Post market surveillance risk assesment re-evaluation

Vandagraph VST Sensors

Carried out by Derek Lamb
13 / 10 / 17

VIAMED

- Stock References Review
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Stock References Review

Stock Reference	Description
8000004	Cable assembly for oxygen sensor 8010004
8010000	Oxygen Sensor - VST2200
8010001	Oxygen Sensor - APD5
8010002	Oxygen Sensor - APD11
8010002	Oxygen Sensor - APD11
8010003	Oxygen Sensor - VR1700
8010004	Oxygen Sensor - R17JJ-CCR
8010005	Oxygen Sensor - VST1700
8010006	Oxygen Sensor - rEvo CR22D
8010006	Oxygen Sensor - rEvo CR22D
8010007	Oxygen Sensor - NaNS01
8010007	Oxygen Sensor - NaNS01
8010008	Oxygen Sensor - NaNM01
8010008	Oxygen Sensor - NaNM01
8010009	Oxygen Sensor - VST1200
8010009	Oxygen Sensor - VST1200
8010010	Oxygen Sensor - RBL-23D
8010011	Oxygen Sensor - VR2200
8010011	Oxygen Sensor - VR2200
8010012	Oxygen Sensor - SC-I22D
8010012	Oxygen Sensor - SC-I22D
8010014	Oxygen Sensor - K-22D
8010015	Oxygen Sensor - UDT-22
8010016	Oxygen Sensor - Hammerhead HH22
8010017	Oxygen Sensor - VMS1700
8010018	Oxygen Sensor - Triton T22D
8010019	Oxygen Sensor - SG-22
8010019	Oxygen Sensor - SG-22
8010020	Oxygen Sensor - type 22D
8010020	Oxygen Sensor - type 22D
8010021	Oxygen Sensor - DST-2200
8010022	Oxygen Sensor - APD16
8010023	Oxygen Sensor - APD8
8010023	Oxygen Sensor - APD8
8010024	Oxygen Sensor - UDT-24
8010025	Oxygen Sensor -
8010026	Oxygen Sensor -
8010030	Oxygen Sensor - VST1703D
8010031	Oxygen Sensor - VST1704D
8010032	Oxygen Sensor - VST2200D
8010050	Oxygen Sensor - JFD (non-mag).
8010051	Oxygen Sensor - Avon (non-mag).

Comments on Stock references review:

added newer sensors to list, including the under development / review products

Supplier Review

Stock Ref.	Description	Supplier A/C	Supplier P/N	Supplier Name	Rating
8010000	Oxygen Sensor - VST2200	00007282	1001570	EnviteC-Wismar GmbH	A
8010001	Oxygen Sensor - APD5	00007282	1001570	EnviteC-Wismar GmbH	A
8010002	Oxygen Sensor - APD11	00007282	1001581	EnviteC-Wismar GmbH	A
8010003	Oxygen Sensor - VR1700	00007282	1001580	EnviteC-Wismar GmbH	A
8010004	Oxygen Sensor - R17JJ-CC	00007282	1001721	EnviteC-Wismar GmbH	A
8010005	Oxygen Sensor - VST1700	00007282	1001580	EnviteC-Wismar GmbH	A
8010006	Oxygen Sensor - rEvo CR2	00007282	1001570	EnviteC-Wismar GmbH	A
8010007	Oxygen Sensor - NaNS01	00007282	1001581	EnviteC-Wismar GmbH	A
8010008	Oxygen Sensor - NaNM01	00007282	1001570	EnviteC-Wismar GmbH	A
8010010	Oxygen Sensor - RBL-23D	00007282	1001930	EnviteC-Wismar GmbH	A
8010012	Oxygen Sensor - SC-I22D	00007282	1002106	EnviteC-Wismar GmbH	A
8010014	Oxygen Sensor - K-22D	00007282	1001570	EnviteC-Wismar GmbH	A
8010015	Oxygen Sensor - UDT-22	00007282	1001570	EnviteC-Wismar GmbH	A
8010016	Oxygen Sensor - Hammerhe	00007282	1002305	EnviteC-Wismar GmbH	A
8010017	Oxygen Sensor - VMS1700	00007282	1001580	EnviteC-Wismar GmbH	A
8010018	Oxygen Sensor - Triton T	00007282	1001570	EnviteC-Wismar GmbH	A
8010019	Oxygen Sensor - SG-22	00007282	1001570	EnviteC-Wismar GmbH	A
8010020	Oxygen Sensor - type 22D	00007282	1001570	EnviteC-Wismar GmbH	A
8010021	Oxygen Sensor - DST-2200	00007282	1001570	EnviteC-Wismar GmbH	A
8010022	Oxygen Sensor - APD16	00007282	1002226	EnviteC-Wismar GmbH	A
8010023	Oxygen Sensor - APD8	00007282	1002225	EnviteC-Wismar GmbH	A
8010024	Oxygen Sensor - UDT-24	00007282	1002289	EnviteC-Wismar GmbH	A
8010030	Oxygen Sensor - VST1703D	00007282		EnviteC-Wismar GmbH	A
8010031	Oxygen Sensor - VST1704D	00007282		EnviteC-Wismar GmbH	A
8010032	Oxygen Sensor - VST2200D	00007282		EnviteC-Wismar GmbH	A
8010050	Oxygen Sensor - JFD (non	00007282	1002461	EnviteC-Wismar GmbH	A
8000004	Cable assembly for oxyge	0009192	8000004		Needs Grading

Comments on Suppliers:

Envitec one of the most reliable viamed supppliers, and is just as efficient with regard VST sensors

