**SCOPE**

The purpose of this procedure is to outline the detailed system used within the Company for the processing and investigation of complaints from customers.

**RESPONSIBILITIES**

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

**DEFINITION**

A customer complaint is defined as any report, written or verbal, expressing customer dissatisfaction with the company's products or services. These could be against such as:
Device identity / labelling errors.
Reliability: Inability to perform, consistently throughout warranty or service period.
Safety: Possible harm to patient or operator.
Effectiveness: Inability to perform as intended.
Performance: Inability to perform to published specifications.
Durability: Inability to perform throughout warranty / service period.
Exceptions to the above definitions are such as: routine calibration, product maintenance, technical enquiries, product updating, customer suggestions for additional features, credit enquiries etc.

**TELEPHONE COMPLAINTS**

The name and address is noted in a diary / telephone log. The details of the complaint are recorded and a customer complaint form is raised. Where necessary the return of the Item will be asked for.
The serial number will be noted and the warranty period checked. Where required, a replacement item will be shipped with a full Delivery note etc. If appropriate, arrangements will be made for a Sales person to call on the customer.

**GOODS RETURNED**

Upon receipt, the product will be processed for investigation, with an S.R.S. raised, and passed to the relevant Engineer for an examination.
A copy of the complaint is forwarded to the Managing Director, who will investigate those problems associated with damaged goods or failure to meet specifications.
If the complaint is a failure to comply with a specification, a repeated failure or a premature failure, then the substance of the complaint and preferably the written complaint should be copied to the original manufacturer.
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 the company and / or the original supplier.
If the problem has no present solution the complaint should be entered into the "Current Complaints" file until an answer is found. The customer is contacted & informed of the position. And the Quality Engineer will review progress with the investigator.

**WITHDRAWAL OF SUSPECT PRODUCT**

Substantiated complaints, which could be dangerous or harmful, will require notification to the relevant Competent Authority. In this instance a complete list of users and locations is compiled. If appropriate, the Managing Director will arrange to withdraw remaining items from stock.

The above section (6.1) is also applied if a supplier contacts the company concerning goods already delivered. Sub Distributors are also obliged to keep destination records of products distributed and have a recall mechanism in place.

**FORMAT OF ADVISORY NOTICE**

Users will be contacted by letter or fax notifying them of the problem, wit a clear description of the problem and possible effects, a solution if available, advice on how to circumnavigate the problem if a method exists. Copies of the original manufacturers information will be enclosed where appropriate. EBME and / or Engineering departments should be informed.

Incidents as defined in the MDD will be reported on their form “Appendix 3”. Response will be immediate and instant referral to the MDD guidelines, following the Incident Action plan on their “Appendix 4”. The Notified Body / CMDCAS will be informed at the same time as the MDD. Notification of incidents will be indicated on the customer complaints form.

Associated Documents:

MDD guidelines

Non-conformity Procedure VOP/10.01