VOP			
Viamed Operating sub Process			
VOP 09 Repairs and Servicing			
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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.

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.

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 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
Green – Production

General Repairs which require a Quotation before repair are entered into the Intrastats Customer Repairs System (SRS) and the accounts package. The repairs is then placed together with the appropriate paperwork and Tracking Barcode 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 (Section 4.1) and tested. A request for credit will be raised and 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 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 disposed of.

REPAIRS PROCEDURE

The appropriate Engineer carries out the repair, or work required. Ensuring the equipment is clean and tests 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, 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, 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 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 is 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 forwarding 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 endorsed 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 with out 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 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. Field service ESD (Electrical sensitive devises) 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.
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, will be tested, returned to 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.

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.