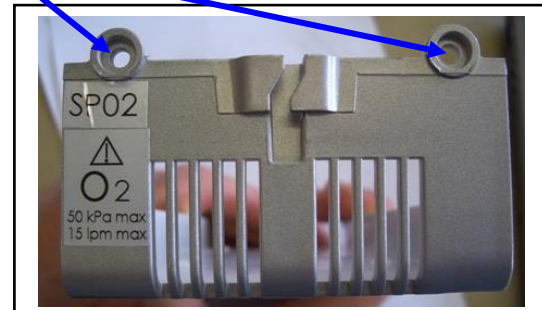


Fig 8

8. Leave the unit back in its original position and careful remove the unit avoid touching it of the fixture to reduce the risk of scratching.
9. Power up the unit and verify the following:
 - Ensure LCD screen is adequately aligned with upper housing window.
 - There is no dust or scratches on the display of window of the keypad (it may be necessary to remove the protective lining to complete this check).

FINAL LABELLING CHECK

1. Complete the following labelling checks:
 - Check that all labelling is attached to the unit. See figs 9-15 of this section.
 - Check that there are no air bubbles or cosmetic defects on the labels.

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- Check that the labelling orientation / straightness is acceptable.
- Check that the labels are correctly bonded to the unit.



Fig 9

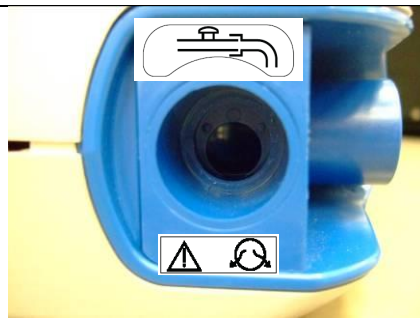


Fig 10



Fig 11

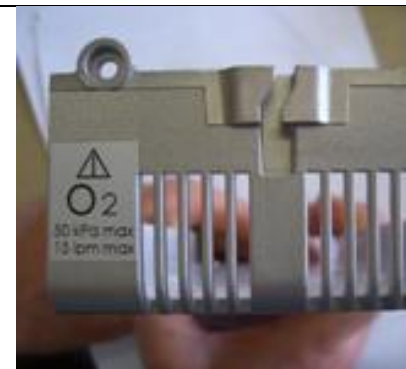


Fig 12



Fig 13 (label content may differ)

Fig 14

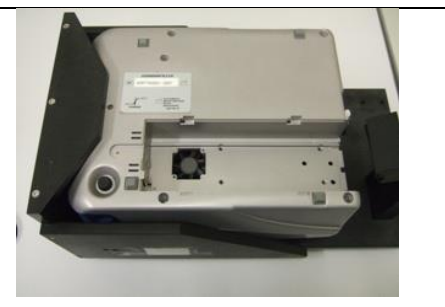


Fig 15

2. Check to ensure the product S/N label attached to the unit is as per format in fig 16.

Fig 16

Template # 10034696



Ensure the product S/N label attached to the unit is as per format.

Note: The serial number pictured in fig 16 is for representation purposes only and serial numbers will vary.



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Serial Number

Year

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UNIT CHECK:

1. Once the unit is fully assembled, switch on and check that the LCD screen is illuminating and that there are no cosmetic anomalies on the LCD screen or on the keypad window, ref fig 1.
2. After switching on the vent ensure the DC light is illuminated and the screen is clear from any cosmetic anomalies and appears as per fig 1 below.
3. Once this action has been completed switch off the unit & place on the charge rack awaiting electrical safety test.

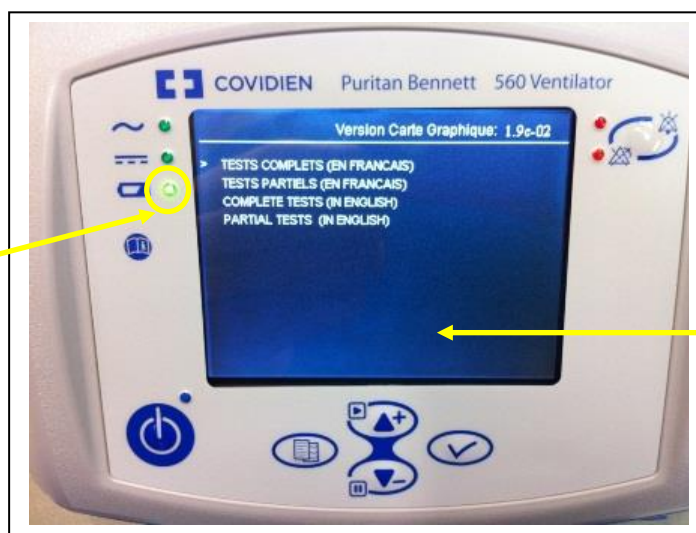


Fig 1

DC LED on keypad

Representation of
clear LCD screen

DHR LOG 10038461:

1. Before moving unit to next stage, ensure that all applicable sections of DHR LOG 10038461 are completed and signed.
2. Sign & Date DHR **10038461** to confirm all elements have been successfully completed.