



12/Mar/2012

Post market Surveillance and Risk Assessment Re-evaluation

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|---|
|   |
| Tom Thumb                                 |
| Viamed Product                            |
| Post market Surveillance                  |
| Risk Assessment                           |
| Stock References Review                   |
| Supplier Review                           |
| Sales Review                              |
| Country Sales Review                      |
| Stock Returns Review                      |
| Design Changes Review                     |
| User Manuals Review                       |
| Labels Review                             |
| Document Updates Review                   |
| Internal Issues Review                    |
| Clinical Information Review               |
| FDA Incidents Review                      |
| Carried out by Derek Lamb on 12 / 03 / 12 |

## Stock References Reviewed

| Stock Reference | Description                             |
|-----------------|---|
| 0310027         | Tom Thumb Infant Resuscitator (Air).    |
| 0310029         | Tom Thumb Infant Resuscitator (Air).    |
| 0310030         | Tom Thumb Infant Resuscitator.          |
| 0310031         | Tom Thumb Infant Resuscitator (Oxygen). |
| 0310032         | Tom Thumb Infant Resuscitator (Oxygen). |
| 0310033         | Tom Thumb Infant Resuscitator (Oxygen). |
| 0310034         | Tom Thumb Infant Resuscitator (Oxygen). |
| 0310072         | Tom Thumb Infant Resuscitator.          |
| 0310074         | Tom Thumb Infant Resuscitator.          |
| 0310075         | Tom Thumb Infant Resuscitator.          |
| 0310076         | Tom Thumb Infant Resuscitator.          |
| 0310080         | Tom Thumb Infant Resuscitator (RO).     |
| 0310082         | Tom Thumb Infant Resuscitator (RO).     |
| 0310092         | Tom Thumb Infant Resuscitator (TG).     |
| 0310093         | Tom Thumb Infant Resuscitator.          |
| 0310094         | Tom Thumb Infant Resuscitator.          |
| 0310098         | Tom Thumb Oxygen Flow.                  |
| 0310099         | Tom Thumb Oxygen Vent.                  |
| 0320102         | Tom Thumb Rectangular Mounting Block.   |
| 0320103         | Tom Thumb Rectangular Mounting Block.   |
| 0330200         | TT460 MAIN Body Block                   |
| 0330201         | TT480/490 MAIN Body Block               |
| 0330202         | TT495 MAIN Body Block                   |
| 0330203         | Pressure gauge for `Tom Thumb` Infant   |
| 0330204         | Flowmeter (air) 0-15 Lpm                |
| 0330205         | Flowmeter Meter Bolt                    |
| 0330206         | Blocking Bolt And Nut                   |
| 0330207         | Blanking Bolt                           |
| 0330208         | Inlet 10 mm                             |
| 0330209         | Outlet 15mm                             |
| 0330210         | Precision Valve                         |
| 0330211         | Adjustable Valve                        |
| 0330212         | Diamond Copper Washer                   |
| 0330213         | O Ring Thick                            |
| 0330214         | O Ring Thin                             |
| 0330215         | Clamp Spacer                            |
| 0330216         | Screws For Clamp                        |
| 0330217         | Oxygen hose 1m. C/W indirect probe &    |
| 0330218         | Oxygen Hose 3m. C/W indirect probe &    |
| 0330219         | Right Angle For Hose                    |
| 0330220         | Fomblin Grease                          |
| 0330221         | Lock Tight                              |
| 0330222         | Precision Valve Spring                  |
| 0330223         | Adjustable Valve Spring                 |
| 0330224         | Precision Valve Body                    |

| Stock Reference | Description                        |
|-----------------|------------------------------------|
| 0330225         | Precision/Adjustable Valve Seating |
| 0330227         | Precision/Adjustable Valve Seat    |
| 0330228         | Precision Valve Adjustable Screw   |
| 0330229         | Adjustable Valve Body              |
| 0330230         | Adjustable Valve Screw             |
| 0330231         | Adjustable Valve Internal Stop     |
| 0330232         | Adjustable Valve Collar            |
| 0330233         | Adjustable Valve Center Screw      |
| 0330234         | Adjustable Valve Side Screw        |
| 0330235         | Inlet Restrictor                   |
| 0330236         | Replacement Gauge Face.            |
| 0330296         | Blanking Bolt                      |

Comments on Stock references review:

Some new configuration part numbers have been added, - and formalised configurations to specific part numbers,ensures better tracability in the future, Nothing change from existing CE file specifications.