Sales Information

Stock Reference	Description	2011	2012	2013	2014	2015	2016	2017
8000004	Cable assembly for oxyge	905	2060	3532	6800	2850	6600	6000
8010000	Oxygen Sensor - VST2200	79	123	20	36	19		32
8010001	Oxygen Sensor - APD5		2					
8010002	Oxygen Sensor - APD11	3						
8010002	Oxygen Sensor - APD11	3						
8010003	Oxygen Sensor - VR1700	707	726	642	130			
8010004	Oxygen Sensor - R17JJ-CC	797	1103	1648	2348	2602	3063	3514
8010005	Oxygen Sensor - VST1700				6		12	
8010006	Oxygen Sensor - rEvo CR2	501	1910	2100	2400	2700	2950	2700
8010006	Oxygen Sensor - rEvo CR2	501	1910	2100	2400	2700	2950	2700
8010007	Oxygen Sensor - NaNS01	558	751	1600	2600	1450	1400	1100
8010007	Oxygen Sensor - NaNS01	558	751	1600	2600	1450	1400	1100
8010008	Oxygen Sensor - NaNM01	30	450	1000	1100	1200	1300	1200
8010008	Oxygen Sensor - NaNM01	30	450	1000	1100	1200	1300	1200
8010009	Oxygen Sensor - VST1200							
8010009	Oxygen Sensor - VST1200							
8010010	Oxygen Sensor - RBL-23D		138	100	100		150	78
8010011	Oxygen Sensor - VR2200	3						
8010011	Oxygen Sensor - VR2200	3						
8010012	Oxygen Sensor - SC-I22D	249	1900	1787	2000	1771	1850	1500
8010012	Oxygen Sensor - SC-I22D	249	1900	1787	2000	1771	1850	1500
8010014	Oxygen Sensor - K-22D		54	180	270	225	375	300
8010015	Oxygen Sensor - UDT-22				15		3	
8010016	Oxygen Sensor - Hammerhe			301	260	115	108	54
8010017	Oxygen Sensor - VMS1700				500	420	410	360
8010018	Oxygen Sensor - Triton T				250	100	200	150
8010019	Oxygen Sensor - SG-22				100	200	100	
8010019	Oxygen Sensor - SG-22				100	200	100	
8010020	Oxygen Sensor - type 22D				50	700	760	840
8010020	Oxygen Sensor - type 22D				50	700	760	840
8010021	Oxygen Sensor - DST-2200						16	15
8010022	Oxygen Sensor - APD16				5500	3500	2800	2600
8010023	Oxygen Sensor - APD8				200	100	180	150
8010023	Oxygen Sensor - APD8				200	100	180	150
8010024	Oxygen Sensor - UDT-24					9	19	
8010025	Oxygen Sensor -							
8010026	Oxygen Sensor -							
8010030	Oxygen Sensor - VST1703D							
8010031	Oxygen Sensor - VST1704D					2		
8010032	Oxygen Sensor - VST2200D							
8010050	Oxygen Sensor - JFD (non							27
8010051	Oxygen Sensor - Avon (non-mag).							

Comments on Sales Information:

Currently selling roughly 20-25k sensor per year

Countries Review

Country	2011	2012	2013	2014	2015	2016	2017
AU Austria		[X]					
B Belgium	[X]	[X]	[X]	[X]	[X]	[X]	[X]
CZ Czech Republic	[X]	[X]	[X]	[X]	[X]	[X]	[X]
DE Denmark	[X]	[X]	[X]	[X]	[X]	[X]	[X]
F France				[X]	[X]	[X]	[X]
G Germany	[X]	[X]	[X]	[X]	[X]	[X]	[X]
HA HAWAII		[X]					
IT Italy		[X]		[X]	[X]	[X]	[X]
ML Malta							[X]
SW Sweden	[X]	[X]					
TH Thailand	[X]	[X]	[X]	[X]		[X]	[X]
UK United Kingdom	[X]	[X]	[X]	[X]	[X]	[X]	[X]
USA U.S.A.	[X]	[X]	[X]	[X]	[X]	[X]	[X]

Comments on Sales to Countries:

Countries limited by the OEM manufacturers.

Comments on Risks with Sales to Countries:

Returns and Q.A. Fails Review

Stock Reference	Fault	2011	2012	2013	2014	2015	2016	2017
8010000	No Fault Found		3					
8010003	Connector - Corrosion			2	3			
8010003	Low Output During Dive				1			
8010003	No Fault Found				8			
8010003	No Output				2			
8010004	Needs Evaluating							3
8010004	Cable Connections Faulty				1			
8010004	CCN147						10	9
8010004	High Output				2	2	19	
8010004	Linearity Error						9	
8010004	Low Output					1	3	
8010004	No Fault Found	3		2	4	2	2	
8010004	No Output				3	2	2	
8010004	Response Time Out Of Specification						1	
8010004	Unstable Output Signal				1	1	4	2
8010004	Zero Offset Signal Out Of Tolerance				2		3	
8010006	Needs Evaluating							3
8010006	CCN147							5
8010006	Conformal Coating On Connector				2			
8010006	Electrolyte Leakage - Out Of Warranty							11
8010006	High Output					7	12	5
8010006	Intermittent Output					3	2	5
8010006	Low Output				1	1		1
8010006	No Fault Found				2			
8010006	No Output				1			5
8010006	Out Of Warranty							1
8010006	PCB Corrosion - Out Of Warranty Period							8
8010006	Thermistor Connections Loose						1	
8010006	Unstable				1			
8010006	Zero Offset Out Of Tolerance				1			1
8010007	Connector - Corrosion					1	1	
8010007	Connector And PCB - Corrosion					3		
8010007	High Output					2		1
8010007	Linearity Error				1			
8010007	Low Output				1	2		
8010007	No Fault Found			2	12	3	1	1
8010007	No Output				2	1	2	3
8010007	Output Cap Unattached				2			
8010007	PCB - Movement Within Casing					2		
8010007	PCB Corrosion					2	1	
8010007	Unstable Output Signal			1	1	4	8	6
8010007	Zero Offset Signal Out Of Tolerance				2		1	

