Internal Audit Check list			
VIAMED LTD SERVICE LOGS			
Created:	17/May 1995	**Audit No 24**	
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Audit Date	24-8-26	Auditor HELEN LAMB	

Company / ISO Section	Criteria of ISO Section	Auditor Comments / Issues
Viamed Ltd ISO13485:2016 7.5.1	**Control of production and service provision** Production and service provision shall be planned, carried out, monitored and controlled to ensure that product conforms to specification. As appropriate, production controls shall include but are not limited to: a) documentation of procedures and methods for the control of production (see 4.2.4); b) qualification of infrastructure; c) implementation of monitoring and measurement of process parameters and product characteristics; d) availability and use of monitoring and measuring equipment; e) implementation of defined operations for labelling and packaging; f) implementation of product release, delivery and post-delivery activities. The organization shall establish and maintain a record (see 4.2.5) for each medical device or batch of medical devices that provides traceability to the extent specified in 7.5.9 and identifies the amount manufactured and amount approved for distribution. The record shall be verified and approved.	Doc index Roles + tasks Management Review Purchasing system
Viamed Ltd ISO13485:2016 7.5.3	**Installation activities** The organization shall document requirements for medical device installation and acceptance criteria for verification of installation, as appropriate. If the agreed customer requirements allow installation of the medical device to be performed by an external party other than the organization or its supplier, the organization shall provide documented requirements for medical device installation and verification of installation. Records of medical device installation and verification of installation performed by the organization or its supplier shall be maintained (see 4.2.5).	Doc index Tech files procedures
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.	Doc index Tech files QA systems

	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).	
Viamed Ltd ISO13485:2016 7.5.6	**Validation of processes for production and service provision** 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).	Doc index Bar code System Management Review Training Records Calibration index
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;	Doc index Route Map

	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 calendar
Viamed Ltd ISO13485:2016 8.4	**Analysis of data** The organization shall document procedures to determine, collect and analyse appropriate data to demonstrate the suitability, adequacy and effectiveness of the quality management system. The procedures shall include determination of appropriate methods, including statistical techniques and the extent of their use. The analysis of data shall include data generated as a result of monitoring and measurement and from other relevant sources and include, at a minimum, input from: a) feedback; b) conformity to product requirements; c) characteristics and trends of processes and product including opportunities for improvement; d) suppliers; e) audits; f) service reports, as appropriate. If the analysis of data shows that the quality management system is not suitable, adequate or effective, the organization shall use this analysis as input for improvement as required in 8.5. Records of the results of analyses shall be maintained (see 4.2.5).	Doc index Audit calendar QA system

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Answer questions 1-4, Any non conformance generate an Issue.

1. Review Last years Audit. Update processes if required.
Are all follow on Issue resolved satisfactory.

Nothing outstanding

INTRASTATS STOCK MENU – SERVICE VISITS – *Service Visits.* No Non Conformances
All Active and Single visit services should be shown.

2. Are Any service Visits Over Due

Note Tracking ID 34 in the Example,

No Service visit carried out

Service Logs

To Add new Servicing / Start by finding the Hospital / Company via Intrastats CRM
Use the 'O' Delivery account

KEY
Recuring Service
Once Only Service

Tracking ID	Service ID	Recur Months	Opera	Location	Description	Equipment List	Due Date	Scheduled Date	ORD's
34	12	12	00004990	**Sunderland Royal Hospital**	Delivery Suite and Neonatal Unit	**48 Items**	**26/01/15**	---	ORD69051
33	9	12	00004260	**Royal Preston Hospital**	Resus cabinets, Delivery Suite	**41 Items**	**03/04/15**	---	
35	29	12	00000780	**Burnley General Hospital**	Resus Cabinets and Blenders	**28 Items**	**11/09/15**	---	
36	27	12	00000550	**Royal Blackburn Hospital**	Resus cabinet and blender annual service	**12 Items**	**17/09/15**	---	
14	14	0	00005210	**Walsall Manor Hospital**	Tom Thumb Conversions and Upgrade	**4 Items**	**15/02/13**	---	
13	13	0	00001350	**County Durham & Darlington Hospital**	maternity tom thumbs	**10 Items**	**18/04/13**	---	
28	28	0	00000591	**Royal Bolton Hospital**	Resus cabinet upgrade to include blender	**32 Items**	**17/05/13**	---	
25	18	0	00002370	**Westmorland General Hospital**	Resus cabinet upgrade to include blender	**1 Items**	**19/06/14**	---	
30	23	0	00003580	**North Manchester General Hosp**	Resus cabinet and blender annual service	**16 Items**	**30/07/14**	---	

