



P/N: 10039897
REV: AH
TITLE: PB560 PACK

PROCESS INSTRUCTIONS

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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	For previous change history refer to Rev W in AGILE
AA	EC045533		Refer to Agile	Refer to Agile	Updates as per QAP056 redlines, no change to process.
AB	EC089803		Refer to Agile	Refer to Agile	Add Visual Aid for Outer label Verification requirement
AC	EC102789		Refer to Agile	Refer to Agile	Updates as per QAP056 FY18 Redlines
AD	EC113729		Refer to Agile	Refer to Agile	Remove reference to SW revision LX010103 and replace with LX010104.
AE	EC117821		Refer to Agile	Refer to Agile	Remove software download from pack. All software download will be performed in P/N 10036007.
AF	EC124148		Refer to Agile	Refer to Agile	Update images for Air inlet label and ship carton wrap around label per homecare update.
AG	EC129900		Refer to Agile	Refer to Agile	Add update for generation of additional label for liscence plate – needed for scanning of unit to SAP at shipping.
AH	EC 128729		Refer to Agile	Refer to Agile	Add instruction to upload date of manufacture

1. SCOPE

To provide manufacturing personnel with all the necessary instructions to Pack.

Note: A line clearance must be performed when switching between region specific PB560 ventilators, refer to table 1 in procedure section and appropriate BOM.

2. REFERENCES

10012479	Generic Cleaning Log
G-AMFG-1814-00	Cosmetic Criteria, Monitors / PB500/Gen1/INVOS 5100c/HT70
10095161	PB560 assembly procedure 1.
10095162	PB560 assembly procedure 2.
10095163	PB560 assembly procedure 3.
10038461	PB560 DHR
G-AMFG-2733-00	Label printing procedure
G-AMFG-1817-00	Line Clearance Procedure
10021754	Product Release Authorisation
10021500	Rework/Repair Procedure
G-AMFG-2909-00	BPCS Backflushing Procedure
G-AMFG-2910-00	BPCS Picking Procedure
G-AMFG-1165-00	Pareto Chart Procedure
10021526	Lot Code and Serial Number Assignment procedure
BOM in the system	4096600
10097245	PB500 pack log/ licence plate log
10149038 -	VERIFICATION SCANNER OPERATING PROCEDURE
10148650	PRINTING GENERIC SHIPPING CARTON LABELS USING CLICK PRINT
QS0002016	UDI Barcode Grading Verification Procedure
G-AMFG-2913-00	Printing Labels using Labelview

3. GENERAL REQUIREMENTS

MATERIALS & TOOLING

Item	Description
2	Kim wipes P/N 901731
3	Lint free cloth
4	Isopropyl Alcohol

BOM P/NS AND BALLOON NUMBERS

- ❖ A BOM must be printed from Galway BPCS or Agile (per G-AMFG-2910-00) at the start of each week/build by the Line lead / Production Supervisor and signed and dated. This BOM must be maintained on the line for reference. Production operators must check this BOM against all material on line to ensure for correct Revisions. Any discrepancies inform Line Lead/Supervisor.
- ❖ Refer to the approved Galway BPCS BOM for the cross reference of p/ns to balloon numbers as referenced in this procedure



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4. PROCEDURE:

