



# VIA MED

## Tom Thumb

Hand held, gas powered resuscitation unit.

Class IIb  
Via Rule Special Rule 9  
Assesment Route Annex II  
NBOG MD 1100

Carried out by Derek Lamb  
29 / 09 / 15



# VIA MED

-  Stock References Review
-  Supplier Review
-  Sales Review
-  Countries Review
-  Returns Review
-  Design Changes Review
-  User Instructions Review
-  Labels Review
-  Document Updates Review
-  Internal Issues Review
-  Clinical / FDA Incidents online search
-  Risk ISO 14971 : 2012 Review

# Stock References Review

| 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.           |
| 0310096         | Tom Thumb Oxygen Vent with Pole Mount    |
| 0310097         | Tom Thumb Infant Resuscitator (TG).      |
| 0310098         | Tom Thumb Oxygen Flow.                   |
| 0310099         | Tom Thumb Oxygen Vent.                   |
| 0310250         | Tom Thumb Conversion Kit.                |
| 0320102         | Tom Thumb Rectangular Mounting Block.    |
| 0320103         | Tom Thumb Rectangular Mounting Block.    |
| 0330185         | Wing Nut Screw Black 25mm Thread         |
| 0330190         | Universal clamp - 44mm horizontal        |
| 0330191         | Clamp Spacer                             |
| 0330193         | Pressure gauge: 63mm dial -5 to +60 cmWG |
| 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         | Gauge Seal                               |
| 0330213         | O Ring Thick                             |
| 0330214         | O Ring Thin                              |

| Stock Reference | Description                              |
|-----------------|--|
| 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 OT20 Grease 100g tube            |
| 0330221         | Lock Tight                               |
| 0330222         | Precision Valve Spring                   |
| 0330223         | Adjustable Valve Spring                  |
| 0330224         | Precision Valve Body                     |
| 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 Centre Screw            |
| 0330234         | Adjustable Valve Side Screw              |
| 0330235         | Inlet Restrictor                         |
| 0330236         | Replacement Gauge Face.                  |
| 0330241         | TT480/490 MAIN Body Block                |
| 0330242         | Medirail Mounting Bracket                |
| 0330243         | Adjustable Valve Side Screw. Bag 100     |
| 0330246         | Blocking Bolt And Nut                    |
| 0330247         | Blanking Bolt                            |
| 0330248         | Inlet 10 mm                              |
| 0330249         | Outlet 15mm                              |
| 0330250         | Oxygen hose 1.5m. C/W DIN fitting:       |
| 0330251         | Oxygen hose 3.0m. C/W DIN fitting:       |
| 0330263         | Oxygen Hose 2m. C/W indirect probe &     |
| 0330268         | Air Hose 3m. C/W indirect probe &        |
| 0330291         | Inlet 10mm Thumbelina Inlet              |
| 0330292         | Outlet 15mm Thumbelina                   |
| 0330295         | Outlet 10mm do not use                   |
| 0330296         | Blanking Bolt                            |
| 0330297         | Clamp Spacer - dove tailed.              |
| 0330300         | Key Ring chain 1 inch ball               |
| 0330800         | Label - pressure control for Tom Thumb   |
| 0340000         | Labour - Tom Thumb infant resuscitator.  |
| 0340001         | Training - Tom Thumb infant resuscitator |
| 0340002         | Training - Tom Thumb infant resuscitator |
| 0350120         | Packing box for Tom Thumb TT480.         |
| 0350121         | Packing box for Tom Thumb TT490 Series.  |
| 0380000         | Annual service - Tom Thumb               |

| Stock Reference | Description                              |
|-----------------|--|
| 0380030         | Tom Thumb Infant Resuscitator.           |
| 0390003         | Tom Thumb Instruction Manual             |
| 0390004         | Leaflet - Tom Thumb Infant Resuscitator. |
| 0390005         | Tom Thumb Training Manual                |
| 0390006         | Tom Thumb Instruction Manual             |
| 0390007         | Tom Thumb Instruction Manual             |
| 0390008         | Tom Thumb Serial Number Label            |
| 0390009         | `Tom Thumb` Label                        |
| 0390011         | Tom Thumb CE Label                       |
| 0390015         | Tom Thumb label                          |
| 0390016         | Address label for Tom Thumb gauge.       |
| 0390017         | Gauge label - Tom Thumb                  |
| 0390020         | Tom Thumb Service Manual                 |
| 0390021         | Tom Thumb Service Manual TT460           |
| 0390022         | Tom Thumb Service Manual TT480           |
| 0390023         | Tom Thumb Service Manual TT490-15        |
| 0390024         | Tom Thumb Service Manual TT496           |
| 0390060         | Tom Thumb Instruction Manual - TT495     |

Comments on Stock references review:

