

	<i>Document Title, Revision No.</i> MDR Procedure, Rev. 001
	<i>Approved by:</i>
	<i>Approval date:</i>

1. **Purpose:** To ensure that complaints are evaluated in a timely and effective manner for the purpose of identifying and reporting MDR eligible events.
2. **Scope:** This procedure is applicable to all employees who receive information regarding an product malfunction, or a patient injury or death reported to be associated with a product. It is used as a companion to the Complaint Investigation procedure.
3. **Procedure:**

3.1 MDR Reporting

3.1.1 MDR status determination – The reportability of an event is determined by use of the Complaint Investigation Form, in which prompts the user to complete a MedWatch form (FDA Form 3500A) under condition of:

3.1.1.1 Malfunctions known to have been associated with patient injury or death within the previous two years.

3.1.1.1.2 Malfunctions resulting in patient injury.
Patients are considered injured by report or if any type of medical intervention is required as the result of malfunction or suspected malfunction.

3.1.1.1.3 Malfunctions resulting in patient death.

3.1.2 MedWatch form completion - Information regarding MDR reportable events are submitted to FDA for review on MedWatch forms.

3.1.2.1.1 MedWatch forms must be typed or completed with FDA provided software instead of hand written.

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3.1.3 **30-Day Deadline** – MedWatch forms must be completed and postmarked within 30 days of any Alpha Industry employee receiving information regarding an MDR reportable event.

3.1.4 **5-Day Deadline** – MedWatch forms must be completed and postmarked within 5 days of any employee receiving information regarding an MDR reportable event where the manufacturer initiates remedial action to protect public health (such as a recall), or which is specified in writing by FDA to the company as reportable within 5 days.

3.1.5 **Baseline reports** – A Medical Device Reporting Baseline Report (Form FDA 3417) is submitted with the MedWatch form for the first reportable event associated with each device model.

3.2 MDR Submission – MedWatch and baseline reports are submitted to the FDA via certified mail, per the instructions on the form.

4. Records:

4.1 MDR file contents – MDR files are maintained as complaint files, with the addition of:

- 4.1.1 A copy of the submitted MedWatch form(s)
- 4.1.2 A copy of the submitted baseline report (when applicable)
- 4.1.3 All customer correspondence relevant to the event
- 4.1.4 All FDA correspondence relevant to the event
- 4.1.5 Certified mailing slips and returned receipts

4.2 MDR file location – MDR files are maintained in hard copy format as a part of the complaint filing system.

- 4.2.1 MDR files are visually identifiable within the complaint filing system by a permanent red marker or label.

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4.3 MDR file maintenance – MDR files are maintained for a period of 2 years after the date of event.