## Supplier Information on Main and Component Parts

| Stock Reference | Description                           | Supplier A/C | Supplier Name                  | Rating |
|-----------------|---------------------------------------|--------------|--------------------------------|--------|
| 0320221         | Pole Clamp without slide bracket.     | 00007317     | Inspiration Healthcare Limited | B      |
| 0320103         | Tom Thumb Rectangular Mounting Block. | 00009022     | Tanda Engineering Ltd          | A      |
| 0330216         | Screws For Clamp                      | 00009061     | Farnell                        | A      |
| 0330210         | Precision Valve                       | 00009117     | JNK Tooling                    | b      |
| 0330211         | Adjustable Valve                      | 00009117     | JNK Tooling                    | b      |
| 0330224         | Precision Valve Body                  | 00009117     | JNK Tooling                    | b      |
| 0330227         | Precision/Adjustable Valve Seat       | 00009117     | JNK Tooling                    | b      |
| 0330228         | Precision Valve Adjustable Screw      | 00009117     | JNK Tooling                    | b      |
| 0330234         | Adjustable Valve Side Screw           | 00009117     | JNK Tooling                    | b      |
| 0330235         | Inlet Restrictor                      | 00009117     | JNK Tooling                    | b      |
| 0330207         | Blanking Bolt                         | 00009123     | RS Components Ltd              | B      |
| 0330213         | O Ring Thick                          | 00009123     | RS Components Ltd              | B      |
| 0330214         | O Ring Thin                           | 00009123     | RS Components Ltd              | B      |
| 0330216         | Screws For Clamp                      | 00009123     | RS Components Ltd              | B      |
| 0330220         | Fomblin Grease                        | 00009123     | RS Components Ltd              | B      |
| 0330221         | Lock Tight                            | 00009123     | RS Components Ltd              | B      |
| 0330296         | Blanking Bolt                         | 00009123     | RS Components Ltd              | B      |
| 0320060         | Flowmeter (Oxygen) 0-15 Lpm.          | 00009150     | Therapy Equipment Ltd          | A      |
| 0330055         | Universal clamp - 44mm horizontal     | 00009150     | Therapy Equipment Ltd          | A      |
| 0330204         | Flowmeter (air) 0-15 Lpm              | 00009150     | Therapy Equipment Ltd          | A      |
| 0330212         | Diamond Copper Washer                 | 00009150     | Therapy Equipment Ltd          | A      |
| 0330217         | Oxygen hose 1m. C/W indirect probe &  | 00009150     | Therapy Equipment Ltd          | A      |
| 0330218         | Oxygen Hose 3m. C/W indirect probe &  | 00009150     | Therapy Equipment Ltd          | A      |
| 0330250         | Oxygen hose 1.5m. C/W DIN fitting:    | 00009150     | Therapy Equipment Ltd          | A      |
| 0330268         | Air Hose 3m. C/W indirect probe &     | 00009150     | Therapy Equipment Ltd          | A      |
| 3210011         | NeoPEEP neonatal single patient use   | 00009602     | Bunzl Healthcare               | C      |
| 3210071         | Single use silicone round facemask    | 00009602     | Bunzl Healthcare               | C      |
| 3210011         | NeoPEEP neonatal single patient use   | 00009721     | Marshall Products Limited      | B      |
| 3210071         | Single use silicone round facemask    | 00009721     | Marshall Products Limited      | B      |
| 0330200         | TT460 MAIN Body Block                 | 00010160     | KSJ Engineering Limited        | B      |
| 0330201         | TT480/490 MAIN Body Block             | 00010160     | KSJ Engineering Limited        | B      |
| 0330202         | TT495 MAIN Body Block                 | 00010160     | KSJ Engineering Limited        | B      |
| 0330205         | Flowmeter Meter Bolt                  | 00010160     | KSJ Engineering Limited        | B      |
| 0330206         | Blocking Bolt And Nut                 | 00010160     | KSJ Engineering Limited        | B      |
| 0330208         | Inlet 10 mm                           | 00010160     | KSJ Engineering Limited        | B      |
| 0330209         | Outlet 15mm                           | 00010160     | KSJ Engineering Limited        | B      |
| 0330215         | Clamp Spacer                          | 00010160     | KSJ Engineering Limited        | B      |
| 0330203         | Pressure gauge for `Tom Thumb` Infant | 00010395     | Wika Instruments Ltd           | B      |
| 0330236         | Replacement Gauge Face.               | 00010395     | Wika Instruments Ltd           | B      |
| 0330200         | TT460 MAIN Body Block                 | 00010725     | MAJ Hi-Spec Ltd                | B      |
| 0330201         | TT480/490 MAIN Body Block             | 00010725     | MAJ Hi-Spec Ltd                | B      |
| 0330202         | TT495 MAIN Body Block                 | 00010725     | MAJ Hi-Spec Ltd                | B      |
| 0330205         | Flowmeter Meter Bolt                  | 00010725     | MAJ Hi-Spec Ltd                | B      |
| 0330206         | Blocking Bolt And Nut                 | 00010725     | MAJ Hi-Spec Ltd                | B      |
| 0330207         | Blanking Bolt                         | 00010725     | MAJ Hi-Spec Ltd                | B      |
| 0330208         | Inlet 10 mm                           | 00010725     | MAJ Hi-Spec Ltd                | B      |

