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Ministry of Health

DSC
مركز سلامة الدواء
Drug Safety Center

Guideline on Medical Device Reporting in Sultanate of Oman.

Drug Safety Center

2026

First Edition

Document Title	Medical Device Reporting in Sultanate of Oman
Document Type	Guidance
Directorate/Institution	Drug Safety Center
Targeted Group	Manufactures, Local agents, Importers and medical device users
Document Author	Medical Device Vigilance Section
Designation	Medical Device Vigilance Section
Document Reviewer	Director of Medical Device Department
Designation	Director of Medical Device Department
Release Date	July 2026
Review Frequency	Every 3 years

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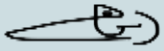
Signature		**Signature**	
Date	**2026/07/15**	**Date**	**2026/07/15**

Acknowledgments

The preparation of this guideline was undertaken by the Medical Device Vigilance Section/ Medical Device Department. The Drug Safety Center extends its sincere gratitude to all staff members of the section for their dedicated efforts. Special acknowledgment is given to the members of the Medical Device Vigilance Section Task Force for their invaluable contributions, in particular:

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Table of Contents

Acronyms	4
Definitions	5
CHAPTER ONE	8
Introduction	8
Purpose	9
Scope	9
Structure	9
CHAPTER TWO	10
Procedure	10
CHAPTER THREE	12
Responsibilities	12
CHAPTER FOUR	15
Document History and Version Control	15
References	15
Annexes	16
Appendix 1	16
Appendix 2	20

Acronyms:

MOH	**Ministry of Health**
DSC	**Drug Safety Center**
MDD	**Medical Device Department**
FSCA	**Field Safety Corrective Action**

Definitions

Medical Device	Medical device' means any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purpose(s) of: o Diagnosis, prevention, monitoring, treatment or alleviation of disease, o Diagnosis, monitoring, treatment, alleviation of or compensation for an injury, o Investigation, replacement, modification, or support of the anatomy or of a physiological process, o Supporting or sustaining life, o Control of conception, o Disinfection of medical devices, o Providing information by means of in vitro examination of specimens derived from the human body; and does not achieve its primary intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its intended function by such means.
Manufacturer	means any natural or legal person with responsibility for design and/or manufacture of a medical device with the intention of making the medical device available for use, under his name; whether or not such a medical device is designed and/or manufactured by that person himself or on his behalf by another person(s).
Medical Device Adverse Event	Any defect or change in the characteristics or performance of a medical device that may directly or indirectly cause or contribute to the death or serious injury of a user.

Medical Device Incident	Any malfunction or deterioration in the characteristics or performance of a medical device, including use error or inadequacy in the labelling or instructions for use, which has led, may have led, or might lead to the death of a patient, or user or of other persons, or to a serious deterioration in their state of health.
Medical Device Complaints	written, electronic or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, usability, safety or performance of a medical device that has been released from the organization's control or related to a service that affects the performance of such medical devices. Note: Complaint include reporting medical devices incidents result from any defect or change in the characteristics or performance of a medical device that may not directly or indirectly cause or contribute to the death or serious injury of a user.
Malfunction or Deterioration	A failure of a device to perform in accordance with its intended purpose when used in accordance with the manufacturer's instructions
Serious public health threat	Any event type, which results in imminent risk of death, serious injury, or serious illness that requires prompt remedial action
Unanticipated death or unanticipated serious injury	A death or serious injury is considered unanticipated if the condition leading to the event was not considered in a risk analysis performed during the design and development phase of the device. There must be documented evidence in the design file that such analysis was used to reduce the risk to an acceptable level.
Use error	Act, or omission of an act, that has a different result to that intended by the manufacturer or expected by the operator. Use error includes slips, lapses, mistakes and reasonably foreseeable misuse

Abnormal use	Act or omission of an act by the operator or user of a medical device as a result of conduct that is beyond any reasonable means of risk control by the manufacturer. Note: Foreseeable misuse that is warned against in the instructions for use is considered abnormal use if all other reasonable means of risk control have been exhausted.
Field Safety Corrective Action (FSCA)	An action taken by the manufacturer to limit or reduce the risks compromising the safety of a medical device or supply.
Medical Device Vigilance	Monitoring and tracking of medical devices and supplies after they have been marketed locally. By engaging in activities related to discovering, evaluating, understanding and preventing harmful effects or any other related problems.

CHAPTER ONE

Introduction

Medical Device Reporting Guidance is a guideline dedicated to describe the mechanisms of reporting of medical device adverse events and certain malfunctions issues, the guideline also illustrates types of adverse event reporting, the role of the reporters, local agents and Manufactures in this regard. Potential device-related safety issues should be reported to the regulatory authority to contribute to benefit-risk assessments of these products.

