

Reporting and investigating adverse events and complaints of medical devices or Safety alerts and field safety corrective action (FSCA) for medical devices

Mohammed Majrashi, PhD
Executive Director of Surveillance and Biometrics,
Saudi FDA



Definition - Post-Market Surveillance activities

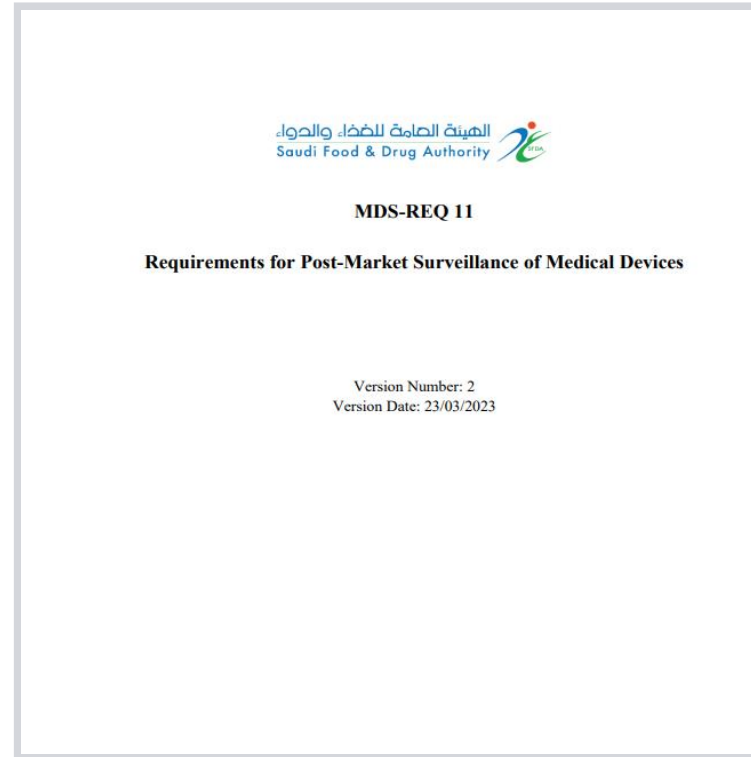
Is a set of activities conducted to collect and evaluate experience gained from medical devices that have been placed on the market, and to identify the need to take any action.

It's the practice of monitoring the safety of a medical device after it has been released on the market in order to ensure the **safety** and **performance** of medical device and used as intended by the manufacturers and to resolve and share with other users any useful, preventive or corrective information

Requirements for Post-Market Surveillance of Medical Devices

purpose

The purpose of this document is to specify and clarify the requirements for post-market surveillance of medical devices including the procedures and activities listed in the “Scope” below.