Stock references are upto date

# Supplier Review

| Stock Ref. | Description              | Supplier A/C | Supplier P/N    | Supplier Name            | Rating |
|------------|--------------------------|--------------|-----------------|--------------------------|--------|
| 0320221    | Pole Clamp without slide | 00007317     | IHCPC1-SPECIAL  | Inspiration Healthcare L | A      |
| 0320103    | Tom Thumb Rectangular Mo | 00009022     | PP8694          | Tanda Engineering Ltd    | A      |
| 0330185    | Wing Nut Screw Black 2   | 00009032     | 3335            | R & L Enterprises Ltd    | B      |
| 0330190    | Universal clamp - 44mm h | 00009032     | A4916           | R & L Enterprises Ltd    | B      |
| 0330191    | Clamp Spacer             | 00009032     | A4917           | R & L Enterprises Ltd    | B      |
| 0330242    | Medirail Mounting Bracke | 00009032     | 822             | R & L Enterprises Ltd    | B      |
| 0330216    | Screws For Clamp         | 00009061     | 483-9616        | Farnell                  | A      |
| 0330234    | Adjustable Valve Side Sc | 00009073     | 020865070206020 | Modern Screws            | B      |
| 0330243    | Adjustable Valve Side Sc | 00009073     | 020865070206020 | Modern Screws            | B      |
| 0330193    | Pressure gauge: 63mm dia | 00009097     | 74656           | GNW - Gauges North West  | B      |
| 0330210    | Precision Valve          | 00009117     | 9901-40         | JNK Tooling              | B      |
| 0330211    | Adjustable Valve         | 00009117     | 9901-18         | JNK Tooling              | B      |
| 0330224    | Precision Valve Body     | 00009117     | 9901-39         | JNK Tooling              | B      |
| 0330227    | Precision/Adjustable Val | 00009117     | 9901-12         | JNK Tooling              | B      |
| 0330228    | Precision Valve Adjustab | 00009117     | 9901-38         | JNK Tooling              | B      |
| 0330230    | Adjustable Valve Screw   | 00009117     | 9901-09         | JNK Tooling              | B      |
| 0330234    | Adjustable Valve Side Sc | 00009117     | 020865070206020 | JNK Tooling              | B      |
| 0330235    | Inlet Restrictor         | 00009117     | 0330235         | JNK Tooling              | B      |
| 0330207    | Blanking Bolt            | 00009123     | 0330207         | RS Components Ltd        | B      |
| 0330213    | O Ring Thick             | 00009123     | 129-050         | RS Components Ltd        | B      |
| 0330214    | O Ring Thin              | 00009123     | 129-044         | RS Components Ltd        | B      |
| 0330216    | Screws For Clamp         | 00009123     | 483-9616        | RS Components Ltd        | B      |
| 0330220    | Fomblin OT20 Grease 100  | 00009123     | 666-4893        | RS Components Ltd        | B      |
| 0330221    | Lock Tight               | 00009123     | 514-515         | RS Components Ltd        | B      |
| 0330296    | Blanking Bolt            | 00009123     | 367-6098        | RS Components Ltd        | B      |
| 0320060    | Flowmeter (Oxygen) 0-15  | 00009150     | 6501            | Therapy Equipment Ltd    | A      |
| 0330030    | Dovetail (male)          | 00009150     | 4505            | Therapy Equipment Ltd    | A      |
| 0330055    | Universal clamp - 44mm h | 00009150     | 2002            | Therapy Equipment Ltd    | A      |
| 0330204    | Flowmeter (air) 0-15 Lpm | 00009150     | 6502            | Therapy Equipment Ltd    | A      |
| 0330212    | Gauge Seal               | 00009150     | 6650-05         | Therapy Equipment Ltd    | A      |
| 0330217    | Oxygen hose 1m. C/W indi | 00009150     | ZZ HOSE 1M      | Therapy Equipment Ltd    | A      |
| 0330218    | Oxygen Hose 3m. C/W indi | 00009150     | ZZ HOSE 3M      | Therapy Equipment Ltd    | A      |
| 0330250    | Oxygen hose 1.5m. C/W DI | 00009150     |                 | Therapy Equipment Ltd    | A      |
| 0330251    | Oxygen hose 3.0m. C/W DI | 00009150     |                 | Therapy Equipment Ltd    | A      |
| 0330263    | Oxygen Hose 2m. C/W indi | 00009150     | ZZ HOSE 2M      | Therapy Equipment Ltd    | A      |
| 0330268    | Air Hose 3m. C/W indirec | 00009150     | ZZ HOSE 3M      | Therapy Equipment Ltd    | A      |
| 0390006    | Tom Thumb Instruction Ma | 00009345     |                 | Duffield Printers        | A      |
| 0390007    | Tom Thumb Instruction Ma | 00009345     |                 | Duffield Printers        | A      |
| 0350120    | Packing box for Tom Thum | 00009353     | RPT10B          | Rajapack Ltd             | B      |
| 0350121    | Packing box for Tom Thum | 00009353     | RPT17B          | Rajapack Ltd             | B      |
| 0390004    | Leaflet - Tom Thumb Infa | 00009360     |                 | Print Centre             | B      |
| 0390004    | Leaflet - Tom Thumb Infa | 00009363     |                 | Impress Print            | B      |

| Stock Ref. | Description              | Supplier A/C | Supplier P/N | Supplier Name            | Rating |
|------------|--------------------------|--------------|--------------|--------------------------|--------|
| 3210011    | NeoPEEP neonatal single  | 00009602     | M6800100BLUE | Bunzl Healthcare         | C      |
| 3210071    | Single use silicone roun | 00009602     | M6200500D    | Bunzl Healthcare         | C      |
| 3210011    | NeoPEEP neonatal single  | 00009721     | M6800100BLUE | Marshall Products Limite | B      |
| 3210071    | Single use silicone roun | 00009721     | M6200500D    | Marshall Products Limite | B      |
| 0330800    | Label - pressure control | 00009930     |              | Renlim Labels            | B      |
| 0330200    | TT460 MAIN Body Block    | 00010160     | 0330200      | KSJ Engineering Limited  | B      |
| 0330201    | TT480/490 MAIN Body Bloc | 00010160     | 0330201      | KSJ Engineering Limited  | B      |
| 0330202    | TT495 MAIN Body Block    | 00010160     | 0330202      | KSJ Engineering Limited  | B      |
| 0330205    | Flowmeter Meter Bolt     | 00010160     | 9901-02      | KSJ Engineering Limited  | B      |
| 0330206    | Blocking Bolt And Nut    | 00010160     | 0330206      | KSJ Engineering Limited  | B      |
| 0330208    | Inlet 10 mm              | 00010160     | 0330208      | KSJ Engineering Limited  | B      |
| 0330209    | Outlet 15mm              | 00010160     | 0330209      | KSJ Engineering Limited  | B      |
| 0330215    | Clamp Spacer             | 00010160     | 9901-22      | KSJ Engineering Limited  | B      |
| 0330241    | TT480/490 MAIN Body Bloc | 00010160     | 9901-01      | KSJ Engineering Limited  | B      |
| 0330246    | Blocking Bolt And Nut    | 00010160     | 9901-06      | KSJ Engineering Limited  | B      |
| 0330248    | Inlet 10 mm              | 00010160     | 4701-61      | KSJ Engineering Limited  | B      |
| 0330249    | Outlet 15mm              | 00010160     | 9901-34      | KSJ Engineering Limited  | B      |
| 0330295    | Outlet 10mm do not use   | 00010160     | 0330295      | KSJ Engineering Limited  | B      |
| 0330203    | Pressure gauge for `Tom  | 00010395     | 611.10.063   | Wika Instruments Ltd     | B      |
| 0330236    | Replacement Gauge Face.  | 00010395     | 1391682      | Wika Instruments Ltd     | B      |
| 0390015    | Tom Thumb label          | 00010665     | TT IR        | Pendle Signs & Plastics  | B      |
| 0390016    | Address label for Tom Th | 00010665     | TT ADR       | Pendle Signs & Plastics  | B      |
| 0390017    | Gauge label - Tom Thumb  | 00010665     | TT VIA       | Pendle Signs & Plastics  | B      |
| 0330200    | TT460 MAIN Body Block    | 00010725     | 0330200      | MAJ Hi-Spec Ltd          | B      |
| 0330201    | TT480/490 MAIN Body Bloc | 00010725     | 0330201      | MAJ Hi-Spec Ltd          | B      |
| 0330202    | TT495 MAIN Body Block    | 00010725     | 0330202      | MAJ Hi-Spec Ltd          | B      |
| 0330205    | Flowmeter Meter Bolt     | 00010725     | 9901-02      | MAJ Hi-Spec Ltd          | B      |
| 0330206    | Blocking Bolt And Nut    | 00010725     | 0330206      | MAJ Hi-Spec Ltd          | B      |
| 0330207    | Blanking Bolt            | 00010725     | 0330207      | MAJ Hi-Spec Ltd          | B      |
| 0330208    | Inlet 10 mm              | 00010725     | 0330208      | MAJ Hi-Spec Ltd          | B      |
| 0330209    | Outlet 15mm              | 00010725     | 0330209      | MAJ Hi-Spec Ltd          | B      |
| 0330219    | Right Angle For Hose     | 00010770     | 2020         | Chelmer Pneumatics Ltd   | B      |
| 0120140    | Adapter 15mm I.D. - 15m  | 00011844     | PF 1515      | Instrumentation Industri | B      |
| 0330222    | Precision Valve Spring   | 00012028     | C6409        | Harlow Springs Limited   | B      |
| 0330223    | Adjustable Valve Spring  | 00012028     | 9968         | Harlow Springs Limited   | B      |
| 0330300    | Key Ring chain 1 inch ba | 00012395     | BC6          | Seton                    | B      |

