



# VIA MED

## Heat Shields

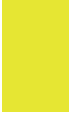
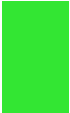
Simple tunnel to restrict heat loss. Available with and without feet ends.

Class I  
Via Rule Rule 1  
Assesment Route Annex II  
NBOG MD 0100

Carried out by Derek Lamb  
30 / 05 / 14



# VIA MED

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# Stock References Review

| Stock Reference | Description                  |
|-----------------|------------------------------|
| PP8100          | Heat Shield Open Ends        |
| PP8101          | Heat Shield one end open     |
| PP8102          | Heat Shield Both Ends Closed |
| PP8103          | Heat Shield Open Ends        |
| PP8104          | Heat Shield One End Closed   |
| PP8105          | Heat Shield Both Ends Closed |
| PP8106          | Heat Shield Open Ends        |
| PP8107          | Heat Shield Open One End     |
| PP8108          | Heat Shield Both Ends Closed |
| PP8109          | Heat Shield Open Ends        |
| PP8110          | Heat Shield One End Closed   |
| PP8111          | Heat Shield Both Ends Closed |
| PP8112          | Heat Shield Open Ends        |
| PP8113          | Heat Shield One End Closed   |
| PP8114          | Heat Shield Both Ends Closed |
| PP8601          | Heat Shield Open Ends        |
| PP8620          | Heat Shield One End Closed   |
| PP8633          | Heat Shield                  |
| PP8761          | Heat Shield Both Ends Open   |
| PP8779          | Heat Shield Open Ends        |
| PP8786          | Heat Shield                  |

Comments on Stock references review:

All stock references are correct

# Supplier Review

| Stock Reference | Description                | Supplier A/C | Supplier Name         | Rating |
|-----------------|----------------------------|--------------|-----------------------|--------|
| PP8109          | Heat Shield Open Ends      | 00009022     | Tanda Engineering Ltd | A      |
| PP8112          | Heat Shield Open Ends      | 00009022     | Tanda Engineering Ltd | A      |
| PP8633          | Heat Shield                | 00009022     | Tanda Engineering Ltd | A      |
| PP8761          | Heat Shield Both Ends Open | 00009022     | Tanda Engineering Ltd | A      |
| PP8779          | Heat Shield Open Ends      | 00009022     | Tanda Engineering Ltd | A      |
| PP8786          | Heat Shield                | 00009022     | Tanda Engineering Ltd | A      |

Comments on Suppliers:

Supplier reivew uptodate

# Sales Information

| Stock Reference | Description                  | 2008 | 2009 | 2010 | 2011 | 2012 | 2013 | 2014 |
|-----------------|------------------------------|------|------|------|------|------|------|------|
| PP8100          | Heat Shield Open Ends        |      |      |      |      |      |      |      |
| PP8101          | Heat Shield one end open     |      |      |      |      |      |      |      |
| PP8102          | Heat Shield Both Ends Closed |      |      |      |      |      |      |      |
| PP8103          | Heat Shield Open Ends        |      |      |      |      |      |      |      |
| PP8104          | Heat Shield One End Closed   |      |      |      |      |      |      |      |
| PP8105          | Heat Shield Both Ends Closed |      |      |      |      |      |      |      |
| PP8106          | Heat Shield Open Ends        |      |      |      |      |      |      |      |
| PP8107          | Heat Shield Open One End     |      |      |      |      |      |      |      |
| PP8108          | Heat Shield Both Ends Closed |      |      |      |      |      |      |      |
| PP8109          | Heat Shield Open Ends        |      |      |      |      |      |      |      |
| PP8110          | Heat Shield One End Closed   |      |      |      |      |      |      |      |
| PP8111          | Heat Shield Both Ends Closed |      |      |      |      |      |      |      |
| PP8112          | Heat Shield Open Ends        |      |      |      |      |      |      |      |
| PP8113          | Heat Shield One End Closed   |      |      |      |      |      |      |      |
| PP8114          | Heat Shield Both Ends Closed |      |      |      |      |      |      |      |
| PP8601          | Heat Shield Open Ends        |      |      |      |      |      |      |      |
| PP8620          | Heat Shield One End Closed   |      |      |      |      |      |      |      |
| PP8633          | Heat Shield                  |      |      |      |      |      |      |      |
| PP8761          | Heat Shield Both Ends Open   | 8    | 2    |      |      | 7    | 2    |      |
| PP8779          | Heat Shield Open Ends        |      |      |      |      | 2    |      |      |
| PP8786          | Heat Shield                  |      |      |      |      |      |      | 1    |

Comments on Sales Information:

limited low sales but still selling

# Countries Review

| Country           | 2008 | 2009 | 2010 | 2011 | 2012 | 2013 | 2014 |
|-------------------|------|------|------|------|------|------|------|
| UK United Kingdom | [X]  | [X]  |      |      | [X]  | [X]  | [X]  |

Comments on Sales to Countries:

only sell to uk

Comments on Risks with Sales to Countries:

no risk selling to uk

# Returns Review

Comments on Returns:

Zero returns,

Comments on Risks with Returns and Potential Re-work:

n/a zero returns

# Design Changes Review

Showing Documents Filed in Y 14 Design Changes

Comments on Design Changes:

no design changes

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 |
|-------------|-----------------------------------------------|--------------------|
| 7688        | Heat Shields Instructions for Use User Manual | 15/02/11           |

Comments on User Instructions:

no user instruction updates

Comments on Risks User Instructions:

n/a

# Labels Review

Showing Documents Filed in F 7 / F 8 Labels

| Document ID | Description                  | Date Added/Updated |
|-------------|------------------------------|--------------------|
| 9169        | No accessory labels          | 18/10/11           |
| 7498        | Head Box Oxygen Hoods Labels | 21/01/11           |

Comments on Labels:

no changes to labels

Comments on Risks Labels:

n/a

# Documentation Updates / Changes

Comments on Document Changes:

updated specification sheet,

Comments on Risks with Document Changes:

no risks with document updates

# Internal Issues Review

Number of Issues reviewed: 3

| Issue ID | Subject                         |
|----------|---------------------------------|
| 47511    | New Part Number Required        |
| 48362    | Label Description Needed        |
| 47530    | Orders , Production suggestions |

Comments on Issues:

no problems found in the Issues system

Comments on Risks with Issues:

no risks found in the Issues system

# 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 :

found a recently uploaded but old article on use of heat shields in line with phototherapy.  
interesting but not really clinical report.

