STANDARD OPERATING PROCEDURE

Title: Returned Goods Procedure

Effective Date: _____

Approvals (Signature and Date):

_____	_____	_____
Responsible Department Head	Technical Authority	QA/QC

1. PURPOSE

1.1 This document defines the procedure to follow when returning [illegible] products to [illegible]

2. SCOPE

2.1 This procedure applies to all [illegible] products and equipment including kits, disposables, devices and instruments.

2.2 This procedure applies to all products returned to [illegible] from customers, [illegible] offices, and distribution centers worldwide.

3. RESPONSIBILITY

3.1 Customer Service is responsible for assigning RGA numbers, maintaining the RGA Log, and tracking returned goods.

3.2 The Technical Application Specialist, [illegible] representative, or distributor is responsible for coordinating product return with the customer site and Customer Service Department [illegible]

3.3 Material Control is responsible for receiving, handling, and final delivery of returned products.

4. REFERENCES AND APPLICABLE DOCUMENTS

4.1 Customer RGA Form, located in [illegible]® Instrument Manual.
4.2 SOP 09-0011 Customer Complaint Procedure (Customer Action Report)
4.3 SOP 05-0011 [illegible]® [illegible] Instrument Decontamination Procedure
4.4 SOP 09-0015 Material Review Board
4.5 SOP 10-0005 Receiving And Handling Human Specimens
4.6 SOP 05-0004 Instrument Service And Repair Procedure
4.7 SOP 10-0002 Materials Control-Receiving Procedures
4.8 SOP 12-0034 Biohazard Exposure Control Plan
4.9 CFR 42, Title 72, Interstate shipment of Etiologic Agents

5. MATERIALS AND EQUIPMENT

5.1 None

6. HEALTH AND SAFETY CONSIDERATIONS

6.1 Instruments which may have been exposed to human biological material must be decontaminated per instructions on the Customer RGA Form located in the [illegible]® Instrument Manual prior to shipment to [illegible] If decontamination has not been confirmed on the form, instruments must be

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