Comments on Suppliers:

Supplier reviews are upto date,

# Sales Information

| Stock Reference | Description                             | 2009 | 2010 | 2011 | 2012 | 2013 | 2014 | 2015 |
|-----------------|---|------|------|------|------|------|------|------|
| 0310027         | Tom Thumb Infant Resuscitator (Air).    |      |      |      |      |      |      |      |
| 0310029         | Tom Thumb Infant Resuscitator (Air).    |      |      |      |      |      |      |      |
| 0310030         | Tom Thumb Infant Resuscitator.          | 70   | 90   | 146  | 259  | 94   | 129  | 47   |
| 0310031         | Tom Thumb Infant Resuscitator (Oxygen). |      |      |      |      |      |      |      |
| 0310032         | Tom Thumb Infant Resuscitator (Oxygen). |      | 6    |      |      | 3    |      |      |
| 0310033         | Tom Thumb Infant Resuscitator (Oxygen). |      |      |      |      |      |      |      |
| 0310034         | Tom Thumb Infant Resuscitator (Oxygen). | 4    |      | 2    |      | 1    | 2    | 1    |
| 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).     |      |      |      | 2    |      |      |      |
| 0310082         | Tom Thumb Infant Resuscitator (RO).     |      |      |      |      |      |      |      |
| 0310092         | Tom Thumb Infant Resuscitator (TG).     |      |      |      |      |      |      |      |
| 0310093         | Tom Thumb Infant Resuscitator.          |      |      | 4    |      |      |      |      |
| 0310094         | Tom Thumb Infant Resuscitator.          |      |      | 4    |      | 9    |      |      |
| 0310096         | Tom Thumb Oxygen Vent with Pole Mount   |      |      |      |      | 1    |      |      |
| 0310097         | Tom Thumb Infant Resuscitator (TG).     |      |      |      |      | 5    | 7    | 15   |
| 0310098         | Tom Thumb Oxygen Flow.                  |      |      |      |      |      |      |      |
| 0310099         | Tom Thumb Oxygen Vent.                  | 5    |      |      |      | 1    | 1    |      |
| 0310250         | Tom Thumb Conversion Kit.               |      |      |      | 6    | 6    | 28   |      |
| 0320102         | Tom Thumb Rectangular Mounting Block.   |      |      |      |      |      |      |      |
| 0320103         | Tom Thumb Rectangular Mo                |      |      |      |      |      |      |      |
| 0330185         | Wing Nut Screw Black 2                  |      |      |      |      |      |      |      |
| 0330190         | Universal clamp - 44mm h                |      |      |      |      | 2    | 100  | 50   |
| 0330191         | Clamp Spacer                            |      |      |      |      | 1    |      |      |
| 0330193         | Pressure gauge: 63mm dia                |      |      |      |      |      |      | 15   |
| 0330200         | TT460 MAIN Body Block                   |      |      |      |      |      |      |      |
| 0330201         | TT480/490 MAIN Body Bloc                |      |      | 1    |      |      |      |      |
| 0330202         | TT495 MAIN Body Block                   |      |      |      |      | 1    |      |      |
| 0330203         | Pressure gauge for `Tom                 | 36   | 32   | 18   | 10   | 21   | 9    |      |
| 0330204         | Flowmeter (air) 0-15 Lpm                |      |      |      |      |      |      |      |
| 0330205         | Flowmeter Meter Bolt                    |      |      |      |      |      |      |      |
| 0330206         | Blocking Bolt And Nut                   |      |      | 16   | 12   | 10   |      |      |
| 0330207         | Blanking Bolt                           |      |      |      |      |      |      |      |
| 0330208         | Inlet 10 mm                             |      |      | 46   | 12   | 10   |      |      |
| 0330209         | Outlet 15mm                             |      |      |      |      |      |      | 15   |
| 0330210         | Precision Valve                         | 2    | 4    | 5    |      | 3    | 2    | 1    |
| 0330211         | Adjustable Valve                        |      | 4    | 2    | 2    | 3    | 3    | 3    |
| 0330212         | Gauge Seal                              | 42   | 78   | 51   | 40   | 28   | 28   | 55   |
| 0330213         | O Ring Thick                            | 53   | 18   | 98   | 8    | 34   | 193  | 49   |
| 0330214         | O Ring Thin                             | 298  | 163  | 504  | 48   | 227  | 137  | 308  |



