Tom Thumb

ISO 60601-1

Produced by
Derek Lamb
Date: 20/03/12
Version: 1332256919

4.30 Essential performance
Applicable No
Status
(15/Aug/11 Derek Lamb)

4.40 Expected LIfe
Applicable No
Status
(15/Aug/11 Derek Lamb)

4.50 Equivalent safety for ME equipment & ME systems
Applicable No
Status
(15/Aug/11 Derek Lamb)

4.60 Parts that contact the patient
Applicable No
Status
(15/Aug/11 Derek Lamb)

4.70 Single fault conditions
Applicable No
Status
(15/Aug/11 Derek Lamb)

4.80 Are all components used within their specified ratings
Applicable No
Status
(15/Aug/11 Derek Lamb)

4.90 Are there any Components of high integrity in ME equipment
Applicable No
Status
(15/Aug/11 Derek Lamb)

4.10 Supply mains for ME equipment
Applicable No
Status
(15/Aug/11 Derek Lamb)

4.10.1 Has the instrument an internal supply
Applicable No
Status
(15/Aug/11 Derek Lamb)

4.10.1 Is the instrument connected to an external supply
Applicable No
Status
(15/Aug/11 Derek Lamb)

4.10.1 Is the instrument connected to the mains supply
Applicable No
Status
(15/Aug/11 Derek Lamb)

4.10.1 Source of power for ME equipment
Applicable No
Status
(15/Aug/11 Derek Lamb)

4.11 Power input
Applicable No
Status
(15/Aug/11 Derek Lamb)

5.10 Type tests
Applicable No
Status
(15/Aug/11 Derek Lamb)

5.20 Number of samples
Applicable No
Status
(15/Aug/11 Derek Lamb)

5.30 Ambient Tempearture Humidity Atmospheric pressure
Applicable No
Status
(15/Aug/11 Derek Lamb)

5.40 Other conditions
Applicable No
Status
(15/Aug/11 Derek Lamb)

5.50 Supply votages type of current nature of supply frequency
Applicable No
Status
(15/Aug/11 Derek Lamb)

5.9.2.1 Test Finger
Applicable No
Status
(15/Aug/11 Derek Lamb)

5.9.2.2 Test Hook
Applicable No
Status
(15/Aug/11 Derek Lamb)

5.9.2.3 Actuating mechanisms
Applicable No
Status
(15/Aug/11 Derek Lamb)

6.20 Is the classification Class II
Applicable No
Status
(15/Aug/11 Derek Lamb)

6.20 Is the classification Class I
Applicable No
Status
(15/Aug/11 Derek Lamb)

6.20 Protection against electric shock
Applicable No
Status
(15/Aug/11 Derek Lamb)

6.30 Protection against ingress of water or particulate matter
Applicable No
Status
(15/Aug/11 Derek Lamb)

6.40 Methods of Sterilisation
Applicable No
Status
(15/Aug/11 Derek Lamb)

6.50 Suitability for ude in an Oxygen rich environment
Applicable No
Status
(15/Aug/11 Derek Lamb)

6.60 Mode of operation non continuous
Applicable No
Status
(15/Aug/11 Derek Lamb)

6.60 Mode of operation (continuous or non -continuous)
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.1.1 Usability of the identification marking and documents
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.1.2 Legibility of markings Drawings
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.1.2 Legibility of markings Safety signs
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.1.2 Legibility of markings Instructive statements
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.1.2 Legibility of markings Warning statements
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.1.3 Durability of Marking 15 seconds with a cloth soaked in isopropyl alcohol
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.1.3 Durability of Marking 15 seconds with a cloth soaked in distilled water
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.2.1 Minimum requirements for marking of ME equipment and interchangeable parts
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.2.2 Identification of manufacturer
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.2.3 Is the advisory symbole used
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.2.4 Is packaging marked with a Trademark of manufacturer or supplier
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.2.4 Are Accessories marked with a Trademark of manufacturer or supplier
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.2.5 ME equipment intended to receive power from other equipment
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.2.6 Is label permanent next to connection point
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.2.6 Does label state phase for more than single phase
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.2.6 Does range have between max & min
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.2.6 Connection to the supply mains
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.2.7 Is rating plainly identified in documents
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.2.7 Is mean given if range is >10%
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.2.7 Are upper and lower ratings given for each
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.2.7 Does equipment have several rated voltages
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.2.7 Is wattage under 0.9 watts is rating in volt amps
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.2.7 Is wattage over 0.9 watts is rating in watts
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.2.8.2 Is output frequency rated when applicable
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.2.8.2 Is outputcurrent rated
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.2.8.2 Is output voltage rated
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.2.9 Is the device marked with the correct IP classification
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.2.10 Are Applied parts marked Defibrillator proof
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.2.10 Are Applied parts marked BF
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.2.10 Are Applied parts marked B
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.2.10 Applied parts
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.2.12 Are Fuses marked breaking capacity
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.2.12 Are Fuses marked speed
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.2.12 Are Fuses marked current
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.2.12 Are Fuses marked voltage
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.2.13 Is a warning in documentation
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.2.13 Is a warning sign prominently located
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.2.13 Can the equipment produce non obvious Physiological effects
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.2.14 Are High Voltage terminals marked with symbol
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.2.14 High Voltage terminal devices
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.2.15 Are requirements for Cooling conditions marked
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.2.15 Cooling conditions
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.2.17 Is Protective packaging marked for Hazardous substances
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.2.17 Is Protective packaging marked for Humidity
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.2.17 Is Protective packaging marked for special handling measures in transport
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.2.17 Protective packaging
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.2.18 Is maximum supply pressure from an External pressure source marked adjacent to each inpu
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.2.18 External pressure source
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.2.19 Is Functional earth terminal marked
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.2.20 Removable protective means are they marked "replace"
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.2.20 Removable protective means
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.3 Are maximum power loading of Heaters & Lamps removable without a tool marked near device
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.3.1 Heating elements or lampholders
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.3.2 Is the presence of High Voltage parts marked with symbol
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.3.3 Is the hazard of LIthium batteries or fuel cells marked
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.3.3 Is type of Battery and mode of insertion marked
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.3.3 Batteries
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.3.4 Are Fuses Thermal cutouts and over current releases accessable only by a tool marked
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.3.4 Fuses Thermal cutouts. and over current releases
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.3.5 Is Protective earth terminal marked with symbol on fixed part of equipment
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.3.5 Protective earth terminals
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.3.6 Functional earth terminals
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.3.6a Is Functional earth terminal marked with symbol
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.3.7 Is marking for 3 phase in accordance with IEC 60445
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.3.7 Are terminals exclusively for neutral marked
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.3.7 Are Supply terminals marked adjacent to terminals
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.3.7 Supply termials
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.3.8 Temperature of Supply terminals & compartment must be < 75C
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.3.8 Temperature of Supply terminals
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.40 Are any push momentary switches indicated indicated by other unambiguous means
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.40 Are any push momentary switches indicated by an adjacent indicator light
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.40 Are momentary switches marked with symbol 60417-5011
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.40 Are all push switchesindicated by other unambiguous means
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.40 Are all switches indicated by an adjacent indicator light
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.40 Are all switches Marked
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.40 Do all switches have ON OFF positions
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.4.1 Power switches see 080a-h
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.4.2 Are different positions of Control devices marked by numbers or symbols IEC60417-524
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.4.3 Are Units of measure in SI units ISO31
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.50 Are Safety Signs selected from ISO7010
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.50 Safety Signs
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.6.1 Does an Explanation of symbols appear in the intructions for use
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.6.2 Are Symbols from Annex D used
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.70 Colours of the insulation of conductors