## 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 :

no reports found,

# Risk ISO 14971 : 2012 Review

|            | Negligible   | Minor        | Serious      | Critical     | Catastrophic |
|------------|--------------|--------------|--------------|--------------|--------------|
| Improbable | Acceptable   | Acceptable   | Acceptable   | Acceptable   | Acceptable   |
| Remote     | Acceptable   | Acceptable   | Acceptable   | Unacceptable | Unacceptable |
| Occasional | Acceptable   | Acceptable   | Unacceptable | Unacceptable | Unacceptable |
| Probable   |              | Unacceptable | Unacceptable | Unacceptable | Unacceptable |
| Frequent   | Unacceptable | Unacceptable | Unacceptable | Unacceptable | Unacceptable |

C.2.1 What is the intended use and how is the medical device to be used

| [ID] | Reference Question                                                                  | Applys | Risk  | Probability | Overall    |
|------|-------------------------------------------------------------------------------------|--------|-------|-------------|------------|
| 1    | what is the medical device`s role relative to diagnosis,                            | No     | ---   | ---         | n/a        |
| 2    | what is the medical device`s role relative to prevention                            | No     | ---   | ---         | n/a        |
| 3    | what is the medical devices role relative to monitoring                             | No     | ---   | ---         | n/a        |
| 4    | what is the medical devices role relative to treatment                              | Yes    | Minor | Occasional  | Acceptable |
| 5    | what is the medical devices role relative to alleviation of disease                 | No     | ---   | ---         | n/a        |
| 6    | what is the medical devices role relative to compensation for injury or handicap    | No     | ---   | ---         | n/a        |
| 7    | what is the medical devices role relative to replacement or modification of anatomy | No     | ---   | ---         | n/a        |
| 8    | what is the medical devices role relative to control of conception                  | No     | ---   | ---         | n/a        |
| 9    | does the medical device sustain life                                                | No     | ---   | ---         | n/a        |
| 10   | does the medical device support life                                                | No     | ---   | ---         | n/a        |
| 11   | is special intervention necessary in the case of failure of the medical device      | No     | ---   | ---         | n/a        |
| 330  | What are the indications for use e.g. patient population                            | No     | ---   | ---         | n/a        |

C.2.10 Is the medical device intended to modify the patient environment

| [ID] | Reference Question                                                    | Applys | Risk       | Probability | Overall    |
|------|-----------------------------------------------------------------------|--------|------------|-------------|------------|
| 56   | Factors that should be considered include temperature                 | Yes    | Negligible | Improbable  | Acceptable |
| 57   | Factors that should be considered include humidity                    | No     | ---        | ---         | n/a        |
| 58   | Factors that should be considered include atmospheric gas composition | No     | ---        | ---         | n/a        |
| 59   | Factors that should be considered include pressure                    | No     | ---        | ---         | n/a        |
| 60   | Factors that should be considered include light                       | No     | ---        | ---         | n/a        |

C.2.11 Are measurements taken

| [ID] | Reference Question                                                                                                              | Applys | Risk | Probability | Overall |
|------|---------------------------------------------------------------------------------------------------------------------------------|--------|------|-------------|---------|
| 61   | Factors that should be considered include the variables measured and the accuracy and the precision of the measurement results. | No     | ---  | ---         | n/a     |

C.2.12 Is the medical device interpretative

| [ID] | Reference Question                                                                                                                                                                       | Applys | Risk | Probability | Overall |
|------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|------|-------------|---------|
| 62   | Factors that should be considered include whether conclusions are presented by the medical device from input or acquired data                                                            | No     | ---  | ---         | n/a     |
| 63   | Factors that should be considered include whether conclusions are presented by the medical device from the algorithms used                                                               | No     | ---  | ---         | n/a     |
| 64   | Factors that should be considered include whether conclusions are presented by the medical device from the confidence limits                                                             | No     | ---  | ---         | n/a     |
| 65   | Factors that should be considered include whether conclusions are presented by the medical device. Special attention should be given to unintended applications of the data or algorithm | No     | ---  | ---         | n/a     |

C.2.13 Is the medical device intended for use in conjunction with other medical devices, medicines or other medical technologies

| [ID] | Reference Question                                                                                        | Applys | Risk  | Probability | Overall    |
|------|-----------------------------------------------------------------------------------------------------------|--------|-------|-------------|------------|
| 66   | Factors that should be considered include identifying any other medical devices                           | No     | ---   | ---         | n/a        |
| 67   | Factors that should be considered include identifying any other medicines                                 | No     | ---   | ---         | n/a        |
| 68   | Factors that should be considered include identifying any other medical technologies that can be involved | Yes    | Minor | Improbable  | Acceptable |

C.2.14 Are there unwanted outputs of energy or substances

| [ID] | Reference Question                                                                           | Applys | Risk | Probability | Overall |
|------|----------------------------------------------------------------------------------------------|--------|------|-------------|---------|
| 69   | Energy-related factors that should be considered include vibration,                          | No     | ---  | ---         | n/a     |
| 70   | Energy-related factors that should be considered include heat,                               | No     | ---  | ---         | n/a     |
| 71   | Energy-related factors that should be considered include radiation,                          | No     | ---  | ---         | n/a     |
| 72   | Energy-related factors that should be considered include noise,                              | No     | ---  | ---         | n/a     |
| 73   | Energy-related factors that should be considered include ionizing radiation,                 | No     | ---  | ---         | n/a     |
| 74   | Energy-related factors that should be considered include non-ionizing radiation,             | No     | ---  | ---         | n/a     |
| 75   | Energy-related factors that should be considered include ultraviolet/ radiation,             | No     | ---  | ---         | n/a     |
| 76   | Energy-related factors that should be considered include visible radiation,                  | No     | ---  | ---         | n/a     |
| 77   | Energy-related factors that should be considered include infrared radiation,                 | No     | ---  | ---         | n/a     |
| 78   | Energy-related factors that should be considered include contact temperatures                | No     | ---  | ---         | n/a     |
| 79   | Energy-related factors that should be considered include leakage currents                    | No     | ---  | ---         | n/a     |
| 80   | Energy-related factors that should be considered include electric fields                     | No     | ---  | ---         | n/a     |
| 81   | Energy-related factors that should be considered include magnetic fields                     | No     | ---  | ---         | n/a     |
| 82   | Substance-related factors that should be considered include substances used in manufacturing | No     | ---  | ---         | n/a     |