| Stock Reference | Description                              | 2009 | 2010 | 2011 | 2012 | 2013 | 2014 | 2015 |
|-----------------|--|------|------|------|------|------|------|------|
| 0330215         | Clamp Spacer                             | 1    |      |      |      |      |      |      |
| 0330216         | Screws For Clamp                         |      | 4    |      |      |      |      |      |
| 0330217         | Oxygen hose 1m. C/W indi                 | 14   | 8    |      |      | 6    | 6    | 2    |
| 0330218         | Oxygen Hose 3m. C/W indi                 | 28   | 15   | 20   | 2    | 7    | 17   | 14   |
| 0330219         | Right Angle For Hose                     |      | 1    | 2    |      |      |      |      |
| 0330220         | Fomblin OT20 Grease 100                  |      |      |      |      |      |      | 1    |
| 0330221         | Lock Tight                               |      |      |      |      |      |      |      |
| 0330222         | Precision Valve Spring                   |      |      |      | 1    |      |      |      |
| 0330223         | Adjustable Valve Spring                  |      |      |      | 2    |      | 1    |      |
| 0330224         | Precision Valve Body                     |      |      |      |      |      |      |      |
| 0330225         | Precision/Adjustable Valve Seating       |      |      |      |      |      |      |      |
| 0330227         | Precision/Adjustable Val                 |      | 1    |      | 2    | 1    |      | 2    |
| 0330228         | Precision Valve Adjustab                 |      |      |      |      |      |      |      |
| 0330229         | Adjustable Valve Body                    |      |      |      |      | 1    |      |      |
| 0330230         | Adjustable Valve Screw                   |      |      |      |      |      |      |      |
| 0330231         | Adjustable Valve Internal Stop           |      |      |      |      |      |      |      |
| 0330232         | Adjustable Valve Collar                  |      |      |      |      |      |      |      |
| 0330233         | Adjustable Valve Centre Screw            |      |      |      |      |      |      |      |
| 0330234         | Adjustable Valve Side Sc                 |      |      |      |      |      | 3    |      |
| 0330235         | Inlet Restrictor                         |      | 5    |      |      |      |      | 1    |
| 0330236         | Replacement Gauge Face.                  | 17   | 22   | 12   | 5    | 13   | 14   | 4    |
| 0330241         | TT480/490 MAIN Body Bloc                 |      |      |      |      |      |      |      |
| 0330242         | Medirail Mounting Bracke                 |      |      |      |      |      |      |      |
| 0330243         | Adjustable Valve Side Sc                 |      |      |      |      |      |      |      |
| 0330246         | Blocking Bolt And Nut                    |      |      |      |      |      |      |      |
| 0330247         | Blanking Bolt                            |      |      |      |      |      |      |      |
| 0330248         | Inlet 10 mm                              |      |      |      |      |      |      |      |
| 0330249         | Outlet 15mm                              |      |      |      |      |      |      |      |
| 0330250         | Oxygen hose 1.5m. C/W DI                 |      |      |      |      |      |      |      |
| 0330251         | Oxygen hose 3.0m. C/W DI                 |      |      |      |      |      |      |      |
| 0330263         | Oxygen Hose 2m. C/W indi                 |      |      |      |      | 3    | 12   | 2    |
| 0330268         | Air Hose 3m. C/W indirec                 |      |      |      |      |      |      |      |
| 0330291         | Inlet 10mm Thumbelina Inlet              |      |      |      |      |      |      |      |
| 0330292         | Outlet 15mm Thumbelina                   |      |      |      |      |      |      |      |
| 0330295         | Outlet 10mm do not use                   | 2    |      |      |      |      |      | 8    |
| 0330296         | Blanking Bolt                            |      |      |      |      |      |      |      |
| 0330297         | Clamp Spacer - dove tailed.              |      | 7    |      |      |      |      |      |
| 0330300         | Key Ring chain 1 inch ba                 |      |      |      |      |      |      |      |
| 0330800         | Label - pressure control                 |      |      |      |      |      |      |      |
| 0340000         | Labour - Tom Thumb infant resuscitator.  |      |      |      |      |      |      |      |
| 0340001         | Training - Tom Thumb infant resuscitator |      |      |      |      |      |      |      |
| 0340002         | Training - Tom Thumb infant resuscitator |      |      |      |      |      |      |      |
| 0350120         | Packing box for Tom Thum                 |      |      |      |      |      |      |      |
| 0350121         | Packing box for Tom Thum                 |      |      |      |      |      |      |      |
| 0380000         | Annual service - Tom Thumb               |      |      |      |      |      |      |      |

| Stock Reference | Description                          | 2009 | 2010 | 2011 | 2012 | 2013 | 2014 | 2015 |
|-----------------|--------------------------------------|------|------|------|------|------|------|------|
| 0380030         | Tom Thumb Infant Resuscitator.       |      |      |      |      |      |      |      |
| 0390003         | Tom Thumb Instruction Manual         |      |      |      |      |      |      |      |
| 0390004         | Leaflet - Tom Thumb Infa             | 35   |      | 6    |      | 50   |      | 10   |
| 0390005         | Tom Thumb Training Manual            |      |      |      |      |      |      |      |
| 0390006         | Tom Thumb Instruction Ma             |      | 12   | 6    |      |      | 20   |      |
| 0390007         | Tom Thumb Instruction Ma             |      | 12   | 6    |      |      |      |      |
| 0390008         | Tom Thumb Serial Number Label        |      |      |      |      |      |      |      |
| 0390009         | `Tom Thumb` Label                    |      |      |      |      |      |      |      |
| 0390011         | Tom Thumb CE Label                   |      |      |      |      |      |      |      |
| 0390015         | Tom Thumb label                      |      |      |      |      |      |      |      |
| 0390016         | Address label for Tom Th             |      |      |      |      |      |      |      |
| 0390017         | Gauge label - Tom Thumb              |      |      |      |      |      |      |      |
| 0390020         | Tom Thumb Service Manual             |      |      |      |      |      |      |      |
| 0390021         | Tom Thumb Service Manual TT460       |      |      |      |      |      |      |      |
| 0390022         | Tom Thumb Service Manual TT480       |      |      |      |      |      |      |      |
| 0390023         | Tom Thumb Service Manual TT490-15    |      |      |      |      |      |      |      |
| 0390024         | Tom Thumb Service Manual TT496       |      |      |      |      |      |      |      |
| 0390060         | Tom Thumb Instruction Manual - TT495 |      |      |      |      |      |      |      |

