

Validated

Internal Audit Check list

CE Files

Created:	17/May 1995	Audit No 12	VM3/COP VOP01
Revised:	11 July 2011	Last printed 30/04/2007 02:13:00 PM	Page 1 of 1
Audit Date	8-5-15	Auditor H L A P B	ISO

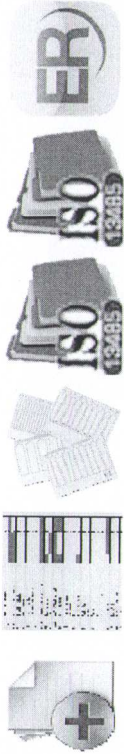
Paper files are becoming obsolete as electronic documentation supersedes them.
 All CE Technical files should be in Intrastats Documentation centre.
 All Archive electronic & scanned documents are stored electronically in Paperport
 All Archive paper documents are in Paper CE Files.
 Any documents missing from Intrastats can be found in Paperport or hard copy files.
 Emails can be found in Goldmine and documentation in Intrastats

Question	Y/N	Response/Answer
Check and list current CE Files in : Intrastats;	Y	See attached
Does it agree with products being sold requiring CE File	Y	#1 #Dech to produce reverse lookup to prove products belong to a file
Do all Products have a CE File		
Check Cross reference in Intrastats : Family Types		
Are all the Products present	Y	See #1
Do all files contain the Basic information required Are there any Red areas	Y	yes but none relating to required section
Are MDA guidelines are available for classification information. Library and electronically	Y	checked Apger + Neomarks
Check that form RG2 has been completed and submitted to MDA for any Class I products	Y	
Check that the files classification information for Canada is in their required format.	Y	
Have there been any product changes since the last Audit	Y	
Have Risk assessments been completed on change	Y	
Have there been any classification changes	No	
Any new accessories.		X
Any label changes		X
Any User information changes		X
Any sales leaflet changes		X
Any Data sheet changes		X
Any maintenance or service manual changes		X
Any other major changes effecting CE Files		X

#1 done but unsure how to produce a report for all products. Currently done on a product by product basis #60911



Technical Files



- [Viamed Product](#)
- [Viamed OBL product](#)
- [OEM Product](#)
- [Vandagraph Product](#)
- [General Technical File](#)
- [Development - Viamed Product](#)
- [Development - OBL Product](#)
- [Old Viamed Product](#)
- [VST OBL Product](#)
- [General Project](#)
- [Development - Viamed Product - Stopped](#)
- [Non Real Files - Ignore](#)

CE File Name	Technical File Type	Tools
(22) Apgar Timer 2	Viamed Product	  
(53) COT Lids	Viamed Product	  
(18) Heat Shields	Viamed Product	  
(25) Microstim MkIII	Viamed Product	  
(8) Nova Oxygen Tents	Viamed Product	  
(21) Oxygen Hoods	Viamed Product	  
(19) Phototherapy Light Shields	Viamed Product	  
(13) Resuscitation Unit and TC400	Viamed Product	  
(7) T Adaptors	Viamed Product	  
(16) Tom Thumb	Viamed Product	  
(20) Tube Holder	Viamed Product	  
(66) V1000 Foetal Heart Simulator	Viamed Product	  
(47) Capnograph	Viamed OBL product	  
(15) Envitec Oxygen Sensors	Viamed OBL product	  
(45) FlowSensors	Viamed OBL product	  
(77) NeoMask Phototherapy Eye Occlusion Shields	Viamed OBL product	  
(23) Pulse Oximeter VM-2160	Viamed OBL product	  

(33) [Pulse Oximeter VM2101 Finger SpO2](#)

(40) [Pulse Oximeter VM2105 Finger SpO2](#)

(31) [Pulse Oximetry Sensors 4000 Series](#)

(27) [Temperature Probes BPM](#)

(97) [Versastream](#)

(76) [David Scot Products Blue Diamond](#)

(57) [Inspiration Blenders](#)

(86) [Invasive blood pressure transducers Smiths](#)

(102) [Maxtec Neo Drymax Absorbent pads](#)

