## DOCUMENT APPROVALS

| Authors: | | | |
|---|---|---|---|
| **PRINT NAME** | **POSITION** | **SIGNATURE** | **DATE** |
| Radha Arichandran | QA/RA Manager | | 30 Nov 2023 |

| Reviewer (s) and Approver (s): | | | |
|---|---|---|---|
| **PRINT NAME** | **POSITION** | **SIGNATURE** | **DATE** |
| Chris Dawson | Director | *Chris Dawson* | 30 Nov 2023 |

## Table of Content

## 1. PURPOSE

This procedure defines the requirements for handling product feedback & complaints. Specifically, receipt, review, evaluation, and investigation of complaints associated with medical devices that are manufactured and/or designed by Ultimate Healthcare Limited.

## 2. SCOPE

This Standard Operating Procedure applies to all products or services provided by Ultimate Healthcare Limited.

## 3. DEFINITIONS

The definitions of acronyms and terms used within this procedure is listed below:

| Acronym/Term | Definitions |
|---|---|
| UHL | Ultimate Healthcare Ltd |
| Awareness Date | The date the first person in UHL becomes aware of any issue that fits the definition of a complaint |
| CAPA | Corrective and Preventive Action. |
| Complaint | any written, electronic or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, usability, safety (including misuse that creates a hazard or unsafe use), effectiveness or performance of a device that has been released from the organization's control or related to a service that affects the performance of such medical devices. |
| Feedback | Customer satisfaction, opinion, comments and expression of interest in a product and/or service |
| Good Faith Effort | A minimum of three attempts shall be made to obtain any information that is required to perform an investigation of the complaint and to satisfy regulatory reporting requirements as applicable |

Further Definitions are referenced in UHQP 29 Vigilance System

## 4. ROLES AND RESPONSBILITIES

The roles and responsibilities discussed within this procedure are listed below:

| Role | Responsibilities |
|---|---|
| Sales | • Facilitate the return of product |
| Customer services | • Providing communications between UHL and customer(s) |
| Warehouse | • Receipt of returned item(s) |
| Personnel | • All UHL personnel shall be trained in this procedure<br>• All employees or persons acting on behalf of UHL are responsible for notifying the QA department within one business day of becoming aware of a complaint, via email Feedback@ultimatehealthcare.co.uk |
| Quality Function | • Administering the complaints procedure i.e. receipt, review and investigation, root cause determination, documenting any associated corrective and or preventative actions trending and timely closure of complaints/ feedback<br>• Evaluating information received to determine if the information constitutes a complaint<br>• Determining the need to report the information to the appropriate regulatory authorities |

## 5. PROCEDURE

**5.1** Complaint information**,** communication and documentation shall be provided in English. Documents that are pertinent to the processing of the complaint shall be summarized or directly translated by the originator. To expedite the complaint process (phone information or e-mail the intent of the communication and provide the translation later). English is the UHL language of record and shall be used to translate documents for complaint handling.

**5.2** Supporting documents that are not controlled Quality Records shall be attached to the Feedback record/ folder and named descriptively. Supporting documents that are controlled Quality Records can be referenced within the Feedback record.

### 5.3 Complaint intake

5.3.1 Any UHL employee or person acting on behalf of UHL who becomes aware of a customer complaint by email, phone, fax, mail, social media, verbally or other means shall forward the complaint information to the QA department. The targeted timeframe is one (1) business day. Contractors and consultants are considered to be UHL employees or employees acting on behalf of UHL.

5.3.2 The complaint information shall be forwarded to the Ultimate Feedback inbox Feedback@ultimatehealthcare.co.uk. All details relevant to the complaint must be provided including supporting documentation (e.g. emails, letters, videos and images).

5.3.3 Complaints and feedback must be logged on UHQPF 26 feedback form.

5.3.4 The QA representative shall evaluate the information received to determine if it constitutes a complaint.

5.3.5 The complaint/ feedback intake steps are defined in UHWI – 31.1.

5.3.6 If there has been a delay of greater than 1 business day in notifying of an event, the responsible party shall provide a rationale and document it on UHQPF 26.

5.3.7 The QA representative shall provide an acknowledgement email that the complaint has been logged.

5.3.8 If it is determined that the customer/ complainant shall be returning product, information relating to product disposition after the investigation has been completed is also required e.g. return to facility, storage etc.