DHR Part Number Label

Print 1 Part Number label from label view and attach to the DHR

PACK MATERIAL LIST		
Part Number	Part Description	Balloon number
Refer to BOM	LABEL, BATTERY CHARGE DATE, LEGENDAIR, XL2	2
Refer to BOM	LABEL, PB 540, CLASS 9 UN 3481	3
Refer to BOM	PB560 PORTABLE VENTILATOR	6
Refer to BOM	OUTER SHIPPING CARTON 15.83" X 13.07" X 15.43"	4
Refer to BOM	LTR CUST BULLETIN PB500 SUSTAINMENT SW RELEASE	24
Refer to BOM	O2 FITTING MALE	5
Refer to BOM	ELECTRIC FILTER WITH FOAM	20
Refer to BOM	EU POWER CORD	8
Refer to BOM	HANG, CABLE 6.6X4.3	9
Refer to BOM	CLIP HANG CABLE 6.6X4.3	10
Refer to BOM	PB 540 CARRYING BAG	18
Refer to BOM	BAG,8 X 10, PROTECTIVE	23
Refer to BOM	BAG, POLY, 16 X 18, .004 MM	17
Refer to BOM	CIRC.ADT DOPPIA LINEA AIROX II	21
Refer to BOM	TAPE, SCOTCH 3/4" WIDE	16
Refer to BOM	TAPE, SEALING,2", CLEAR PASTIC	13
Refer to BOM	BAG, ZIP, POLY,2-1/2"WX3"L (STS)	15
Refer to BOM	BAG, LARGE TIJ, PLX	7
Refer to BOM	LABEL,560, OUTER CARTON WRAP LABEL, POD, MULTILANGUAGE	1
Refer to BOM	PACKING LIST, PB560 VENTILATOR, ENGLISH	12
Refer to BOM	Features software	27
Refer to BOM	CD-ROM, PB560 CLINICIAN'S MANUAL	22

SKU ASSIGNMENT:

Select the SKU the ventilator will be assigned to. Indicate SKU assignment on DHR.

Description	BOM number
PURITAN BENNETT 560 VENTILATOR	4096600
PB560 VENTILATOR EU-Div	4096600-01
PB560 VENTILATOR JAPAN	4096600-02
PB560 VENTILATOR APAC	4096600-03
PB560 VENTILATOR LATAM	4096600-04
PB560 VENTILATOR EMEA	4096600-05
PB560 VENTILATOR CAN/ANZ	4096600-06

Label / Cosmetic Inspection prior to pack

Complete the following labelling checks:

- Check that all labelling are present on the unit. See figs 1-6 of this section (labels highlighted with red dots).
- Check that there are no air bubbles or cosmetic defects on the labels
- Check that the labelling orientation / straightness is acceptable
- Check that the labels are correctly bonded to the unit
- Verify that the revision has been completed on the DHR

Unit Cosmetic Check

- Do a visual inspection of unit, checking for cosmetic defects, and clean it if necessary using alcohol and clean using lint free cloth. Refer to G-AMFG-1814-00

Test data check

- Check that the Calibration, Final, and Leakage Current Test Data sheets are present

S/N Check

- Check that DHR S/N matches the product S/N.

DHR - Tick check boxes on 10038461 DHR to verify checks have been completed



Fig 1

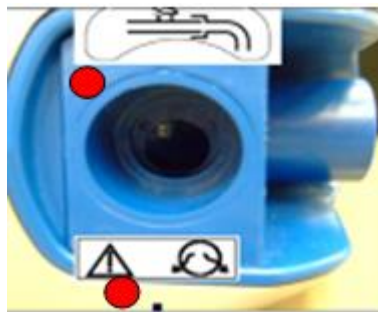


Fig 2



Fig 3



Fig 4

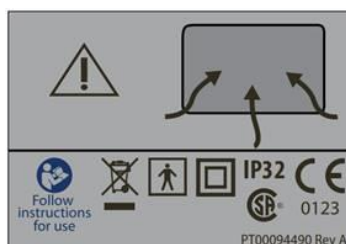


Fig 5

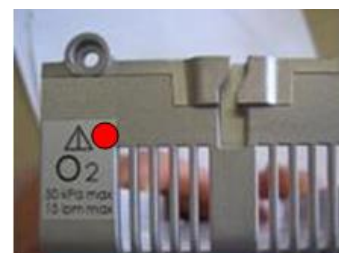


Fig 6

Filter foam Check

- Ensure that filter foam is centred in the slot and the white side of the filter is facing out. See Fig 7



Fig 7

Note:

- Ensure that there are no gaps around the edges and the filter foam is not pinched by the housing. See figs 8 and 9 for examples of unacceptable foam assembly