| [ID] | Reference Question                                                                       | Applys | Risk | Probability | Overall |
|------|------------------------------------------------------------------------------------------|--------|------|-------------|---------|
| 83   | Substance-related factors that should be considered include substances used in cleaning  | No     | ---  | ---         | n/a     |
| 84   | Substance-related factors that should be considered include substances used in testing   | No     | ---  | ---         | n/a     |
| 85   | Other substance-related factors that should be considered include discharge of chemicals | No     | ---  | ---         | n/a     |
| 86   | Other substance-related factors that should be considered include waste products         | No     | ---  | ---         | n/a     |
| 87   | Other substance-related factors that should be considered include body fluids            | No     | ---  | ---         | n/a     |

#### C.2.15 Is the medical device susceptible to environmental influences

| [ID] | Reference Question                                                                                     | Applys | Risk | Probability | Overall |
|------|--------------------------------------------------------------------------------------------------------|--------|------|-------------|---------|
| 88   | Factors that should be considered include the operational environment                                  | No     | ---  | ---         | n/a     |
| 89   | Factors that should be considered include the transport environment                                    | No     | ---  | ---         | n/a     |
| 90   | Factors that should be considered include the storage environment                                      | No     | ---  | ---         | n/a     |
| 91   | Factors that should be considered include light                                                        | No     | ---  | ---         | n/a     |
| 92   | Factors that should be considered include temperature                                                  | No     | ---  | ---         | n/a     |
| 93   | Factors that should be considered include humidity                                                     | No     | ---  | ---         | n/a     |
| 94   | Factors that should be considered include vibrations                                                   | No     | ---  | ---         | n/a     |
| 95   | Factors that should be considered include spillage                                                     | No     | ---  | ---         | n/a     |
| 96   | Factors that should be considered include susceptibility to variations in power                        | No     | ---  | ---         | n/a     |
| 97   | Factors that should be considered include susceptibility to variations in cooling supplies             | No     | ---  | ---         | n/a     |
| 98   | Factors that should be considered include susceptibility to variations in electromagnetic interference | No     | ---  | ---         | n/a     |

#### C.2.16 Does the medical device influence the environment

| [ID] | Reference Question                                                                      | Applys | Risk | Probability | Overall |
|------|-----------------------------------------------------------------------------------------|--------|------|-------------|---------|
| 99   | Factors that should be considered include the effects on power and cooling supplies     | No     | ---  | ---         | n/a     |
| 100  | Factors that should be considered include the emission of toxic materials               | No     | ---  | ---         | n/a     |
| 101  | Factors that should be considered include the generation of electromagnetic disturbance | No     | ---  | ---         | n/a     |

#### C.2.17 Are there essential consumables or accessories associated with the medical device

| [ID] | Reference Question                                                            | Applys | Risk | Probability | Overall |
|------|-------------------------------------------------------------------------------|--------|------|-------------|---------|
| 102  | Factors that should be considered include specifications for such consumables | No     | ---  | ---         | n/a     |
| 103  | Factors that should be considered include specifications for such accessories | No     | ---  | ---         | n/a     |

| [ID] | Reference Question                                                                                              | Applies | Risk | Probability | Overall |
|------|-----------------------------------------------------------------------------------------------------------------|---------|------|-------------|---------|
| 104  | Factors that should be considered include any restrictions placed upon users in their selection of consumables. | No      | ---  | ---         | n/a     |
| 105  | Factors that should be considered include any restrictions placed upon users in their selection of accessories. | No      | ---  | ---         | n/a     |

#### C.2.18 Is maintenance or calibration necessary

| [ID] | Reference Question                                                                                                   | Applies | Risk | Probability | Overall |
|------|----------------------------------------------------------------------------------------------------------------------|---------|------|-------------|---------|
| 106  | Factors that should be considered include whether maintenance or calibration are to be carried out by the operator   | No      | ---  | ---         | n/a     |
| 107  | Factors that should be considered include whether maintenance or calibration are to be carried out by the user       | No      | ---  | ---         | n/a     |
| 108  | Factors that should be considered include whether maintenance or calibration are to be carried out by the specialist | No      | ---  | ---         | n/a     |
| 109  | Factors that should be considered include are special substances or equipment necessary for proper maintenance       | No      | ---  | ---         | n/a     |
| 110  | Factors that should be considered include are special substances or equipment necessary for proper calibration       | No      | ---  | ---         | n/a     |

#### C.2.19 Does the medical device contain software

| [ID] | Reference Question                                                                     | Applies | Risk | Probability | Overall |
|------|----------------------------------------------------------------------------------------|---------|------|-------------|---------|
| 111  | Factors that should be considered include whether software is intended to be installed | No      | ---  | ---         | n/a     |
| 112  | Factors that should be considered include whether software is intended to be verified  | No      | ---  | ---         | n/a     |
| 113  | Factors that should be considered include whether software is intended to be modified  | No      | ---  | ---         | n/a     |
| 114  | Factors that should be considered include whether software is intended to be exchanged | No      | ---  | ---         | n/a     |

#### C.2.2 Is the medical device intended to be implanted

| [ID] | Reference Question                                                                             | Applies | Risk | Probability | Overall |
|------|------------------------------------------------------------------------------------------------|---------|------|-------------|---------|
| 12   | Factors that should be considered include the location of implantation,                        | No      | ---  | ---         | n/a     |
| 13   | Factors that should be considered include the characteristics of the patient population        | No      | ---  | ---         | n/a     |
| 14   | Factors that should be considered include the characteristics of the patient age               | No      | ---  | ---         | n/a     |
| 15   | Factors that should be considered include the characteristics of the patient weight            | No      | ---  | ---         | n/a     |
| 16   | Factors that should be considered include the characteristics of the patient physical activity | No      | ---  | ---         | n/a     |
| 17   | Factors that should be considered include the effect of ageing on implant performance          | No      | ---  | ---         | n/a     |

| [ID] | Reference Question                                                              | Applies | Risk | Probability | Overall |
|------|---------------------------------------------------------------------------------|---------|------|-------------|---------|
| 18   | Factors that should be considered include the expected lifetime of the implant  | No      | ---  | ---         | n/a     |
| 19   | Factors that should be considered include the reversibility of the implantation | No      | ---  | ---         | n/a     |