### 5.4 Reportable events

5.4.1 All complaints shall be reviewed to determine if the event involves an event / incident that is required to be reported to the relevant competent authority - Refer to UHQP 29 Vigilance System.

5.4.2 Should any new information be received during the investigation which may change the initial reportability decision, the reportability decision shall be re-done.

5.4.3 Regulatory reporting shall be performed in accordance with UHQP 29 Vigilance System.

### 5.5 Complaints investigation

5.5.1 All complaints irrespective of reporting status shall be investigated via the complaints handling process. The Complaint Investigation steps are outlined in UHWI-31.1 and UHQPF 26.

5.5.2 Any complaint involving the possible failure of a device, labelling, or packaging to meet any of its specifications shall be reviewed, evaluated, and investigated, unless such investigation has already

been performed for the same event related to the same device. In this case another investigation is not necessary, it is acceptable to refer to a previous investigation with relevant supporting documentation available in the complaint file.

5.5.3 Any additional information (verbal, written, photographic etc.) received by any UHL employee or agent / distributor pertaining to a complaint shall be forwarded to the QA department for inclusion in the complaint record and to assist the complaint investigation.

5.5.4 To pursue any additional information that was not available at the time of initial receipt of the complaint, the Complaints Investigator or designee shall contact the complainant by email or phone (Good Faith Effort).

5.5.5 A minimum of three attempts shall be made to obtain any information that is required to satisfy regulatory reporting requirements and to assist in the investigation of the complaint. At least one follow up attempt shall be in writing (letter, email and fax are acceptable) and all three attempts shall be documented.

5.5.6 Any verbal conversations (e.g. between customers / complainants and UHL employees / agents / distributors) relating to the complaint investigation shall be documented e.g. via email or a signed and dated memo.

5.5.7 The Complaint investigation determines whether or not a corrective action is required. If upon review the complaint represents an increase in risk or a new risk that is not included in the applicable product risk document, the Quality department will be required to ensure the risk document is updated in accordance with Risk Management procedure UHQP 08. If a new risk is identified and found to be unacceptable, the Quality department shall ensure that it is escalated to a non-conformance (UHQP 30 Corrective and Preventive Action).

5.5.8 Once the investigation activity has been completed, the Complaint Investigator shall document the investigation summary and any conclusion(s) on UHPQF 26. Appropriate supporting documentation is attached to the Complaint or stored in the feedback folder.

5.5.9 If any complaint is not investigated, justification shall be documented. Detailed justification with strong rationale is needed in the case that complaints are not investigated. This justification shall be documented and saved in the corresponding feedback folder. Any relevant documentation to assist with the rationale shall be attached. The complaint shall be cancelled or closed with the justification recorded on UHPQF 26

5.5.10 If an investigation determines activities outside the organization contributed to the complaint, relevant information shall be exchanged between UHL and the external party.

### 5.6 Complaint Investigation Approval

5.6.1 When the investigation activity has been completed, the Complaints Investigator shall submit the record for approval.

5.6.2 QA shall review the submitted investigation to ensure that all steps of the investigation were performed

### 5.7 Reopening a Record

Product Inquiry, Complaint or Product Return records shall be re-opened when any of the following occur:

- New information is received (e.g., medical records, device return).
- An error is identified.
- Clarification is needed.
- Upon request from a regulatory agency

