

<b>VOP</b>			
<b>Viamed Operating sub Process</b>			
<b>VOP 09 Repairs and Servicing</b>			
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		See the Route Map for related ISO Standards.	

### **SCOPE**

This procedure is established to describe the system used within the company for the control of Repairs and controlling the requirements of On-site servicing of Viamed equipment within a Hospital or Company. It is used in conjunction with the individual sub procedures, which show the relevant information necessary.

### **RESPONSIBILITIES**

It is the responsibility of the Managing Director, to ensure that the contents of this procedure, and related procedures, are adhered to.

To ensure that the customer requirements are defined and that adequate resources and personnel are available to complete the service. It is the responsibility of the service engineer to ensure that the job is completed to the customer requirements.

### **OBJECTIVES**

It is the Objective of this VOP to demonstrate the processes used for Repairs and Servicing, with in the company and with the customer. It will include how to deal with contaminated equipment and repairs, quotes, warranty and out of warranty repairs. The flow of repairs through the company and the process of repairs and servicing outside the company. Also the evaluation of the repairs in the system with regards to the PMS and Customer Complaints.

### **REPAIRS COMING IN**

The company undertakes the repair and service of equipment. These repairs may take place at Viamed or at the customers premises and are carried out by those persons who have undergone the appropriate training. They may be returned either by a customer for repair, specification checking, calibration, or safety checks, from demonstration, requiring workshop attention before re-issue or equipment from with in the company that may require attention.

The company is notified by the customer of a required repair and a SRS (Service Returns Sheet) is Generated, in Intrastats. Then given to the customer to note on their paperwork before returning. Once the SRS has been generated. As many details are filled in about the customer and the repair as possible, into the SRS system.

Company address, contact details, email address, telephone number, department etc.  
Type of instrument, part number, serial no and details of the fault or service required.

All repairs received in will be assessed for contamination, either in the form of a visual check or a review of the originating country, or the shipping method. We are now aware that Pandemics can and

do affect us and we will aim to protect our staff. If a repair comes in from a country or areas that has incidents of infection, that can be pass on through shipped parcels. We will use gloves and where suitable, masks. Then isolate them and use appropriate and recommended methods to de contaminate them. Before any work or assessment is carried out.

This applies to any repair received:

Including from customers e.g. Hospitals, companies or private buyer. In the UK or from Overseas. Products received back from hospitals will all be treated as if no decontamination certificate has been received. Therefore all such products will be handled with care using disposable gloves and where suitable, masks. Then isolated and the use of appropriate and recommended methods to de contaminate will be used. (see VM3COP27.51).

Once opened the same process applies, if we have a repair that shows evidence of contamination we will proceed as above. The repair will be made safe before any work or assessment is carried out.

Once received we book the repair in to the Goods in book (Ref Procedure VOP20). Then locate the SRS on the system fill in any further information.

Warranty status is checked at the booking in stage, this can be amended by the engineer if damage has occurred that voids the warranty.

We then add in the individual items and accessories and each one gets a SRN (Service Returns Number). Then we print the SRS sheet off twice one for the repair and one with the original paperwork in the file. The barcodes are printed for each item and placed in the ducket, with the paperwork and the repair. These are then taken to the engineer.

Use the duckets where possible:

Blue – UK Repairs and Sales

Red – Urgent

Orange – Export

General Repairs which require a Quotation before repair are entered into the Intrastats Customer Repairs System (SRS). The repairs is then placed together with the appropriate paperwork into the appropriate prioritised ducket. When this is looked at by the engineer, an assessment is made and a quote is generated. This is communicated with the customer and an order number is requested. So we can go ahead with the repair. If the repair quote is rejected, then the item is returned to the customer. VOP 22 Picking, Packing and dispatch.

### **WARRANTY REPLACEMENT PROCEDURE**

It is Viamed policy to replace items such as sensors under warranty if required immediately on customer notification of 'failure' and the following procedure will then apply:

Generate SRS number and fill in the system.