Stock Reference	Fault	2011	2012	2013	2014	2015	2016	2017
8010008	Electrolyte Leakage			1				
8010008	High Output						6	
8010008	Low Output						1	1
8010008	No Fault Found			3	3	1	3	
8010008	No Output			2			1	
8010008	Output Cap Unattached							1
8010008	PCB Corrosion						1	
8010008	Unstable Output Signal			1	1	1	1	
8010008	Zero Offset Signal Out Of Tolerance				3			
8010010	Electrolyte Leakage							2
8010010	PCB Corrosion						22	
8010010	Zero Offset Signal Out Of Tolerance				10			3
8010012	Needs Evaluating							2
8010012	CCN147					97		
8010012	Electrolyte Leakage						4	
8010012	High Output				1		3	
8010012	Linearity Error			12		5	3	
8010012	Low Output				3			
8010012	No Fault Found			1	96	1		3
8010012	No Output				4			
8010012	Out Of Warranty					1		1
8010012	PCB - Movement Within Casing					28		
8010012	Unstable Output Signal				3	1	2	2
8010012	Zero Offset Signal Out Of Tolerance				23	3	1	
8010014	Low Output				1			
8010014	Zero Offset Signal Out Of Tolerance				1			
8010016	No Fault Found					1		3
8010016	No Output					1		
8010016	Output Cap Unattached				1			
8010016	Unstable Output Signal							3
8010016	Zero Offset Signal Out Of Tolerance				1			
8010017	Needs Evaluating							1
8010017	Low Output							1
8010017	No Fault Found				3			
8010017	No Output					1		2
8010017	Output Cap Unattached						1	1
8010017	Unstable Output Signal							1
8010017	Zero Offset Signal Out Of Tolerance					2		
8010018	No Fault Found				1			
8010022	CCN147					4		
8010022	Connector - Corrosion					2	1	
8010022	Connector And PCB - Corrosion					7	6	1
8010022	Connector Off Centre				3			
8010022	Damaged Sensor					1		
8010022	Defective Sensor Housing				1			

Stock Reference	Fault	2011	2012	2013	2014	2015	2016	2017
8010022	Electrolyte Leakage					1		
8010022	High Output					3	3	3
8010022	Linearity Error					2	1	1
8010022	Low Output					2	2	2
8010022	No Fault Found					3	2	5
8010022	No Output				1	8	2	
8010022	Out Of Warranty							15
8010022	Output Cap Unattached				1			
8010022	PCB - Movement Within Casing				3	1		
8010022	PCB Corrosion					2	2	
8010022	Unstable Output Signal					4	3	3
8010022	Zero Offset Signal Out Of Tolerance				1	2		
8010023	Low Output							1

Comments on Returns:

128 returns (not all failures) out of 20620 units sold,
0.0062% failure rate. very reliable product range

Comments on Risks with Returns and Potential Re-work:

Design Changes Review

Showing Documents Filed in Y 14 Design Changes

Comments on Design Changes:

no changes yet

Comments on Risks with Design Changes:

User Instructions Review

Showing Documents Filed in F 5 User Instructions

Document ID	Description	Date Added/Updated
15467	Vandagraph VST Sensors Instructions for Use User Manual	14/08/15

Comments on User Instructions:

no instructions supplier as only sell to oem customer who provide instructions with the overall end product

Comments on Risks User Instructions:

Labels Review

Showing Documents Filed in F 7 / F 8 Labels

Document ID	Description	Date Added/Updated
16256	Vandagraph VST Sensors Labels	05/02/16
13764	Vandagraph VST Sensors Labels Symbols - VST Oxygen Sensor Labels	13/05/14
13762	Vandagraph VST Sensors Labels Symbols - VST Oxygen Sensor Bag La...	13/05/14

Comments on Labels:

no label changes,
labels agreed as per customers requirements.

Comments on Risks Labels:

Documentation Updates / Changes

Document ID	Description	Date Added/Updated
22397	Vandagraph VST Sensors Clinical Trials Reports Reviews and Post ...	02/10/17

Comments on Document Changes:

no changes

Comments on Risks with Document Changes:

Internal Issues Review

Number of Issues reviewed: 26

Issue ID	Subject
102563	Office Meeting Any Other Business 8010006 stock location
102565	Office Meeting Any Other Business 8010008 stock
105369	Office Meeting Sales Back Orders Review - By Customer Backorder 00009191 8000004 ORD88788
104305	Office Meeting Sales Back Orders Review - By Customer Backorder VST0001 8010004 VSORD00835
105370	Office Meeting Sales Back Orders Review - By Customer Backorder VST0004 8000004 VSORD00854
104864	Office Meeting Sales Back Orders Review - By Customer Backorder VST006 8010006 VSORD00843
105326	Office Meeting Sales Back Orders Review - By Customer Backorder VST009 8010012 VSORD00852
104863	Office Meeting Sales Back Orders Review - By Customer Backorder VST025 8010020 VSORD00837
105041	Office Meeting Sales Back Orders Review - By Customer Backorder VST029 8010021 VSORD00846
105364	Office Meeting Purchase Order Requirements VST sensor stock 8010007 & 8010008
105363	Office Meeting Purchase Order Requirements VST sensor stock 8010007 & 8010008
104675	Office Meeting Back Order Report VSTPO00723 8010004 //
104676	Office Meeting Back Order Report VSTPO00723 8010006 //
104677	Office Meeting Back Order Report VSTPO00723 8010008 //
104678	Office Meeting Back Order Report VSTPO00723 8010012 //
104679	Office Meeting Back Order Report VSTPO00723 8010014 //
104680	Office Meeting Back Order Report VSTPO00723 8010016 //
104681	Office Meeting Back Order Report VSTPO00723 8010017 //
104682	Office Meeting Back Order Report VSTPO00723 8010018 //
104683	Office Meeting Back Order Report VSTPO00723 8010023 //
105140	Office Meeting Back Order Report VSTPO00724 8010018 //
105139	Office Meeting Back Order Report VSTPO00725 8010017 //
105137	Office Meeting Back Order Report VSTPO00726 8010012 //
105135	Office Meeting Back Order Report VSTPO00727 8010004 //