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.7.1 Are all Protective earth conductor identified by Yellow & Green
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.7.1 Is Protective earth conductor Yellow & green throughout its length
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.7.2 Protective earth connections
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.7.3 Are any other wires Green and Yellow insulation
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.7.3 Green and Yellow insulation
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.7.4 Is Neutral conductor coloured light Blue
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.7.4 Neutral conductor
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.7.5 Are colours of Power cord conductors in accordance with IEC60227-1 or IEC 60245-1
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.8.1 Is Colour of Indicator Lights Ready for use Green
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.8.1 Is Colour of Indicator Lights Caution Yellow
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.8.1 Is Colour of Indicator Lights Warning RED
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.8.1 Colours of Indicator Lights
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.82 Is RED used only in emergency
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.82 Colours of controls
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.9.1 General
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.9.2.1 General
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.9.2.2 Do Instructions fo use include warning on multiple socket outlets
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.9.2.2 Do Instructions fo use include risks of interference by EMC
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.9.2.2 Do Instructions fo use include risks of interference by other ME equipment
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.9.2.2 Do Instructions fo use include risks of electric shock & protective earth
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.9.2.2 Do Instructions fo use include Warning and safety notices
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.9.2.3 Is eqipment specified for connection to a separate power supply
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.9.2.3 ME eqipment specified for connection to a separate power supply
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.9.2.4 Is there a warning on loss of power
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.9.2.4 if unit contains a battery are thereinstructions for its replacement
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.9.2.4 if unit contains a battery are there warning to remove battery if not in use for some ti
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.9.2.4 if unit contains a battery are there warning staements for periodic checking or replacer
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.9.2.4 Electrical power source
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.9.2.5 Do Instructions include restrictions on applied parts
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.9.2.5 Do Instructions include restrictions on other equipment and networks etc.
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.9.2.5 Do Instructions include expected materials the operator or patient may be exposed to
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.9.2.5 Do Instructions include expected positions of the operator or patient
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.9.2.5 Do Instructions include physical,and performance characteristics of the equipment
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.9.2.5 Do Instructions include how the equipment functions
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.9.2.5 Do Instructions include a brief description
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.9.2.6 Do instructions containcontact information for persons qualified for Installation
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.9.2.6 Do instructions contain Installation instructions
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.9.2.7 Do Instructions contain instructions on obstruction to disconnection from the supply ma
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.9.2.7 Isolation from the supply mains
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.9.2.8 Do instructions contain A pre-use checklist
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.9.2.8 Do instructions contain information for treatment or handling before use incl. accessori
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.9.2.8 Do instructions contain necessary information for Start up procedure
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.9.2.9 Do Instructions contain information the replacement of materials consumed
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.9.2.9 Do Instructions contain information the connection & disconnection of accessories
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.9.2.9 Do Instructions contain information the connection & disconnection of detachable parts
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.9.2.9 Do Instructions contain information the sequence of operation
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.9.2.9 Do Instructions contain information the function of controls display and signals
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.9.2.9 Do Instructions contain information necessary to operate the equipment
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.9.2.10 Do instructions include an explanation of messages incl. important causes and possible
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.9.2.10 Do instructions include system & error & fault messages
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.9.2.11 Do instructions include Shutdown procedure
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.9.2.12 Do Instructions include Cleaning, disinfection and sterilisation appropiate parameters
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.9.2.12 Do Instructions include Cleaning, disinfection and sterilisation
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.9.2.12 Cleaning disinfection and sterilisation
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.9.2.13 Do Instructions cover rechargeable batteries
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.9.2.13 Do Instructions cover frequency of parts on which preventive maintenance should be perf
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.9.2.13 Do Instructions cover parts on which preventive maintenance should be performed
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.9.2.13 Do Instructions cover routine maintenance
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.9.2.13 Do Instructions cover calibration
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.9.2.13 Do Instructions cover calibration frequency
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.9.2.13 Do Instructions cover preventive maintenance inspection frequency
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.9.2.13 Do Instructions cover preventive maintenance inspection
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.9.2.13 Maintenance
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.9.2.14 Does instructions include information on external power supplies
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.9.2.14 Does instructions include a list of Accessories supplementtary equipment used materia
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.9.2.14 Accessories supplementtary equipment used material
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.9.2.15 Does Instruction contain information on mimimizing these risks
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.9.2.15 Does Instruction contain information on disposal of waste products residues etc
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.9.3 Does Technical description include classifications of equipment
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.9.3 Does Technical description include description of equipment and functions
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.9.3 Does Technical description include warning "If modified appropiate testing is required"
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.9.3 Does Technical description include warning "Do not modify without authorisation"
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.9.3 Does Technical description include warning "No modification allowed"
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.9.3 Does Technical description include information on oil levels
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.9.3 Does Technical description include information on isolating the equipment
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.9.3 Does Technical description include information on cooling liquid chemical composition
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.9.3 Does Technical description include information on cooling liquid flow
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.9.3 Does Technical description include information on cooling liquid pressure
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.9.3 Does Technical description include information on special installation requirements
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.9.3 Does Technical description include information on range,accuracy,and precision of values c
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.9.3 Does Technical description include information on environmental conditions for storage
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.9.3 Does Technical description include information on environmental conditions for transport
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.9.3 Does Technical description include information on environmental conditions for use
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.9.3 Does Technical description include information required in 7.2
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.7.3.2 Does Technical manual include info on replacing special components
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.7.3.2 Does Technical manual include info on replacing of interchangeable & detachable parts
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.7.3.2 Does Technical manual include info on replacing non detachable mains cords
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.7.3.2 Does Technical manual include full rating and type of fuses
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.7.3.2 Replacement of fuses Power supply cords and other parts
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.9.3.3 Are Circuit diagrams, components parts list etc made available in Technical manual.
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.9.3.3 Circuit diagrams, components parts list etc.
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.9.3.4 Does Technical manual describe compliance with 8.11.1
Applicable No
Status
(15/Aug/11 Derek Lamb)