#### C.2.20 Does the medical device have a restricted shelf-life

| [ID] | Reference Question                                                         | Applies | Risk | Probability | Overall |
|------|----------------------------------------------------------------------------|---------|------|-------------|---------|
| 115  | Factors that should be considered include labelling                        | No      | ---  | ---         | n/a     |
| 116  | Factors that should be considered include indicators                       | No      | ---  | ---         | n/a     |
| 117  | Factors that should be considered include disposal of such medical devices | No      | ---  | ---         | n/a     |

#### C.2.21 Are there any delayed or long-term use effects

| [ID] | Reference Question                                           | Applies | Risk | Probability | Overall |
|------|--------------------------------------------------------------|---------|------|-------------|---------|
| 118  | Factors that should be considered include ergonomic effects  | No      | ---  | ---         | n/a     |
| 119  | Factors that should be considered include cumulative effects | No      | ---  | ---         | n/a     |

#### C.2.22 To what mechanical forces will the medical device be subjected

| [ID] | Reference Question                                                                                                                                          | Applies | Risk | Probability | Overall |
|------|-------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|------|-------------|---------|
| 120  | Factors that should be considered include whether the forces to which the medical device will be subjected are under the control of the user                | No      | ---  | ---         | n/a     |
| 121  | Factors that should be considered include whether the forces to which the medical device will be subjected are controlled by interaction with other persons | No      | ---  | ---         | n/a     |

#### C.2.23 What determines the lifetime of the medical device

| [ID] | Reference Question                                           | Applies | Risk  | Probability | Overall    |
|------|--------------------------------------------------------------|---------|-------|-------------|------------|
| 122  | Factors that should be considered include ageing             | Yes     | Minor | Remote      | Acceptable |
| 123  | Factors that should be considered include battery depletion. | No      | ---   | ---         | n/a        |

#### C.2.24 Is the medical device intended for single use

| [ID] | Reference Question                                                                        | Applies | Risk | Probability | Overall |
|------|-------------------------------------------------------------------------------------------|---------|------|-------------|---------|
| 124  | Factors that should be considered include does the medical device self-destruct after use | No      | ---  | ---         | n/a     |
| 125  | Factors that should be considered include Is it obvious that the device has been used     | No      | ---  | ---         | n/a     |

#### C.2.25 Is safe decommissioning or disposal of the medical device necessary

| [ID] | Reference Question                                                                                                               | Applys | Risk | Probability | Overall |
|------|----------------------------------------------------------------------------------------------------------------------------------|--------|------|-------------|---------|
| 126  | Factors that should be considered include the waste products that are generated during the disposal of the medical device itself | No     | ---  | ---         | n/a     |
| 127  | Factors that should be considered include does it contain toxic material                                                         | No     | ---  | ---         | n/a     |
| 128  | Factors that should be considered include does it contain hazardous material                                                     | No     | ---  | ---         | n/a     |
| 129  | Factors that should be considered include is the material recyclable                                                             | No     | ---  | ---         | n/a     |

#### C.2.26 Does installation or use of the medical device require special training or special skills

| [ID] | Reference Question                                                                                           | Applys | Risk | Probability | Overall |
|------|--------------------------------------------------------------------------------------------------------------|--------|------|-------------|---------|
| 130  | Factors that should be considered include the novelty of the medical device                                  | No     | ---  | ---         | n/a     |
| 131  | Factors that should be considered include the likely skill and training of the person installing the device. | No     | ---  | ---         | n/a     |

#### C.2.27 How will information for safe use be provided

| [ID] | Reference Question                                                                                                                                           | Applys | Risk | Probability | Overall |
|------|--------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|------|-------------|---------|
| 132  | Factors that should be considered include whether information will be provided directly to the end user by the manufacturer                                  | No     | ---  | ---         | n/a     |
| 133  | Factors that should be considered include will it involve the participation of third parties such as installers                                              | No     | ---  | ---         | n/a     |
| 134  | Factors that should be considered include will it involve the participation of third parties such as care providers                                          | No     | ---  | ---         | n/a     |
| 135  | Factors that should be considered include will it involve the participation of third parties such as health care professionals                               | No     | ---  | ---         | n/a     |
| 136  | Factors that should be considered include will it involve the participation of third parties such as pharmacists                                             | No     | ---  | ---         | n/a     |
| 137  | Factors that should be considered include will it involve whether this will have implications for training                                                   | No     | ---  | ---         | n/a     |
| 138  | commissioning and handing over to the end user and whether it is likely/possible that installation can be carried out by people without the necessary skills | No     | ---  | ---         | n/a     |
| 139  | based on the expected life of the device, whether re-training or re-certification of operators or service personnel would be required                        | No     | ---  | ---         | n/a     |

#### C.2.28 Will new manufacturing processes need to be established or introduced

| [ID] | Reference Question                                                 | Applys | Risk | Probability | Overall |
|------|--------------------------------------------------------------------|--------|------|-------------|---------|
| 140  | Factors that should be considered include new technology           | No     | ---  | ---         | n/a     |
| 141  | Factors that should be considered include new scale of production. | No     | ---  | ---         | n/a     |

C.2.29 Is successful application of the medical device critically dependent on human factors

| [ID] | Reference Question         | Applies | Risk | Probability | Overall |
|------|----------------------------|---------|------|-------------|---------|
| 142  | such as the user interface | No      | ---  | ---         | n/a     |