Raise a chargeable order to be sent with the replacement item(s), quoting the SRS and SRN numbers on it.

On receipt of the failed item/s back from the customer it will be booked in and tested. A request for credit will be raised and the credit sent to the customer. This ensures that goods are returned to us for review.

If the warranty is out of date, the customer is informed and either an order is obtained for the repair or a quote prepared for customer approval.

Once approved the items and SRN numbers are then sent, in duckets, to the workshop.

If the quote is not approved the customer is asked the next course of action. Either goods are returned to the customer or can be disposed of on request from the customer.

### **REPAIRS PROCEDURE**

The appropriate Engineer carries out the repair, or work required. Ensuring the equipment is clean and tests in accordance with the original manufacturers specifications and the relevant procedure. All information is filled in on the SRS in Intrastats.

Each operative will ensure that they have enough spare part components, available to do the average daily repairs. If short of supply, then they will fill in the warehouse request stock page in Intrastats, then pick the stock and scan the parts in Returns Engineer Mode. A SRN number is needed to access this section.

When doing repairs the operative will remove the lowest numbered ducket from the shelf, this is his / her priority system. Only those duckets that are red or orange take preference over this system.

Taking the first item from the ducket, the operative will conduct a fault diagnosis. If there is no fault found with the item then the system is filled in accordingly, the paperwork printed and replaced in the ducket and forwarded for testing. Where items have been diagnosed as being faulty, but cannot subsequently be repaired for either practical or economic reasons, then this will be recorded on the system, the paperwork printed and replaced in the ducket and forwarded to testing.

- a) Only current Intrastats Document Index procedures will be used.
- b) Only approved tools and jigs will be used.
- c) The work area must be clean and tidy.
- d) Appropriate clean clothing for the task must be worn.
- e) Hands must be washed before entering and leaving the work area.
- f) The soldering iron must be the correct temperature.
- g) Antistatic precautions, if required, should be tested before use.
- h) Finger cots, gloves, masks etc. must be worn when instructed to do so.
- i) Current HSE rules and advice must be followed at all times.

All labelling is done in accordance with the manufacturing procedure.

When faulty items are to be repaired then the operative will retrieve the appropriate Manufacturing procedure form in the Intrastats Document Index, to use as the basis for repair. Using the procedure the relevant repair and testing is undertaken so as to ensure the items are brought within original manufacturers specifications. The system is then filled in accordingly and the item is replaced in the ducket and forwarded to testing. Repaired and No Fault Found items will all be thoroughly cleaned with Isopropyl Alcohol prior to being forwarded for test. Following satisfactory testing the items are forwarded to Goods out for checking, invoicing and dispatch back to the customer.

### **REPAIR REWORK PROCEDURE**

When a fault or cosmetic problem has been found at the testing stage then the system will be updated as such and the goods will be returned to the operative for rework. He / she will check the nature of the fault and repair it accordingly. Once the fault has been corrected, and the item meets the specifications, the operative will test it and forward it for re-testing. Following successful retest it is processed in the normal manner.

### **REPAIR LOAN SERVICE**

We offer a loan service for customers returning items for repair, so that they are never without a unit. We send out the equipment on a SOR (Sale or Return) then they return their equipment for repair, once completed we return the repair and our goods are returned.

### **SERVICING AT CUSTOMER PREMISES**

At the appointed date for the service, the Engineer will ensure that he has all the correct tooling and Calibrated test equipment together with access to Intrastats. Once he has arrived at the hospital, the Engineer will perform the service and subsequent calibration in line with the requirements of the Operating procedure. He will then complete, sign and date the Test report. Intrastats will be updated on return to office and complete service reports sent to the hospital. Confirmation service reports have been received before the service is invoiced and completed.