7.9.3.4 Mains isolation
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.10 Will safety be compromised by accidental detachment of conductors and connectors breaking f
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.10 Will safety be compromised by unintended movement of a component
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.10 Will safety be compromised by interuption of any one power carrying conducter between sepa
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.10 Will safety be compromised by interuption of any one supply conductor
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.10 Will safety be compromised by o/c of any one protective earth 8.6l
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.10 Will safety be compromised by s/c and o/c circuit of any componentconnected in parallel
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.10 Will safety be compromised by any one creapage or air clearance complying to 8.9
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.10 Will safety be compromised by short circuit of any one insulation complying to 8.8
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.10 Will safety be compromised by open circuit of any or all earth connections not complying w
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.10 Will safety be compromised by creapage or air clearance not complying with 8.9
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.10 Will safety be compromised by short of any or all insulation not complying with 8.8
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.10 Will safety be compromised by any Transposition of supply connections
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.10 Will safety be compromised by any external voltage or current on the signal input
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.2.1 Has the unit been tested with the correct PSU
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.2.1 Connennection to a separate power sorce
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.2.2 Wil it be hazardous if the polarity of the external psu is reversed
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.2.2 Connection to an external d.c.power source
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.30 If used to deliver electrical energy is Classification of Applied parts BF
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.30 If used in a direct cardiac application is Classification of Applied parts CF
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.40 Can any access covers be removed without the use of a tool
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.40 Can any parts inside be touched with the test pin.
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.40 Do Instructions warn operator about toching the patient and accessable parts eg. fuses, lig
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.40 Does current from to or between patient connections exceeed 8.7.4
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.4.2 Accessible parts including Applied parts
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.4.3 Does voltage between pins of a disconected plug exceed 60v after 1 sec.
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.4.3 ME equipment intended to be connected to a power source by a plug
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.4.4 If automatic discharge is not possible does the capacitor have the symbol IEC60417-5037
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.4.4 Do any capacitive circuits have a residual voltage >60v after de-energising
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.4.4 Internal capacitive circuits
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.5.1 Does the equipment have two Means of protectiom (MOP)
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.5.1.2 Does protective earth comply with 8.6
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.5.1.2 Do creapage distances comply withTable 12
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.5.1.2 Does solid insulation comply with dielectric strength 8.8
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.5.1.2 Means of patient protection (MOP)
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.5.1.3 Do creapage distances comply with Table 13-16 or IEC 60950-1
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.5.1.3 Does solid insulation comply with 8.8 or IEC 60950-1
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.5.1.3 Means of operator protection (MOOP)
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.5.2 Separation of parts
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.5.2.1 Do F-Type Applied parts comply with 8.7.4 and 8.8.3
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.5.2.1 F-Type Applied parts
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.5.5.2 Do Type B Applied Parts comply with 8.7..4 and 8.8.3
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.5.5.2 Type B Applied Parts
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.5.2.3 Test finger application
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.5.2.3 Is air clearance between connector pins and flat surface >0.5mm
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.5.2.3 Can any connector/conductive part come in contact with a 100mm diameter plate
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.5.2.3 Can any connector/conductive part on a patient lead Patient Leads become earthed while
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.5.2.3 Patient Leads
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.5.3 What is aximum mains voltage internally powered 250v max
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.5.3 What is aximum mains voltage polyphase 250v max
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.5.3 What is aximum mains voltage single phase 250v max
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.5.4 If double insulated what is insulation voltage subjected to
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.5.4 Does ripple on DC voltage exceed 10% of average
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.5.4 Working voltage what is the highest measured voltage
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.5.4 Working voltage
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.5.5 Defibrillation-proof Applied parts
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.5.5.1 Defibrillation protection
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.5.5.2 Energy reduction test
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.6 Protective earthing function earthing and potential equalisation of ME
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.6.2 Is Protective earth terminal used as a mechanical connection between parts
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.6.2 Are Protective earth terminal clampscrews insulated
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.6.2 Does Protective earth terminal need a tool to loosen cable clamp
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.6.3 Is Protective earthing used as a moving part
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.6.3 Protective earthing of moving parts
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.6.4 Does Impedance between protective earth and protected earth in mains plug < 100mohm
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.6.4 Does Impedance between protective earth and any earthed part < 100mohm
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.6.4 Does Impedance between protective earth and any appliance inlet earth pin < 100mohm
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.6.4 Impedance and current carrying capability
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.6.5 Are Surface coatings removed at point of contact of protective earth
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.6.7 Does the mains cord incorporate a Potential Equalisation conductor
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.6.7 Does information ona Potential Equalisation conductor appear in the Instruction manual
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.6.7 Is a Potential Equalisation conductor marked with a symbol IEC60417-5021provided
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.6.7 Is a Potential Equalisation terminal used as a protective earth connection
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.6.7 Can the Potential Equalisation conductor be detached without the use of a tool
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.6.7 Is risk of Potential Equalisation accidental disconnection minimised
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.6.7 Is a Potential Equalisation terminal accessible to the operator in any position
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.6.7 Is a Potential Equalisation conductor provided
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.6.8 Is Functional earth terminal used as a protective earth connection
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.6.9 Class II ME Equipment Is there an explanation in the Instruction manual
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.6.9 Class II ME Equipment are there two means of protection
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.6.9 Class II ME Equipment are the insulation screens Green & Yellow
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.6.9 Class II ME Equipment is the earth connected only as a functional earth
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.6.9 Class II ME Equipment
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.7.0 Are Leakage currents and patient auxillary currents limited to 8.7.3
