DOCUMENTATION

The purpose of this document is to describe the system in use at the company in order to ensure that all significant documents are subject to control, and that only correct issues of relevant documents are available and in use. Viamed Operating Procedures are binding instructions, and all members of staff are required to conform to the requirements therein.
The requirement for new Procedures, or changes to procedures can originate from any person within the company. These requirements will be discussed and agreed by management before processing.
It is the responsibility of the Managing Director, or a person appointed by him e.g. the Quality Manager and/or Technical Engineer, to ensure the origination, upkeep, revision, control and authorisation of documentation, including technical documents, work instructions, specifications, records and forms and procedures.
Documents such as procedures, instructions, specifications etc. are retained as "Word" documents, Autocad & PCB documents, and are also stored electronically (Read Only) therefore making them available to all personnel, for information purposes. All other relevant documentation, such as international standards and technical literature is retained in the Company's library and can be withdrawn by authorised personnel only. This withdrawal must be signed for, using a tracer file.

DOCUMENT CHANGE / AMENDMENT

All essential documents contain a change / revision facility. This is controlled by date revised and last date printed. Printed is either electronic or hard copy. Departmental heads are responsible for ensuring prompt removal of obsolete documents from all points of use. After many revisions, a document may be fully Re-Issued as the next number status.
Where significant changes have been made to a Company document / management system e.g. new or major modifications to procedures or a reduction in quality surveillance, or to such as the Design / CE Files, then the appropriate Notified Body(s) will be informed in writing, with copies of the changes where required.
It is the responsibility of the originator of any change order to ensure that documents becoming obsolete are promptly destroyed or returned for filing.
After the retention period (as defined in the document register) has expired, the documents will be archived, in various locations, or destroyed, depending on the nature of the document. The Managing Director will take this decision.

TECHNICAL DOCUMENTATION

When engineering drawings and / or specifications are created for manufacturing purposes, the documents will be authorised by signature on the final draft copy, and computer initialled on the final master copy, as verification of current issue. This authorisation will be vested in a senior person responsible for technical matters. These documents will be controlled in the same manner as previously stated above.
Manufacturers manuals and technical data sheets, British and International standards, together with any regulatory guidance documents are maintained in the library for reference purposes. Where applicable, these documents are also stored electronically (old versions are not removed).
All relevant Standards are filed and indexed in a master standards file in numerical order and are maintained up to date annually by reference to the BS guide.
Quality records are identifiable to the product and the responsibility for records, how they are filed and their retention periods are set out in the Document Register.
A network is installed and the central File server holds a master copy of the most used files, which require shard access. All centrally held files are backed up routinely and copied to CD-ROM by the IT Director.
All CE & Design files are maintained by the Technical engineer and are also available for viewing electronically.. These files are backed up on CD-ROM.
All documents are being entered systematically into the Viamed Intrastat system which is intende to replace the existing Paper and electronic systems