| Stock Reference | Description                  | Supplier A/C | Supplier Name                  | Rating |
|-----------------|------------------------------|--------------|--------------------------------|--------|
| 0330209         | Outlet 15mm                  | 00010725     | MAJ Hi-Spec Ltd                | B      |
| 0330219         | Right Angle For Hose         | 00010770     | Chelmer Pneumatics Ltd         | B      |
| 0120140         | Adapter 15mm I.D. - 15mm I.D | 00011844     | Instrumentation Industries Inc | B      |
| 0330222         | Precision Valve Spring       | 00012028     | Harlow Springs Limited         | B      |
| 0330223         | Adjustable Valve Spring      | 00012028     | Harlow Springs Limited         | B      |

Comments on Suppliers:

No new suppliers added, supplier ratings still valid.

## Sales Information

| Stock Reference | Description                             | 2006 | 2007 | 2008 | 2009 | 2010 | 2011 | 2012 |
|-----------------|---|------|------|------|------|------|------|------|
| 0310027         | Tom Thumb Infant Resuscitator (Air).    |      |      |      |      |      |      |      |
| 0310029         | Tom Thumb Infant Resuscitator (Air).    |      |      |      |      |      |      |      |
| 0310030         | Tom Thumb Infant Resuscitator.          | 29   | 33   | 102  | 58   | 80   | 121  | 50   |
| 0310031         | Tom Thumb Infant Resuscitator (Oxygen). |      |      |      |      |      |      |      |
| 0310032         | Tom Thumb Infant Resuscitator (Oxygen). | 5    | 2    |      |      | 6    |      |      |
| 0310033         | Tom Thumb Infant Resuscitator (Oxygen). |      |      |      |      |      |      |      |
| 0310034         | Tom Thumb Infant Resuscitator (Oxygen). | 1    | 1    |      | 4    |      | 1    |      |
| 0310072         | Tom Thumb Infant Resuscitator.          |      |      | 11   |      |      |      |      |
| 0310074         | Tom Thumb Infant Resuscitator.          |      |      |      |      |      |      |      |
| 0310075         | Tom Thumb Infant Resuscitator.          |      |      |      |      |      |      |      |
| 0310076         | Tom Thumb Infant Resuscitator.          |      |      |      |      |      |      |      |
| 0310080         | Tom Thumb Infant Resuscitator (RO).     |      |      |      |      |      |      |      |
| 0310082         | Tom Thumb Infant Resuscitator (RO).     |      |      |      |      |      |      |      |
| 0310092         | Tom Thumb Infant Resuscitator (TG).     |      |      | 2    |      |      |      |      |
| 0310093         | Tom Thumb Infant Resuscitator.          |      |      |      |      |      | 2    |      |
| 0310094         | Tom Thumb Infant Resuscitator.          |      |      |      |      |      | 4    |      |
| 0310098         | Tom Thumb Oxygen Flow.                  |      |      |      |      |      |      |      |
| 0310099         | Tom Thumb Oxygen Vent.                  |      |      |      | 5    |      |      |      |
| 0320102         | Tom Thumb Rectangular Mounting Block.   |      |      |      |      |      |      |      |
| 0320103         | Tom Thumb Rectangular Mounting Block.   |      |      | 1    |      |      |      |      |
| 0330200         | TT460 MAIN Body Block                   |      |      |      |      |      |      |      |
| 0330201         | TT480/490 MAIN Body Block               | 5    | 1    |      |      |      | 1    |      |
| 0330202         | TT495 MAIN Body Block                   |      |      |      |      |      |      |      |
| 0330203         | Pressure gauge for `Tom Thumb` Infant   | 17   | 19   | 17   | 30   | 20   | 13   | 4    |
| 0330204         | Flowmeter (air) 0-15 Lpm                |      |      |      |      |      |      |      |