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.7.2 Do allowable values in 8.7.3 apply in Single fault conditions
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.7.2 Single fault conditions
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.7.3 Allowable values 8.7.3b
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.7.4.1 General
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.7.4.2 Measuring supply circuits
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.7.4.3 Connection to the measuring supply circuit
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.7.4.4 Measuring device
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.7.4.5 Measurement of earth leakage
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.7.4.6 Measurement of touch current
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.7.4.7 Measurement of the patient leakage current
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.7.4.8 Measurement of patient auxillary current
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.7.4.9 ME equipment with multiple patient connections
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.8.1 General
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.8.2 Distance through solid insulation or use of thin sheet material Is working voltage <71v
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.8.2 Distance through solid insulation or use of thin sheet material
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.8.3 Dialectric strength
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.8.4 Insulation other than wire insulation
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.8.4.1 Mechanical strength and resistance to heat
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.8.4.2 Resitance to environmental stress
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.9.1.1 General
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.9.1.2 Creepage distance and air clearances complying with IEC 60950-1
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.9.1.3 Crepage distances across glass mica ceramic and similar materials
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.9.1.4 Minimum creepage distance
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.9.1.5 Is equipment rated for high altitutes over 2,000 mtrs
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.9.1.6 Interpolation
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.9.1.7 Material groups classification
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.9.1.8 Pollution degree classification
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.9.1.9 Overvoltage category classification
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.9.1.10 Air clearance for main parts
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.9.1.11 Supply overvaoltage
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.9.1.12 Secondary circuits
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.9.1.13 Peak working voltages above 1400v peak or DC
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.9.1.14 Minimum creapage distance for two means of operator protection
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.9.1.15 Creepage distances & air clearances for defibrillator proof applied parts
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.9.2 Application
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.9.3.1 General
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.9.3.2 Insulating compound forming solid insulation between conductive parts
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.9.3.3 Insulating compound forming a cemented joint with other insulating parts
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.9.3.4 Thermal cycling
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.9.4 Measurement of creepage distances and air clearances
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.10.1 Fixing of components could unwanted movement result in a hazard
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.10.1 Fixing of components
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.10.2 Fixing of wiring, are clamped stranded conductors soldered
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.10.2 Fixing of wiring, could accidental detachment result in a hazard
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.10.2 Fixing of wiring
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.10.3 Connections between different parts of ME equipment
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.10.4.1 Is maximum voltage on cord connected foot switches and held held controls 42.4V peak ac
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.10.5 Are internal cables & wiring protected against contact with a moving part,friction or sha
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.10.5 mechanical protection of wiring
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.10.6 Guiding rollers for insulated conductors
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.10.7 Insulation of internal wiring
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.11.1 Is a fuse or a semiconductor used as an isolating means
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.11.1 Is a switch incorporated in the mains lead
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.11.1 If external is it described in the Instruction manual
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.11.1 Can all circuitry Isolation from the supply mains on all poles simultaneously
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.11.1 Isolation from the supply mains
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.11.1a Subclause
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.11.1b Subclause
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.11.1c Subclause
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.11.1.h Subclause
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.11.1.i Subclause
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.11.2 Do Multiple socket outlets comply with 16.2d and 16.9.2.1
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.11.2 Multiple socket outlets
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.11.3.1 Is the mains plug only fitted with one cord
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.11.3.1 Application
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.11.3.2 Does cord comply with IEC60345-1:2003 Annex A or IEC60227-1:1993 Annex A
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.11.3.2 Types
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.11.3.3 Does Cross-sectional area of supply cord conductors comply with table 17
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.11.3.3 Cross-sectional area of supply cord conductors
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.11.3.4 Do Appliance couplers comply with 8.11.3.5 & 8.11.3.6
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.11.3.5 Does the cord anchorage prevent the cord being pushed into the equipment
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.11.3.5 Is the cord anchorage used to fix any other componenthe cord insulation
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.11.3.5 Is the cord anchorage designed so that a screw bears directly on the cord insulation
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.11.3.5 Is the cord anchorage made from metal but insulatedl
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.11.3.5 Is the cord anchorage made from metal but insulated by a means of protection
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.11.3.5 Is the cord anchorage made from insulating material
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.11.3.5 Is the cord relieved from abrasion
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.11.3.5 Is the cord relieved from twisting
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.11.3.5 Is the cord relieved from strain
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.11.3.5 Cord anchorage
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.11.3.6 Are Cord guards protected against excessive bending at the inlet
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.11.4.1 Are clamps used on external conductors used to fix any other component
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.11.4.1 Are terminals alone used to maintain the conductors in position
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.11.4.2 If a wire escapes is short circuiting of a means of protection likely
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.11.4.2 Are terminals accessible without the aisd of a tool
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.11.4.2 Are terminals marked 7.3
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.11.4.2 Are terminals for re-wirable cords grouped together for convenient connection
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.11.4.2 Arrangement for main Terminal devices
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.11.4.3 Is internal wiring subject to stress when the conductors are tightened or loosened
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.11.4.3 Fixing of mains terminals
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.11.4.4 Connections to mains terminals with clamping require special preparation of conductors
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.11.4.5 Accessibility of the connection
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.11.5 Is there adequate room to allow the conductors to be easily connected 8.10.5
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.11.5 is a Mains fuse or over current release in each supply lead
Applicable No
Status
(15/Aug/11 Derek Lamb)