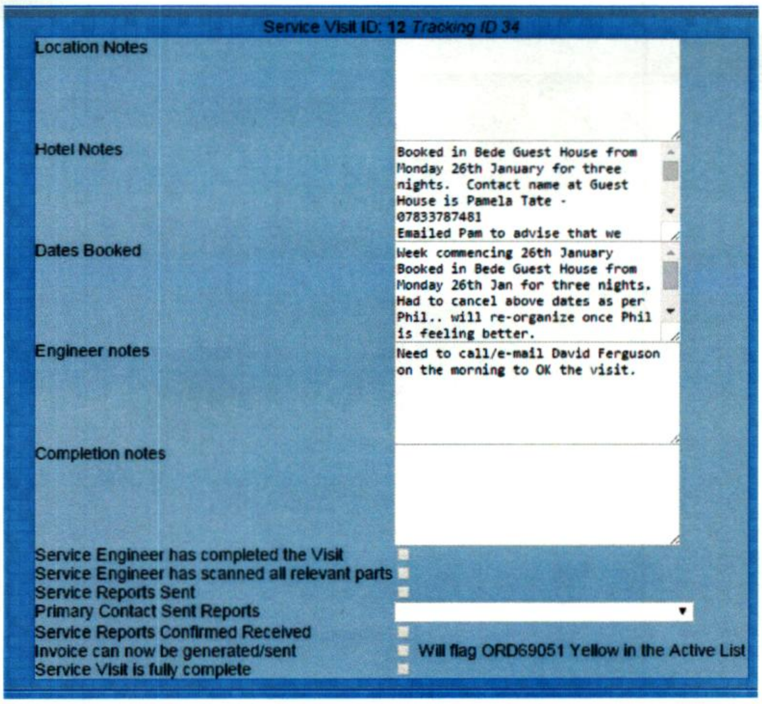
customer now returning items to us.

Has the Over due Visit got any Action notes:

Click: 

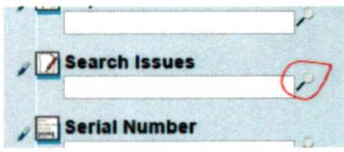
N/A

3. Have any over due Visit NOT got any action **notes?**



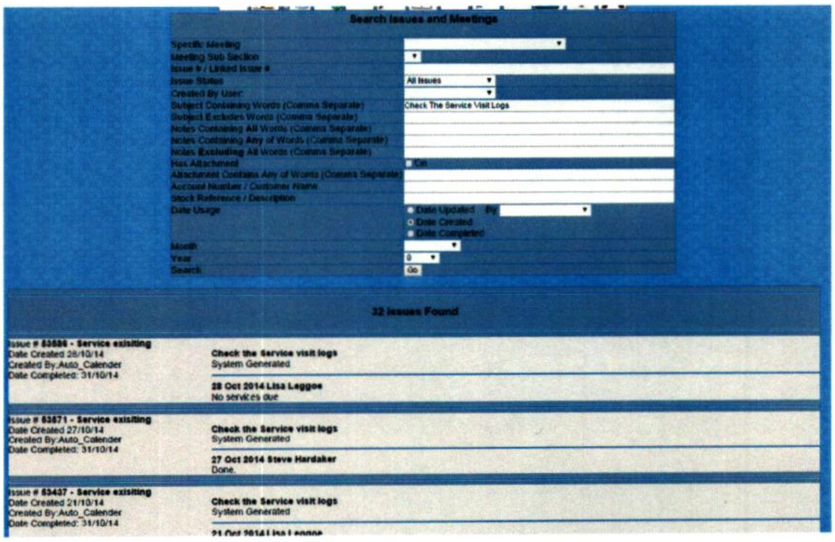
N/A

Drop out of the Service Visit Section, Search Intrastats



In the Subject Contains Words box type: ***Check The Service Visit Logs***

You should see a list of system generated tasks to 2 Different employees,
Scroll down the list,



N/A

4. Are more than 1 Issue outstanding per user.

N/A

5. Any problems found in the Issues system not being addressed.

NO

Sub Processes Linked to Audit
Review the below processes tasks and audits and ensure they are completed in a timely manner.

List Processes Per Title

Clone from Docid

Servicing Onsite				
Process Scope	**Roll Task** **Roll Audit**	**Risk**	**Action**	*
PROCESSID **7985** To ensure we do not have any overdue service requirements to our customers. Have any overdue visits not got any action notes. NO ONSITE VISITS ANYMORE, Process not currently required	Task: 1115 390496 ✓ Company Secretary Audit :1116 401435 ✓ Managing Director	Freq 1 Risk 1 Overall 1	Task 6M Audit 12M	
Audits				
Process Scope	**Roll Task** **Roll Audit**	**Risk**	**Action**	*
PROCESSID **7889** To carry out Audit 24 Servicing Viamed	Task:	Freq 1 Risk 2 Overall 2	Audit 12M	

Any follow on issues must be identified with Observation Issue or a Non Conformance Issue. If the issue is a Non Conformance a QC21 form must be filled in, as per the QC21 form procedure, and investigated as such.	Audit :288 404521 Company Secretary Audit			
Office Processes				
Process Scope	**Roll Task** **Roll Audit**	**Risk**	**Action**	*
PROCESSID **5857** Ensuring customer onsite service visits are completed	Task: 233 405851 ✓ Office Processes Audit :234 403903 ✓ Managing Director	Freq 2 Risk 1 Overall 2	Task 1W Audit 1M	
PROCESSID **7760** Send letters to existing customers to remind them that a service is due on their equipment	Task: 607 406121 x Marketing Processes in term Audit :898 406249 ✓ Company Secretary	Freq 1 Risk 1 Overall 1	Task 1W Audit 4W	

Rolling Tasks Linked to Document :Task (233) Task (607) Task (288) Task (1115)