According to Decision 113/2020, Article (90), the users of the medical devices must inform the Drug Safety Center about any adverse events/complaints related to the use of the medical devices within a period of time from the date of their occurrence according to the severity level described in this guideline.

These reports are to be received by the Medical Device Vigilance Section which is responsible to set the necessary requirements to ensure the quality of marketed medical devices in the Sultanate and following up on the obligation of those requirements, create a database that includes all reports resulting from the use of medical devices from adverse effects, warnings, or any necessary measures and precautions in this regard, Exchange of information related to the incident of medical devices with the competent authorities in other countries, workshop awareness for consumers and health care providers related to using of medical devices and their incidents.

The reporters (manufacturers, device user facilities, and importers) are required to submit several types of reports for adverse events and complaints of medical device. The health care professionals, patients and consumers to submit reports about serious adverse events that may be associated with a medical device, as well as use errors, product quality issues, and therapeutic failures. These reports, along with data from other sources, can provide critical information that helps improve patient safety.

Purpose

The purpose of this guidance is to guide and encourage all healthcare institutions, importers, patients and professionals to the importance of reporting problems associated with medical devices.

Scope

- All medical devices which are existing and marketed in Sultanate of Oman.
- This guidance is applied to Medical Device manufacturers, their local agents, suppliers, distributors, healthcare professionals and patients.

Structure

This is the first version of this guidance and it consists of several chapters. Chapter one covers a brief introduction to the guideline as well as the purpose, scope and structure. Chapter two explains the procedure of medical device reporting. Chapter three covers the required documents and roles and responsibilities in regard to adverse/incident event and complaints reporting. Chapter four comprises of the annexes section including document history and version control table, references and appendixes which consists of a selection of several templates of creating different policy documents.

CHAPTER TWO

Procedure:

- **Events required to be reported:**

Anyone can report an adverse events and complaints associated with a medical device to Medical Device Vigilance Section. Patients, users, healthcare professionals and suppliers are all encouraged to report the following incidents:

- Adverse events that lead to death or injuries to users or patients, or may lead to possible harm, while the medical device is directly or indirectly linked to this incident
- Incidents and complaints related to the efficiency, quality of the medical device.

Appendix (1): Examples of Adverse Events, Incidents and Complaint.

- **How to report:**

Reporting shall be done by completing the attached form (Appendix 2) and submitting it via the following email address: **vigilance-md@moh.gov.om**

The Medical Device Reporting Form is also available at the following link:
https://moh.gov.om/media/pbybg2yj/medical-device-reporting-form-15072026_1.pdf

- **Reporting Time Frame:**

Medical Device Vigilance Section should be informed according to the severity of the adverse event or complaint during time frame set below:

- Report within (**two**) working days when the event or accident poses a serious threat to public health.

- Report within (**10**) working days when the event or accident leads to unexpected death or serious unexpected injury.
- Report within (**30**) working days for all events and accidents that are not associated with high risks or injuries to the users.

CHAPTER THREE

Responsibilities:

- Manufacturers, importers and distributors shall provide the Medical Device Vigilance Section with investigation reports, technical documents and test reports related to the medical device associated with the adverse event based on the stage of investigation and the availability of information.
- The testing of medical devices shall be conducted at the expense of the importer or local agent through the manufacturer or in an accredited lab, in accordance to related international standards, practices and procedures (e.g. the international standard ISO 2859-1).
- Manufacturers, importers and distributors shall establish a tracking system to record all information related to the supply and distribution of medical devices.
- The department will evaluate all submitted reports and information and may request additional information or action if necessary.
- The user is required to preserve the sample and evidence, and make them available upon request.

Investigation Report Types:

1. Initial Report:

   defined as the first information submitted by the manufacturer about adverse event, and complaint, but the information is incomplete and supplementary information will need to be submitted.

2. Follow-up Report:

   defined as a report that provides supplementary information or progress update about the adverse event and complaint.

3. Final Report:

   Final Report is defined as the last submitted report about the adverse event, complaint. In addition, has all details, action taken, and recommendation. The recommended

corrective or preventive action will be evaluated by Medical Device Vigilance Section to insure the safety efficiency and quality of medical device.

4. Any other technical documents and testing reports related to the device.

Investigation conclusion and final report submission:

Investigation procedures shall be concluded and the final report shall be submitted to the Medical Device Vigilance Section within:

- 15 days from the date of occurrence or awareness of adverse events or complaint that does not require testing or technical evaluation.
- 30 days from the date of occurrence or awareness of adverse events or complaint that require testing the device inside Oman.
- 90 days from the date of occurrence or awareness of adverse events or complaint that require testing the device outside Oman.