Issue ID	Subject
105136	Office Meeting Back Order Report VSTPO00728 8010022 //
105138	Office Meeting Back Order Report VSTPO00729 8010007 //

Comments on Issues:

no non conformances, customer complaints
mainly order processing issues

Comments on Risks with Issues:

Clinical / FDA Incidents online search

Clinical Investigation online review

Do any of the Results indicate a Risk / Problem :
Do any of the Results indicate outdated Technology :
Comments on Clinical Search :

n/a

Review of online FDA Incident reports

Do any of the Results indicate a Risk / Problem :
Do any of the Results indicate outdated Technology :
Comments on Clinical Search :

n/a

Risk ISO 14971 : 2012 Summary

13 Oct 2017 File 54 Vandagraph VST Sensors Risk Assesment Questions

Risk Action

	Negligible	Minor	Serious	Critical	Catastrophic
Improbable	No Action	No Action	No Action	Risk Benefits	Unacceptable
Remote	No Action	No Action	Risk Benefits	Unacceptable	Unacceptable
Occasinal	No Action	Risk Benefits	Unacceptable	Unacceptable	Unacceptable
Probable	Risk Benefits	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	Ref Question	Applys	Risk	Probability	Overall
[1]	what is the medical device`s role relative to diagnosis,				
[2]	what is the medical device`s role relative to prevention				
[3]	what is the medical devices role relative to monitoring				
[4]	what is the medical devices role relative to treatment				
[5]	what is the medical devices role relative to alleviation of disease				
[6]	what is the medical devices role relative to compensation for injury or handicap				
[7]	what is the medical devices role relative to replacement or modification of anatomy				
[8]	what is the medical devices role relative to control of conception				
[9]	does the medical device sustain life				
[10]	does the medical device support life				
[11]	is special intervention necessary in the case of failure of the medical device				
[330]	What are the indications for use e.g. patient population				

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

ID	Ref Question	Applys	Risk	Probability	Overall
[56]	Factors that should be considered include temperature				
[57]	Factors that should be considered include humidity				
[58]	Factors that should be considered include atmospheric gas composition				
[59]	Factors that should be considered include pressure				
[60]	Factors that should be considered include light				

C.2.11 Are measurements taken

ID	Ref 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.				

C.2.12 Is the medical device interpretative

ID	Ref 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				
[63]	Factors that should be considered include whether conclusions are presented by the medical device from the algorithms used				
[64]	Factors that should be considered include whether conclusions are presented by the medical device from the confidence limits				
[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				

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

ID	Ref Question	Applys	Risk	Probability	Overall
[66]	Factors that should be considered include identifying any other medical devices				
[67]	Factors that should be considered include identifying any other medicines				
[68]	Factors that should be considered include identifying any other medical technologies that can be involved				

C.2.14 Are there unwanted outputs of energy or substances

ID	Ref Question	Applys	Risk	Probability	Overall
[69]	Energy-related factors that should be considered include vibration,				
[70]	Energy-related factors that should be considered include heat,				
[71]	Energy-related factors that should be considered include radiation,				
[72]	Energy-related factors that should be considered include noise,				
[73]	Energy-related factors that should be considered include ionizing radiation,				
[74]	Energy-related factors that should be considered include non-ionizing radiation,				

ID	Ref Question	Applys	Risk	Probability	Overall
[75]	Energy-related factors that should be considered include ultraviolet/ radiation,				
[76]	Energy-related factors that should be considered include visible radiation,				
[77]	Energy-related factors that should be considered include infrared radiation,				
[78]	Energy-related factors that should be considered include contact temperatures				
[79]	Energy-related factors that should be considered include leakage currents				
[80]	Energy-related factors that should be considered include electric fields				
[81]	Energy-related factors that should be considered include magnetic fields				
[82]	Substance-related factors that should be considered include substances used in manufacturing				
[83]	Substance-related factors that should be considered include substances used in cleaning				
[84]	Substance-related factors that should be considered include substances used in testing				
[85]	Other substance-related factors that should be considered include discharge of chemicals				
[86]	Other substance-related factors that should be considered include waste products				
[87]	Other substance-related factors that should be considered include body fluids				

C.2.15 Is the medical device susceptible to environmental influences

ID	Ref Question	Applys	Risk	Probability	Overall
[88]	Factors that should be considered include the operational environment				
[89]	Factors that should be considered include the transport environment				
[90]	Factors that should be considered include the storage environment				
[91]	Factors that should be considered include light				
[92]	Factors that should be considered include temperature				
[93]	Factors that should be considered include humidity				
[94]	Factors that should be considered include vibrations				
[95]	Factors that should be considered include spillage				
[96]	Factors that should be considered include susceptibility to variations in power				
[97]	Factors that should be considered include susceptibility to variations in cooling supplies				
[98]	Factors that should be considered include susceptibility to variations in electromagnetic interference				

C.2.16 Does the medical device influence the environment

ID	Ref Question	Applys	Risk	Probability	Overall
[99]	Factors that should be considered include the effects on power and cooling supplies				
[100]	Factors that should be considered include the emission of toxic materials				
[101]	Factors that should be considered include the generation of electromagnetic disturbance				

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

ID	Ref Question	Applys	Risk	Probability	Overall
[102]	Factors that should be considered include specifications for such consumables				
[103]	Factors that should be considered include specifications for such accessories				
[104]	Factors that should be considered include any restrictions placed upon users in their selection of consumables.				
[105]	Factors that should be considered include any restrictions placed upon users in their selection of accessories.				