| 0330205         | Flowmeter Meter Bolt                    |      |      |      |      |      |      |      |
| 0330206         | Blocking Bolt And Nut                   |      |      |      |      |      | 16   |      |
| 0330207         | Blanking Bolt                           |      |      |      |      |      |      |      |
| 0330208         | Inlet 10 mm                             |      |      |      |      |      | 46   |      |
| 0330209         | Outlet 15mm                             |      |      | 5    |      |      |      |      |
| 0330210         | Precision Valve                         | 13   | 1    |      | 2    | 2    | 4    |      |
| 0330211         | Adjustable Valve                        | 5    | 4    | 1    |      | 2    | 1    |      |
| 0330212         | Diamond Copper Washer                   | 13   | 19   | 34   | 29   | 55   | 31   | 11   |
| 0330213         | O Ring Thick                            | 26   | 52   | 14   | 40   | 13   | 77   |      |
| 0330214         | O Ring Thin                             | 125  | 142  | 163  | 235  | 135  | 358  |      |
| 0330215         | Clamp Spacer                            |      |      | 4    | 1    |      |      |      |
| 0330216         | Screws For Clamp                        |      |      | 28   |      | 4    |      |      |
| 0330217         | Oxygen hose 1m. C/W indirect probe &    | 1    |      |      | 8    | 2    |      |      |
| 0330218         | Oxygen Hose 3m. C/W indirect probe &    |      | 12   | 6    | 28   | 13   | 15   |      |
| 0330219         | Right Angle For Hose                    |      |      |      |      | 1    | 2    |      |
| 0330220         | Fomblin Grease                          |      |      |      |      |      |      |      |
| 0330221         | Lock Tight                              |      |      |      |      |      |      |      |
| 0330222         | Precision Valve Spring                  |      |      |      |      |      |      | 1    |
| 0330223         | Adjustable Valve Spring                 | 5    |      |      |      |      |      | 1    |
| 0330224         | Precision Valve Body                    |      |      |      |      |      |      |      |
| 0330225         | Precision/Adjustable Valve Seating      |      | 5    |      |      |      |      |      |

| Stock Reference | Description                      | 2006 | 2007 | 2008 | 2009 | 2010 | 2011 | 2012 |
|-----------------|----------------------------------|------|------|------|------|------|------|------|
| 0330227         | Precision/Adjustable Valve Seat  | 4    |      |      |      | 1    |      | 2    |
| 0330228         | Precision Valve Adjustable Screw | 4    |      |      |      |      |      |      |
| 0330229         | Adjustable Valve Body            |      | 1    |      |      |      |      |      |
| 0330230         | Adjustable Valve Screw           |      |      |      |      |      |      |      |
| 0330231         | Adjustable Valve Internal Stop   |      |      |      |      |      |      |      |
| 0330232         | Adjustable Valve Collar          |      |      |      |      |      |      |      |
| 0330233         | Adjustable Valve Center Screw    |      |      |      |      |      |      |      |
| 0330234         | Adjustable Valve Side Screw      |      |      |      |      |      |      |      |
| 0330235         | Inlet Restrictor                 | 1    | 4    |      |      | 5    |      |      |
| 0330236         | Replacement Gauge Face.          | 2    | 20   | 5    | 9    | 17   | 6    |      |
| 0330296         | Blanking Bolt                    |      |      |      |      |      |      |      |

Comments on Sales Information:

Unit Still selling,

## New Countries

| Country           | 2006 | 2007 | 2008 | 2009 | 2010 | 2011 | 2012 |
|-------------------|------|------|------|------|------|------|------|
| B Belgium         |      |      | [X]  | [X]  |      |      |      |
| BRA Brazil        |      | [X]  |      |      |      |      |      |
| CAN Canada        |      |      |      | [X]  |      |      |      |
| F France          | [X]  | [X]  | [X]  | [X]  | [X]  | [X]  |      |
| IT Italy          |      |      |      |      | [X]  |      |      |
| MA Malaysia       |      |      |      | [X]  |      |      |      |
| NE Netherlands    |      |      |      |      |      |      |      |
| RU Russia         |      |      |      | [X]  | [X]  | [X]  | [X]  |
| SWI Switzerland   | [X]  |      |      | [X]  |      |      |      |
| T Turkey          |      |      |      | [X]  |      |      |      |
| UK United Kingdom | [X]  | [X]  | [X]  | [X]  | [X]  | [X]  | [X]  |

Comments on Sales to Countries:

No new countries from 2010,

Comments on Risks with Sales to Countries:

No new countries from 2010 - No new risks.



## Returns Information

| Stock Reference | Fault                                  | 2006 | 2007 | 2008 | 2009 | 2010 | 2011 | 2012 |
|-----------------|--|------|------|------|------|------|------|------|
| 0310030         | Converted to TT480                     |      |      | 1    |      |      |      | 1    |
| 0310030         | Damaged Pressure Gauge                 |      | 1    | 2    | 4    | 2    |      |      |
| 0310030         | n/a                                    | 1    |      |      |      |      |      |      |
| 0310030         | No Fault Return to Stock               |      |      |      |      |      |      |      |
| 0310030         | Serviced                               | 1    |      | 2    | 3    |      |      |      |
| 0310030         | Serviced / adjusted factory set valves |      |      |      | 2    | 1    |      |      |
| 0310030         | Tested                                 |      |      |      | 1    |      |      |      |
| 0310032         | Adjusted factory set valves            |      |      |      |      | 1    |      |      |
| 0310032         | Calibrated Gauge                       |      |      |      | 1    |      |      |      |
| 0310032         | Converted to TT480                     |      |      |      |      |      |      | 1    |
| 0310032         | Damaged Pressure Gauge                 |      |      |      |      | 1    |      |      |
| 0310032         | Serviced                               | 2    |      | 1    |      |      |      |      |
| 0310032         | Serviced / adjusted factory set valves |      |      |      | 1    | 2    |      |      |
| 0310032         | Tested                                 |      |      |      | 1    |      |      |      |
| 0310033         | Serviced                               |      | 1    |      |      |      |      |      |
| 0310034         | Adjusted factory set valves            |      |      |      | 2    |      |      |      |
| 0310034         | Damaged Pressure Gauge                 |      |      | 1    |      |      |      |      |
| 0310034         | Serviced                               | 1    | 1    |      |      |      |      |      |
| 0310034         | Serviced / adjusted factory set valves |      |      |      |      | 2    | 1    |      |

### Comments on Returns:

Returns still show the unit is very reliable, most repair logs related to service and or conversion.

### Comments on Risks with Returns and Potential Re-work:

No Risks identified to repairs / rework and or service.

# Design Changes / Product Changes

## Showing Documents Filed in Y 14 Design Changes

Comments on Design Changes:

No new documents in Design changes

Comments on Risks with Design Changes:

No Documents added, so no new risks identified.

# User Instructions

## Showing Documents Filed in F 5 User Instructions

| Document ID | Description   | Date Added/Updated |
|-------------|---|--------------------|
| 8512        | Tom Thumb Instructions for Use User Manual NeoPEEP    | 06/07/11           |
| 8506        | Instructions For Use Tom Thumb TT495                  | 06/07/11           |
| 8503        | Tom Thumb Instructions for Use / User Manual TT490-15 | 06/07/11           |
| 5107        | Instructions For Use Tom Thumb TT480                  | 23/02/09           |

Comments on User Instructions:

Instructions up to date, no indications a change is needed.