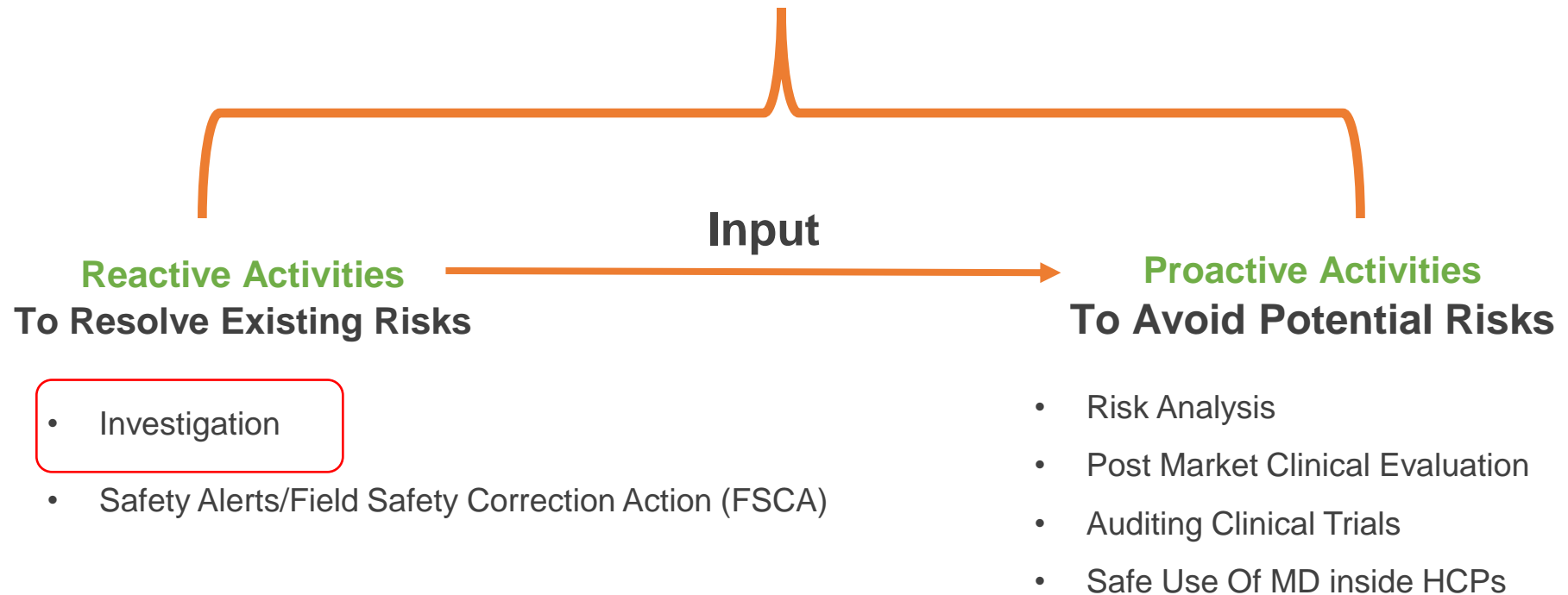
Requirements for Post-Market Surveillance of Medical Devices

➤ **The requirements for post-market surveillance of medical devices including the procedures and activities below:**

- 1 Reporting and investigation of adverse events and complaints of medical devices
- 2 Reporting violating medical devices
- 3 Safety alerts and field safety corrective action (FSCA) for medical devices
- 4 Appointing a contact officer with the National Center of Medical Devices Reporting
- 5 Reprocessing of medical devices
- 6 Resale, loaning or donating used medical devices
- 7 After-sale and maintenance services for medical devices
- 8 Destruction of used medical devices



Post-Market Surveillance Activities



Reporting and investigation of adverse events and complaints of medical devices

■ Adverse Event of Medical Devices :

- 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**.

■ Complaint:

- Any kind of communication whether written or oral about insufficiency related to the medical device or its quality, efficiency, efficacy, usability, safety or performance, in addition to insufficiency related to the service that impacts the performance of the medical device.

Reporting and investigation of adverse events and complaints

■ Reporting timeline

Shall report to the SFDA as follows:

- Within **(2 days)** from the date of occurrence or awareness of adverse events or complaint, in case it represents a serious public health threat.
- Within **(10 days)** from the date of occurrence or awareness of adverse events or complaint, in case it represents a threat that may cause or contribute, directly or indirectly, in death or serious injury.
- Within **(30 days)** from the date of occurrence or awareness of adverse events or complaint, in case it represents any effect other than what mentioned in the aforementioned items.

Reporting and investigation of adverse events and complaints

■ Required Documents

- Shall provide to SFDA the applicable investigation reports.
- SFDA will evaluate all submitted reports and information and may request additional information or action if necessary.

Documents requested from AR:

- Similar reports (both locally or outside KSA)
- Customers list (hospitals, clinics, public...etc.)
- Related communication with concerned customer/s must be documented
- Marketing Authorization information.