C.2.18 Is maintenance or calibration necessary

ID	Ref Question	Applys	Risk	Probability	Overall
[106]	Factors that should be considered include whether maintenance or calibration are to be carried out by the operator				
[107]	Factors that should be considered include whether maintenance or calibration are to be carried out by the user				
[108]	Factors that should be considered include whether maintenance or calibration are to be carried out by the specialist				
[109]	Factors that should be considered include are special substances or equipment necessary for proper maintenance				
[110]	Factors that should be considered include are special substances or equipment necessary for proper calibration				

C.2.19 Does the medical device contain software

ID	Ref Question	Applys	Risk	Probability	Overall
[111]	Factors that should be considered include whether software is intended to be installed				
[112]	Factors that should be considered include whether software is intended to be verified				
[113]	Factors that should be considered include whether software is intended to be modified				

ID	Ref Question	Applys	Risk	Probability	Overall
[114]	Factors that should be considered include whether software is intended to be exchanged				

C.2.2 Is the medical device intended to be implanted

ID	Ref Question	Applys	Risk	Probability	Overall
[12]	Factors that should be considered include the location of implantation,				
[13]	Factors that should be considered include the characteristics of the patient population				
[14]	Factors that should be considered include the characteristics of the patient age				
[15]	Factors that should be considered include the characteristics of the patient weight				
[16]	Factors that should be considered include the characteristics of the patient physical activity				
[17]	Factors that should be considered include the effect of ageing on implant performance				
[18]	Factors that should be considered include the expected lifetime of the implant				
[19]	Factors that should be considered include the reversibility of the implantation				

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

ID	Ref Question	Applys	Risk	Probability	Overall
[115]	Factors that should be considered include labelling				
[116]	Factors that should be considered include indicators				
[117]	Factors that should be considered include disposal of such medical devices				

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

ID	Ref Question	Applys	Risk	Probability	Overall
[118]	Factors that should be considered include ergonomic effects				
[119]	Factors that should be considered include cumulative effects				

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

ID	Ref Question	Applys	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				

ID	Ref Question	Applys	Risk	Probability	Overall
[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				

C.2.23 What determines the lifetime of the medical device

ID	Ref Question	Applys	Risk	Probability	Overall
[122]	Factors that should be considered include ageing				
[123]	Factors that should be considered include battery depletion.				

C.2.24 Is the medical device intended for single use

ID	Ref Question	Applys	Risk	Probability	Overall
[124]	Factors that should be considered include does the medical device self-destruct after use				
[125]	Factors that should be considered include Is it obvious that the device has been used				

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

ID	Ref 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				
[127]	Factors that should be considered include does it contain toxic material				
[128]	Factors that should be considered include does it contain hazardous material				
[129]	Factors that should be considered include is the material recyclable				

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

ID	Ref Question	Applys	Risk	Probability	Overall
[130]	Factors that should be considered include the novelty of the medical device				
[131]	Factors that should be considered include the likely skill and training of the person installing the device.				

C.2.27 How will information for safe use be provided

ID	Ref 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				

ID	Ref Question	Applys	Risk	Probability	Overall
[133]	Factors that should be considered include will it involve the participation of third parties such as installers				
[134]	Factors that should be considered include will it involve the participation of third parties such as care providers				
[135]	Factors that should be considered include will it involve the participation of third parties such as health care professionals				
[136]	Factors that should be considered include will it involve the participation of third parties such as pharmacists				
[137]	Factors that should be considered include will it involve whether this will have implications for training				
[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				
[139]	based on the expected life of the device, whether re-training or re-certification of operators or service personnel would be required				

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

ID	Ref Question	Applys	Risk	Probability	Overall
[140]	Factors that should be considered include new technology				
[141]	Factors that should be considered include new scale of production.				

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

ID	Ref Question	Applys	Risk	Probability	Overall
[142]	such as the user interface				

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

ID	Ref Question	Applys	Risk	Probability	Overall
[143]	Factors that should be considered are user interface design features that can contribute to use error				
[144]	Examples of interface design features include control and indicators,				
[145]	Examples of interface design features include symbols used,				
[146]	Examples of interface design features include ergonomic features				
[147]	Examples of interface design features include physical design and layout,				

ID	Ref Question	Applys	Risk	Probability	Overall
[148]	Examples of interface design features include hierarchy of operation				
[149]	Examples of interface design features include menus for software driven devices				
[150]	Examples of interface design features include visibility of warnings,				
[151]	Examples of interface design features include audibility of alarms				
[152]	Examples of interface design features include standardization of colour coding				

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

ID	Ref Question	Applys	Risk	Probability	Overall
[153]	Factors that should be considered include the consequence of use error				
[154]	Factors that should be considered include whether the distractions are commonplace				
[155]	Factors that should be considered include whether the user can be disturbed by an infrequent distraction				

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

ID	Ref Question	Applys	Risk	Probability	Overall
[156]	Factors that should be considered include the possibility of wrong connections				
[157]	Factors that should be considered include similarity to other products connections,				
[158]	Factors that should be considered include connection force,				
[159]	Factors that should be considered include feedback on connection integrity				
[160]	Factors that should be considered include over- and under-tightening.				