(100) [Posey Armboards / ID bracelet and Wraps](#)

(81) [PROJECT_36 Alcohol Meters](#)

(50) [VG900 Spo2 Tester](#)

(94) [Zoll Products](#)

(72) [Argo-naught Analysers](#)

(17) [Blu-OX / Tek-OX](#)

(60) [Gas Pump box](#)

(98) [Pump box 7910300](#)

(67) [Quick-ox gas sampler](#)

(34) [Vandagraph VN202](#)

(51) [VN202 LITE](#)

(59) [VN450 Gas Analysers Ar-Gone Gas Analyzer](#)

(101) [Beijing Choice Products](#)

(84) [Billiband Phototherapy Eye Shield](#)

(46) [Blue Point AX/MX Cable Replacement](#)

(2) [Generic CE File Attached to All](#)

(99) [Maxtec Oxygen Monitors / Sensors](#)

(39) [Microstim Tester](#)

(37) [Mixcheck Helium Analyser](#)

(26) [Pippa C-Lect](#)

(35) [Saadat Patient Monitors](#)

(49) [Shuttleworth Cabinet](#)

(96) [Teledyne Medical Oxygen Monitors and Sensors](#)

(41) [Teledyne Oxygen Sensors](#)

(42) [Teledyne R-15](#)

(52) [Nasal Cannula](#)

[Viamed OBL product](#)

[Viamed OBL product](#)

[Viamed OBL product](#)

[Viamed OBL product](#)

[Viamed OBL product](#)

[OEM Product](#)

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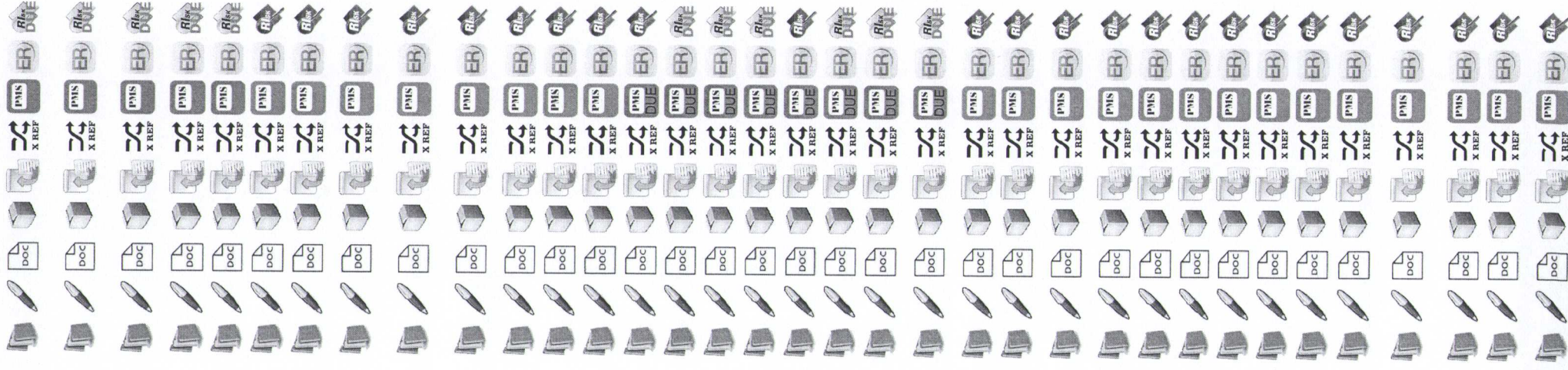
[General Technical File](#)

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[General Technical File](#)

[Development - Viamed Product](#)



(58) [Oxycal Oxygen sensor simulator](#)

(70) [Project 2 Oxygen content](#)

(36) [Thumbelina](#)

(32) [Neopeep & NeoPIP](#)

(29) [NIBP cuffs](#)

(28) [Oxygen Monitor BPM](#)

(12) [Anaestim II](#)

(6) [Microstim](#)

(9) [Oxygen Therapy Chair](#)

(65) [SpO2 800 series](#)