C.2.29.1 Can the user interface design features contribute to use error

| [ID] | Reference Question                                                                                    | Applies | Risk | Probability | Overall |
|------|-------------------------------------------------------------------------------------------------------|---------|------|-------------|---------|
| 143  | Factors that should be considered are user interface design features that can contribute to use error | No      | ---  | ---         | n/a     |
| 144  | Examples of interface design features include control and indicators,                                 | No      | ---  | ---         | n/a     |
| 145  | Examples of interface design features include symbols used,                                           | No      | ---  | ---         | n/a     |
| 146  | Examples of interface design features include ergonomic features                                      | No      | ---  | ---         | n/a     |
| 147  | Examples of interface design features include physical design and layout,                             | No      | ---  | ---         | n/a     |
| 148  | Examples of interface design features include hierarchy of operation                                  | No      | ---  | ---         | n/a     |
| 149  | Examples of interface design features include menus for software driven devices                       | No      | ---  | ---         | n/a     |
| 150  | Examples of interface design features include visibility of warnings,                                 | No      | ---  | ---         | n/a     |
| 151  | Examples of interface design features include audibility of alarms                                    | No      | ---  | ---         | n/a     |
| 152  | Examples of interface design features include standardization of colour coding                        | No      | ---  | ---         | n/a     |

C.2.29.2 Is the medical device used in an environment where distractions can cause use error

| [ID] | Reference Question                                                                                       | Applies | Risk | Probability | Overall |
|------|----------------------------------------------------------------------------------------------------------|---------|------|-------------|---------|
| 153  | Factors that should be considered include the consequence of use error                                   | No      | ---  | ---         | n/a     |
| 154  | Factors that should be considered include whether the distractions are commonplace                       | No      | ---  | ---         | n/a     |
| 155  | Factors that should be considered include whether the user can be disturbed by an infrequent distraction | No      | ---  | ---         | n/a     |

C.2.29.3 Does the medical device have connecting parts or accessories

| [ID] | Reference Question                                                                  | Applies | Risk | Probability | Overall |
|------|-------------------------------------------------------------------------------------|---------|------|-------------|---------|
| 156  | Factors that should be considered include the possibility of wrong connections      | No      | ---  | ---         | n/a     |
| 157  | Factors that should be considered include similarity to other products connections, | No      | ---  | ---         | n/a     |
| 158  | Factors that should be considered include connection force,                         | No      | ---  | ---         | n/a     |
| 159  | Factors that should be considered include feedback on connection integrity          | No      | ---  | ---         | n/a     |
| 160  | Factors that should be considered include over- and under-tightening.               | No      | ---  | ---         | n/a     |

C.2.29.4 Does the medical device have a control interface

| [ID] | Reference Question                                                                        | Applys | Risk | Probability | Overall |
|------|-------------------------------------------------------------------------------------------|--------|------|-------------|---------|
| 161  | Factors that should be considered include spacing,                                        | No     | ---  | ---         | n/a     |
| 162  | Factors that should be considered include , coding,                                       | No     | ---  | ---         | n/a     |
| 163  | Factors that should be considered include grouping,                                       | No     | ---  | ---         | n/a     |
| 164  | Factors that should be considered include mapping,                                        | No     | ---  | ---         | n/a     |
| 165  | Factors that should be considered include modes of feedback                               | No     | ---  | ---         | n/a     |
| 166  | Factors that should be considered include modes of blunders                               | No     | ---  | ---         | n/a     |
| 167  | Factors that should be considered include slips                                           | No     | ---  | ---         | n/a     |
| 168  | Factors that should be considered include control differentiation                         | No     | ---  | ---         | n/a     |
| 169  | Factors that should be considered include visibility                                      | No     | ---  | ---         | n/a     |
| 170  | Factors that should be considered include direction of activation                         | No     | ---  | ---         | n/a     |
| 171  | Factors that should be considered include direction of change                             | No     | ---  | ---         | n/a     |
| 172  | Factors that should be considered include whether the controls are continuous or discrete | No     | ---  | ---         | n/a     |
| 173  | Factors that should be considered include the reversibility of settings or actions        | No     | ---  | ---         | n/a     |

#### C.2.29.5 Does the medical device display information

| [ID] | Reference Question                                                              | Applys | Risk | Probability | Overall |
|------|---------------------------------------------------------------------------------|--------|------|-------------|---------|
| 174  | Factors that should be considered include visibility in various environments    | No     | ---  | ---         | n/a     |
| 175  | Factors that should be considered include orientation                           | No     | ---  | ---         | n/a     |
| 176  | Factors that should be considered include the visual capabilities of the user   | No     | ---  | ---         | n/a     |
| 177  | Factors that should be considered include populations and perspectives          | No     | ---  | ---         | n/a     |
| 178  | Factors that should be considered include clarity of the presented information  | No     | ---  | ---         | n/a     |
| 179  | Factors that should be considered include units                                 | No     | ---  | ---         | n/a     |
| 180  | Factors that should be considered include colour coding                         | No     | ---  | ---         | n/a     |
| 181  | Factors that should be considered include accessibility of critical information | No     | ---  | ---         | n/a     |

#### C.2.29.6 Is the medical device controlled by a menu

| [ID] | Reference Question                                                                   | Applys | Risk | Probability | Overall |
|------|--------------------------------------------------------------------------------------|--------|------|-------------|---------|
| 182  | Factors that should be considered include complexity and number of layers            | No     | ---  | ---         | n/a     |
| 183  | Factors that should be considered include awareness of state                         | No     | ---  | ---         | n/a     |
| 184  | Factors that should be considered include location of settings                       | No     | ---  | ---         | n/a     |
| 185  | Factors that should be considered include navigation method                          | No     | ---  | ---         | n/a     |
| 186  | Factors that should be considered include number of steps per action                 | No     | ---  | ---         | n/a     |
| 187  | Factors that should be considered include sequence clarity and memorization problems | No     | ---  | ---         | n/a     |

| [ID] | Reference Question                                                                                                                                                      | Applys | Risk | Probability | Overall |
|------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|------|-------------|---------|
| 188  | Factors that should be considered include importance of control function relative to its accessibility and the impact of deviating from specified operating procedures. | No     | ---  | ---         | n/a     |

#### C.2.29.7 Will the medical device be used by persons with special needs

| [ID] | Reference Question                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Applys | Risk | Probability | Overall |
|------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|------|-------------|---------|
| 189  | Factors that should be considered include the user, their mental and physical abilities, skill and training, ergonomic aspects, the use environment, installation requirements, and the patient's capability to control or influence the use of the medical device. Special attention should be paid to users with special needs, such as handicapped persons, the elderly and children. Their special needs might include assistance by another person to enable the use of a medical device. Is the medical device intended to be used by individuals with various skill levels and cultural backgrounds | No     | ---  | ---         | n/a     |