8.11.6 Cross sectional area of Internal wiring of the mains part
Applicable No
Status
(15/Aug/11 Derek Lamb)

9.1 Mechanical hazards of ME equipment & systems
Applicable No
Status
(15/Aug/11 Derek Lamb)

9.2.1 General
Applicable No
Status
(15/Aug/11 Derek Lamb)

9.2.2.2 Do Gaps comply with Table 20
Applicable No
Status
(15/Aug/11 Derek Lamb)

9.2.2.3 Safe distance
Applicable No
Status
(15/Aug/11 Derek Lamb)

9.2.2.4.1 Access to trapping zone 15.3
Applicable No
Status
(15/Aug/11 Derek Lamb)

9.2.2.4.1 Access to trapping zone
Applicable No
Status
(15/Aug/11 Derek Lamb)

9.2.2.4.2 can Fixed guards be dismantled without a tool
Applicable No
Status
(15/Aug/11 Derek Lamb)

9.2.2.4.2 Fixed guards
Applicable No
Status
(15/Aug/11 Derek Lamb)

9.2.2.4.3 Is there an interlocking device preventing starting and stops.
Applicable No
Status
(15/Aug/11 Derek Lamb)

9.2.2.4.3 Do Movable guards remain attacfhed when guard is open
Applicable No
Status
(15/Aug/11 Derek Lamb)

9.2.2.5 Continuous activation
Applicable No
Status
(15/Aug/11 Derek Lamb)

9.2.2.6 Speed of movements
Applicable No
Status
(15/Aug/11 Derek Lamb)

9.2.3.1 Unintended movement
Applicable No
Status
(15/Aug/11 Derek Lamb)

9.2.3.2 Overtravel
Applicable No
Status
(15/Aug/11 Derek Lamb)

9.2.4 Emergency stopping devices
Applicable No
Status
(15/Aug/11 Derek Lamb)

9.30 Are there any Hazards associated with surfaces corners and edges
Applicable No
Status
(15/Aug/11 Derek Lamb)

9.4.2.1 Instability in transport position
Applicable No
Status
(15/Aug/11 Derek Lamb)

9.4.2.2 Instability excluding transport
Applicable No
Status
(15/Aug/11 Derek Lamb)

9.4.2.3 Instability form horizontal and vertical forces
Applicable No
Status
(15/Aug/11 Derek Lamb)

9.4.2.4 Castors and wheels
Applicable No
Status
(15/Aug/11 Derek Lamb)

9.4.2.4.2 Forces of propulsion
Applicable No
Status
(15/Aug/11 Derek Lamb)

9.4.2.4.3 Movement over a threshold
Applicable No
Status
(15/Aug/11 Derek Lamb)

9.4.3 Instability from unwanted lateral movement (including sliding)
Applicable No
Status
(15/Aug/11 Derek Lamb)

9.4.3.2 Instability excluding transport
Applicable No
Status
(15/Aug/11 Derek Lamb)

9.4.4 Grips and other handling devices
Applicable No
Status
(15/Aug/11 Derek Lamb)

9.5.1 Protective means
Applicable No
Status
(15/Aug/11 Derek Lamb)

9.5.2 Cathode ray tubes
Applicable No
Status
(15/Aug/11 Derek Lamb)

9.6.1 General
Applicable No
Status
(15/Aug/11 Derek Lamb)

9.6.2 Acoustic energy
Applicable No
Status
(15/Aug/11 Derek Lamb)

9.6.2.1 Audible Acoustic energy
Applicable No
Status
(15/Aug/11 Derek Lamb)

9.6.2.2 Infrasound & ultrasound energy
Applicable No
Status
(15/Aug/11 Derek Lamb)

9.6.3 Hand Transmitted Vibration
Applicable No
Status
(15/Aug/11 Derek Lamb)

9.7.2 Pneumatic & hydraulic parts
Applicable No
Status
(15/Aug/11 Derek Lamb)

9.7.3 Maximum pressure
Applicable No
Status
(15/Aug/11 Derek Lamb)

9.7.4 Pressure rating of ME Equipment parts
Applicable No
Status
(15/Aug/11 Derek Lamb)

9.7.6 Pressure control devices
Applicable No
Status
(15/Aug/11 Derek Lamb)

9.7.7 Pressure relief device
Applicable No
Status
(15/Aug/11 Derek Lamb)

9.8 Hazards associated with support systems
Applicable No
Status
(15/Aug/11 Derek Lamb)

9.8.1 General
Applicable No
Status
(15/Aug/11 Derek Lamb)

9.8.2 Tensile Safety factor
Applicable No
Status
(15/Aug/11 Derek Lamb)

9.8.3.2 Static forces due to loading from persons
Applicable No
Status
(15/Aug/11 Derek Lamb)

9.8.3.3 Dynamic forces due to loading from persons
Applicable No
Status
(15/Aug/11 Derek Lamb)

9.8.4.2 Use after activation of a mechanical protective device
Applicable No
Status
(15/Aug/11 Derek Lamb)

9.8.4.3 Mechanical protective device intended for single activation
Applicable No
Status
(15/Aug/11 Derek Lamb)

9.8.5 Systems with mechanical protective devices
Applicable No
Status
(15/Aug/11 Derek Lamb)

10.1.1 ME equipment not intended to produce diagnostic or therapeutic X-radiation
Applicable No
Status
(15/Aug/11 Derek Lamb)

10.1.2 ME equipment intended to produce diagnostic or therapeutic X-radiation
Applicable No
Status
(15/Aug/11 Derek Lamb)

10.2 Alpha,Beta,gama.neutron and other particle radiation
Applicable No
Status
(15/Aug/11 Derek Lamb)

10.3 Microwave radiation
Applicable No
Status
(15/Aug/11 Derek Lamb)

10.4 Lasers and LEDs
Applicable No
Status
(15/Aug/11 Derek Lamb)

10.5 Other visible electromagnetic radiation
Applicable No
Status
(15/Aug/11 Derek Lamb)

10.6 Infrared radiation
Applicable No
Status
(15/Aug/11 Derek Lamb)

10.7 Ultraviolet radiation
Applicable No
Status
(15/Aug/11 Derek Lamb)

10.7 Ultraviolet radiation
Applicable No
Status
(15/Aug/11 Derek Lamb)

11.1.1 Maximum temperature during normal use
Applicable No
Status
(15/Aug/11 Derek Lamb)

11.1.2 Temperature of applied parts
Applicable No
Status
(15/Aug/11 Derek Lamb)

11.1.2.2 Applied parts not intended to supply heat to a patient
Applicable No
Status
(15/Aug/11 Derek Lamb)

11.1.4 Are Guards only removable with a tool
Applicable No
Status
(15/Aug/11 Derek Lamb)

11.2.1 Do enclosures have Strength and rigidity to prevent fire in ME equipment
Applicable No
Status
(15/Aug/11 Derek Lamb)

11.2.2.1 Risk of fire in an oxygen rich environment
Applicable No
Status
(15/Aug/11 Derek Lamb)

11.2.2.1a Subclause
Applicable No
Status
(15/Aug/11 Derek Lamb)

11.2.2.1b 2 Subclause
Applicable No
Status
(15/Aug/11 Derek Lamb)

11.2.2.1b 3 Subclause
Applicable No
Status
(15/Aug/11 Derek Lamb)

11.2.2.2. Are External exhausts for oxygen rich environment located so that a risk of ignition
Applicable No
Status
(15/Aug/11 Derek Lamb)

11.2.2.2. External exhausts for oxygen rich environment
Applicable No
Status
(15/Aug/11 Derek Lamb)

11.2.2.3 Electrical connections in oxygen rich environments
Applicable No
Status
(15/Aug/11 Derek Lamb)

11.2.3 Would failure of insulation be detremental
Applicable No
Status
(15/Aug/11 Derek Lamb)

11.2.3 Would failure of a pneumatic component be detremental
Applicable No
Status
(15/Aug/11 Derek Lamb)

11.2.3 Would failure of a component be detremental
Applicable No
Status
(15/Aug/11 Derek Lamb)

11.2.3 Would failure of a barrier be detremental
Applicable No
Status
(15/Aug/11 Derek Lamb)

11.2.3 Would failure of a ventilation sytemem be detremental
Applicable No
Status
(15/Aug/11 Derek Lamb)

11.2.3 Single fault conditions related to oxygen rich environments
Applicable No
Status
(15/Aug/11 Derek Lamb)

11.30 Are insulated wires classified to FV-1
Applicable No
Status
(15/Aug/11 Derek Lamb)

11.30 Are connectors pcbs insulating component mounts classified to FV-2
Applicable No
Status
(15/Aug/11 Derek Lamb)

11.30 Constructional requirement for fire enclosures of ME equipment
Applicable No
Status
(15/Aug/11 Derek Lamb)

11.40 Is the Me equipment & ME systems intended for use with flammable anaesthetics
Applicable No
Status
(15/Aug/11 Derek Lamb)

