

STANDARD OPERATING PROCEDURE

Title: Customer Complaint Procedure

Effective Date: _____

Approvals (Signature and Date):

Responsible Department Head

Technical Authority

QA/QC

1. PURPOSE

- 1.1 The purpose of this procedure is to describe how to respond to a customer complaint. Customer complaints are defined in Section 8.1.

2. SCOPE

- 2.1 Complaints expressed by clinical investigators, customers and employees during use of the product are reported using this procedure.
- 2.2 This procedure applies to all finished goods.
- 2.3 The FDA, or other local regulatory body has the authority to review actual complaint records related to all regulated products. Research Use Only products are not governed by the FDA. European Notified Body can review only complaints pertaining to CE marked products.

3. RESPONSIBILITY

- 3.1 Company employees, representatives and distributors are responsible for reporting all customer complaints to Customer Service or local Customer Action Report (CAR) Coordinator.
- 3.2 Customer Service or local CAR Coordinator is responsible for:
- 3.2.1 Reviewing the CAR Report Form, and determining the need for further customer service or technical support after consultation with appropriate experts.
 - 3.2.2 Assigning a CAR number to the report
 - 3.2.3 Maintaining copies of all local CAR documentation
 - 3.2.4 Ensuring all follow-up customer service actions are completed and forwarding the CAR form to QA/QC Manager.
- 3.3 The QA/QC Manager is responsible for:
- 3.3.1 Determining the need for a complaint investigation and assigning the investigation.
 - 3.3.2 Determining whether a product problem has been confirmed.
 - 3.3.3 Determining whether a complaint requires review by Material Review Board.
- 3.4 Assigned complaint investigators are responsible for completing and documenting the investigation in a timely manner.

- 3.5 Quality Assurance is responsible for tracking complaint investigation, corrective action, and verifying resolution in a timely fashion. This includes preparation of periodic CAR status and tracking reports.
- 3.6 Document Control is responsible for the retention of all original complaint records and reports.

4. REFERENCES AND APPLICABLE DOCUMENTS

- 4.1 Company Quality Manual for references to applicable regulatory requirements.
- 4.2 09-0011-LOG-1.0, Customer Action Report Log
- 4.3 09-0179-SOP-1.0, Medical Device Reporting (MDR) Procedure (Domestic Market)
- 4.4 09-0178-SOP-1.0, Medical Device Reporting (MDR) Procedure (European Market)
- 4.5 09-0015-SOP-1.0, Material Review Board
- 4.6 09-0217-SOP-1.0, Quality Improvement Project Monitoring System
- 4.7 10-0017-SOP-1.0, Returned Goods Procedure
- 4.8 05-0004-SOP-1.0, Instrument Service and Repair Procedure
- 4.9 12-0035-SOP-1.0, General Record Keeping Procedure

5. MATERIALS AND EQUIPMENT

- 5.1 CAR File Storage Cabinets

6. HEALTH AND SAFETY CONSIDERATIONS

- 6.1 None

7. DOCUMENTATION REQUIREMENTS

- 7.1 Customer Action Report Form - Attachment B
- 7.2 CAR Investigation Form - Attachment C
- 7.3 Customer Action Report (CAR) Log - Attachment D
- 7.4 Quarterly and Annual Reports on Customer Complaints
- 7.5 Other CAR file documentation as described in Section 8.13.2.

8. PROCEDURE

Note: Refer to Attachment A for an overview of this procedure.

- 8.1 Definition of Complaint - Any written or oral expression of dissatisfaction relative to:
 - 8.1.1 The product's identity, quality, durability, reliability, safety, effectiveness, or performance.
 - 8.1.2 The product's packaging or labeling (including manuals and inserts).
 - 8.1.3 The use of the product (procedural complaint).
 - 8.1.4 Service received.
- 8.2 Source of Complaints
 - 8.2.1 A verbal or written complaint from a customer may be received over the telephone or in person by any employee, distributor or representative of .

- 8.2.2 Failure of an QA/QC released product during internal use, customer training, or observed during installation/servicing is also documented using this procedure.
- 8.3 Initiation of a Complaint, CAR Report Form (Attachment B)
- Note: Good documentation practices (see 12-0035-SOP-1.0) must be followed in documenting activities relating to complaints. This includes completing all information spaces on the forms with either the information, "N/A" if not applicable, or "Unknown" if efforts to obtain missing information fail.
- 8.3.1 If a customer contact (verbal or written) meets the definition of a complaint described in section 8.1, the representative will initiate a CAR Report Form within 7 days (see Attachment B)
- 8.3.2 Customer/Technical Service and/or the local CAR Coordinator along with the Representative will attempt to resolve the problem over the phone. A summary of the initial actions or responses to the customer is recorded on the CAR Form
- 8.3.3 representative completes page 1 of the CAR report form (Attachment B) and forwards the form to Customer Service or the local CAR Coordinator.
- 8.3.3.1 If the answer to any of the MDR questions is "yes" or there is a possibility the answer is "yes", immediately contact Clinical and/or Regulatory Affairs for guidance before completing the MDR section. An MDR reportable incident is defined in 09-0179-SOP-1.0, MDR Procedure (Domestic Market) and 09-0178-SOP-1.0 MDR Procedure (European Market).
- 8.3.3.2 If the complaint is deemed MDR reportable by Clinical and/or Regulatory Affairs, forward a copy of the CAR and all relevant documentation to the appropriate Regulatory Affairs Manager within 24 hours. The Regulatory Affairs Manager will handle the event as described in 09-0179-SOP-1.0 (Domestic) and 09-0178-SOP-1.0 (European).
- 8.4 Customer Service or local CAR Coordinator Review
- 8.4.1 Customer Service or the local CAR Coordinator will assign a CAR number from a Log of sequential numbers. Quality Assurance will also assign an additional US CAR number, issued from the same log used by the US Customer Service (See attachment D), to all CARs received from outside the US. If an assigned number is later canceled, the reason for the cancellation is documented in the appropriate log(s).
- 8.4.2 Customer Service or the local CAR Coordinator will review the report and determine if additional action or customer follow-up is required and assign follow-up to a representative. Additional customer follow-up may include dispatching of a Field Support Personnel to the customer site, the replacement of defective products, return of defective products to (10-0017-SOP-1.0).
- 8.4.3 Customer Service or the local CAR Coordinator will investigate local service complaints before forwarding the form to Quality Assurance Department.
- 8.4.4 All customer service actions are documented and attached to the form.
- 8.4.5 Customer Service or the local CAR Coordinator will sign and date the CAR Evaluation Form and forward the original form to QA Department.
- 8.5 Initial QA/QC Manager review: Determination of Need for Investigation.