Comments on Sales Information:

Units still selling

# Countries Review

| Country           | 2009 | 2010 | 2011 | 2012 | 2013 | 2014 | 2015 |
|-------------------|------|------|------|------|------|------|------|
| B Belgium         | [X]  |      |      | [X]  | [X]  |      |      |
| BRA Brazil        |      |      |      |      |      |      |      |
| C China           |      |      |      |      |      | [X]  |      |
| CAN Canada        | [X]  |      |      |      |      |      |      |
| CZ Czech Republic |      |      |      |      |      | [X]  | [X]  |
| F France          | [X]  | [X]  | [X]  | [X]  | [X]  | [X]  | [X]  |
| HK Hong Kong      |      |      | [X]  |      |      |      |      |
| IN India          |      |      |      |      | [X]  |      |      |
| IT Italy          |      | [X]  |      |      |      |      |      |
| MA Malaysia       | [X]  |      |      |      |      |      |      |
| NE Netherlands    |      |      |      |      |      | [X]  | [X]  |
| NG Nigera         |      |      |      |      |      | [X]  |      |
| PA Pakistan       |      |      |      |      |      |      | [X]  |
| RU Russia         | [X]  | [X]  | [X]  | [X]  | [X]  | [X]  |      |
| SAU Saudi Arabia  |      |      |      | [X]  | [X]  |      |      |
| SRI Sri Lanka     |      |      |      |      |      |      | [X]  |
| SWI Switzerland   | [X]  |      |      |      |      |      | [X]  |
| T Turkey          | [X]  |      |      | [X]  | [X]  |      |      |
| UAE U A E         | [X]  |      |      |      |      |      |      |
| UK United Kingdom | [X]  | [X]  | [X]  | [X]  | [X]  | [X]  | [X]  |

Comments on Sales to Countries:

New sales to Pakistan , Sri Lanka

Comments on Risks with Sales to Countries:

No risks identified with new countrys

# Returns Review

| Stock Reference | Fault                                  | 2009 | 2010 | 2011 | 2012 | 2013 | 2014 | 2015 |
|-----------------|--|------|------|------|------|------|------|------|
| 0310030         | Adjusted factory set valves            |      |      |      |      | 3    |      |      |
| 0310030         | Calibrated Gauge                       |      |      |      |      |      |      | 1    |
| 0310030         | Converted to TT480                     |      |      |      | 1    |      |      |      |
| 0310030         | Damaged Pressure Gauge                 | 4    | 2    |      |      |      | 1    | 1    |
| 0310030         | n/a                                    |      |      |      |      |      |      |      |
| 0310030         | No Fault Found                         | 1    |      |      |      |      |      |      |
| 0310030         | No Fault Return to Stock               |      |      |      |      |      |      |      |
| 0310030         | Replace gauge and service              |      |      |      |      |      | 1    | 1    |
| 0310030         | Serviced                               | 3    |      |      |      |      |      |      |
| 0310030         | Serviced / adjusted factory set valves | 2    | 1    |      | 3    | 11   | 11   | 10   |
| 0310030         | Tested                                 | 1    |      |      |      |      |      | 1    |
| 0310032         | Adjusted factory set valves            |      | 1    |      |      |      |      |      |
| 0310032         | Calibrated Gauge                       | 1    |      |      |      |      |      |      |
| 0310032         | Converted to TT480                     |      |      |      | 1    |      |      |      |
| 0310032         | Damaged Pressure Gauge                 |      | 1    |      |      |      |      |      |
| 0310032         | Serviced                               |      |      |      |      |      |      |      |
| 0310032         | Serviced / adjusted factory set valves | 1    | 2    |      |      | 1    |      |      |
| 0310032         | Tested                                 | 1    |      |      |      | 1    |      |      |
| 0310033         | Replace gauge and service              |      |      |      |      |      |      | 1    |
| 0310033         | Serviced                               |      |      |      |      |      |      |      |
| 0310034         | Adjusted factory set valves            | 2    |      |      |      |      |      |      |
| 0310034         | Damaged Pressure Gauge                 |      |      |      |      |      |      |      |
| 0310034         | Serviced                               |      |      |      |      | 1    |      |      |
| 0310034         | Serviced / adjusted factory set valves |      | 2    | 1    | 1    | 2    |      | 5    |
| 0310034         | Unchecked - Returned to Stock          |      |      |      |      |      |      |      |
| 0310080         | Replace gauge and service              |      |      |      |      |      | 1    |      |
| 0310094         | Converted to TT480                     |      |      |      |      | 9    |      |      |
| 0310097         | Serviced / adjusted factory set valves |      |      |      |      |      | 1    | 1    |
| 0310098         | Serviced / adjusted factory set valves |      |      |      |      |      | 3    | 1    |
| 0310099         | Serviced / adjusted factory set valves |      |      |      |      |      | 2    |      |
| 0330217         | Unchecked - Returned to Stock          |      |      |      |      |      |      |      |
| 0390023         | Serviced                               |      |      |      |      |      |      |      |

## Comments on Returns:

Very few returns outside of normal service.  
Main Issue damaged gauge.