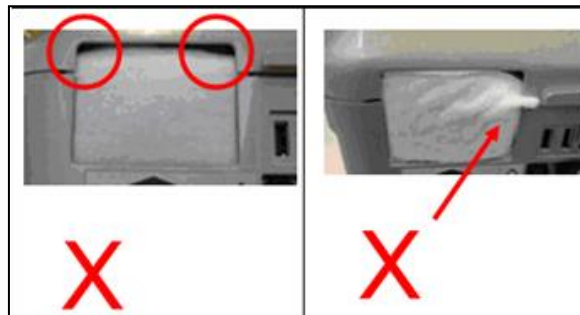
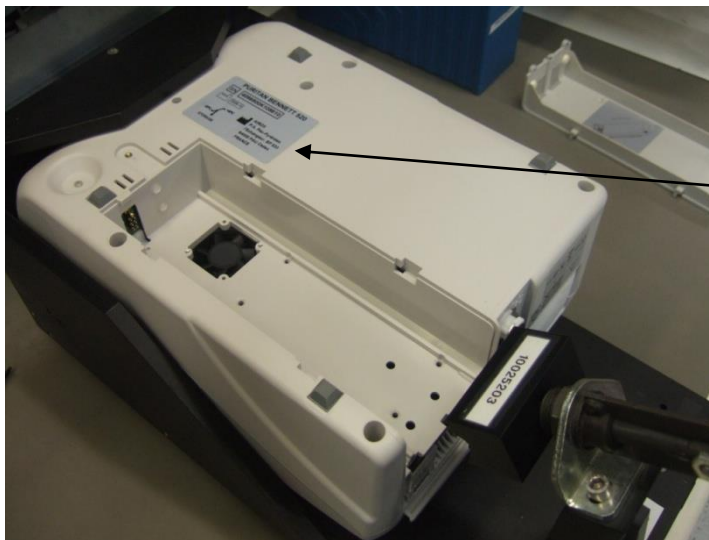


Fig 8

Fig 9

Product Serial Number/product label attachment and verification

- 1) Scan temporary serial number on recess of bottom enclosure in order to generate 2 x product serial number from Toshiba printer as per G-AMFG-2913-00.
- 2) Apply 1 x product serial number label to appropriate section of PHR.
- 3) Remove temporary serial number from bottom enclosure and apply to appropriate section of PHR.
- 4) Fix the product serial number (blln #7.22) to the window of the product label (blln 7.11), ensuring it is straight.
- 5) Follow instructions as per QS0002016 "UDI Barcode Grading Verification Procedure and Date of Manufacture upload." Sign and date relevant section of PHR. If barcode grading result for UUT is a fail, contact the line lead/engineer.
- 6) Attach the product label to the unit as shown in fig. 1.



Attach ID label, readable in the direction as shown

Fig 1

Carton Labelling for PB560

1. Obtain the pack labels and complete labelling **revision check and record on DHR, 10038461**. Note that each part must be individually verified.
2. Verify that battery has been fully charged by checking the test section on the DHR
3. Generate shipping label Bln#1 (ref procedure G-AMFG-2733-00), for the ship carton. Ref Fig 1 of this section
4. To verify ship label barcode grading, follow instructions as per QS0002016 "UDI Barcode Grading Verification Procedure." Sign and date relevant section of PHR. If barcode grading result for UUT is a fail, contact the line/Engineer

Note: Verification of barcode label may be completed while label is attached to the carton or on flat surface.

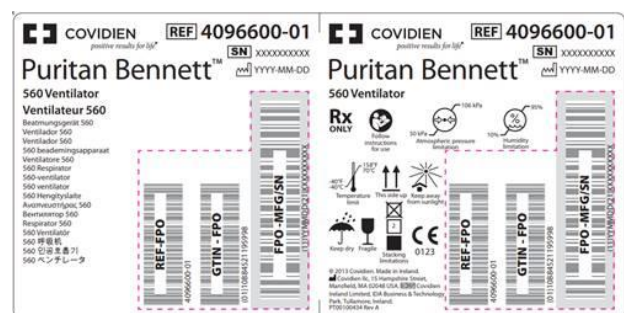
5. Apply shipping label to the ship carton and apply second shipping label to the opposite outer corner of the carton.
6. Apply last charge date label (bln # 2) to carton as per fig 1 of this section.
7. Apply class 9 label (bln # 3) to front of carton, angled as per fig 1 of this section.
8. Once packed, tick the pass boxes of the DHR 10038461 pack section after verifying all pack parts have been included.
9. Labels must be reviewed for Print Quality and Completeness. If any discrepancies are identified, please contact line engineer/line lead for direction.