#### C.2.29.8 Can the user interface be used to initiate user actions

| [ID] | Reference Question                                                                                                                                                                                                                                   | Applys | Risk | Probability | Overall |
|------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|------|-------------|---------|
| 190  | Factors that should be considered include the possibility of initiating a deliberate action for the user to enter a controlled operation mode, which enlarges the risks for the patient and which creates awareness for the user for this condition. | No     | ---  | ---         | n/a     |

#### C.2.3 Is the medical device intended to be in contact with the patient or other persons

| [ID] | Reference Question                                                                            | Applys | Risk | Probability | Overall |
|------|-----------------------------------------------------------------------------------------------|--------|------|-------------|---------|
| 20   | Factors that should be considered include the nature of the intended contact                  | No     | ---  | ---         | n/a     |
| 21   | Factors that should be considered include the nature of the intended contact surface contact  | No     | ---  | ---         | n/a     |
| 22   | Factors that should be considered include the nature of the intended contact invasive contact | No     | ---  | ---         | n/a     |
| 23   | Factors that should be considered include the nature of the intended the period of contact    | No     | ---  | ---         | n/a     |
| 24   | Factors that should be considered include the nature of the intended the frequency of contact | No     | ---  | ---         | n/a     |

#### C.2.30 Does the medical device use an alarm system

| [ID] | Reference Question                                                             | Applys | Risk | Probability | Overall |
|------|--------------------------------------------------------------------------------|--------|------|-------------|---------|
| 191  | Factors that should be considered are the risk of false alarms                 | No     | ---  | ---         | n/a     |
| 192  | Factors that should be considered are the risk of missing alarms               | No     | ---  | ---         | n/a     |
| 193  | Factors that should be considered are the risk of disconnected alarm systems   | No     | ---  | ---         | n/a     |
| 194  | Factors that should be considered are the risk unreliable remote alarm systems | No     | ---  | ---         | n/a     |

| [ID] | Reference Question                                                                                               | Applies | Risk | Probability | Overall |
|------|------------------------------------------------------------------------------------------------------------------|---------|------|-------------|---------|
| 195  | Factors that should be considered are the medical staffs possibility of understanding how the alarm system works | No      | ---  | ---         | n/a     |

#### C.2.31 In what ways might the medical device be deliberately misused

| [ID] | Reference Question                                                                      | Applies | Risk | Probability | Overall |
|------|-----------------------------------------------------------------------------------------|---------|------|-------------|---------|
| 196  | Factors that should be considered are incorrect use of connectors                       | No      | ---  | ---         | n/a     |
| 197  | Factors that should be considered are disabling safety features or alarms               | No      | ---  | ---         | n/a     |
| 198  | Factors that should be considered are neglect of manufacturer's recommended maintenance | No      | ---  | ---         | n/a     |

#### C.2.32 Does the medical device hold data critical to patient care

| [ID] | Reference Question                                                                     | Applies | Risk | Probability | Overall |
|------|----------------------------------------------------------------------------------------|---------|------|-------------|---------|
| 199  | Factors that should be considered include the consequence of the data being modified   | No      | ---  | ---         | n/a     |
| 200  | Factors that should be considered include the consequence of the data being corrupted. | No      | ---  | ---         | n/a     |

#### C.2.33 Is the medical device intended to be mobile or portable

| [ID] | Reference Question                                           | Applies | Risk | Probability | Overall |
|------|--------------------------------------------------------------|---------|------|-------------|---------|
| 201  | Factors that should be considered are the necessary grips,   | No      | ---  | ---         | n/a     |
| 202  | Factors that should be considered are the necessary handles, | No      | ---  | ---         | n/a     |
| 203  | Factors that should be considered are the necessary wheels,  | No      | ---  | ---         | n/a     |
| 204  | Factors that should be considered are the necessary, brakes, | No      | ---  | ---         | n/a     |
| 205  | Factors that should be considered are, mechanical stability  | No      | ---  | ---         | n/a     |
| 206  | Factors that should be considered are, durability            | No      | ---  | ---         | n/a     |

#### C.2.34 Does the use of the medical device depend on essential performance

| [ID] | Reference Question                                                                                 | Applies | Risk | Probability | Overall |
|------|----------------------------------------------------------------------------------------------------|---------|------|-------------|---------|
| 207  | Factors that should be considered are the characteristics of the output of life-supporting devices | No      | ---  | ---         | n/a     |
| 208  | Factors that should be considered are the operation of an alarm                                    | No      | ---  | ---         | n/a     |

#### C.2.4 What materials or components are utilized in the medical device or are used with, or are in contact with, the medical device

| [ID] | Reference Question                                                               | Applies | Risk | Probability | Overall |
|------|----------------------------------------------------------------------------------|---------|------|-------------|---------|
| 25   | Factors that should be considered include compatibility with relevant substances | No      | ---  | ---         | n/a     |
| 26   | Factors that should be considered include compatibility with tissues             | No      | ---  | ---         | n/a     |
| 27   | Factors that should be considered include compatibility with body fluids         | No      | ---  | ---         | n/a     |

| [ID] | Reference Question                                              | Applies | Risk | Probability | Overall |
|------|-----------------------------------------------------------------|---------|------|-------------|---------|
| 28   | whether characteristics relevant to safety are known            | No      | ---  | ---         | n/a     |
| 29   | is the device manufactured utilizing materials of animal origin | No      | ---  | ---         | n/a     |

#### C.2.5 Is energy delivered to or extracted from the patient

| [ID] | Reference Question                                                                                                       | Applies | Risk | Probability | Overall |
|------|--------------------------------------------------------------------------------------------------------------------------|---------|------|-------------|---------|
| 30   | Factors that should be considered include the type of energy transferred                                                 | No      | ---  | ---         | n/a     |
| 31   | Factors that should be considered include the type of energy its control                                                 | No      | ---  | ---         | n/a     |
| 32   | Factors that should be considered include the type of energy its quality                                                 | No      | ---  | ---         | n/a     |
| 33   | Factors that should be considered include the type of energy its intensity                                               | No      | ---  | ---         | n/a     |
| 34   | Factors that should be considered include the type of energy its duration                                                | No      | ---  | ---         | n/a     |
| 35   | Factors that should be considered include whether energy levels are higher than those currently used for similar devices | No      | ---  | ---         | n/a     |