Roles and Responsibilities in regard to adverse event and complaint Reporting:

Roles of the reporters:

- Healthcare professionals should report to the Medical Device Vigilance Section any complaint or adverse event associated with medical devices occurs within their facilities and cooperate with department during investigation process.
- All details relating to adverse event/ complaint are recorded accurately; including date, time, and the medical device name, model, serial / lot number.
- If Adverse Event occurred: protect patient and staff, protect equipment/ environment, isolate equipment (including disposables), record information, internal reporting (risk manager. Biomedical engineering Section).
- The user is required to preserve the sample and evidence, and make them available upon request.

Roles of Local Agent/importer:

- All local agent should be aware of how to handle adverse event/complaints that are reported to them.
- Local agent is required to report to the Medical Device Vigilance Section and the manufacturer when they learn that one of their devices may have caused or contributed to a death or serious injury.
- The local agent and the manufacturer should have an agreed practice outlining:
  - How the investigation or evaluation of adverse event/ complaint, if appropriate, should be conducted by the distributor on behalf of the manufacturer.
  - How and what information should be recorded.
  - What testing / evaluation needs to be conducted and where.

Roles of the manufacturer:

- Manufacturers are required to report through their local agent to the Medical Device Vigilance Section when they have acknowledged that one of their devices may cause or contribute to death or serious injury.
- The manufacturer must ensure that all adverse events/ complaint are examined and investigated in a timely and appropriate manner.
- The manufacturer must ensure that users are informed of any associated risks with their products. Additionally, the manufacturer must organize and coordinate any identified field safety corrective actions in a timely manner. If necessary, the manufacturer must also organize and coordinate a device recall.
- The manufacturer must ensure that the local agent/distributor knows the role in the completion of corrective actions and recalls.

CHAPTER FOUR

Document History and Version Control

Version	Description	Review Date
1	Initial Release	10/05/2026
2		
3		

References:

- **Saudi Food and Drug Authority (SFDA)** Guidance on requirements for reporting of incident and adverse event of medical devices.
- **Saudi Food and Drug Authority (SFDA)** (2023) Requirements for post market surveillance of medical devices.
- **Global Harmonization Task Force (GHTF).** (1999) Adverse Event Reporting Guidance for the Medical Device Manufacturer or its Authorized Representative.

Annexes

Appendix 1: Examples of adverse events, incidents and complaints:

1. Loss of sensing after a pacemaker has reached end of life. Elective replacement indicator did not show up in due time, although it should have according to device specification.
2. On an X-ray vascular system during patient examination, the C arm had uncontrolled motion. The patient was hit by the image intensifier and his nose was broken. The system was installed, maintained, and used according to manufacturer's instructions.
3. It was reported that a monitor suspension system fell from the ceiling when the bolts holding the swivel joint broke off. Nobody was injured in the surgical theater at that time but a report is necessary (near incident). The system was installed, maintained, and used according to manufacturer's instructions.
4. Sterile single use device packaging is labelled with the caution 'do not use if package is opened or damaged'. The label is placed by incorrect design on inner packaging. Outer package is removed but device is not used during procedure. Device is stored with inner packaging only which does not offer a sufficient sterile barrier.
5. A batch of out-of-specification blood glucose test strips is released by manufacturer. Patient uses strips according to instructions, but readings provide incorrect values leading to incorrect insulin dosage, resulting in hypoglycemic shock and hospitalization.
6. Premature revision of an orthopedic implant due to loosening. No cause yet determined.
7. An infusion pump stops, due to a malfunction, but fails to give an alarm. Patient receives under-infusion of needed fluids and requires extra days in hospital to correct.
8. Manufacturer of a pacemaker released on the market identified a software bug. Initial risk assessment determined risk of serious injury as remote. Subsequent failure results in new risk assessment by manufacturer and the determination that the likelihood of occurrence of a serious injury is not remote.
9. Patients undergoing endometrial ablation of the uterus suffered burns to adjacent organs. Burns of adjacent organs due to thin uterine walls were an unanticipated side effect of ablation.
10. Manufacturer does not change ablation device label and fails to warn of this side effect which may be produced when the device is working within specification.