Comments on Risks User Instructions:

no risks identified

# Labels

## Showing Documents Filed in F 7 / F 8 Labels

| Document ID | Description                                      | Date Added/Updated |
|-------------|--|--------------------|
| 7322        | Tom Thumb Labels Warning labels - print template | 06/10/10           |
| 5922        | Tom Thumb Labels mediprema labels                | 14/05/09           |
| 2972        | Tom Thumb Labels Caution Label                   | 31/01/08           |
| 2206        | Tom Thumb Labels TT490 label                     | 19/06/07           |
| 2205        | Tom Thumb Labels TT Gauge label                  | 19/06/07           |
| 2204        | Tom Thumb Labels Tomb Thumb Infant Resuscitator  | 19/06/07           |
| 2203        | Tom Thumb Labels Tom Thumb Labels                | 19/06/07           |
| 2202        | Tom Thumb Labels Original Labels                 | 19/06/07           |
| 2200        | Tom Thumb Labels labels 1994                     | 19/06/07           |
| 2199        | Tom Thumb Labels F. Tom Thumb Labels             | 19/06/07           |
| 2198        | Tom Thumb Labels Check Pressure                  | 19/06/07           |
| 2197        | Tom Thumb Labels Address Label                   | 19/06/07           |

### Comments on Labels:

New warning label now added to the main block, removing the need for the stick out label we used before.  
All other labels are appropriate

### Comments on Risks Labels:

No risks associated with new label.

## Documentation Updates / Changes

| Document ID | Description                                |
|-------------|--|
| 10721       | Manufacturing Route Supplier Addresses (2) |
| 9789        | Tom Thumb Post Market Surveillance         |

Comments on Document Changes:

VM3COP documents updated, mostly cosmetic changes, and

Comments on Risks with Document Changes:

No Risks identified with new documentation

# Review of Issues

Number of Issues reviewed: 26

| Issue ID | Subject  |
|----------|--|
| 34748    | Tom Thumb routine service parts  |
| 28434    | Eden Medical   |
| 28433    | Eden Medical   |
| 33141    | allocations list credit for 12 tom thumbs that had their part number changed |
| 27210    | Tom Thumb packaging labels   |
| 28097    | Tom Thumb with a pole clamp  |
| 27617    | Controlled Documents require Attention                                       |
| 28862    | Need a stock take on part number 0330208                                     |
| 28715    | 0310034  |
| 30106    | New part numbers for Tom Thumb brass parts                                   |
| 30105    | New part numbers for Tom Thumb brass parts                                   |
| 30104    | New part numbers for Tom Thumb brass parts                                   |
| 30103    | New part numbers for Tom Thumb brass parts                                   |
| 30102    | New part numbers for Tom Thumb brass parts                                   |
| 28100    | New tom Thumb part number  |
| 26853    | Tom Thumb with rectangular mounting block                                    |
| 31556    | Top label needed   |
| 33276    | Time setting error - Veterinary capnograph (mainstream)                      |
| 28307    | Required urgently - pole clamps for ORD51390                                 |
| 34970    | Capnograph battery failure   |
| 33643    | JSC Pro-forma invoice PRO01841   |
| 33642    | JSC Pro-forma invoice PRO01841   |
| 33641    | JSC Pro-forma invoice PRO01841   |
| 32978    | Lost Customers - Infant Resus and Blenders                                   |
| 34323    | 0310030 Ryan Swaine Sales Forcasts   |
| 34322    | 0310030 Ryan Swaine Sales Forcasts   |

Comments on Issues:

24 Issues found in the system with links to Tom Thumbs, Most relate to demo units, Stock Issues

Comments on Risks with Issues:

No Risks Identified from the Issues system.

## Review of online clinical reports

Do any of the Results indicate a Risk / Problem : No

Do any of the Results indicate outdated Technology : No

Comments on Clinical Search :

<http://pediatrics.aappublications.org/content/124/1/422.full.pdf>

Relates to infant resus in general as ethics decision not equipment related

[http://circ.ahajournals.org/content/112/24\\_suppl/IV-188.full](http://circ.ahajournals.org/content/112/24_suppl/IV-188.full)

American guide lines - again relates to when to resus, not really realting to how to resus and or what equipment

No risks hove been found in the searchs..

No evidence the technology is outdated

## Review of online FDA Incident reports

Do any of the Results indicate a Risk / Problem : No

Do any of the Results indicate outdated Technology : No

Comments on Clinical Search :

Nothing found searching FDA Reports infant resus.