Customer Complaints and Vigilance

VM3/COP/10

RESPONSIBILITIES

It is the responsibility of the Managing Director, or a designated person, and senior management to ensure that the requirements of this procedure are strictly adhered to, and that the relevant documentation is fully completed.

DEFINITION

A Complaint is defined as any report, written or oral, with or without a return product, expressing Customer dissatisfaction with:

Device identity: labeling errors
Reliability: Inability to perform in a consistent manner throughout the warranty period or specified service period.
Safety: Possible harm to patient or operator.
Effectiveness: Inability to perform as intended.
Performance: Inability to perform in compliance with the published specifications.
Durability: Inability to perform throughout warranty period or specified service period.

Definition Exceptions:

Routine calibration, product maintenance, technical inquiries, product updating to current approved revision levels, customer suggestions for more product features, credit inquiries, delivery periods and stock shortages etc., are not considered complaints

REFERENCE DOCUMENTS

Customer Complaint Report (QC12)
Customer Complaint Report Index (QC11)
Service Repair Note (QC09). Intrastats.
Risk assessment for MDD Notification (QC44), Doc ID 11751

TELEPHONE COMPLAINTS

Note name and address in the telephone log on Intrastats.
If the complaint cannot be answered pass the complaint to the Managing Director or Director and to Technical Staff for investigation.
If the complaint cannot be answered i.e. Not a user associated problem request the instrument or accessory be returned Generate a Returns number from Intrastats and quote the number to the customer.
Fully record details of complaint in the SRS Fields.

If the complaint warrants immediate action, raise an Issue in intrastats under Customer Complaints and 'Issue To' a director.

GOODS RETURNED TO VIAMED

Upon receipt, the product will be placed in a ducket and a service repair form, Intrastats SRS raised by Goods In staff with supply date referenced on it. Then it is entered in the Goods IN Book on Intrastats (Ref procedure VM/COP/09 Section 4.1.2).
Pass to Engineers for examination with a copy of any accompanying paperwork, the complaint report and the SRS. If repaired the procedure will be as in VM/COP/09.

Copy of complaint is to be sent to the Managing Director, who will investigate those problems associated with damaged goods or failure to meet specification in spite of QA Inspection Corrective Action, will be recorded.
If the complaint is a failure to comply with a specification, a repeated failure, or a premature failure (e.g. sensors), then the substance of the complaint and preferably the written complaint should be copied to the original manufacturer (See procedure VM/COP/06).

If the complaint is common or has a known explanation a letter should be sent explaining the current position and the action being taken by ourselves and/or the original supplier.
If the problem has no present solution the complaint should be filed in the CURRENT COMPLAINTS file with the SRS, and all the relevant copies of the paperwork until an answer is found. The customer is contacted and informed of the position, and the Office Team Leader reviews progress with the person responsible for investigating the problem. The Quality Engineer will review progress with the investigator. The Complaint Report is filed in the complaints file and attached to the contact in intrastats.

VIGILANCE SYSTEM

Should the complaint escalate to withdrawal of suspected product or require advisory notices -
QC11 Paper file index will be added to and refer back to the intrastats Issue number and the QC44 Risk assessment form started.

All correspondence regarding the complaint shall be logged against the original customer complaint issue number, all Emails / forms can be scanned and linked to the Issue number

Vigilance system will be carried out in accordance with the current MEDDEV 2.12.-1 See Document index. Version of MEDDEV 2.12-1 is check for version control once per calender year.

WITHDRAWAL OF SUSPECT PRODUCT OR NOTICE FROM SUPPLIER

Substantiated complaints which could be dangerous or harmful will require notification to the relevant Competent Authority. In this situation a complete list of users or locations should be assembled see VM3/COP/10.02.

If appropriate the Managing Director will arrange to withdraw remaining items from stock.

Sub Distributors must also keep records of destinations of products distributed and have in existence recall methods.

RECALL OF SUSPECT PRODUCT

See VM3/COP/10.02 For product recall process.

REPAIR OF SUSPECT PRODUCT

Repairs will be in accordance with VM/COP/09
Customer complaint Report QC12 will be raised for the duration of the recall

FORMAT OF ADVISORY NOTICE

Users will be contacted by letter, Email, Fax, or Telephone followed by a letter notifying them of the problem. The information in the letter should contain a clear description of the problem and its possible effects. A solution if available. Advice on how to circumnavigate the problem if a method exists. Copies of the Original manufacturers information should be enclosed. Information on Order No: Invoice Number: Date of purchase: Equipment type and Equipment Serial number should be included where available
A list of users/purchasers can be obtained as in VM3/COP/10.02
EBME and/or engineering departments should be informed.
Incidents as defined in the MDD will be reported on form Appendix 3 (MDD) and CMDCAS guidance documents.

Response will be immediate and instant referral to the MDD guidelines following the Incident Action plan on Appendix 4 .Risk assessment to determine MDD notification is carried out on (QC44)

The Notified Body and any other National body requiring notification will be informed at the same time as the MDD
Notification of incidents will be indicated on Customer Complaint Report Index (QC11) & (QC12).

NOTIFICATION OF NOTIFIED BODIES.

Where it is identified that product has been shipped abroad while following VM3/COP/10.02.
Any external notified bodies / medical authorities will be informed of the recall / advisory notice,

eg.

Sales to U.K. - M.H.R.A
Sales to Canada – Canada Health will be informed following CMDCAS Guidance Documents
Sales to Taiwan – Food and Drug administration, ministry of health and welfare, TFDA.

BSI Technical Manager shall be Emailed, and BSI's current reporting process carried out.

TIME SCALE OF REPORTING

The following time lines apply in a case of:
Serious public health threat: IMMEDIATELY (without any delay that could not be justified) but not later than 2 calendar days after awareness.

Death or UNANTICIPATED serious deterioration in state of health: IMMEDIATELY (without any delay that could not be justified) after the link between the device and the event but not later than 10 elapsed calendar days following the date of awareness of the event.

Others: IMMEDIATELY (without any delay that could not be justified) after the link between the device and the event but not later than 30 elapsed calendar days following the date of awareness of the event. If after becoming aware of a potentially reportable INCIDENT there is still uncertainty about whether the event is reportable, the report must be submitted within the time frame required for that type of INCIDENT.