Standard operating procedure (SOP) · OPT-SOP-003 · Version 1.0 · Approved by the ASF Expert Committee

Supports: 15.6

At a glance

- Each complaint about a product or service is recorded on OPT-FRM-005.
- Returns and replacements are handled as the complaints rule sets (INC-POL-002).
- Each complaint is reviewed, and the action is recorded.
- The patient is told the outcome.
- Stop and get help straight away if: a complaint about a product is not recorded or not answered.

1. Purpose

To learn from complaints about products and services, and act on them (15.6).

2. Scope

Applies to	Clinical and support staff in the hospital
Locations	All wards, clinics and departments of the facility
When	Whenever the activity described is carried out
Does not apply to	Activities covered by another document listed in section 15

3. Definitions

Term	Meaning
Clinical lead	The doctor or nurse in charge of the area at the time

4. Background

A complaint about a product or a service is information about what is going wrong. Recording and acting on it, and telling the patient what was done, improves the service.

5. Responsibilities

Role	Responsibility	Competence
Practice manager	Owns the complaints route	Manager
Lead optometrist or audiologist	Reviews product complaints	Clinician

6. Materials and equipment

Item	Requirement	Condition
Records and forms named in this document	Current version	Checked before use

7. Safety

- Stop and call for help if a patient is at immediate risk. Do not delay urgent care to complete paperwork.

8. Before you start

- Confirm the forms and equipment named in this document are available and current.

9. Procedure

Step 1. Record.

- Record each complaint on OPT-FRM-005 with the product.

Key point: Every complaint.

Step 2. Review and act.

- Review the complaint and act: return, replacement or change.

Key point: Reviewed, acted on.

Step 3. Tell the patient.

- Tell the patient the outcome.

Key point: Outcome told.

10. Decision points

- No decision points in this procedure.

11. Special situations

Situation	Action
Out of hours	Follow the same steps. Use the on-call contact on the wall of the area.

12. Escalation

- Any serious problem goes to the duty clinical lead at once and to the clinical director the same day.

13. Monitoring

Measure	Target	Frequency	Owner	If not met
Complaints recorded and answered	100%	Monthly	Practice manager	Escalate to chief executive

14. Records

Record	Kept in	Retention
Record named in this document	Patient record or the area file	the period set by the facility’s records policy years

15. Training

- Staff are trained in this document at induction and refreshed each year, with a recorded competency check.

16. Related documents

ID	Title	Use
OPT-FRM-005	Product complaint record	Record
INC-POL-002	Complaints and feedback (existing, reused)	Policy

17. Evidence

Reference	Note
E-009	Based on the ASF Expert Committee consensus and the WHO World report on hearing (2021).
E-006	ASF Policy Framework v1.2. Adapted.
E-009	ASF Expert Committee consensus.

18. Change history

Version	Date	What changed	Approval
1.0	the date of approval	First version	set Expert Committee approval

E-learning for this document

- **Complaints Handling and Patient Feedback** (T-12)

References

- Accréditation Sans Frontières (2026). ASF Policy Framework v1.2. (E-006)
- Accréditation Sans Frontières (2026). ASF Expert Committee consensus on Standard 1. (E-009)

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