Note 1: Part number circled is the p/n of the wrap around label and the rev of same is recorded on associated PHR.

Note 2: Fig 2 is a representation of a complete carton label.



Fig 1



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 Covidien Inc, 15 Hampshire Street,
 Mansfield, MA 02048 USA. **EC REP** Covidien
 Ireland Limited, IDA Business & Technology
 Park, Tullamore, Ireland.
 PT00100434 Rev A

Fig 2

PREPARATION OF CABLE GRIP

Materials:

Balloon Number	Description
8	EU Power Cord
10	Clip Hang Cable
9	Hang, Cable

Process:

1. Push the hang, cable onto the cable between the ferrite and the ventilator connection plug. Orientate as shown in fig 2 & 3.

Fig 1

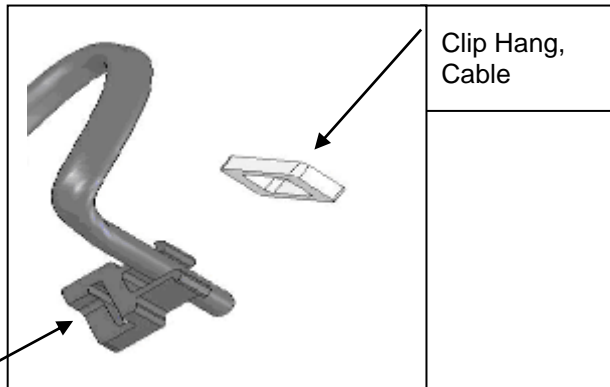


Fig 2



Fig 3



Fig 4

2. Using the 10025244 fixture, squeeze the legs of hang, cable as per fig 2 and push the clip Hang, Cable on as per fig 3
3. Ensure that the clip is securely in place on the cable.

Note: Ensure that the power cord packaged has a similar plug to that shown in fig 4



Fig 1

PACKAGING FOR PB560

Note: Pack carton trolley (fig 1) is provided at pack station and can be used as required when placing relevant material into outer shipping carton.



Fig 2

1. Remove protective film from LCD Display, fig 2 of this section
2. Place unit (blln #6) in to the clear plastic bag (blln #17) and tape (blln #16), ensure unit is neatly bagged and taped Closed, fig 3.
3. Leave foam on bench and place unit into foam slot, as per fig 4.
4. Place opposite foam side over unit, as per fig 5



blln #16

Fig 3



Fig 4



Fig 5



Fig 6



Fig 7

Place the foam encased unit into the outer shipping carton



Fig 8



Signed second copy of
Electrical safety report

CD p/n, bln #22



Fig.9a



O2 connector, Bln # 5

Fig.9b



Fig.9c



Filter, Bln # 20

Fig.9d

5. Carefully place the foam encased unit into the outer shipping carton (bln #4) as per fig 6 & fig 7.

6. Place EU power cord (bln # 8) into plastic bag (bln#7) and position in carton. Add signed second copy, of electrical safety report with comment 'passed electrical safety test' from DHR, and slide document between carton and unit foam protection, as show, in fig 8

7. Add CD (clinician's manual Bln #22) into carton, Fig 9a. Place O2 male fitting (bln # 5) Fig. 9b, into small zip lock bag (bln # 15) and tape (bln#16) to top of protective PB560 bag – above hand well. As per fig 9c.

8. Add filter foam p/n 2963300 (bln# 20) into carton as per fig 9d. Filter foam package label contains p/n 2963399. This is equivalent.