- 8.5.1 All CARs are sent to QA/QC Manager, or designate, for review. A designate must have a thorough knowledge of the product in order to make an informed, reasonable decision as to the severity and significance of the complaint.
- 8.5.2 The QA/QC Manager, or designate, determines the need for additional investigation to confirm the existence of the problem. If no additional investigation is required, a record is made on the CAR of the rationale used to arrive at this decision. If an investigation is required, an investigator is assigned responsibility for the investigation. The QA/QC Manager has the option of designating an investigation plan. The investigation may include the following:
 - 8.5.2.1 Testing of retention sample or product returned from the customer,
 - 8.5.2.2 Review of the development, production and/or stability records,
 - 8.5.2.3 Review of the customer data.
- 8.6 The original CAR is returned to Quality Assurance.
 - 8.6.1 If no investigation is necessary, Quality Assurance will:
 - 8.6.1.1 Record an entry of "N" in the "Investigate?" column of the CAR log.
 - 8.6.1.2 Send a copy of the CAR to the appropriate CAR Coordinator for evaluation of a secondary response to the customer. Refer to Section 8.12 for discussion of secondary response to the customer.
 - 8.6.1.3 Upon return of the CAR Closure form and documentation (if any) from the CAR Coordinator, the CAR is closed.
 - 8.6.2 If an investigation is required:
 - 8.6.2.1 The QA department will update the CAR log with the investigator name(s) and send the investigator a copy of the CAR, an Investigation Form (Attachment C) and copies of all related documents.
 - 8.6.2.2 Quality Assurance periodically follows-up to confirm that investigations are carried out in a timely manner. This includes preparation of periodic CAR status reports.
- 8.7 CAR Investigation and Documentation:
 - 8.7.1 Upon receipt of the investigation request and CAR package, the investigator will perform at least the investigation directed by the QA/QC Manager. If the investigator requires others to assist with the investigation, the investigator may notify Quality Assurance. QA will add their names in the investigator's column of the CAR log.
 - 8.7.2 The records of the investigation are documented and the assigned investigator signs and dates the Investigation Report form and sends the form and copies of all documentation to QA.
 - 8.7.3 All investigations must be documented, regardless of outcome.
- 8.8 QA/QC Manager review after Investigation completion:
 - 8.8.1 The QA/QC Manager determines:
 - 8.8.1.1 If a product problem is confirmed, indeterminate, or not confirmed. The indeterminate category will be used when a complete investigation cannot be performed because a product cannot be returned for evaluation.

8.8.1.2 If a complaint requires MRB review. Complaints where a product problem has been ruled out or are indeterminate do not require MRB review. If a product problem is confirmed, the complaint may not require MRB review if the investigation determines that the product problem is being addressed by a Quality Improvement Project. However, the QA/QC Manager has the discretion of forwarding any complaint to MRB for review. The QA/QC Manager may call an immediate MRB meeting if the problem may cause serious, adverse health consequences or death.

8.8.1.3 If further vendor communication is required see Section 10.

8.9 Quality Assurance CAR system administration:

Following investigation completion and QA/QC Manager’s review, Quality Assurance will assign a complaint type for trending purposes. Complaint types and examples are listed in the following table:

COMPLAINT TYPES

Complaint Type	Examples
1 - reagent problem	- cloudy, contaminated, or leaking reagent - absence of or incorrect labeling
2 - device problem	- leaking column - broken or incorrectly assembled part - incorrect labeling
3 - hardware problem	- mechanical failure of instrument or computer. - broken part
4 - software problem	- data mismanagement - inadequate control of process - software bug/virus
5 - packaging problem	- product damaged in transit
6 - labeling / procedural problem	- error, omission, or contradicting information in labels, insert, manuals, or field service bulletins. - difficulty in understanding instructional insert - difficulty in following instructional insert
7 - service problem	- late delivery - shipment of wrong product - shipment of incorrect quantities - untimely response to customer inquiry
8 - other	- Self explanatory
9 - processing problem	- A problem related to patient sample such as low yield or purity and no operator error is indicated.
10 - Operator Error	- Operator did not follow manual, instructions, insert, or protocol.

8.9.1.1 Quality Assurance will update the CAR log to reflect the QA/QC Manager’s conclusions. For product problem coding, enter a “Y”, “Ind”, or “N” as appropriate. For MRB review enter “N” or “Y - pending” as appropriate.

8.9.1.2 If MRB review is not required, QA will forward a photocopy of the complete CAR to the appropriate CAR Coordinator or Customer Service Representative for secondary response to the customer as described in section 8.12.