Investigation reports include:

- A. Initial Report**
- B. Follow-up Report**
- C. Final Report**

Reporting and investigation of adverse events and complaints

■ Investigation completion

The investigation must be completed, and the final report shall be submitted as per following:

- Within **60 days** from the date of occurrence or awareness of adverse events or complaint that require testing the device outside KSA.
- Within **30 days** from the date of occurrence or awareness of adverse events or complaint that require testing the device inside KSA.
- Within **15 days** from the date of occurrence or awareness of adverse events or complaint that does not require testing or technical evaluation.

Who Can Report



Public



Companies

- Distributers
- Importers
- Authorized Representatives



How to Report



19999



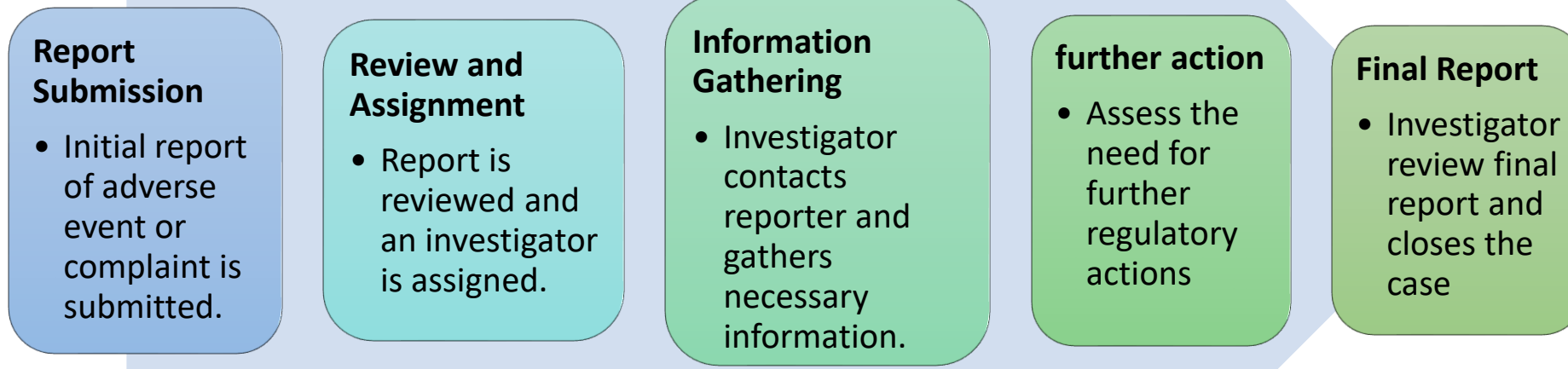
Email



NCMDR



Investigation Process



Immediate Actions for Adverse Events/and complaints

1

Protect Patients and Staff

- Ensure immediate safety of all individuals involved. This is the top priority in any adverse event.

2

Secure Equipment and Environment

- Isolate the device and related materials. Prevent further use until a thorough investigation is completed.

3

Internal Reporting

- Document the adverse events using internal processes. This ensures a clear record for further analysis.

4

Notify SFDA

- Report the adverse events to regulatory authorities promptly. This initiates the official investigation process.

Preservation of Evidence



Save All Disposables

- Retain all single-use items associated with the adverse events. These can provide crucial clues during investigation.



Photographic Documentation

- Take detailed pictures of the device and surrounding area. Visual evidence is invaluable for analysis.