#### C.2.6 Are substances delivered to or extracted from the patient

| [ID] | Reference Question                                                                   | Applies | Risk | Probability | Overall |
|------|--------------------------------------------------------------------------------------|---------|------|-------------|---------|
| 36   | Factors that should be considered include whether the substance is delivered         | No      | ---  | ---         | n/a     |
| 37   | Factors that should be considered include whether the substance is extracted         | No      | ---  | ---         | n/a     |
| 38   | Factors that should be considered include whether it is a single substance           | No      | ---  | ---         | n/a     |
| 39   | Factors that should be considered include whether it is a range of substances        | No      | ---  | ---         | n/a     |
| 40   | Factors that should be considered include maximum transfer rates and control thereof | No      | ---  | ---         | n/a     |
| 41   | Factors that should be considered include minimum transfer rates and control thereof | No      | ---  | ---         | n/a     |

#### C.2.7 Are biological materials processed by the medical device for subsequent

| [ID] | Reference Question | Applies | Risk | Probability | Overall |
|------|--------------------|---------|------|-------------|---------|
| 43   | re-use,            | No      | ---  | ---         | n/a     |
| 44   | transfusion        | No      | ---  | ---         | n/a     |
| 45   | transplantation    | No      | ---  | ---         | n/a     |

#### C.2.8 Is the medical device supplied sterile or intended to be sterilized by the user, or are other microbiological controls applicable

| [ID] | Reference Question                                                                              | Applies | Risk | Probability | Overall |
|------|-------------------------------------------------------------------------------------------------|---------|------|-------------|---------|
| 46   | Factors that should be considered include whether the medical device is intended for single use | No      | ---  | ---         | n/a     |

| [ID] | Reference Question                                                                                                   | Applys | Risk | Probability | Overall |
|------|----------------------------------------------------------------------------------------------------------------------|--------|------|-------------|---------|
| 47   | Factors that should be considered include whether the medical device is intended for re-use packaging                | No     | ---  | ---         | n/a     |
| 48   | Factors that should be considered include shelf-life issues                                                          | No     | ---  | ---         | n/a     |
| 49   | Factors that should be considered include limitation on the number of re-use cycles                                  | No     | ---  | ---         | n/a     |
| 50   | Factors that should be considered include method of product sterilization                                            | No     | ---  | ---         | n/a     |
| 51   | Factors that should be considered include the impact of other sterilization methods not intended by the manufacturer | No     | ---  | ---         | n/a     |

#### C.2.9 Is the medical device intended to be routinely cleaned and disinfected by the user

| [ID] | Reference Question                                                                                                                              | Applys | Risk  | Probability | Overall    |
|------|-------------------------------------------------------------------------------------------------------------------------------------------------|--------|-------|-------------|------------|
| 52   | Factors that should be considered include the types of cleaning or disinfecting agents to be used                                               | No     | ---   | ---         | n/a        |
| 53   | Factors that should be considered include any limitations on the number of cleaning cycles.                                                     | No     | ---   | ---         | n/a        |
| 54   | Factors that should be considered include The design of the Medical device can influence the effectiveness of routine cleaning and disinfection | No     | ---   | ---         | n/a        |
| 55   | Factors that should be considered include the effect of cleaning and disinfecting agents on the safety or performance of the device.            | Yes    | Minor | Remote      | Acceptable |

#### D.2 Energy hazards and contributory factors

| [ID] | Reference Question            | Applys | Risk | Probability | Overall |
|------|-------------------------------|--------|------|-------------|---------|
| 222  | Mechanical force              | No     | ---  | ---         | n/a     |
| 223  | Gravity Falling               | No     | ---  | ---         | n/a     |
| 224  | Suspended masses              | No     | ---  | ---         | n/a     |
| 225  | Stored energy                 | No     | ---  | ---         | n/a     |
| 226  | Torsion, Shear & Tensile      | No     | ---  | ---         | n/a     |
| 227  | High Pressure Fluid injection | No     | ---  | ---         | n/a     |
| 230  | Moving parts                  | No     | ---  | ---         | n/a     |
| 231  | Moving & positioning patient  | No     | ---  | ---         | n/a     |
| 232  | Unintended motion             | No     | ---  | ---         | n/a     |
| 233  | Patient support failure       | No     | ---  | ---         | n/a     |
| 234  | Pressure vessel rupture       | No     | ---  | ---         | n/a     |
| 235  | Acoustic pressure             | No     | ---  | ---         | n/a     |
| 236  | Ultrasonic energy             | No     | ---  | ---         | n/a     |
| 237  | Infrasound energy             | No     | ---  | ---         | n/a     |

#### D.3 Toxic hazards and contributory factors

| [ID] | Reference Question | Applys | Risk | Probability | Overall |
|------|--------------------|--------|------|-------------|---------|
| 241  | Bio-contamination  | No     | ---  | ---         | n/a     |
| 242  | Bacteria           | No     | ---  | ---         | n/a     |

| [ID] | Reference Question                         | Applies | Risk | Probability | Overall |
|------|--------------------------------------------|---------|------|-------------|---------|
| 243  | Viruses                                    | No      | ---  | ---         | n/a     |
| 244  | Other agents prions                        | No      | ---  | ---         | n/a     |
| 245  | Bio-incompatibility                        | No      | ---  | ---         | n/a     |
| 246  | Incorrect formulation chemical composition | No      | ---  | ---         | n/a     |
| 247  | Toxicity                                   | No      | ---  | ---         | n/a     |
| 248  | Allergenicity/ irritancy                   | No      | ---  | ---         | n/a     |
| 249  | Mutagenicity                               | No      | ---  | ---         | n/a     |
| 250  | Oncogenicity                               | No      | ---  | ---         | n/a     |
| 251  | Carcinogenicity                            | No      | ---  | ---         | n/a     |
| 252  | Re and/or cross infection                  | No      | ---  | ---         | n/a     |
| 253  | Pyrogenicity                               | No      | ---  | ---         | n/a     |