DOCUMENT REGISTER

Form No	Title	Responsibility	Location	Retention	Withdrawn
QC 01	Duplicate Order Book	Office Staff	General Office	1 Year	
QC 02	Stock Record	Office Staff	General Office	On-going	
QC 03	Invoice	Office Staff	General Office	On-going	
QC 04	Purchase Order	Office Staff	General Office	11 Years	
QC 05	Investigation Report	Regulatory Affairs	Quality Office	11 Years	
QC 06	Supplier Questionnaire	Regulatory Affairs	Quality Office	On-going	12/10/2004
QC 07	Training Requirements	Regulatory Affairs	Quality Office	On-going	
QC 08	G.R.N.	Stock Controller	Stores	11 Years	
QC 09	S.R.N.	Office Staff	General Office	On-going	
QC 10	Electrical Safety Test	Technical Engineer	Design Office	On-going	
QC 11	Customer Complaint Index	Regulatory Affairs	Quality Office	11 Years	
QC 12	Customer Complaint Form	Regulatory Affairs	Quality Office	11 Years	
QC 13	Certificate of Conformity	Regulatory Affairs	Quality Office	On-going	
QC 14	Calibration Register	Technical Engineer	Design Office	On-going	
QC 15	Calibration Record	Technical Engineer	Design Office	On-going	
QC 16	Training Record	M.D.	Quality Office	On-going	
QC 17	Internal Audit Checklist	Regulatory Affairs	Quality Office	3 Years	
QC 18	Internal Audit Report	Regulatory Affairs	Quality Office	3 Years	
QC 19	Stock Transfer Note	Stock Controller	General Office	11 Years	
QC 20	Document Update	Quality Engineer	Library	On-going	12/10/2004
QC 21	Non-conformance / Withdrawal	Technical Engineer	Design Office	3 Years	
QC 22	Job Description & Spec	Technical Engineer	Design Office	On-going	12/10/2004
QC 23	Estimated Timescales	Technical Engineer	Design Office	On-going	12/10/2004
QC 24	Design Review	Technical Engineer	Design Office	On-going	12/10/2004
QC 25	Progress Plan	Technical Engineer	Design Office	On-going	12/10/2004
QC 26	Work Log	Technical Engineer	Design Office	On-going	12/10/2004
QC 27	Purchases	Technical Engineer	Design Office	On-going	12/10/2004
QC 28	Post Design Changes	Regulatory Affairs	CE Library	On-going	
QC 29	Documentation Checklist	Regulatory Affairs	CE Library	On-going	
QC 30	Project Validation	Regulatory Affairs	CE Library	On-going	
QC 31	Daily Repair Log	Production Engineer	Production	3 Years	
QC 32	Daily Production Log	Production Engineer	Production	3 Years	
QC 33	Tom Thumb Test Sheets	Mech. Engineer	Quality Office	On-going	
VOP 1-18	Viamed Operating sub processes	Owner			
VOP 01	Company Documentation	Quality		On-going	
VOP01.01	Procedure Checking & Revision	Quality		On-going	
VOP 02	Responsibilities	Directors		On-going	
VOP 03	Office Process	Sales		On-going	
VOP 04	Vigilance	Sales		On-going	
VOP 05	Supplier Control	Directors		On-going	
VOP 06	Measurement Control	Production		On-going	
VOP 07	Stock Control.	Production		On-going	
VOP 08	Production	Production		On-going	
VOP 09	Repairs	Production		On-going	
VOP 10	Corrective & Preventive Actions	Quality		On-going	
VOP 11	Equipment Control	Technical		On-going	
VOP 12	Human Resources	Directors		On-going	
VOP 13	Process monitoring	Quality		On-going	
VOP 14	Servicing	Sales		On-going	
VOP 15	Data & Information Analysis	Quality		On-going	
VOP 16	Health & Safety	Quality		On-going	
VOP 17	Design & Development	Technical		On-going	
VOP 18	Maintenance & Environment	Directors		On-going	
Procedure No	Title	Form No	Form Title	Retention	Withdrawn
VM/COP/01	Amendment Control				

VM/COP/02	Organisation and Responsibilities				
VM/COP/03	Enquiries/Orders/Contract Review	QC01	Telephone Order	On-going	
		QC03	Invoice/Despatch Note Set	11 Years	
VM/COP/04	Purchasing	QC04	Purchase Order	11 Years	
		QC05	Purchase Order (Specialist Suppl)	On-going	
VM/COP/04	Purchasing	QC04	Purchase Order		
		QC05	Purchase Order (Specialist Suppl)		
		QC 06	Supplier Questionaire		
		QC07	Register of Approved Suppliers		
VM/COP/05	Receipt of Goods - Quality Assurance	QC02	Stock Record		
VM/COP/06	Rejected Goods - Vendor Quality Control. Preventative Action	QC08	Goods Return Note		
VM/COP/07	Handling, Storage and Stock Control	QC19	Stock Transfer Note		
VM/COP/08	Process Control - Picking, Packing,	QC03	Invoice/Despatch Note Set	On-going	
	Despatch and Installation	QC13	Certificate of Conformity	On-going	
VM/COP/09	Repairs	QC09	Service Repair Note (SRN)	On-going	
		QC10	Electrical Safety Test Record	On-going	
		QC10b	Computer generated		
	Maintenance of Service & production Equipment				
VM/COP/10	Customer Complaints & Withdrawal of product	QC11	Customer Complaint Index		
	Suspect Product	QC12	Customer Complaint Report		
	Incident Reporting	App 3	MDD Incident Form		
VM/COP/11	Calibration Equipment	QC14	Register of Calibrated		
		QC15	Calibration Record Card		
VM/COP/12	Training	QC16	Training Record Card		
VM/COP/13	System Audits and Reviews	QC17	System Audit Programme		
VM/COP/13	System Audits and Reviews	QC18	Non Conformance		
M/COP/14	Documentation, Records and Computer backup	QC20	Documentation Update		
VM/COP/15	Price Updating				
VM/COP/16	Design & Design construction	QC22	Job Description & Specification		
		QC23	Project Time scales		
		QC24	Design Review		
		QC25	Job Progress		
		QC26	Work Logs		
		QC27	Purchases		
		QC28	Design Changes		
		QC29	Documentation Check List Check		
		QC30	Project Validation		
		QC23	Project Time scales		
		QC24	Design Review		
		QC25	Job Progress		