- Clerical updates

### 5.8 Compliant Metrics

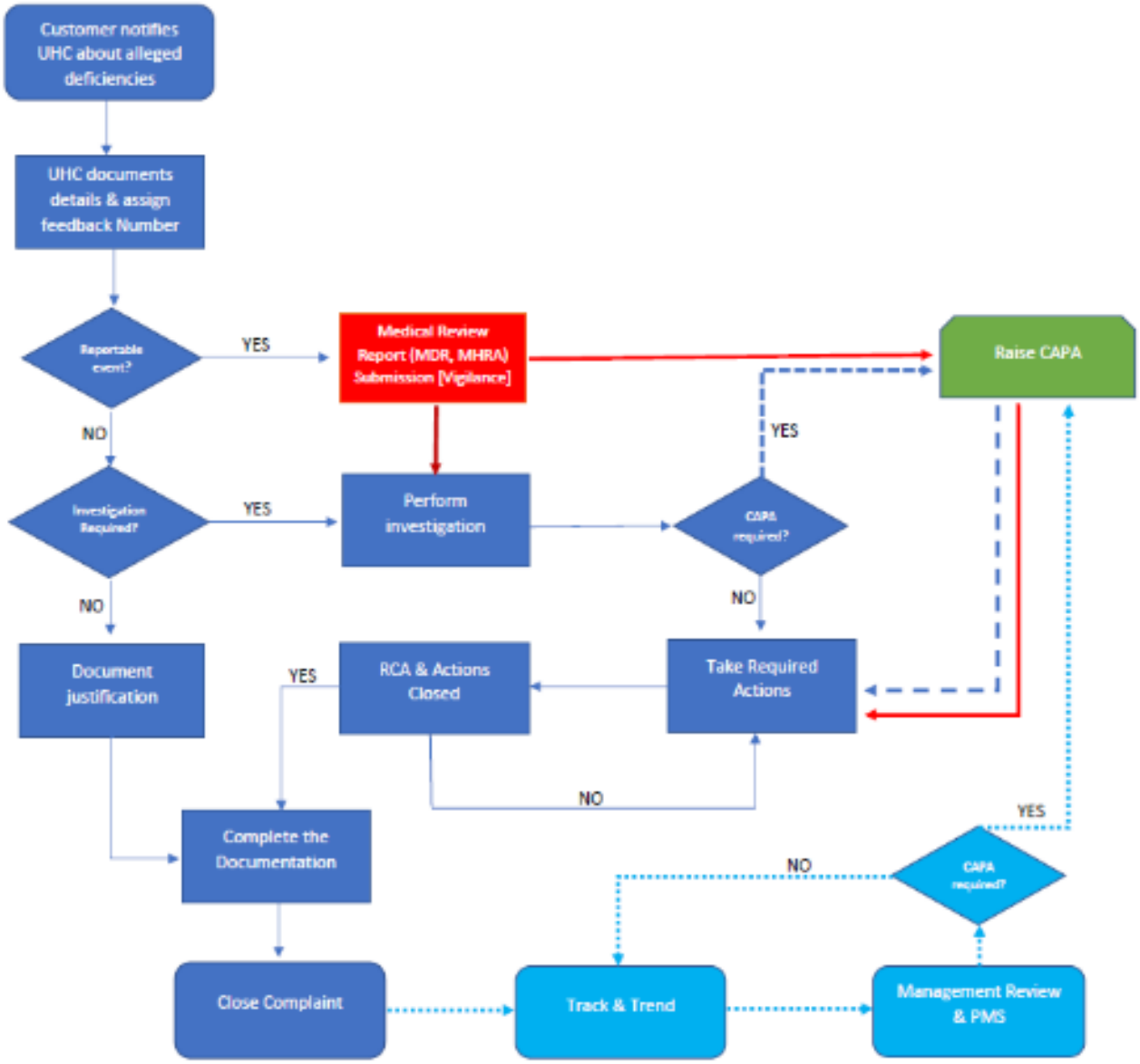
Refer to UHWI-31.1 for details of data collected, analysed and monitored in order to perform trend investigation analysis identified from product complaints.