(44) [Thermometer Probes \(Betatherm\)](#)

(61) [XXX DO NOT USE Pulse Oximeter Finger Probes 800 Series](#)

(89) [PROJECT_42 8010022 Oxygen Sensor Ambient Pressure Diving](#)

(91) [PROJECT_45 8010018 Oxygen Sensor - M3S](#)

(92) [PROJECT_48 80100xx Oxygen Sensor template file](#)

(54) [Vandagraph VST Sensors](#)

(68) [PROJECT_13 CO2 Solid state sensor](#)

(74) [PROJECT_14 Tom Thumb With Blender](#)

(88) [PROJECT_15 Microstim DB4](#)

(80) [PROJECT_16 Sealed waterproof SpO2](#)

(85) [PROJECT_19 SpO2 - Masimo sensors](#)

(82) [PROJECT_21 SpO2 - SpHb](#)

(78) [PROJECT_34 Replacement 2160](#)

(79) [PROJECT_40 TFDA Capnograph](#)

(83) [PROJECT_41 VM2500 Series Packaging](#)

(90) [PROJECT_43 CapnoTrue B](#)

(103) [PROJECT_47 80100xx Series Oxygen Sensors](#)

(93) [PROJECT_50 Spinal Anaesthesia Monitoring System](#)

(95) [PROJECT_51 Flowcap](#)

(43) [MS Tester Syringe Driver](#)

(75) [PROJECT_39 TEST PROJECT](#)

(63) [xx Blank DO NOT USE](#)

[Development - Viamed Product](#)

[Development - Viamed Product](#)

[Development - Viamed Product](#)

[Development - OBL Product](#)

[Development - OBL Product](#)

[Development - OBL Product](#)

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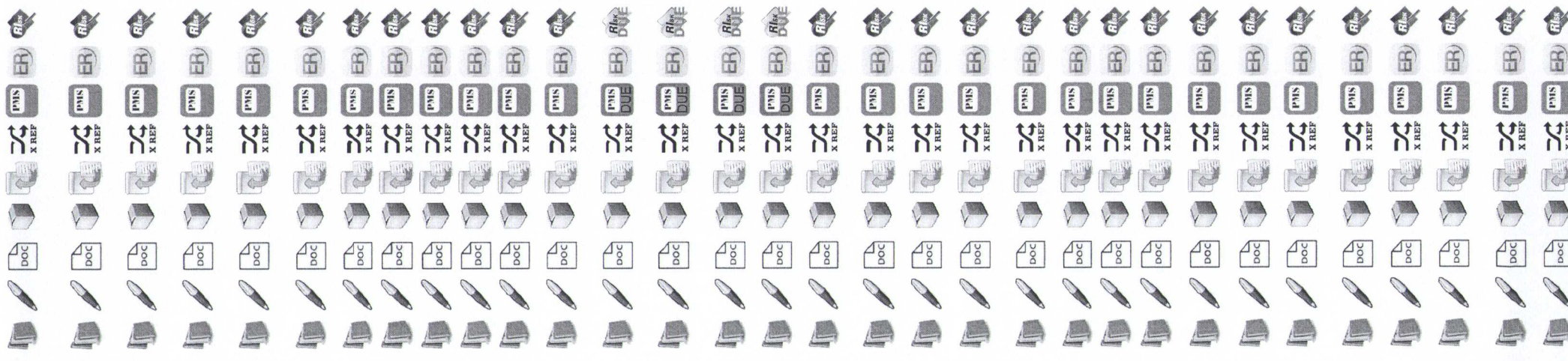
[General Project](#)

[General Project](#)

[Development - Viamed Product - Stopped](#)

[Development - Viamed Product - Stopped](#)

[Non Real Files - Ignore](#)



- (62) XX DONT USE Pulse Oximeter Extension Cables 800 Series
- (64) XX DONT USE Pulse Oximeter Y Probes 800 Series
- (56) xxx Empty File
- (38) zztest not real file

Non Real Files - Ignore

Non Real Files - Ignore

Non Real Files - Ignore

Non Real Files - Ignore