C.2.29.4 Does the medical device have a control interface

ID	Ref Question	Applys	Risk	Probability	Overall
[161]	Factors that should be considered include spacing,				
[162]	Factors that should be considered include , coding,				
[163]	Factors that should be considered include grouping,				
[164]	Factors that should be considered include mapping,				
[165]	Factors that should be considered include modes of feedback				
[166]	Factors that should be considered include modes of blunders				
[167]	Factors that should be considered include slips				
[168]	Factors that should be considered include control differentiation				

ID	Ref Question	Applys	Risk	Probability	Overall
[169]	Factors that should be considered include visibility				
[170]	Factors that should be considered include direction of activation				
[171]	Factors that should be considered include direction of change				
[172]	Factors that should be considered include whether the controls are continuous or discrete				
[173]	Factors that should be considered include the reversibility of settings or actions				

C.2.29.5 Does the medical device display information

ID	Ref Question	Applys	Risk	Probability	Overall
[174]	Factors that should be considered include visibility in various environments				
[175]	Factors that should be considered include orientation				
[176]	Factors that should be considered include the visual capabilities of the user				
[177]	Factors that should be considered include populations and perspectives				
[178]	Factors that should be considered include clarity of the presented information				
[179]	Factors that should be considered include units				
[180]	Factors that should be considered include colour coding				
[181]	Factors that should be considered include accessibility of critical information				

C.2.29.6 Is the medical device controlled by a menu

ID	Ref Question	Applys	Risk	Probability	Overall
[182]	Factors that should be considered include complexity and number of layers				
[183]	Factors that should be considered include awareness of state				
[184]	Factors that should be considered include location of settings				
[185]	Factors that should be considered include navigation method				
[186]	Factors that should be considered include number of steps per action				
[187]	Factors that should be considered include sequence clarity and memorization problems				
[188]	Factors that should be considered include importance of control function relative to its accessibility and the impact of deviating from specified operating procedures.				

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

ID	Ref 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				

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

ID	Ref Question	Applys	Risk	Probability	Overall
[190]	Factors that should be considered include the possibility of initiatinig 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.				

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

ID	Ref Question	Applys	Risk	Probability	Overall
[20]	Factors that should be considered include the nature of the intended contact				
[21]	Factors that should be considered include the nature of the intended contact surface contact				
[22]	Factors that should be considered include the nature of the intended contact invasive contact				
[23]	Factors that should be considered include the nature of the intended the period of contact				
[24]	Factors that should be considered include the nature of the intended the frequency of contact				

C.2.30 Does the medical device use an alarm system

ID	Ref Question	Applys	Risk	Probability	Overall
[191]	Factors that should be considered are the risk of false alarms				
[192]	Factors that should be considered are the risk of missing alarms				
[193]	Factors that should be considered are the risk of disconnected alarm systems				
[194]	Factors that should be considered are the risk unreliable remote alarm systems				
[195]	Factors that should be considered are the medical staffs possibility of understanding how the alarm system works				

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

ID	Ref Question	Applys	Risk	Probability	Overall
[196]	Factors that should be considered are incorrect use of connectors				
[197]	Factors that should be considered are disabling safety features or alarms				
[198]	Factors that should be considered are neglect of manufacturer`s recommended maintenance				

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

ID	Ref Question	Applys	Risk	Probability	Overall
[199]	Factors that should be considered include the consequence of the data being modified				
[200]	Factors that should be considered include the consequence of the data being corrupted.				

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

ID	Ref Question	Applys	Risk	Probability	Overall
[201]	Factors that should be considered are the necessary grips,				
[202]	Factors that should be considered are the necessary handles,				
[203]	Factors that should be considered are the necessary wheels,				
[204]	Factors that should be considered are the necessary, brakes,				
[205]	Factors that should be considered are, mechanical stability				
[206]	Factors that should be considered are,durability				

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

ID	Ref Question	Applys	Risk	Probability	Overall
[207]	Factors that should be considered are the characteristics of the output of life-supporting devices				
[208]	Factors that should be considered are the operation of an alarm				

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	Ref Question	Applys	Risk	Probability	Overall
[25]	Factors that should be considered include compatibility with relevant substances				
[26]	Factors that should be considered include compatibility with tissues				

ID	Ref Question	Applys	Risk	Probability	Overall
[27]	Factors that should be considered include compatibility with body fluids				
[28]	whether characteristics relevant to safety are known				
[29]	is the device manufactured utilizing materials of animal origin				

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

ID	Ref Question	Applys	Risk	Probability	Overall
[30]	Factors that should be considered include the type of energy transferred				
[31]	Factors that should be considered include the type of energy its control				
[32]	Factors that should be considered include the type of energy its quality				
[33]	Factors that should be considered include the type of energy its intensity				
[34]	Factors that should be considered include the type of energy its duration				
[35]	Factors that should be considered include whether energy levels are higher than those currently used for similar devices				

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

ID	Ref Question	Applys	Risk	Probability	Overall
[36]	Factors that should be considered include whether the substance is delivered				
[37]	Factors that should be considered include whether the substance is extracted				
[38]	Factors that should be considered include whether it is a single substance				
[39]	Factors that should be considered include whether it is a range of substances				
[40]	Factors that should be considered include maximum transfer rates and control thereof				
[41]	Factors that should be considered include minimum transfer rates and control thereof				

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

ID	Ref Question	Applys	Risk	Probability	Overall
[43]	re-use,				
[44]	transfusion				
[45]	transplantation				

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

ID	Ref Question	Applys	Risk	Probability	Overall
[46]	Factors that should be considered include whether the medical device is intended for single use				
[47]	Factors that should be considered include whether the medical device is intended for re-use packaging				
[48]	Factors that should be considered include shelf-life issues				
[49]	Factors that should be considered include limitation on the number of re-use cycles				
[50]	Factors that should be considered include method of product sterilization				
[51]	Factors that should be considered include the impact of other sterilization methods not intended by the manufacturer				

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

ID	Ref Question	Applys	Risk	Probability	Overall
[52]	Factors that should be considered include the types of cleaning or disinfecting agents to be used				
[53]	Factors that should be considered include any limitations on the number of cleaning cycles.				
[54]	Factors that should be considered include The design of the Medical device can influence the effectiveness of routine cleaning and disinfection				
[55]	Factors that should be considered include the effect of cleaning and disinfecting agents on the safety or performance of the device.				

