Viamed + VST

Internal Audit Check list

Returns, Repairs & Service

Created:	17/May 1995	Audit No 11	VOP 09
Revised:	02 July 2019		Page 1 of 11
Audit Date	2-7-19	Auditor Helen Lamb	

Company / ISO Section	Criteria of ISO Section	Auditor Comments / Issues
VST Ltd ISO9001:2015 8.2.1	**Customer communication** Communication with customers shall include: a) providing information relating to products and services; b) handling enquiries, contracts or orders, including changes; c) obtaining customer feedback relating to products and services, including customer complaints; d) handling or controlling customer property; e) establishing specific requirements for contingency actions, when relevant.	Procedures + Contracts Active list
VST Ltd ISO9001:2015 8.5.3	**Property belonging to customers or external providers** The organization shall exercise care with property belonging to customers or external providers while it is under the organization's control or being used by the organization. The organization shall identify, verify, protect and safeguard customers' or external providers' property provided for use or incorporation into the products and services. When the property of a customer or external provider is lost, damaged or otherwise found to be unsuitable for use, the organization shall report this to the customer or external provider and retain documented information on what has occurred. NOTE A customer's or external provider's property can include materials, components, tools and equipment, premises, intellectual property and personal data.	Procedure + Barcode tracking in SRS System
Viamed Ltd ISO13485:2016 7.2.2	**Review of requirements related to product** The organization shall review the requirements related to product. This review shall be conducted prior to the organization's commitment to supply product to the customer (e.g. submission of tenders, acceptance of contracts or orders, acceptance of changes to contracts or orders) and shall ensure that:	SOP procedure

	a) product requirements are defined and documented; b) contract or order requirements differing from those previously expressed are resolved; c) applicable regulatory requirements are met; d) any user training identified in accordance with 7.2.1 is available or planned to be available; e) the organization has the ability to meet the defined requirements. Records of the results of the review and actions arising from the review shall be maintained (see 4.2.5). When the customer provides no documented statement of requirement, the customer requirements shall be confirmed by the organization before acceptance. When product requirements are changed, the organization shall ensure that relevant documents are amended and that relevant personnel are made aware of the changed requirements.	Procedures + intrastats systems for processing customer orders + paperwork. Active list
Viamed Ltd ISO13485:2016 7.5.10	**Customer property** The organization shall identify, verify, protect, and safeguard customer property provided for use or incorporation into the product while it is under the organization's control or being used by the organization. If any customer property is lost, damaged or otherwise found to be unsuitable for use, the organization shall report this to the customer and maintain records (see 4.2.5).	Procedures + intrastats
Viamed Ltd ISO13485:2016 7.5.4	**Servicing activities** If servicing of the medical device is a specified requirement, the organization shall document servicing procedures, reference materials, and reference measurements, as necessary, for performing servicing activities and verifying that product requirements are met. The organization shall analyse records of servicing activities carried out by the organization or its supplier: a) to determine if the information is to be handled as a complaint; b) as appropriate, for input to the improvement process. Records of servicing activities carried out by the organization or its supplier shall be maintained (see 4.2.5).	Service log Supplier review intrastats.
Viamed Ltd	**Validation of processes for production and service provision**	

ISO13485:2016 7.5.6	The organization shall validate any processes for production and service provision where the resulting output cannot be or is not verified by subsequent monitoring or measurement and, as a consequence, deficiencies become apparent only after the product is in use or the service has been delivered. Validation shall demonstrate the ability of these processes to achieve planned results consistently. The organization shall document procedures for validation of processes including: a) defined criteria for review and approval of the processes; b) equipment qualification and qualification of personnel; c) use of specific methods, procedures and acceptance criteria; d) as appropriate, statistical techniques with rationale for sample sizes e) requirements for records (see 4.2.5); f) revalidation, including criteria for revalidation; g) approval of changes to the processes. The organization shall document procedures for the validation of the application of computer software used in production and service provision. Such software applications shall be validated prior to initial use and, as appropriate, after changes to such software or its application. The specific approach and activities associated with software validation and revalidation shall be proportionate to the risk associated with the use of the software including the effect on the ability of the product to conform to specifications. Records of the results and conclusion of validation and necessary actions from the validation shall be maintained (see 4.2.4 and 4.2.5).	Instructions, procedures
Viamed Ltd ISO13485:2016 7.5.8	**Identification** The organization shall document procedures for product identification and identify product by suitable means throughout product realization. The organization shall identify product status with respect to monitoring and measurement requirements throughout product realization. Identification of product status shall be maintained throughout production, storage, installation and servicing of product to ensure that only product that has passed the required inspections and tests or released under an authorized concession is dispatched, used or installed. If required by applicable regulatory requirements, the organization shall document a system to assign unique device identification to the medical device.	Procedures + instructions.