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

No risks identified with return units

# Design Changes Review

Showing Documents Filed in Y 14 Design Changes

Comments on Design Changes:

No design changes have taken place,

Comments on Risks with Design Changes:

N/A

# User Instructions Review

## Showing Documents Filed in F 5 User Instructions

| Document ID | Description  | Date Added/Updated |
|-------------|--|--------------------|
| 15572       | Tom Thumb Instructions for Use / User Manual TT490-15              | 01/09/15           |
| 15571       | Tom Thumb Instructions for Use User Manual TT480                   | 01/09/15           |
| 15570       | Tom Thumb Instructions for Use User Manual 0310027                 | 01/09/15           |
| 15511       | Tom Thumb Instructions for Use User Manual TT480 Instructions D... | 24/08/15           |
| 15510       | Tom Thumb Instructions for Use User Manual TT480 Instructions D... | 24/08/15           |
| 15509       | Tom Thumb Instructions for Use User Manual TT480 Instructions D... | 24/08/15           |
| 13047       | Tom Thumb Instructions for Use User Manual French                  | 14/10/13           |
| 12211       | Tom Thumb Instructions for Use User Manual TT495-15                | 30/11/12           |
| 11732       | Tom Thumb Instructions for Use User Manual                         | 23/03/12           |
| 8512        | Tom Thumb Instructions for Use User Manual NeoPEEP                 | 06/07/11           |
| 8506        | Instructions For Use Tom Thumb TT495                               | 06/07/11           |
| 5107        | Instructions For Use Tom Thumb TT480                               | 23/02/09           |

Comments on User Instructions:

User instructions have been updated to incorporate BSI findings regarding disposal of the device

Comments on Risks User Instructions:

no risks identified with the newer instructions

# Labels Review

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

| Document ID | Description  | Date Added/Updated |
|-------------|--|--------------------|
| 15639       | Tom Thumb Labels Original label sizes                        | 16/09/15           |
| 15638       | Tom Thumb Labels Original labels                             | 16/09/15           |
| 11748       | Tom Thumb Labels 0390016 Address Sticker Round outside Gauge | 27/03/12           |
| 11747       | Tom Thumb Labels Caution Label 0390018 Top Block             | 27/03/12           |
| 11746       | Tom Thumb Labels 0390017 Front of Gauge Sticker              | 27/03/12           |
| 11745       | Tom Thumb Labels 0390015 Front Block Logo Sticker            | 27/03/12           |
| 11744       | Tom Thumb Labels 0390010 Adjustable Value Sticker            | 27/03/12           |
| 11743       | Tom Thumb Labels Part number to Label                        | 27/03/12           |
| 11742       | Tom Thumb Labels TT491 Serial                                | 27/03/12           |
| 11741       | Tom Thumb Labels TT490 Serial                                | 27/03/12           |
| 11740       | Tom Thumb Labels Serial TT480                                | 27/03/12           |
| 5922        | Tom Thumb Labels mediprema labels                            | 14/05/09           |
| 2254        | Tom Thumb Parts List Adj label 04                            | 19/06/07           |
| 2204        | Tom Thumb Labels Tomb Thumb Infant Resuscitator              | 19/06/07           |

### Comments on Labels:

No changes to the labels,  
New documents are old archived documents which have been recently scanned and included into the files.  
Note they are linked into the incorrect section of the ce files Issue will be generated to move them,

### Comments on Risks Labels:

no risks

# Documentation Updates / Changes

| Document ID | Description   | Date Added/Updated |
|-------------|---|--------------------|
| 15746       | Tom Thumb Risk analysis reports Risk assessment                     | 29/09/15           |
| 15734       | Tom Thumb Clinical Trials Reports Reviews and Post Market Survei... | 24/09/15           |
| 15733       | Tom Thumb Clinical Trials Reports Reviews and Post Market Survei... | 24/09/15           |
| 15732       | Tom Thumb Clinical Trials Reports Reviews and Post Market Survei... | 24/09/15           |
| 15731       | Tom Thumb Clinical Trials Reports Reviews and Post Market Survei... | 24/09/15           |
| 15681       | Service Manual Tom Thumb Valves v1.1                                | 21/09/15           |
| 15679       | Service Manual Tom Thumb TT490-15 v1.7                              | 21/09/15           |
| 15677       | Service Manual V1.8 TT480 Tom Thumb                                 | 21/09/15           |
| 15647       | Tom Thumb Training Information Assessment Form Tom Thumb Trainin... | 16/09/15           |
| 15644       | Tom Thumb Training Information 2009                                 | 16/09/15           |
| 15641       | Tom Thumb Training Information Training V1.1                        | 16/09/15           |
| 15639       | Tom Thumb Labels Original label sizes                               | 16/09/15           |
| 15638       | Tom Thumb Labels Original labels                                    | 16/09/15           |
| 15634       | Tom Thumb Description of Accessories                                | 11/09/15           |
| 15624       | Tom Thumb Components Breakdown 9901-02 Flowmeter bolt               | 10/09/15           |
| 15622       | Tom Thumb Components Breakdown 9901-01 Main Block original          | 10/09/15           |
| 15621       | Tom Thumb Description of Accessories                                | 10/09/15           |
| 15587       | Tom Thumb Post Market Clinical Follow-up                            | 03/09/15           |
| 15575       | Tom Thumb Residual Risks to Benefits Residual risks 2015            | 01/09/15           |
| 15572       | Tom Thumb Instructions for Use / User Manual TT490-15               | 01/09/15           |
| 15571       | Tom Thumb Instructions for Use User Manual TT480                    | 01/09/15           |
| 15570       | Tom Thumb Instructions for Use User Manual 0310027                  | 01/09/15           |
| 15522       | Tom Thumb Competitors Information and Patients Neopuff technical... | 24/08/15           |
| 15521       | Tom Thumb Competitors Information and Patients Neopuff specifica... | 24/08/15           |
| 15520       | Tom Thumb Competitors Information and Patients Neopuff solutions    | 24/08/15           |
| 15519       | Tom Thumb Competitors Information and Patients Neopuff operating... | 24/08/15           |
| 15518       | Tom Thumb Competitors Information and Patients Neopuff masks ope... | 24/08/15           |
| 15517       | Tom Thumb Competitors Information and Patients Neopuff key refer... | 24/08/15           |
| 15516       | Tom Thumb Competitors Information and Patients Neopuff catalogue    | 24/08/15           |
| 15515       | Tom Thumb Competitors Information and Patients Neopuff benefits     | 24/08/15           |
| 15512       | Tom Thumb General Certificates Tom Thumb TT480 Instruction Bookl... | 24/08/15           |
| 15511       | Tom Thumb Instructions for Use User Manual TT480 Instructions D...  | 24/08/15           |
| 15510       | Tom Thumb Instructions for Use User Manual TT480 Instructions D...  | 24/08/15           |
| 15509       | Tom Thumb Instructions for Use User Manual TT480 Instructions D...  | 24/08/15           |
| 15497       | Tom Thumb Literature reviews Clinical papers                        | 18/08/15           |
| 15461       | Tom Thumb Packaging Trials and validation                           | 14/08/15           |
| 15454       | Tom Thumb Literature reviews Airmed leaflet PIP & PEEP against b... | 12/08/15           |
| 15439       | Tom Thumb Risk / benefits assessment and Clinical Re evaluation     | 11/08/15           |
| 15416       | Tom Thumb Machinery Equipment                                       | 11/08/15           |
| 15414       | Tom Thumb PPE Equipment   | 11/08/15           |
| 15385       | VM3COP50.15 Packaging Procedures Tom Thumbs                         | 06/08/15           |
| 15379       | VM3COP50.04 Tom Thumb TT495   | 05/08/15           |