11.40 Me equipment & ME systems intended for use with flammable anaesthetics
Applicable No
Status
(15/Aug/11 Derek Lamb)

11.50 Is the Me equipment & ME systems intended for use with flammable agents
Applicable No
Status
(15/Aug/11 Derek Lamb)

11.6 Does the equipment incorporate a reservoir or liquid storage chamber
Applicable No
Status
(15/Aug/11 Derek Lamb)

11.6.1 General
Applicable No
Status
(15/Aug/11 Derek Lamb)

11.6.2 Can overfill or Overflow in ME equipment cause a hazard
Applicable No
Status
(15/Aug/11 Derek Lamb)

11.6.2 Overflow in ME equipment
Applicable No
Status
(15/Aug/11 Derek Lamb)

11.6.3 Spillage on ME Equipment wet parts that could cause a hazard
Applicable No
Status
(15/Aug/11 Derek Lamb)

11.6.3 Spillage on ME Equipment
Applicable No
Status
(15/Aug/11 Derek Lamb)

11.6.5 Can Ingress of water and particulate matter into ME equipment be hazardous
Applicable No
Status
(15/Aug/11 Derek Lamb)

11.6.6 Will Cleaning and disinfection of ME equipment cause damage (see 7.9.1.12)
Applicable No
Status
(15/Aug/11 Derek Lamb)

11.6.7 Will Sterilisation of ME equipment and ME systems cause damage ISO11134/35/37
Applicable No
Status
(15/Aug/11 Derek Lamb)

11.6.7 Sterilisation of ME equipment and ME systems
Applicable No
Status
(15/Aug/11 Derek Lamb)

11.6.8 Compatibility with substances used with ME equipment
Applicable No
Status
(15/Aug/11 Derek Lamb)

11.7. Biocompatibility of ME equipment & ME systems
Applicable No
Status
(15/Aug/11 Derek Lamb)

11.80 Will Interuption of the power supply/supply mains to ME equipment cause a hazard
Applicable No
Status
(15/Aug/11 Derek Lamb)

12.1 Accuracy of controls & instruments
Applicable No
Status
(15/Aug/11 Derek Lamb)

12.2 Useability
Applicable No
Status
(15/Aug/11 Derek Lamb)

12.3 Alarm system
Applicable No
Status
(15/Aug/11 Derek Lamb)

12.4.1 Intentional exceeding of safety limits
Applicable No
Status
(15/Aug/11 Derek Lamb)

12.4.2 Indication of parameters relevant to safety
Applicable No
Status
(15/Aug/11 Derek Lamb)

12.4.3 Can Accidental selection of excessive output values acuse a hazard
Applicable No
Status
(15/Aug/11 Derek Lamb)

12.4.3 Does equipment have High intensity and low intensity outputs
Applicable No
Status
(15/Aug/11 Derek Lamb)

12.4.3 Accidental selection of excessive output values
Applicable No
Status
(15/Aug/11 Derek Lamb)

12.4.4 Incorrect output
Applicable No
Status
(15/Aug/11 Derek Lamb)

12.4.5.1 Limits
Applicable No
Status
(15/Aug/11 Derek Lamb)

12.4.5.2 Diagnostic X-ray equipment
Applicable No
Status
(15/Aug/11 Derek Lamb)

12.4.5.3 Radiotheraphy equipment
Applicable No
Status
(15/Aug/11 Derek Lamb)

12.4.5.4 Other ME equipment producing diagnostic or therapeutic radiation
Applicable No
Status
(15/Aug/11 Derek Lamb)

12.4.6 Diagnostic or therapeutic acoustic pressure
Applicable No
Status
(15/Aug/11 Derek Lamb)

13.1.1 Can the failure of any one component result in a hazardous situation
Applicable No
Status
(15/Aug/11 Derek Lamb)

13.1.1 General
Applicable No
Status
(15/Aug/11 Derek Lamb)

13.1.2 Can temperatures of other components exceed the allowed values in Table 26/27/31/22
Applicable No
Status
(15/Aug/11 Derek Lamb)

13.1.2 Can temperatures of non applied parts exceed the allowed values in Table 23
Applicable No
Status
(15/Aug/11 Derek Lamb)

13.1.2 Can temperatures of applied parts exceed the allowed values in Table 24
Applicable No
Status
(15/Aug/11 Derek Lamb)

13.1.2 Can deformation of enclosures impair 15.3.1
Applicable No
Status
(15/Aug/11 Derek Lamb)

13.1.2 Emissions, deformation or exceeding maximum temperature
Applicable No
Status
(15/Aug/11 Derek Lamb)

13.1.2 Can Emissions of flames,molten metal,poisonous or igniable substances in hazardous quanti
Applicable No
Status
(15/Aug/11 Derek Lamb)

13.1.3 Exceeding leakage current or voltage limits see 8.7.3. & 8.4.2
Applicable No
Status
(15/Aug/11 Derek Lamb)

13.1.3 Exceeding leakage current or voltage limits
Applicable No
Status
(15/Aug/11 Derek Lamb)

13.2.6 Leakage of liquid
Applicable No
Status
(15/Aug/11 Derek Lamb)

13.2.7 Can blocking of filters result in hazard
Applicable No
Status
(15/Aug/11 Derek Lamb)

13.2.7 Can interuption of flow of cooling fluid result in hazard
Applicable No
Status
(15/Aug/11 Derek Lamb)

13.2.7 Can Impairment of ventilation through covering of openings etc result in hazard
Applicable No
Status
(15/Aug/11 Derek Lamb)

13.2.8 Are moving parts or Applied parts likely to be operated while unattended
Applicable No
Status
(15/Aug/11 Derek Lamb)

13.2.8 Has one or more motors with a locked rotor torque smaller than the full load torque
Applicable No
Status
(15/Aug/11 Derek Lamb)

13.2.8 Are moving parts or Applied parts likely to jam
Applicable No
Status
(15/Aug/11 Derek Lamb)

13.2.8 Locking of moving parts
Applicable No
Status
(15/Aug/11 Derek Lamb)

13.2.9 Is equipment single fault safe during short circuiting & open circuiting of motor capaci
Applicable No
Status
(15/Aug/11 Derek Lamb)