	The organization shall document procedures to ensure that medical devices returned to the organization are identified and distinguished from conforming product.	
Viamed Ltd ISO13485:2016 8.2.4	**Internal audit** The organization shall conduct internal audits at planned intervals to determine whether the quality management system: a) conforms to planned and documented arrangements, requirements of this International Standard, quality management system requirements established by the organization, and applicable regulatory requirements; b) is effectively implemented and maintained. The organization shall document a procedure to describe the responsibilities and requirements for planning and conducting audits and recording and reporting audit results. An audit program shall be planned, taking into consideration the status and importance of the processes and area to be audited, as well as the results of previous audits. The audit criteria, scope, interval and methods shall be defined and recorded (see 4.2.5). The selection of auditors and conduct of audits shall ensure objectivity and impartiality of the audit process. Auditors shall not audit their own work. Records of the audits and their results, including identification of the processes and areas audited and the conclusions, shall be maintained (see 4.2.5). The management responsible for the area being audited shall ensure that any necessary corrections and corrective actions are taken without undue delay to eliminate detected nonconformities and their causes. Follow-up activities shall include the verification of the actions taken and the reporting of verification results. NOTE Further information can be found in ISO 19011.	Audit calenda. instructs.
Viamed Ltd ISO13485:2016 8.3.4	**Rework** The organization shall perform rework in accordance with documented procedures that takes into account the potential adverse effect of the rework on the product. These procedures shall undergo the same review and approval as the original procedure. After the completion of rework, product shall be verified to ensure that it meets applicable acceptance criteria and regulatory requirements. Records of rework shall be maintained (see 4.2.5).	Instructs + procedures

QUESTION:	RESPONSE:	Y/N
Check that out of date warranty repairs have received customer approval prior to any repair work being done.		Y
Verify that goods are identified as a Customer Repair and include a SRN Barcode. only ant Barcode when needed.		Y
Check that the QA Records - final inspection, test sheets and safety records are completed. Returns – Repairs Ready for Invoice – View Status. Copy the serial number in to serial number search in Stockbook to get the barcode ID. Paste into QA Report. All available reports will be in here.	1301584 ✓ 642772 ✓ 1271779 ✓ 1320222 ✓ 1214184 ? – Do not QA sealed unit	Y
Check that anti-static precautions are in place and appropriate checks are recorded. Check the workshop, QA and the R+D room. Should these be in place anywhere else around the company.		Y
Check that the correct coloured duckets are being used for Urgent and Export repairs.		Y
Check that the repairs are being worked in priority, and then date order.		Y
Check that completed duckets are placed on the repaired probes shelf with all appropriate paperwork. Check all duckets on the shelves.		Y
Returns – Returns Completed. Pick 5 Invoiced and check the paperwork in the ORD file matches the customer paperwork and the invoice. 1 VSTIN01234 – VSORD01075 ✓ ✓ 2 IN163678 – ORD98995 ✓ ✓ 3 IN163695 – ORD99021 ✓ ✓ 4 IN163427 – ORD98752 ✓ ✓ 5 VSTIN01236 – VSORD01108 ✓ ✓		Y