Repair and maintenance of customer's equipment must be carried out to the Manufacturer's original specifications (including where applicable, authorised modifications) or any other documents necessary to effect a repair/service, in accordance with Intrastats.

Where customer equipment is dismantled, particular care and attention must be taken to ensure identification and segregation of parts so that the equipment can be re-assembled using the original parts.

Anti-static protection will be used when repairing or moving electrostatic sensitive devices. Conductive mats, wrist straps and trays etc. should be checked before use. Field service ESD (Electrical sensitive devices) components should be checked on each visit to the office or at least every six months. All replacement parts must, where possible, conform to the same specification as those parts which they replace. Where this is not possible, the Service engineer must be capable of demonstrating that the replacement parts are suitable in all respects. All removed components must be returned (or offered if large) to the customer and expired consumables will be disposed of. All equipment after repair/servicing will be labelled as follows, the engineer signing and dating the labels or use preprepared labels.

Where requested by a customer, a certificate of conformance QC 13, will be raised and signed by the service engineer and sent.

All repairs are logged onto Intrastats.

Viamed is notified by the customer or the Service calendar in Intrastats and all details recorded in Intrastats CRM. Information required:

- a. The type of instrument, part number, serial number.
- b. Company address, contact on site, telephone number and email address.
- c. Details of the fault.

- d. An order number (for non warranty work).
- e. If required, a quote is sent.

The office staff make arrangements for a visit by a Service Engineer

- a. Where necessary, the engineer will notify the office of non stock items required against that job.
- b. Warehouse request is filled in if items need ordering.
- c. work carried out is recorded on Intrastats.
- d. As necessary, the Engineer will ring the office for non stock items.
- e. The order is processed by the office

### **SERVICE KITS**

Each service engineer is provided with repair kits comprising:-

- a. Standard tool kit a selection of spares contained in a separate box with individual components referenced by part number.
- b. Test equipment.
- c. Access to current procedures.
- d. Each engineer also has access to a selection of manufacturers technical data sheets or manuals relevant to the service required. It is the responsibility of the service engineer to ensure that he/she always has the correct up to date information.
- e. This kit includes complete sets of replaceable parts to be used identified to the equipment type.

### **DEMONSTRATION EQUIPMENT**

Equipment used by End User for a trial period, on SOR or by sales as a demo, once booked in and checked for contamination as detailed above (see VM3COP27.51). Will be tested, returned to the demo area and Barcode checked and if necessary re printed.

Where necessary, an Engineer will check the machine for electrical safety, performance and cleanliness. If a repair is necessary, then a SRN will be completed.

### **MAINTENANCE OF SERVICE AND PRODUCTION EQUIPMENT**

It is the responsibility of the user to check the safety, calibration, and suitability of service and production equipment before it is used.

Equipment will be checked during routine Calibration annually and any manufacturers recommended maintenance carried out and documented in Intrastats.

Any feedback or notes received will be assessed to make sure it is not a complaint, if it is felt it should be a complaint then we will log this in the system.

### **REPAIRS EVALUATION**

Repairs will be evaluated as part of Post Market Surveillance Review.

Repairs are normally exempt from complaints and non conformance except returns over a failure rate of 5% which will be examined in depth.

Normal Service requirement does not constitute a customer complaint.

When the engineers process the repair or return, if they feel that it should be designated as a complaint or if any correspondents from the customer make it appear that it is a complaint. They can in the SRS Engineer and SRS View Mode in the Engineers Page, select the drop down and flag the repair / return as a customer complaint. This will then show on the customer complaints pages where it can be followed up and reviewed.

The criteria for a complaint would be, if a product we have sold, repaired or a service we have carried out, is not up to our usual standard. Or if it has a fault that has not occurred, due to age, general use, or damage by user. We will assess any possible complaints once they have been reported by the engineers or any other staff. In the normal complaints system and at this point we can assess the complaint to see if its warranted and its severity. Then using the existing system we can decide on the action needed.