13.2.9 Interuption and short circuiting of motor capacitors
Applicable No
Status
(15/Aug/11 Derek Lamb)

13.2.10 Additional test criteria for motor operated ME Equipment see 13.2.8 & 13.2.9 and 13.1.2
Applicable No
Status
(15/Aug/11 Derek Lamb)

13.2.10 Additional test criteria for motor operated ME Equipment
Applicable No
Status
(15/Aug/11 Derek Lamb)

13.2.13.1 General overload test conditions
Applicable No
Status
(15/Aug/11 Derek Lamb)

13.2.13.2 Me equipment with heating elements
Applicable No
Status
(15/Aug/11 Derek Lamb)

13.2.13.3 Me equipment with motors
Applicable No
Status
(15/Aug/11 Derek Lamb)

13.2.13..4 Me equipmet rated for non continuos operation
Applicable No
Status
(15/Aug/11 Derek Lamb)

14.20 Documentation
Applicable No
Status
(15/Aug/11 Derek Lamb)

14.30 Risk management plan
Applicable No
Status
(15/Aug/11 Derek Lamb)

14.40 PEMS development cycle
Applicable No
Status
(15/Aug/11 Derek Lamb)

14.50 Does a problem resolution system exist
Applicable No
Status
(15/Aug/11 Derek Lamb)

14.6.2 Risk control
Applicable No
Status
(15/Aug/11 Derek Lamb)

14.70 Does system have a specification
Applicable No
Status
(15/Aug/11 Derek Lamb)

14.70 Requirement specification
Applicable No
Status
(15/Aug/11 Derek Lamb)

14.80 Does system have NETWORK/DATA COUPLING specification
Applicable No
Status
(15/Aug/11 Derek Lamb)

14.80 Does system have maintainability,
Applicable No
Status
(15/Aug/11 Derek Lamb)

14.80 Does system have protection from reasonably foreseeable misuse
Applicable No
Status
(15/Aug/11 Derek Lamb)

14.80 Does system have test interval duration and diagnostic coverage
Applicable No
Status
(15/Aug/11 Derek Lamb)

14.80 Does system have allocation of RISK CONTROL measures to subsystems and components of the F
Applicable No
Status
(15/Aug/11 Derek Lamb)

14.80 Does system have defensive design
Applicable No
Status
(15/Aug/11 Derek Lamb)

14.80 Does system have diversity
Applicable No
Status
(15/Aug/11 Derek Lamb)

14.80 Does system have partitioning of functionality;
Applicable No
Status
(15/Aug/11 Derek Lamb)

14.80 Does system have redundancy
Applicable No
Status
(15/Aug/11 Derek Lamb)

14.80 Does system have fail-safe functions
Applicable No
Status
(15/Aug/11 Derek Lamb)

14.80 Does system have COMPONENTS WTH HIGH-INTEGRITY CHARACTERISTICS;
Applicable No
Status
(15/Aug/11 Derek Lamb)

14.80 Architecture
Applicable No
Status
(15/Aug/11 Derek Lamb)

14.90 Desing and implementation
Applicable No
Status
(15/Aug/11 Derek Lamb)

14.10 Does a Verification plan exist
Applicable No
Status
(15/Aug/11 Derek Lamb)

14.11 Does a PEMS validation exist
Applicable No
Status
(15/Aug/11 Derek Lamb)

14.12 Modification
Applicable No
Status
(15/Aug/11 Derek Lamb)

14.13 Are Connection of PEMS by Network/data coupling to other equipment specified
Applicable No
Status
(15/Aug/11 Derek Lamb)

14.13 Connection of PEMS by Network/data coupling to other equipment
Applicable No
Status
(15/Aug/11 Derek Lamb)

15.10 Arrangement of controls and indicators of ME equipment
Applicable No
Status
(15/Aug/11 Derek Lamb)

15.20 Are replaceable parts easily inspected Serviceability
Applicable No
Status
(15/Aug/11 Derek Lamb)

15.30 Does Mechanical Strength comply with Table 28
Applicable No
Status
(15/Aug/11 Derek Lamb)

15.3.1 General
Applicable No
Status
(15/Aug/11 Derek Lamb)

15.3.2 Does equipment comply with Push test
Applicable No
Status
(15/Aug/11 Derek Lamb)

15.3.3 Does equipment comply with Impact test
Applicable No
Status
(15/Aug/11 Derek Lamb)

15.3.4 Does equipment comply with Drop Test
Applicable No
Status
(15/Aug/11 Derek Lamb)

15.3.4.1 Does Hand held ME equipment comply with free fall test
Applicable No
Status
(15/Aug/11 Derek Lamb)

15.3.4.1 Hand held ME equipment
Applicable No
Status
(15/Aug/11 Derek Lamb)

15.3.4.2 Does Portable ME equipment comply with free fall test
Applicable No
Status
(15/Aug/11 Derek Lamb)

15.3.4.2 Portable ME equipment
Applicable No
Status
(15/Aug/11 Derek Lamb)

15.3.5 Does equipment comply with Rough handling test
Applicable No
Status
(15/Aug/11 Derek Lamb)

15.3.5 Rough handling test
Applicable No
Status
(15/Aug/11 Derek Lamb)

15.3.6 Does equipment comply with Mould stress test
Applicable No
Status
(15/Aug/11 Derek Lamb)

15.3.6 Mould stress test
Applicable No
Status
(15/Aug/11 Derek Lamb)

15.3.7 Have all materials been taken into for Environmental influences
Applicable No
Status
(15/Aug/11 Derek Lamb)

15.4.1 Can connectors be be incorrectly connected to otheroutlets with other functions
Applicable No
Status
(15/Aug/11 Derek Lamb)

15.4.2.1 Do tubular heating elements have protection against overheating
Applicable No
Status
(15/Aug/11 Derek Lamb)

15.4.2.1 Does the equipment incorporate a fluid container and is it protected against overheati
Applicable No
Status
(15/Aug/11 Derek Lamb)

15.4.2.1 Do cut outs affect the safety of the equipment
Applicable No
Status
(15/Aug/11 Derek Lamb)

15.4.2.1 Are there any capacitors or spark supptression devices across cut outs
Applicable No
Status
(15/Aug/11 Derek Lamb)

15.4.2.1 Will loss of functuion due to non self restable cut outs cause a hazard
Applicable No
Status
(15/Aug/11 Derek Lamb)

15.4.2.1 Are restable non self restable cut outs used in addition to Thermostats
Applicable No
Status
(15/Aug/11 Derek Lamb)