## 6. RECORDS

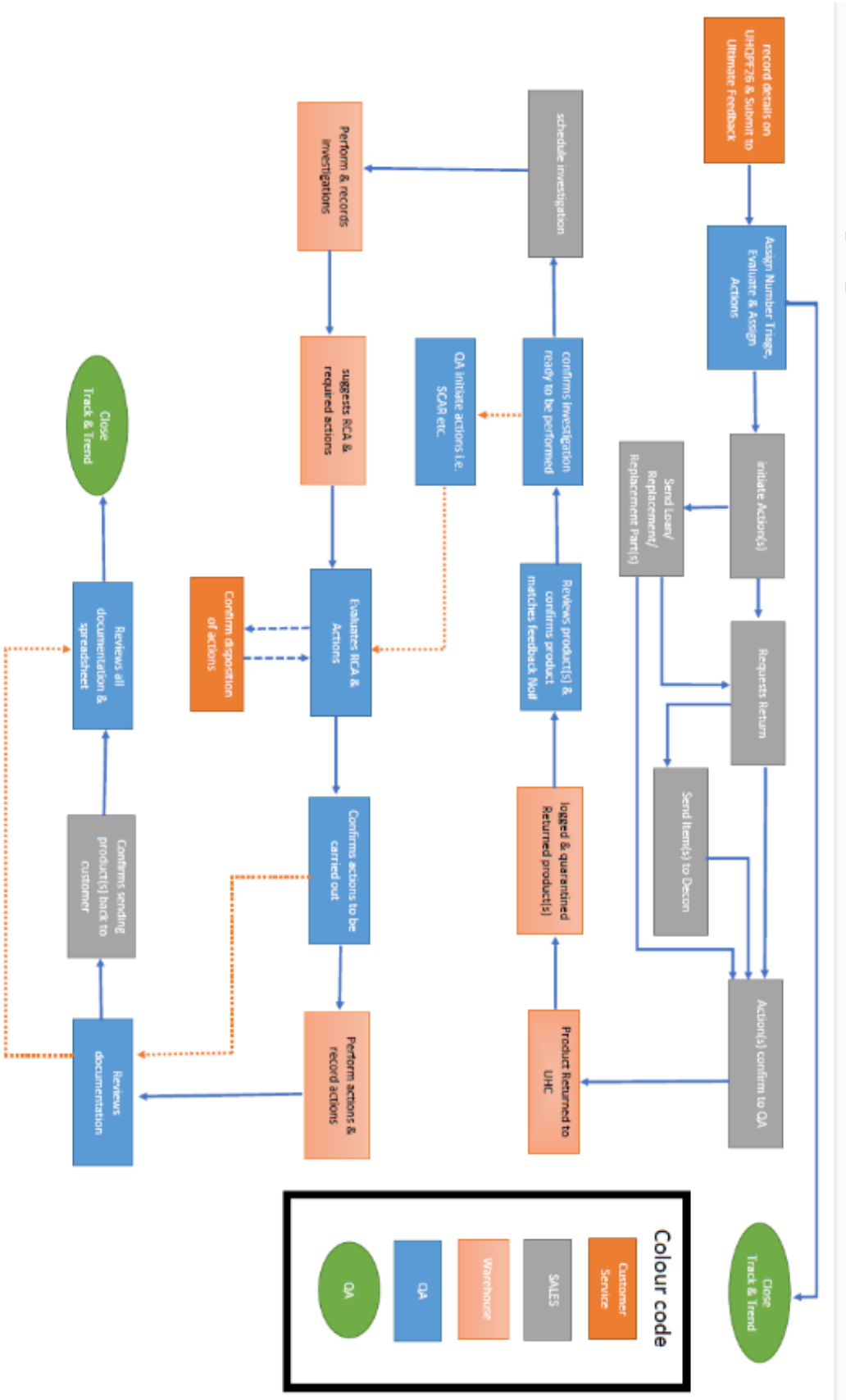
All records that are outputs of performing this process shall be retained in accordance with record retention procedures UHQP 01 Document and Records Control