11. Healthcare professional reported that during implant of a heart valve, the sewing cuff is discovered to be defective. The valve was abandoned and a new valve was implanted and pumping time during surgery was extended.
12. During the use of an external defibrillator on a patient, the defibrillator failed to deliver the programmed level of energy due to malfunction. Patient died.
13. An intravenous set separates, the comatose patient's blood leaks onto the floor, the patient bleeds to death.
14. Unprotected ECG cable plugged into the main electricity supply – patient died.
15. Fatigue testing performed on a commercialized heart valve bioprosthesis demonstrates premature failure, which resulted in risk to public health.
16. After delivery of an orthopedic implant, errors were discovered in heat treatment records leading to non-conforming material properties, which resulted in risk to public health.
17. Testing of retained samples identified inadequate manufacturing process, which may lead to detachment of tip electrode of a pacemaker lead, which resulted in risk to public health.
18. Manufacturer provides insufficient details on cleaning methods for reusable surgical instruments used in brain surgery, despite obvious risk of transmission of CJD.

2. Examples of Use Error and Abnormal Use:

A. Potential Use Errors:

Complaint reports received of events occurring despite proper instructions and proper design according to manufacturer's analysis:

1. Operator presses the wrong button
2. Operator misinterprets the icon and selects the wrong function.
3. Operator enters incorrect sequence and fails to initiate infusion.
4. Operator fails to detect a dangerous increase in heart rate because the alarm limit is set too high and operator is over-reliant on alarm system.
5. Operator cracks catheter connector when tightening.
6. A centrifugal pump is made from material that is known to be incompatible with alcohol

according to the labeling, marking, and product warnings provided with the pump. Some pumps are found to have cracked due to inadvertent cleaning with alcohol.

7. Unintentional use of pipette out of calibration range.
8. Analyzer placed in direct sunlight causing higher reaction temperature than specified.
9. MRI system and suite have large orange warning labels concerning bringing metal near the magnet. Technician brings an oxygen tank into presence of magnet and it moves swiftly across the room into the magnet.

B. Potential Abnormal Uses:

Complaint reports received of events occurring despite proper instructions, and proper design, and proper training according to manufacturer's analysis determined to be beyond any reasonable means of the manufacturer's risk control.

1. Use of a medical device in installation prior to completing all initial performance checks as specified by the manufacturer.
2. Failure to conduct device checks prior to each use as defined by the manufacturer.
3. Continued use of a medical device beyond the manufacturer defined planned maintenance interval as a result of operator's or user's failure to arrange for maintenance.
4. Contrary to the instructions for use, the device was not sterilized prior to implantation. • Pacemaker showed no output after use of electrocautery device on the patient despite appropriate warnings.
5. Product analysis showed that the device was working in accordance to specifications, further investigation revealed that the operator was inadequately trained due to failure to obtain proper training.
6. During placement of a pacemaker lead, an inexperienced physician or other nonqualified individual perforates the heart.
7. Labeling for a centrifugal pump clearly indicates that it is intended for use in bypass operations of less than 6 hours' duration. After considering the pump options, a clinician decides that the pump will be used in pediatric extra-corporeal membrane oxygenation (ECMO) procedures, most of which may last several days. A pump fails due to fatigue cracking and patient bled to death.

8. Safety interlock on a medical laser removed by operator or user.
9. Filter removed and intentionally not replaced resulting in particulate contamination and subsequent device failure.
10. Tanks delivered to a health care facility are supposed to contain oxygen but have nitrogen in them with nitrogen fittings. The maintenance person at the health care facility is instructed to make them fit the oxygen receptacles. Nitrogen is delivered by mistake resulting in several serious injuries.
11. Use of an automated analyzer regardless of the warnings on the screen that calibration is to be verified.
12. Pacemaker patient placed into MRI system with the knowledge of the physician.
13. Ventilator alarm is disabled, preventing detection of risk condition.

Appendix 2: Medical Device Reporting Form

This form is intended to be used to report an adverse events or complaints related to medical devices

General Information:	
Date of this report	
Date of the adverse event/ complaint	

Reporter Information:	
Name	
Job title	
Department	
Establishment Name	
Email	
Mobile Number	

Device Information:	
Device Name	
Model	
Serial No.	
Lot / Batch No.	
Manufacturer	
Country of origin	
Local agent	
Expiration Date	

Is the device available for investigation? Yes☐ No☐

Are other units of the same model similarly affected? Yes☐ No☐

Device current location:

Event Details:

User at the time of the event:

☐ Healthcare professional
☐ Patient
☐ Patient companion
☐ Engineer / Technician
☐ Unknown

Describe the event in details:

Number of affected persons:
Number of affected devices:
Was the device used for its intended purpose? Yes☐ No☐ Unknown☐
Was the device stored and handled according to the manufacturer's recommendations?
Yes☐ No☐ Unknown☐

Notes:

All relevant information, photos of the affected devices, and any supporting documents should be sent to the following email: **vigilance-md@moh.gov.om**