Intrastats Service Logs – are any services overdue, list them. Returns – Service Visits. Look in Notes icon for further info and check any issues attached.	No Recurring Services overdue	✓
Intrastats Service Logs – are any services in progress. Returns – Service Visits. Check the Notes are they being filled in.	A/c 5363 preparing to go	✓
Returns – Repairs in building. Pick 5 from the list and go and find them, check they have the appropriate paperwork. 1 SRS 67157 ✓ 2 SRS 67044 ✓ 3 SRS 67144 – VST } out to supplier ask DL if should be different test. #150200 4 SRS 67143 – VST } 5 SRS 67132 ✓		Y
Check the number of old repairs. Returns – Repairs in building. Find out what is happening with any older than 6 month.		✓ *1
Returns – Ready for quote. Check the 5 oldest from the list and go and find them on the repairs shelf, check they have the appropriate paperwork. 1 SRS 67115 13-6-19 2 SRS 67090 4-6-19 3 4 5		Y
Returns – Quotes sent. Check the 5 oldest to the Quotes file in the office. Are there notes on intrastats and on the paperwork. Intrastats notes / Quotes SRS file 1 SRS67157 ✓ ✓ 2 SRS67116 ✓ ✓ 3 SRS67044 ✓ ✓ 4 SRS67032 ✓ ✓ 5 SAS67031 ✓ ✓		Y

SRS 66618 waiting on customer. #1

SAS66797 #150198 Unread with MG Looks like busy.

SRS 67016 SH#150199 waiting on customer.

Returns – Rep[airs Ready for Invoice. Check the oldest 5 of the Viamed / VST SRS's. Why have they not been invoiced. 1 SRS 67142 - via } Credit both done 23-7-19 2 SRS 67128 - via } 3 SRS 67072 via - Return to supplier waiting decision 4 SRS 66920 - via - SN - in wrong list # 5 SRS 66769 - VST - SN - issue # Using the same 5 copy the Barcode into the QA Report and see if they have QA records.	QA Record. ✓ 0110043 ✓ 0110063 ✓ 0110132 × 4420506 Not QA'ed } sealed units × 8010021 Not QA'ed }	Y
Returns – Calibration Certificates. From the list click View, to go to the calibration certificate. Copy the serial number in to serial number search in Stockbook to get the barcode ID. Paste into QA Report. Check there is a QA Report is available.	AR02724A11 ✓ SE006 ✓ 040967 ✓ AR02736A11 ✓ 440081 ✓	Y

Sub Processes Linked to Audit 11

Review the below processes tasks and ensure they are completed in a timely manner.

Warehouse Team Leader

Process Scope	Brief Description	Responsibility/ Procedure/Training	Measurable Objective	Task	Audit	Freq	Risk	Overall	Action
6847	Quarantine Repairs	27282 VOP 09 Repairs and Servicing							
6862 - *History/Details* The repairs that are currently in the building. Confirm the Stage and Location of repairs	Current Repairs	27282 VOP 09 Repairs and Servicing	No repairs should be found in the incorrect location	150040 × within terms 614 Goods Out	144804 ✓ 895 Managing Director	4	1	4	Task 1W Audit 3M
7138 - *History/Details* To review any new QC 21	Non Conformance Issues Any New	27178 VOP 13 Process Monitoring, System		149703 ✓ 795 Managing	130934 ✓ 796 Company	3	1	3	Task 1M

Forms	QC21 Forms	Reviews, Audits, Management Review, Analysis Data		Director 14967	Secretary 14799					Audit 12M
7674 - *History/Details* Review the repairs ready For invoice List in intrastats.	Check Repairs Ready For Invoice List	27282 VOP 09 Repairs and Servicing		468 Goods Out	469 Goods In	4	1	4		Task 2W Audit 3M
7692	Take Complete Repair Paperwork To Office	24730 VOP 03 Contract Review, Enquires, Office Processes								
7905 - *History/Details* To arrange Supplier Returns Generate RMA box, link items and add faults	Generate RMA Box, Link Items And Add Faults	User Training	Should be no items on the Failed Goods shelf longer than a week	882 Goods In	883 Managing Director	1	1	1		Task 1W Audit 3M

