

COMPANY OPERATING PROCEDURES

1650009 Mask sensor

VM3/COP/50.01

Revision date: 11-Jul-11

Issue: 3

Created on 19/01/2006 12:59:00

Important Notice

This product is not sterile but is used in patient airways. It is important that:-

1. Personal cleanliness is of a high standard
 - a. Clean overall or lab coat
 - b. Hair clean
2. Working area is cleaned, sprayed and wiped down with Isopropyl alcohol
3. Hands are washed
4. Hair is short, or covered if long
5. Clean polythene bags and containers are used at all times.
6. Where possible the lamina flow cabinet is switched on and used
7. Punching and soldering are carried out in the area designated outside the cabinet.

Equipment required: Soldering iron (0060120), solder (0050012), Wire stripper (0060030), flush Cutter (0060010), Snipe nose pliers (0060021), 'helping hand' (0060145),

Parts list:

Qty	Description	Part No.
1	PEP Sensor	LDTO-028K
1	3.5mm in line Jack Socket	
1	Flexicare Insert	HP5105-53
1	Loctite 242	
1	Alcohol	
1	Disposable gloves	

Flexicare adapter

1. Wipe down the punch with alcohol
2. Punch 3.5 mm hole.
3. Ensure there is no swarf
4. Dip into alcohol bath
5. Leave to dry in the lamina flow cabinet

ASSEMBLY OPERATIONS PEP sensor and Jack socket

1. Pre Heat soldering iron temperature to 260°C. Use medium screwdriver tip
2. Collect all required parts and equipment listed above
3. Carefully cut sensor wires about 1 cm from crimp
 - a. PEP sensor is heat sensitive. Always heatsink the crimp while soldering
 - b. The heatshrink should be cleaned with alcohol
 - c. Tin the bare wires and cut to 0.5cms
 - d. Remove by cutting the third (middle) contact
 - e. Tin the socket lugs and carry out soldering quickly
 - f. Bend the tinned wires to match the Jack socket lugs

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- g. Solder PEP sensor jack socket
 - h. Check that the joint is good
4. Clean with alcohol both the socket and sensor
 - a. Do not wipe sensor dry as it may damage coating
5. Leave to dry in lamina flow cabinet using the rack
6. From this point on the product has to be kept clean at all times
7. Work in Lamina flow cabinet
 - a. Use gloves
 - b. Hands must be washed
 - c. Uniform or overall must be clean
8. Add sensor jack socket into the Flexicare adapter
9. Screw on the nut with one drop of Loctite
10. Tighten the nut holding the sensor with long nose pliers
 - a. Pliers should be cleaned and wiped with alcohol
11. Spray the final assembly with alcohol and leave to dry

TESTING

1. Batch testing
2. Attach sensor to a PIPPA and check breathing rate

Labelling

- 1. Fit the LOT number and manufacturing date

Quality Assurance (QA)**Packaging**

1. Pack in 25's in a Polythene bag
2. labelled 1650009 PIPPA Flexicare adapter sensors