		QC26	Work Logs		
		QC27	Purchases		
		QC28	Design Changes		
		QC29	Documentation Check List		
		QC30	Project Validation		
Procedure	**Product**	**Pt No**	**Stk**		
VM3/COP/31.11	Criticare D-Type				
VM3/COP/31.12	Critikon				
VM3/COP/31.13	Critikon Dynamap+				
VM3/COP/31.17	Datex 3				
VM3/COP/31.18	Datascope				
VM3/COP/31.25	Critikon/Sensormedics/Thorkom				
VM3/COP/31.40	Invivo				
VM3/COP/31.45	Kontron				
VM3/COP/31.50	Nellcor				
VM3/COP/31.54	Nonin				
VM3/COP/31.55	Novametrix				
VM3/COP/31.70	Ohmeda				
VM3/COP/31.75	Pacetec				
VM3/COP/31.80	S & W				
VM3/COP/31.85	Simed				
VM3/COP/31.86	Simed V2				
VM3/COP/32	Finger Probe Assembly Instructions SpO2				
VM3/COP/32.01	Medlab Comdek	P854RA			
VM3/COP/32.02	BCI	P855RA			
VM3/COP/32.03	Nellcor	P856RA	18580		
VM3/COP/32.04	Spacelabs	P857RA	18570		
VM3/COP/32.05	Nellcor	P858RA	18580		
VM3/COP/32.06	Pace Tech	P859RA	18590		
VM3/COP/32.07	Simed,Baxter	P86ORA	18600		
VM3/COP/32.08	BCI	P86IRA	18610		
VM3/COP/32.09	Criticare	P862RA	18620		
VM3/COP/32.10	Datascope	P863 RA	18630		
VM3/COP/32.11	Datascope	P864RA	18640		
VM3/COP/32.12	Sensormedics	P865RA	18650		
VM3/COP/32.13	Simed Baxter	P866RA	18660P		
VM3/COP/32.14	Ohmeda	P867RA	18670		
VM3/COP/32.15	Criticare	P869RA	186901		
VM3/COP/32.16	Nonin	P871RA	187101		
VM3/COP/32.17	Datex	P872RA	18720		
VM3/COP/32.18	Datex	P873 RA	18730		
VM3/COP/32.19	Palco	P874RA			
VM3/COP/32.20	Novametrix	P875RA	18750		
VM3/COP/32.21	Novametrix	P876RA	187601		
VM3/COP/32.22	Critikon	P877RA	18770		
VM3/COP/32.23	Invivo	P878RA	18780		
VM3/COP/32.24	Artema	P879RA			
VM3/COP/32.25	Novametrix	P885RA			
VM3/COP/32.26	Kontron	P886RA	18860		
VM3/COP/32.27	Spacelabs	P887RA	18870		
VM3/COP/32.28	S & W	P888RA	18880		
VM3/COP/32.29	Criticare	P889RA	18890		
VM3/COP/32.30	Critikon	P89ORA	18,900		
VM3/COP/32.31	Critikon	P891 RA	18,910		

VM3/COP/32.31	Marquette	P892RA			
VM3/COP/32.33	Hewlett Packard	P895RA			
VM3/COP/32.34	S&W	P896RA			
VM3/COP/33	Extension cables				
VM3/COP/34	Temperature probes				
VM3/COP/35	"Y" Probe Procedures				
VM3/COP/36	Microstim Procedures				
VM3/COP/37	Oxygen Sensors Procedures				
VM3/COP/38	Oxygen Analysers Procedures				
VM3/COP/39	Oxygen Sensor Holder Procedures				
VM3/COP/40	Vandagraph Procedures				
VM3/COP/43	ECG Monitors Procedures				
VM3/COP/45	DL3000				
VM3/COP/46	Pippa Procedures				
VM3/COP/47	Apgar Timer Procedures				
VM3/COP/48	NIBP Calibration Procedures				
VM3/COP/49	Defibrillators Procedures				
VM3COP50	Tom Thumb				
VM3COP51	Resuscitation cabinet				
VM3COP52	Headboxes				
VM3/COP/53	Nufer Procedures				
VM3/COP/54	Mixcheq Procedures				
VM3/COP/56	Foetal Heart Procedures				
VM3COP99	Qa Individual Products				