15.4.2.1 Are cut outs automatically reset
Applicable No
Status
(15/Aug/11 Derek Lamb)

15.4.2.1 Are cut outs reset by a soldering operation
Applicable No
Status
(15/Aug/11 Derek Lamb)

15.4.2.1 Application
Applicable No
Status
(15/Aug/11 Derek Lamb)

15.4.2.2 Is Temperature setting clearly indicated
Applicable No
Status
(15/Aug/11 Derek Lamb)

15.4.3.1 Is there a possibility of accidental short circuits
Applicable No
Status
(15/Aug/11 Derek Lamb)

15.4.3.1 Is there a possibility of gas build up during charge and discharge Housing
Applicable No
Status
(15/Aug/11 Derek Lamb)

15.4.3.1 Housing
Applicable No
Status
(15/Aug/11 Derek Lamb)

15.4.3.2 Can incorrect connection or reversal of polarity cause a hazard
Applicable No
Status
(15/Aug/11 Derek Lamb)

15.4.3.2 Connection
Applicable No
Status
(15/Aug/11 Derek Lamb)

15.4.3.3 Is Protection against overcharging employed
Applicable No
Status
(15/Aug/11 Derek Lamb)

15.4.3.4 Do Lithium batteries comply with IEC600086-4   (7.3.3
Applicable No
Status
(15/Aug/11 Derek Lamb)

15.4.3.4 Lithium batteries
Applicable No
Status
(15/Aug/11 Derek Lamb)

15.4.3.5 Is internally power source protected against Excessive current and votlage protection
Applicable No
Status
(15/Aug/11 Derek Lamb)

15.4.4 Are indicators used when equipment is charging
Applicable No
Status
(15/Aug/11 Derek Lamb)

15.4.4 Do separate Indicators indicate no luminous heaters are operational
Applicable No
Status
(15/Aug/11 Derek Lamb)

15.4.4 Are indicators used when an output exists where prolonged or accidental operation is a ha
Applicable No
Status
(15/Aug/11 Derek Lamb)

15.4.4 Do Indicators indicate ready for use
Applicable No
Status
(15/Aug/11 Derek Lamb)

15.4.4 Do separate Indicators indicate warm up state
Applicable No
Status
(15/Aug/11 Derek Lamb)

15.4.4 Indicators
Applicable No
Status
(15/Aug/11 Derek Lamb)

15.4.5 Preset controls
Applicable No
Status
(15/Aug/11 Derek Lamb)

15.4.6.1 Does disconnection of indicating device need a tool
Applicable No
Status
(15/Aug/11 Derek Lamb)

15.4.6.1 Are all controls corresponding to scale at all times
Applicable No
Status
(15/Aug/11 Derek Lamb)

15.4.6.1 Are all actuating parts secured so they cannot be pulled off or work loose
Applicable No
Status
(15/Aug/11 Derek Lamb)

15.4.6.2 Are stops of adequate mechanical strength
Applicable No
Status
(15/Aug/11 Derek Lamb)

15.4.6.2 Limitation of movement
Applicable No
Status
(15/Aug/11 Derek Lamb)

15.4.7.1 Does hand-held devices comply with 15.3.4.1
Applicable No
Status
(15/Aug/11 Derek Lamb)

15.4.7.1 Will Foot-operated devices support the weight of an adult
Applicable No
Status
(15/Aug/11 Derek Lamb)

15.4.7.2 Accidental operation of ME equipment
Applicable No
Status
(15/Aug/11 Derek Lamb)

15.4.7.3 Entry of liquids
Applicable No
Status
(15/Aug/11 Derek Lamb)

15.4.8 Are any Aluminium wires less than 16mm cross section used in Internal wiring of ME Equipr
Applicable No
Status
(15/Aug/11 Derek Lamb)

15.4.9 Are partially sealed Oil containers provided with an oil level check
Applicable No
Status
(15/Aug/11 Derek Lamb)

15.4.9 Oil containers in mobile equipment fitted with a pressure release device
Applicable No
Status
(15/Aug/11 Derek Lamb)

15.4.9 Oil containers in mobile equipment sealed to prevent leakage
Applicable No
Status
(15/Aug/11 Derek Lamb)

15.4.9 Are Oil containers in portable equipment adequately sealed to prevent loss of oil in any
Applicable No
Status
(15/Aug/11 Derek Lamb)

15.5.1.1 Are Transformers protected against overheating in event of short circiut or overload
Applicable No
Status
(15/Aug/11 Derek Lamb)

15.5.1.1 Transformers
Applicable No
Status
(15/Aug/11 Derek Lamb)

15.5.1.2 Short circuit test
Applicable No
Status
(15/Aug/11 Derek Lamb)

15.5.1.3 Overload test
Applicable No
Status
(15/Aug/11 Derek Lamb)

15.5.2 Do tranformer windings have adequate Dielectric strength
Applicable No
Status
(15/Aug/11 Derek Lamb)

15.5.2 Dielectric strength
Applicable No
Status
(15/Aug/11 Derek Lamb)

15.5.3 Construction of transformers used to provide separation as req by (8.5)
Applicable No
Status
(15/Aug/11 Derek Lamb)

16.10 General requirements for the ME systems
Applicable No
Status
(15/Aug/11 Derek Lamb)

16.20 Accompanying documents of an ME system
Applicable No
Status
(15/Aug/11 Derek Lamb)

16.30 Power supply
Applicable No
Status
(15/Aug/11 Derek Lamb)

16.40 Enclosures
Applicable No
Status
(15/Aug/11 Derek Lamb)

16.50 Separation devices
Applicable No
Status
(15/Aug/11 Derek Lamb)

16.6.1 Touch current
Applicable No
Status
(15/Aug/11 Derek Lamb)

16.6.2 Earth leakage current of multiple socket output
Applicable No
Status
(15/Aug/11 Derek Lamb)

16.6.3 Patient leakage current
Applicable No
Status
(15/Aug/11 Derek Lamb)

16.6.4.1 General condition for ME systems
Applicable No
Status
(15/Aug/11 Derek Lamb)

16.6.4.2 Connection of the ME system to the measuring supply circuit
Applicable No
Status
(15/Aug/11 Derek Lamb)

16.70 Protection against mechanical hazards
Applicable No
Status
(15/Aug/11 Derek Lamb)

16.9.1 Connection terminals and connectors
Applicable No
Status
(15/Aug/11 Derek Lamb)

16.9.2.1 Multiple socket outlet
Applicable No
Status
(15/Aug/11 Derek Lamb)

16.9.2.3 Protection of conductors
Applicable No
Status
(15/Aug/11 Derek Lamb)

17.00 Electromagnetic compatibility of ME equipment and ME systems
Applicable No
Status
(15/Aug/11 Derek Lamb)