#### D.3.12 hygienic standards

| [ID] | Reference Question   | Applies | Risk | Probability | Overall |
|------|----------------------|---------|------|-------------|---------|
| 254  | Degradation          | No      | ---  | ---         | n/a     |
| 255  | Chemical             | No      | ---  | ---         | n/a     |
| 256  | Acids or Alkalis     | No      | ---  | ---         | n/a     |
| 257  | Contaminates         | No      | ---  | ---         | n/a     |
| 258  | Processing aids      | No      | ---  | ---         | n/a     |
| 260  | Testing aids         | No      | ---  | ---         | n/a     |
| 261  | Medical gases        | No      | ---  | ---         | n/a     |
| 262  | Anaesthetic products | No      | ---  | ---         | n/a     |

#### D.4 Electromagnetic fields

| [ID] | Reference Question                                         | Applies | Risk | Probability | Overall |
|------|------------------------------------------------------------|---------|------|-------------|---------|
| 268  | Operation outside prescribed environmental conditions      | No      | ---  | ---         | n/a     |
| 270  | Accidental mechanical damage                               | No      | ---  | ---         | n/a     |
| 271  | Contamination due to waste products and/or device disposal | No      | ---  | ---         | n/a     |

#### D.5

| [ID] | Reference Question           | Applies | Risk | Probability | Overall |
|------|------------------------------|---------|------|-------------|---------|
| 274  | Volume                       | No      | ---  | ---         | n/a     |
| 275  | Supply of medical gases      | No      | ---  | ---         | n/a     |
| 276  | Pressure                     | No      | ---  | ---         | n/a     |
| 277  | Supply of anaesthetic agents | No      | ---  | ---         | n/a     |

#### D.6 Hazards related to the use of the medical device and contributory factors

| [ID] | Reference Question                       | Applies | Risk | Probability | Overall |
|------|------------------------------------------|---------|------|-------------|---------|
| 279  | Inadequate operating instructions        | No      | ---  | ---         | n/a     |
| 280  | Inadequate description of performance    | No      | ---  | ---         | n/a     |
| 281  | Inadequate specification of intended use | No      | ---  | ---         | n/a     |

| [ID] | Reference Question                                                      | Applys | Risk | Probability | Overall |
|------|-------------------------------------------------------------------------|--------|------|-------------|---------|
| 282  | Inadequate disclosure of limitations                                    | No     | ---  | ---         | n/a     |
| 283  | Inadequate specification of accessories                                 | No     | ---  | ---         | n/a     |
| 284  | Inadequate specification of pre-use checks                              | No     | ---  | ---         | n/a     |
| 285  | Over-complicated operating instructions                                 | No     | ---  | ---         | n/a     |
| 286  | Inadequate specification of service and maintenance                     | No     | ---  | ---         | n/a     |
| 287  | Use by unskilled / untrained personnel                                  | No     | ---  | ---         | n/a     |
| 288  | Reasonable foreseeable misuse                                           | No     | ---  | ---         | n/a     |
| 289  | Insufficient warning of side effects                                    | No     | ---  | ---         | n/a     |
| 290  | Incorrect measurement and other metrological aspects                    | No     | ---  | ---         | n/a     |
| 291  | Inadequate warnings of hazards likely with re-use of single use devices | No     | ---  | ---         | n/a     |
| 292  | Misrepresentation of results                                            | No     | ---  | ---         | n/a     |
| 293  | Incompatibility with consumables / accessories / other devices          | No     | ---  | ---         | n/a     |
| 294  | Sharp edges or points                                                   | No     | ---  | ---         | n/a     |

#### D.7 Mistakes judgement errors

| [ID] | Reference Question                                                | Applys | Risk | Probability | Overall |
|------|-------------------------------------------------------------------|--------|------|-------------|---------|
| 295  | Mistakes & judgement errors                                       | No     | ---  | ---         | n/a     |
| 296  | Incorrect or inappropriate output or functionality                | No     | ---  | ---         | n/a     |
| 297  | Erroneous data transfer                                           | No     | ---  | ---         | n/a     |
| 298  | Loss or deterioration in function                                 | No     | ---  | ---         | n/a     |
| 301  | Rule based failure                                                | No     | ---  | ---         | n/a     |
| 302  | Knowledge based failure                                           | No     | ---  | ---         | n/a     |
| 303  | Routine violation                                                 | No     | ---  | ---         | n/a     |
| 304  | Violation or abbreviation of instructions, procedures etc         | No     | ---  | ---         | n/a     |
| 308  | Misrepresentation of results                                      | No     | ---  | ---         | n/a     |
| 311  | Controversial modes or mappings as compared to existing equipment | No     | ---  | ---         | n/a     |

#### D.8

| [ID] | Reference Question                                                                                                                                   | Applys | Risk | Probability | Overall |
|------|------------------------------------------------------------------------------------------------------------------------------------------------------|--------|------|-------------|---------|
| 317  | Loss of mechanical integrity                                                                                                                         | No     | ---  | ---         | n/a     |
| 318  | Inadequate packaging contamination and / or deterioration of the device                                                                              | No     | ---  | ---         | n/a     |
| 320  | Deterioration in function gradual occlusion of fluid / gas path or change in resistance to flow, electrical conductivity as a result of repeated use | No     | ---  | ---         | n/a     |

# Risk ISO 14971 : 2012 Summary

Heat Shields Risk Assessment Document Summary Applicable questions

| Reference Question | Applys | Risk       | Risk Probability | Overall Risk | Assessed By | Assessed On | Risk Completed |
|--------------------|--------|------------|------------------|--------------|-------------|-------------|----------------|
| 4                  | Yes    | Minor      | Occasinal        | Acceptable   | John Lamb   | 26/02/14    | Yes            |
| 55                 | Yes    | Minor      | Remote           | Acceptable   | John Lamb   | 26/02/14    | Yes            |
| 56                 | Yes    | Negligible | Improbable       | Acceptable   | John Lamb   | 26/02/14    | Yes            |
| 68                 | Yes    | Minor      | Improbable       | Acceptable   | John Lamb   | 26/02/14    | Yes            |
| 122                | Yes    | Minor      | Remote           | Acceptable   | John Lamb   | 26/02/14    | Yes            |