Sales Controller

Process Scope	Brief Description	Responsibility/ Procedure/Training	Measurable Objective	Task	Audit	Freq	Risk	Overall	Action
6916	Service exisiting	24730 VOP 03 Contract Review, Enquires, Office Processes 23395 DO NOT USE VOP 14 Servicing Out of Building Servicing							
6917	Service extension	24730 VOP 03 Contract Review, Enquires, Office Processes 23395 DO NOT USE VOP 14 Servicing Out							

of Building Servicing

Audits

Process Scope	Brief Description	Responsibility/ Procedure/Training	Measurable Objective	Task	Audit	Freq	Risk	Overall	Action
7724 - *History/Details* To carry out Audit 11 Repairs And Service Viamed	Audit 11 Repairs And Service Viamed	27178 VOP 13 Process Monitoring, System Reviews, Audits, Management Review, Analysis Data			171 Company Secretary	1	2	2	Audit 12M
7772 - *History/Details* To carry out Audit 11 Repairs And Service VST	Audit 11 Repairs And Service VST	27178 VOP 13 Process Monitoring, System Reviews, Audits, Management Review, Analysis Data			179 Company Secretary	1	2	2	Audit 12M

148471 This within terms Audit

148474 x within terms this Audit

Repairs Controller

Process Scope	Brief Description	Responsibility/ Procedure/Training	Measurable Objective	Task	Audit	Freq	Risk	Overall	Action
7823 - *History/Details* Backup the Fluke ESA615 Safety tester CE Copy any files to the Z Drive - safety tester backupdata	Saftey Tester Data	23322 VOP 11 Equipment Control, Office, Warehouse, Pcs and Equipment		79 Production Processes	711 Managing Director	1	1	1	Task 12M Audit 12M

125148 ✓ 127087 ✓

Office Processes

Process Scope	Brief Description	Responsibility/ Procedure/Training	Measurable Objective	Task	Audit	Freq	Risk	Overall	Action

5857 - *History/Details* Ensuring customer on site service visits are completed	Customer Service Logs	24509 VM3COP20.27 Annual Services for Resuscitation Cabinets 24730 VOP 03 Contract Review, Enquires, Office Processes		233 Office Processes	234 UK Sales Controller	4	1	4	Task 1W Audit 1M
5879 Goods being returned to us usually from customers on our UPS account. We would usually give our account number or send a UPS returns label to them.	Customer Returning Goods On Our UPS Account	17155 VM3COP03.05 Procedures for customer returning goods on our UPS account number 23627 VOP 20 Goods in Purchases, Returns, Repairs, Inspection / Rejection	none – this is done on an ad hock basis and only when customers make the request or we feel it is appropriate.			1	1	1	
5898 - *History/Details* Dispose of depleted oxygen sensors and send customer replacement disposal bags	Processing Depleted Sensors	19667 VM3COP38.14 Depleted Oxygen Sensor Process. VM3COP38.15 Processing Depleted Oxygen Sensors 23627 VOP 20 Goods in Purchases, Returns, Repairs, Inspection / Rejection		406 Goods In	535 Office Processes	4	1	4	Task 2W Audit 2W
7752 - *History/Details* Ensure all outstanding repairs are being dealt with	SRS Folder	27282 VOP 09 Repairs and Servicing		792 Office Processes	793 Managing Director	3	1	3	Task 1M Audit 3M
7760 - *History/Details* Send letters to existing customers to remind them	Send Service Offers	24730 VOP 03 Contract Review, Enquires, Office Processes		607 Marketing Processes	898 Company Secretary	1	1	1	Task 1W Audit

that a service is due on their equipment									4W

Goods Out

Process Scope	Brief Description	Responsibility/ Procedure/Training	Measurable Objective	Task	Audit	Freq	Risk	Overall	Action
7690 - *History/Details* Review the Repairs completed shelf and ship those items that are ready for return to the customer.	Ship Repairs	27282 VOP 09 Repairs and Servicing		492 Goods Out	758 Goods In	5	1	5	Task 1D Audit 1M
7748 - *History/Details* Check the orders against the customer paperwork, that we have generated, for the repair we have received in.	Check Repair Orders	23373 VOP 22 Picking and Packing Dispatch and Goods Out		575 Goods Out		5	2	10	Task 1D
7749 - *History/Details* Check the quotes that we send out for the repairs we have received in.	Check Repair Quotes	23373 VOP 22 Picking and Packing Dispatch and Goods Out		576 Goods Out		5	2	10	Task 1D
7906 - *History/Details* Obtain Returns paperwork / authorisation from supplier to return Items.	Request RMA Based On The RMA Boxes	User Training	RMA unsent List	884 Goods Out		1	1	1	Task 1W