## 7. APPENDICES

### 7.1 Appendix I

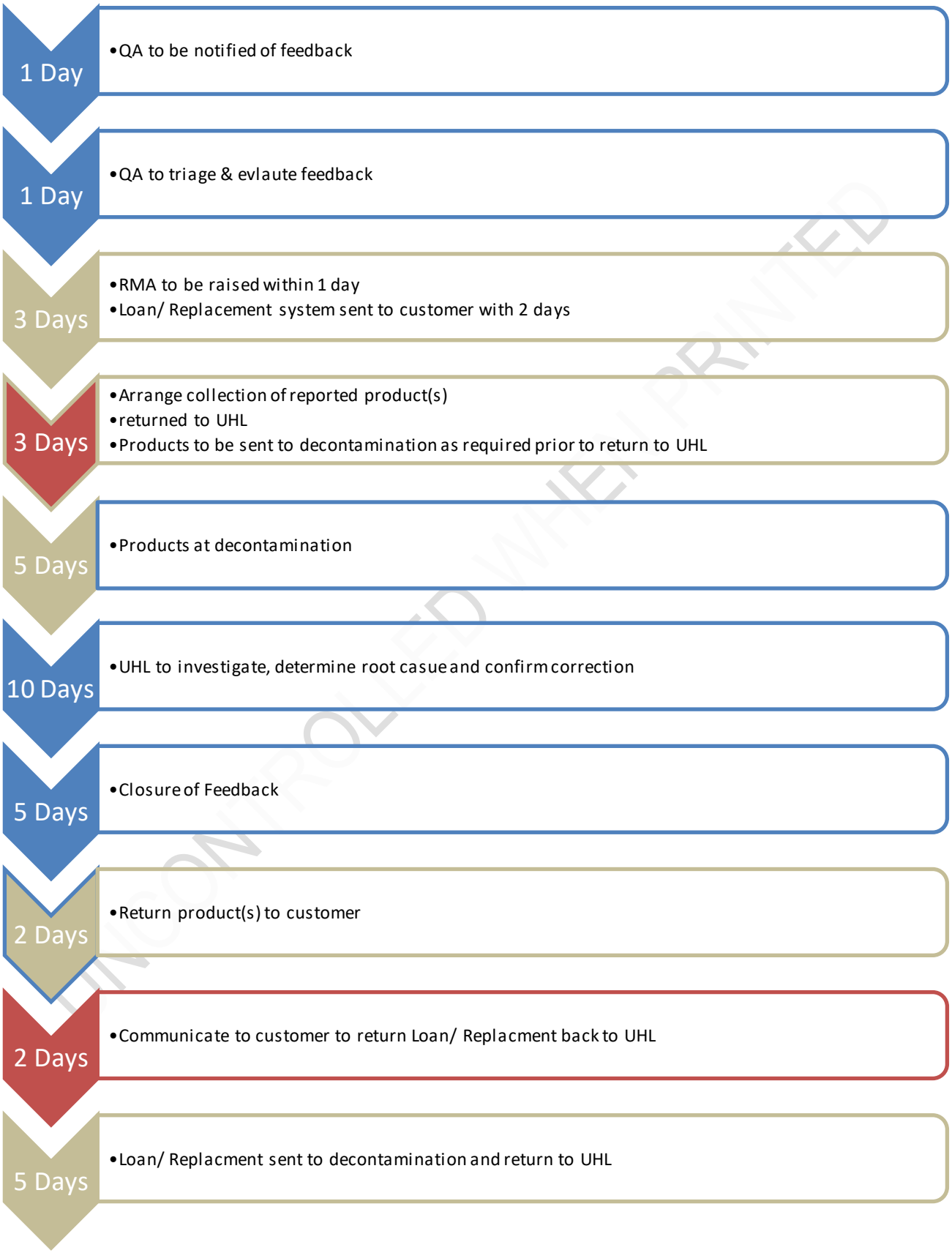


## 7.2 Appendix II



**7.3 Appendix III**

Schedule for the processing of a customer feedback when product is to be returned for investigation



## 8. REFERENCES

| External References |
|---|
| **Standards:**<br>EN ISO 13485 – Medical Devices – QMS – Requirements for Regulatory Purposes<br><br>**Regulations:**<br>EU 93/43 EEC as amended, Medical Device Directive<br>EU 2017/745 Medical Device Regulation |
| **Internal References** |
| UHQM -Quality system Manual<br>UHQP 01 - Document and Record Control<br>UHQP 08 Risk Management<br>UHQP 30 Corrective and Preventive Action<br>UHQP 33 Post market surveillance procedure<br>UHQP 37 - Change control Procedure<br>UHQP 45 Customer Returns Procedure<br>UHQP 45a Customer Returns<br>UHQP 51 Receiving RMAs into the Warehouse |

| Related Forms / Location | Related Records / Location |
|---|---|
| UHQPF 26<br>Feedback log<br>UHQF 45.1 TSQ Form<br>UHQF 51.1 RMA RECEIPT PROCESS LOG | - Y: Drive |

## 9. OWNERSHIP, CHANGE HISTORY AND ISSUE DATE

### 9.1 Document Ownership

| | |
|---|---|
| Document Owner | Quality Department and Human Resources |
| Type of document | Quality Procedure |
| Description | Describes how feedback is managed within Ultimate Healthcare |
| Target audience | All Ultimate Healthcare Employees |
| Author | Rick Singh – QA specialist |
| Department | Quality Department |
| Date of approval | 22Jun2021 |
| Issue Date | 14Jul2021 |
| Periodic Review Date | 2024.07 |
| Internal distribution | All Ultimate Healthcare employees |
| External distribution | On request |
| Availability | Shared IT resource<br>Hard copy (uncontrolled) |

### 9.2 Document Change History

| Rev# | Date | Reason for Change | Author | CR # |
|---|---|---|---|---|
| 9 | 01JUN2021 | Document template change<br>Section 1-5 expanded<br>Section 6 Amended to reflect QMS<br>Section 7 Appendix I & II added<br>Section 8 Internal references & Related Forms / Location expanded<br>Section 9 Updated | R.Singh | CR127 |
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