D.2 Energy hazards and contributory factors

ID	Ref Question	Applys	Risk	Probability	Overall
[222]	Mechanical force				
[223]	Gravity Falling				
[224]	Suspended masses				
[225]	Stored energy				
[226]	Torsion,Shear & Tensile				
[227]	High Pressure Fluid injection				
[230]	Moving parts				
[231]	Moving & positioning patient				
[232]	Unintended motion				
[233]	Patient support failure				
[234]	Pressure vessel rupture				
[235]	Acoustic pressure				
[236]	Ultrasonic energy				
[237]	Infrasound energy				

D.3 Toxic hazards and contributory factors

ID	Ref Question	Applys	Risk	Probability	Overall
[241]	Bio-contamination				
[242]	Bacteria				
[243]	Viruses				
[244]	Other agents prions				
[245]	Bio-incompatibility				
[246]	Incorrect formulation chemical composition				
[247]	Toxicity				
[248]	Allergenicity/ irritancy				
[249]	Mutagenicity				
[250]	Oncogenicity				
[251]	Carcinogenicity				
[252]	Re and/or cross infection				
[253]	Pyrogenicity				

D.3.12 hygienic standards

ID	Ref Question	Applys	Risk	Probability	Overall
[254]	Degradation				
[255]	Chemical				
[256]	Acids or Alkalis				
[257]	Contaminates				
[258]	Processing aids				
[260]	Testing aids				
[261]	Medical gases				
[262]	Anaesthetic products				

D.4 Electromagnetic fields

ID	Ref Question	Applys	Risk	Probability	Overall
[268]	Operation outside prescribed environmental conditions				
[270]	Accidental mechanical damage				
[271]	Contamination due to waste products and/or device disposal				

D.5

ID	Ref Question	Applys	Risk	Probability	Overall
[274]	Volume				
[275]	Supply of medical gases				
[276]	Pressure				
[277]	Supply of anaesthetic agents				

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

ID	Ref Question	Applys	Risk	Probability	Overall
[279]	Inadequate operating instructions				
[280]	Inadequate description of performance				
[281]	Inadequate specification of intended use				
[282]	Inadequate disclosure of limitations				
[283]	Inadequate specification of accessories				
[284]	Inadequate specification of pre-use checks				
[285]	Over-complicated operating instructions				
[286]	Inadequate specification of service and maintenance				
[287]	Use by unskilled / untrained personnel				
[288]	Reasonable foreseeable misuse				
[289]	Insufficient warning of side effects				
[290]	Incorrect measurement and other metrological aspects				
[291]	Inadequate warnings of hazards likely with re-use of single use devices				
[292]	Misrepresentation of results				
[293]	Incompatibility with consumables / accessories / other devices				
[294]	Sharp edges or points				

D.7 Mistakes judgement errors

ID	Ref Question	Applys	Risk	Probability	Overall
[295]	Mistakes & judgement errors				
[296]	Incorrect or inappropriate output or functionality				
[297]	Erroneous data transfer				
[298]	Loss or deterioration in function				
[301]	Rule based failure				
[302]	Knowledge based failure				
[303]	Routine violation				
[304]	Violation or abbreviation of instructions, procedures etc				
[308]	Misrepresentation of results				
[311]	Controversial modes or mappings as compared to existing equipment				

D.8

ID	Ref Question	Applys	Risk	Probability	Overall
[317]	Loss of mechanical integrity				
[318]	Inadequate packaging contamination and / or deterioration of the device				
[320]	Deterioration in function gradual occlusion of fluid / gas path or change in resistance to flow, electrical conductivity as a result of repeated use				

D.9 Fire Risk

ID	Ref Question	Applys	Risk	Probability	Overall
[334]	In terms of the device itself				
[335]	In term of materials used to clean				

D.9 Fire Risk

ID	Ref Question	Applys	Risk	Probability	Overall
[336]	In terms of Materials passing through the device				

D.10 Explosion Risk

ID	Ref Question	Applys	Risk	Probability	Overall
[337]	In terms of the device itself				
[338]	In term of materials used to clean				
[339]	In terms of Materials passing through the device.				

Use By Dates

ID	Ref Question	Applys	Risk	Probability	Overall
[340]	Does the device have and time limitation on the safe use of the device. Note the USE-BY time limit refers to the period before the first use of the device, It does not relate to the number or period of subsequent uses (Lifetime) of the device				

Returns / Service

ID	Ref Question	Applys	Risk	Probability	Overall
[1201]	8010004 Does Fault Code No output Type Fault present a risk				
[1200]	8010004 Does Fault Code Low output Type Fault present a risk				
[1199]	8010004 Does Fault Code Linearity error Type Fault present a risk				
[1198]	8010004 Does Fault Code High output Type Fault present a risk				
[1197]	8010004 Does Fault Code CCN147 Type Fault present a risk				
[1196]	8010004 Does Fault Code Cable connections faulty Type Fault present a risk				
[1195]	8010003 Does Fault Code No output Type Fault present a risk				
[1193]	8010003 Does Fault Code Connector - corrosion Type Fault present a risk				
[1194]	8010003 Does Fault Code Low output during dive Type Fault present a risk				
[477]	Does Fault Code Unstable output signal Type Fault present a risk				

