Product complaint record

Form | OPT-FRM-005

Document type	Form
Title	Product complaint record
Document ID	{{facility.code}}-OPT-FRM-005
Version and status	1.0 | Issued for use. Pending ASF Expert Committee ratification
Prepared by	{{roles.quality_lead.name}}, Quality lead
Reviewed by	{{roles.clinical_director.name}}, Clinical director Date: _____
Approver and signature	{{roles.clinical_director.name}}, Clinical director Signature: _____ Date: _____
Effective date	{{document.effective_date}}
Next review	{{document.review_date}} (12 months, or sooner after any incident or change)
Replaces	None (new document)
Standards and criteria supported	Standard 15 (Optical and Hearing), criterion 15.6
Evidence basis	E-006, E-009
Status of this document	Recommended best-practice model. A hospital may adopt, adapt or replace it with an equivalent that meets the same criteria.

Use this form when

Records each complaint about a product or service, the review and the outcome.

1. How to complete

- Record each complaint at once.
- Record the review and action.
- Record the outcome told to the patient.

2. Items to check

#	Item	Standard or evidence	Yes	No	N/A	Action if No
1	Product or service and date	Yes	[ ]	[ ]	[ ]	Action and who to tell
2	Complaint	Yes	[ ]	[ ]	[ ]	Action and who to tell
3	Return or replacement (yes or no)	Yes or N/A	[ ]	[ ]	[ ]	Action and who to tell
4	Review and action	Yes	[ ]	[ ]	[ ]	Action and who to tell
5	Outcome told to patient (date)	Yes	[ ]	[ ]	[ ]	Action and who to tell

Completed by (name and role): _____ Date/time: _____ Signature: _____

3. Evidence

ID	Source and status
E-009	Based on the ASF Expert Committee consensus and the WHO World report on hearing (2021).

ID	Source and status
E-006	ASF Policy Framework v1.2. Adapted.
E-009	ASF Expert Committee consensus.

EC = ASF Expert Committee consensus.

4. Change history

Version	Date	What changed	Approver and signature
1.0	{{document.effective_date}}	First version	Pending Expert Committee approval