| Document ID | Description   | Date Added/Updated |
|-------------|---|--------------------|
| 15377       | VM3COP50.03.2 Tom Thumb TT490_15_Restricted                         | 05/08/15           |
| 15375       | VM3COP50.01 Tom Thumb TT490 ( 0310031 / 0310033 )                   | 05/08/15           |
| 15373       | VM3COP50.02 Tom Thumb production procedures TT480 ( 0310030 )       | 05/08/15           |
| 15371       | VM3COP50.14 Calibration / Test Sheet Blank Tom Thumbs               | 05/08/15           |
| 15365       | VM3COP50.13 Quality Control Tom Thumb                               | 05/08/15           |
| 15298       | Tom Thumb EC Declaration of Conformance                             | 29/07/15           |
| 15183       | No risks disposal   | 21/07/15           |
| 15118       | Tom Thumb Trade Mark Certificate Tom thumb registration trade ma... | 26/06/15           |
| 15117       | Tom Thumb Trade Mark Certificate Tom thumb registration trade ma... | 26/06/15           |
| 15008       | Tom Thumb Maintenance Parts required for Annual Service of TT480... | 22/05/15           |
| 14506       | Tom Thumb Trade Mark Certificate Trade Mark Company                 | 05/11/14           |
| 14504       | Tom Thumb Trade Mark Certificate                                    | 05/11/14           |
| 14437       | Tom Thumb Promotional Leaflets 0330237 Viamed MH052 Leaflet         | 03/10/14           |
| 14433       | Resuscitation Unit and TC400 Promotional Leaflets Tom Thumb Infa... | 03/10/14           |
| 14193       | Tom Thumb Post Market Surveillance                                  | 26/08/14           |

Comments on Document Changes:

All build procedures have been updated, service sheets updated and QA forms have been updated due to a BSI finding some incorrect numbers in the documentation.  
All the procedures have been reviewed

Comments on Risks with Document Changes:

no risk identified with the newer documentation

# Internal Issues Review

Number of Issues reviewed: 80

| Issue ID | Subject                             |
|----------|-------------------------------------|
| 59228    | 0310030 TT480 build list edits      |
| 59229    | 0310032 & 0310034 build list edits  |
| 61283    | 0310097 - stock memo for Tom Thumb  |
| 61282    | 0310097 - stock memo for Tom Thumb  |
| 60659    | 0310097 Images                      |
| 61501    | 0310097 Tom Thumb TG User Manual    |
| 61310    | 0310097 User Manual                 |
| 56934    | 0330193 to order                    |
| 60091    | 0330222 Precision valve spring      |
| 62951    | Backorder 00000170 0310094 ORD76134 |
| 63209    | Backorder 00000170 0380000 ORD76134 |
| 52327    | Backorder 00000550 0380000 ORD70031 |
| 62093    | Backorder 00000550 0380000 ORD75501 |
| 62210    | Backorder 00000780 0380000 ORD75500 |
| 57415    | Backorder 00000790 0330212 ORD73220 |
| 56788    | Backorder 00001410 0330218 ORD72683 |
| 51867    | Backorder 00001466 0310030 ORD69640 |
| 52051    | Backorder 00001480 0310250 ORD69797 |
| 58896    | Backorder 00001760 0330217 ORD74113 |
| 61013    | Backorder 00002270 0380000 ORD75212 |
| 57007    | Backorder 00002609 0330193 ORD72814 |
| 56875    | Backorder 00002609 0330203 ORD72814 |
| 57468    | Backorder 00002662 0310097 ORD73262 |
| 53325    | Backorder 00003709 0310030 ORD70595 |
| 58397    | Backorder 00003709 0310030 ORD73805 |
| 57839    | Backorder 00003709 0330193 ORD73424 |
| 61481    | Backorder 00003710 0330193 ORD75438 |
| 59438    | Backorder 00003785 0310030 ORD74443 |
| 58170    | Backorder 00003785 0330209 ORD73644 |
| 54888    | Backorder 00003970 0310030 ORD71622 |
| 56771    | Backorder 00004260 0380000 ORD72743 |
| 62117    | Backorder 00004561 0330212 ORD75747 |
| 60088    | Backorder 00004900 0310034 ORD74832 |
| 61760    | Backorder 00004992 0380000 ORD75576 |
| 53999    | Backorder 00005000 0380000 ORD69051 |
| 53495    | Backorder 00005210 0310030 ORD70635 |
| 59371    | Backorder 00005260 0330220 ORD74365 |
| 54162    | Backorder 00007291 0310030 ORD71085 |
| 58421    | Backorder 00007291 0310030 ORD73816 |
| 61156    | Backorder 00007291 0310030 ORD75305 |
| 55388    | Backorder 00007291 0330190 ORD71978 |
| 57323    | Backorder 00007291 0330193 ORD73105 |