ID	Ref Question	Applys	Risk	Probability	Overall
[476]	Does Fault Code Output cap unattached Type Fault present a risk				
[475]	Does Fault Code Low output Type Fault present a risk				
[474]	Does Fault Code CCN147 Type Fault present a risk				
[473]	Does Fault Code PCB - movement within casing Type Fault present a risk				
[472]	Does Fault Code Electrolyte leakage Type Fault present a risk				
[1202]	8010004 Does Fault Code Response time out of specification Type Fault present a risk				
[1203]	8010004 Does Fault Code Unstable output signal Type Fault present a risk				
[1204]	8010004 Does Fault Code Zero offset signal out of tolerance Type Fault present a risk				
[1205]	8010006 Does Fault Code CCN147 Type Fault present a risk				
[1206]	8010006 Does Fault Code Conformal coating on connector Type Fault present a risk				
[1207]	8010006 Does Fault Code High Output Type Fault present a risk				
[1208]	8010006 Does Fault Code Intermittent output Type Fault present a risk				
[1209]	8010006 Does Fault Code Low output Type Fault present a risk				
[1210]	8010006 Does Fault Code No output Type Fault present a risk				
[1211]	8010006 Does Fault Code Thermistor connections loose Type Fault present a risk				
[1212]	8010006 Does Fault Code Unstable output signal Type Fault present a risk				
[1213]	8010006 Does Fault Code Zero offset out of tolerance Type Fault present a risk				
[1214]	8010007 Does Fault Code Type Fault present a risk				
[1215]	8010007 Does Fault Code Electrolyte leakage Type Fault present a risk				
[1216]	8010007 Does Fault Code High output Type Fault present a risk				
[1217]	8010007 Does Fault Code Linearity error Type Fault present a risk				
[1218]	8010007 Does Fault Code Low output Type Fault present a risk				
[1219]	8010007 Does Fault Code No output Type Fault present a risk				
[1220]	8010007 Does Fault Code Output cap detached Type Fault present a risk				
[1221]	8010007 Does Fault Code PCB - movement within casing Type Fault present a risk				
[1222]	8010007 Does Fault Code Unstable output signal Type Fault present a risk				
[1223]	8010007 Does Fault Code Zero offset signal out of tolerance Type Fault present a risk				

ID	Ref Question	Applys	Risk	Probability	Overall
[1224]	8010008 Does Fault Code Electrolyte leakage Type Fault present a risk				
[1225]	8010008 Does Fault Code High output Type Fault present a risk				
[1226]	8010008 Does Fault Code Low output Type Fault present a risk				
[1227]	8010008 Does Fault Code No output Type Fault present a risk				
[1228]	8010008 Does Fault Code Output cap detached Type Fault present a risk				
[1229]	8010008 Does Fault Code PCB corrosion Type Fault present a risk				
[1230]	8010008 Does Fault Code Unstable output signal Type Fault present a risk				
[1231]	8010008 Does Fault Code Zero offset signal out of tolerance Type Fault present a risk				
[1232]	8010010 Does Fault Code Electrolyte leakage Type Fault present a risk				
[1233]	8010010 Does Fault Code PCB corrosion Type User present a risk				
[1234]	8010010 Does Fault Code Zero offset signal out of tolerance Type Fault present a risk				
[1235]	8010012 Does Fault Code Type Fault present a risk				
[1236]	8010012 Does Fault Code CCN147 Type Fault present a risk				
[1237]	8010012 Does Fault Code Electrolyte leakage Type Fault present a risk				
[1238]	8010012 Does Fault Code High output Type Fault present a risk				
[1239]	8010012 Does Fault Code Linearity error Type Fault present a risk				
[1240]	8010012 Does Fault Code Low output Type Fault present a risk				
[1241]	8010012 Does Fault Code No output Type Fault present a risk				
[1242]	8010012 Does Fault Code PCB - movement within casing Type Fault present a risk				
[1243]	8010012 Does Fault Code Unstable output signal Type Fault present a risk				
[1244]	8010012 Does Fault Code Zero offset signal out of tolerance Type Fault present a risk				
[1245]	8010014 Does Fault Code Low output Type Fault present a risk				
[1246]	8010014 Does Fault Code Zero offset signal out of tolerance Type Fault present a risk				
[1247]	8010016 Does Fault Code No output Type Fault present a risk				
[1248]	8010016 Does Fault Code Output cap detached Type Fault present a risk				
[1249]	8010016 Does Fault Code Unstable output signal Type Fault present a risk				

ID	Ref Question	Applys	Risk	Probability	Overall
[1250]	8010016 Does Fault Code Zero offset signal out of tolerance Type Fault present a risk				
[1251]	8010017 Does Fault Code Low output Type Fault present a risk				
[1252]	8010017 Does Fault Code No output Type Fault present a risk				
[1253]	8010017 Does Fault Code Output cap unattached Type Fault present a risk				
[1254]	8010017 Does Fault Code Zero offset signal out of tolerance Type Fault present a risk				
[1255]	8010022 Does Fault Code CCN147 Type Fault present a risk				
[1256]	8010022 Does Fault Code Connector - corrosion Type Fault present a risk				
[1257]	8010022 Does Fault Code Connector and PCB - corrosion Type Fault present a risk				
[1258]	8010022 Does Fault Code Connector off centre Type Fault present a risk				
[1259]	8010022 Does Fault Code Defective sensor housing Type Fault present a risk				
[1260]	8010022 Does Fault Code Electrolyte leakage Type Fault present a risk				
[1261]	8010022 Does Fault Code High output Type Fault present a risk				
[1262]	8010022 Does Fault Code Linearity error Type Fault present a risk				
[1263]	8010022 Does Fault Code Low output Type Fault present a risk				
[1264]	8010022 Does Fault Code No output Type Fault present a risk				
[1265]	8010022 Does Fault Code Output cap detached Type Fault present a risk				
[1266]	8010022 Does Fault Code PCB - movement within casing Type Fault present a risk				
[1267]	8010022 Does Fault Code PCB corrosion Type Fault present a risk				
[1268]	8010022 Does Fault Code Unstable output signal Type Fault present a risk				
[1269]	8010022 Does Fault Code Zero offset signal out of tolerance Type Fault present a risk				

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Risk Assessment Document Summary Applicable questions and Actions