9. Place packing list (Bln#12) and customer letter (bln#24), inserted into protective 8"X10" seal pouch (bln #23), on top of filter foam above O2 connector, with bound edge above foam filter.

10. Verify that the filter, EU power cord with cable grip assembly, O2 male connector & clinician's manual CD (Record rev of CD on DHR) are packed as per procedure and that unit is packed in a clear plastic bag.

Fig 10



Dual bag, Bln # 18

Fig 11



Adult patient circuit, bln #21

Fig 12



11. Place carrying Bag (bln # 18) into clear plastic bag (bln #17) and place into shipping carton fig 10 of this section. Ensure protective foam surround cover is below lip of box to allow for fitting of patient circuit Bln#21

12. Identify adult patient circuit Fig 11 bln#21

Record the lot code of the selected (adult patient) Breathing circuit in the appropriate section of the DHR 10038461.

13. Ensure that there is no damage (ie rip/tear) to the patient circuit packaging before placing into the outer carton.

14. Place adult patient circuit (transparent side down) on top of carrying bag ensuring edges correctly packed into carton –as Fig 12

15. Ensure the careful placement of breathing circuit such that tubing is not bunched.

16. Place the conmined packing list and customer letter on top of the patient circuit before sealing the shipping carton.

17. Once packed check the tick pass boxes of the DHR 10038461 pack section after verifying all pack parts have been included.

18. Close carton and seal using 3 runs of clear tape (bln # 13).



Fig 13

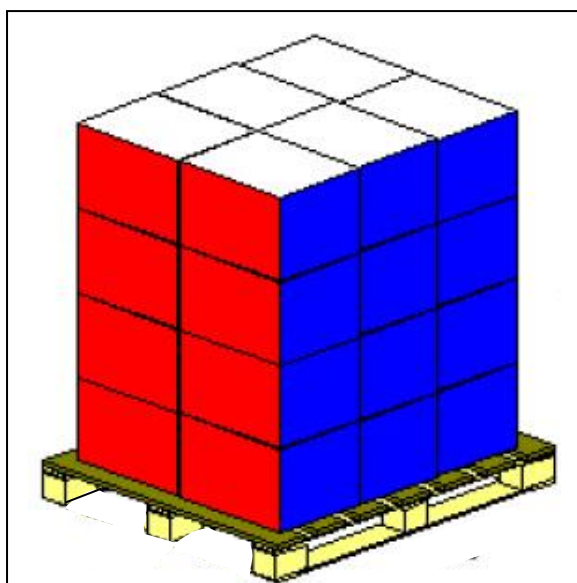


Fig 14

Licence Plate & Shipping

1. Stack units on a Euro pallet (Fig 13) so that the shipping label faces outwards (where possible).

Stack the cartons as per Fig.14 of this section, noting the orientation of the cartons.

NOTE: ONLY STACK THREE HIGH.

2. Once cartons are stacked for shipment on the pallet, add plastic band and shrink wrap pallet.
3. Conduct the PB540/PB560 product release authorisation as per 10021754.
4. Initiate log 10097245 PB500 pack log/ licence plate log
5. Procedure for completion of log 10097245:

Record: part number, description & revision of ventilator apply one copy of the relevant part number label to the licence plate log in the section provided.

Retrieve additional DHR serial number label from DHR and attach to log 10097245, (quantity as required, N/A sections not required, more than one log can be used depending on quantity).

Generate additional 2D barcode label containing S/N and GTIN number. attach to log 10097245.

Tick box for completion of packaging

Sign and date log when complete

This licence plate will be used for shipping purposes only. For Backflushing Purposes the Serial Number must be scanned from the DHR.

6. Trained personnel to complete back flushing and licence plate (ref G-AMFG-2909-00 & G-AMFG-2733-00) respectively.
7. Attach licence plate to pallet.
8. Once backflushing is complete the pallet can be moved to the shipping area.
9. Fig 14 – Pallet stacking orientation.

Forming the carton

1. If the carton is received in flat pack, form the carton and seal the bottom of the carton using three runs of clear tape.