| Issue ID | Subject   |
|----------|---|
| 57268    | Backorder 00007291 0330203 ORD73105                                 |
| 61057    | Backorder 00007291 0330227 ORD75241                                 |
| 57386    | Backorder 00007356 0380000 ORD73194                                 |
| 60311    | Backorder 00007497 0310030 ORD74951                                 |
| 62955    | Backorder 00007603 0330211 ORD76136                                 |
| 54173    | Backorder 00012746 0310097 ORD71102                                 |
| 57517    | Backorder 00012746 0310097 ORD73118                                 |
| 60512    | Backorder 00012746 0310097 ORD75019                                 |
| 61292    | Backorder 00012746 0310097 ORD75377                                 |
| 62917    | Backorder 00012746 0310097 ORD76119                                 |
| 57451    | Box label not working   |
| 61172    | Document Update Request (13190)                                     |
| 58606    | Gauges  |
| 62914    | Inspiration/Inditherm   |
| 60321    | Neopuff potential hazard  |
| 57269    | New Gauge 0330193   |
| 59171    | Parts required for annual service of Tom Thumbs                     |
| 57882    | Precision valve screw 0330228                                       |
| 52534    | Resus cabinet for John Radcliffe Hospital                           |
| 51784    | Resus cabinet service visit - Blackburn Birthing Centre             |
| 51783    | Resus cabinet service visit - Blackburn Birthing Centre             |
| 60664    | Returned Items SOR524   |
| 57332    | Returned Items SOR586   |
| 58036    | Returned Items SOR635   |
| 60501    | SOR524 - Inditherm plc  |
| 57731    | Special QA form for Tom Thumbs                                      |
| 62132    | Steritouch Trademark License Agreement                              |
| 62131    | Steritouch Trademark License Agreement                              |
| 59227    | Tom Thumb production  |
| 57825    | Tom Thumb service sheets  |
| 60868    | Tom Thumb TG 0310097 Inditherm Inspiration Manual                   |
| 60876    | Tom Thumb TT480 Inditherm/Inspiration 0310097 Manual                |
| 60867    | Tom Thumb TT480 Inditherm/Inspiration 0310097 Manual                |
| 61332    | TT480 with Pole Clamp - part number and price required              |
| 62275    | User Manual Instructions and Labels Tom thumb Artwork to Intrastats |
| 56646    | Viamed Website Image Coming Soon                                    |
| 50015    | Web Site Question ID 190  |
| 59039    | Web Site Question ID 484  |

Comments on Issues:

Most issues are relating to stock movements or the updating of the service/qa/procedures documentation.

Comments on Risks with Issues:

Issue 60321, refers to a risk with adjusting the flow rates and the pressure and peep settings have been set on a neopuff device.

We are very specific in the instructions as to setting up the Device,  
Flow first then pip pressure then peep pressure.

# Clinical / FDA Incidents online search

## Clinical Investigation online review

Do any of the Results indicate a Risk / Problem : No  
Do any of the Results indicate outdated Technology : No  
Comments on Clinical Search :

Clinical Evaluation research:

Searched for Clinical papers on

Comparable devices  
Fisher & Paykel Neopuff  
Fanem Babypuff 1020  
GE Healthcare Panda T-Piece System  
GE Healthcare Giraffe T-Piece System  
GE Healthcare Giraffe Stand Alone T-Piece System  
Draeger Resuscitaire T-Piece Resuscitation  
T Piece resusitators

### Results

Obstetric and Intrapartum Emergencies: A practical guide to management.  
Discussing Airway and Newborn Infants.  
Page 243 Recommending use of a bag and mask or preferably a Tom-Thumb type device.  
Published : 2013, 2013

Mid Essex Guideline for Neonatal Resuscitation  
Appendix D – Required equipment Tom Thumb  
2013

Neonatal resuscitation – a practical  
approach. The experience of one UK  
tertiary neonatal unit  
Document id#15733

Optimal neonatal ventilation  
<http://gradworks.umi.com/34/53/3453856.html>  
2011  
by Shelton, Julie A., D.N.P., THE COLLEGE OF ST. SCHOLASTICA, 2011, 72 pages; 3453856

The Neopuff Infant Resuscitator recently selected as a standard of care in the SMMC Neonatal Intensive Care Unit (NICU) and Birthplace, is a method of ventilating neonates that consistently delivers the same pre-set pressure with a consistent blend of oxygen and air; thus adequate ventilation/administration is not dependent on caregiver technique and experience.

University of Kentucky / UK HealthCare Policy and Procedure RC04-04P  
Recommends usage of Neo Puff (T Piece resusitators)  
Document ID#15734

Advantages of the Neopuff Resuscitator Operator sets PIP and PEEP pressures Resuscitator will not deliver PIP or PEEP above set pressures PIP and PEEP pressures are displayed on unit Operator controls the length of inspiratory time Resuscitator delivers 100% free flow oxygen reliably

<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2675376/>  
and  
A comparison of three neonatal resuscitation devices. 2005  
<http://www.ncbi.nlm.nih.gov/pubmed/16081202>  
CONCLUSIONS:

The T-piece resuscitator delivered the desired pressures more accurately, but required greater time to increase the PIP from 20 to 40 cmH<sub>2</sub>O. It was difficult to maintain a prolonged inflation and deliver the desired PEEP with the self-inflating bag even with the PEEP valve in place. There is a need for improvement in the design and function of current manual resuscitation devices and for prospective trials to evaluate the optimal method of bag and mask ventilation during resuscitation of the newborn infant.

NRP (Neonatal Resuscitation Program) 6th Edition  
Lessons in positive pressure ventilation  
includes usage of T Piece resuscitators

Manual of Neonatal Care  
edited by John P. Cloherty, Eric C. Eichenwald, Anne R. Hanse  
It offers greater control over manual ventilation by delivering breaths of reproducible size (peak and end-expiratory pressure) and a simplified method to control delivered breath rate.

Using a regulated means of administration, such as a T-piece resuscitator or ventilator, is preferable.

WORKSHEET for Evidence-Based Review of Science for Emergency Cardiac Care  
2009

Includes Risks / Benefits of T Piece resuscitator units

Document id#15731

and

Document id# 15732

Clinical question :

In newborns (P) requiring positive pressure during resuscitation, is positive pressure ventilation by T-piece resuscitator (I) superior to bag ventilation (C) for improving outcome - specify (O)?  
27 Jan 2010,

CONSENSUS ON SCIENCE:

- There are no clinical studies in newborns requiring positive pressure during resuscitation to support or refute superiority of the T-piece resuscitator over bag ventilation in improving outcome.
- In mechanical models, target inflation pressures are delivered more consistently when using T-piece resuscitators than with self-inflating bags. (LOE 5 - Hussey 2004, F490; Oddie 2005, 109; Finer 2001, 299)
- In mechanical models, PEEP is maintained more consistently with T-piece resuscitators compared with self-inflating bags. (LOE 5 - Finer 2001, 299)
- In mechanical models, the ability to deliver a sustained inflation is better with either a T-piece resuscitator or flow-inflating bag compared with a self-inflating bag. (LOE 5 - Bennett 2005, 113)

## 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 :