Maintain Device Settings

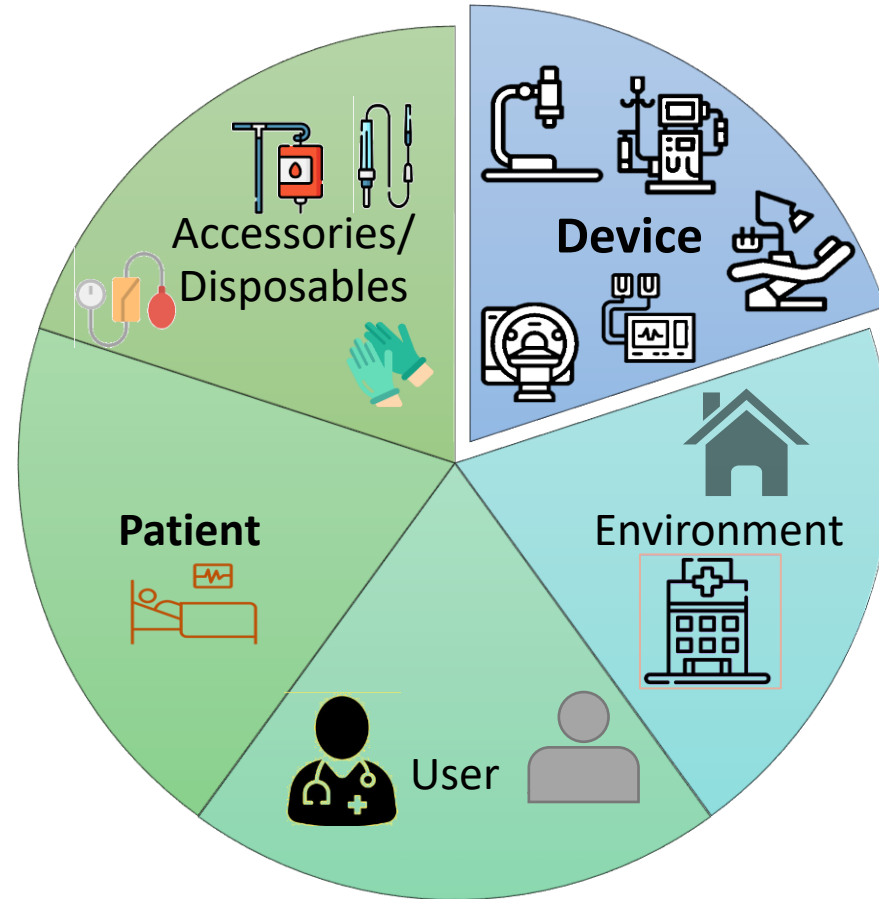
- Do not alter control settings or erase error logs. This preserves critical data for investigators.



Isolate Devices and Accessories

- Secure all related equipment in a safe location. This prevents tampering and ensures a comprehensive investigation.

Probable causes



Device-Related Causes of adverse events

Device failure

Design or labeling error

Manufacturing error

Packaging error

Accessory failure

Software deficiency

Random component failure

Failure of an accessory

Improper maintenance, testing, repair, or lack or failure of pre-use incoming inspection

Improper modification

**Environmental
factor Causes
of adverse
events**

Power supply failure

Medical gas/vacuum systems

**Electromagnetic EMI or Radio
Frequency Interference RFI**

Environmental conditions

**Improper storage (Temperature,
humidity, light)**

User-Related Causes of adverse events

Hacking (Cybersecurity)

Pre-use inspections

Labeling

Mis-assembly

Mise-connection

Incorrect clinical use

Incorrect control settings

Incorrect programming

Spills

Abuse

Inappropriate reliance non automated features

Failure to monitor

Maintenance or incoming inspection

Outcomes of Investigation

1

Manufacturer Improvements

- Enhanced device designs ,safety features, Instruction for user Labelling and Staff Training.

2

Actions for user

- A Safety Communication Notice may be published or advice for training.

3

Regulatory Actions

- Investigations may result in recalls, safety notices, or regulatory guidance updates.



Investigation challenges

Diversity of technologies

Communication

Numerous causes of injuries

Patient variability

Limited information available to/from manufacturer

Adverse events accessories, especially disposable devices, are discarded

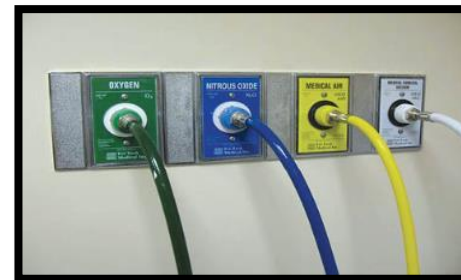
Lose device data

┌ Case study: Investigating an Adverse Events

Oxygen Flowmeter

■ Initial information received:

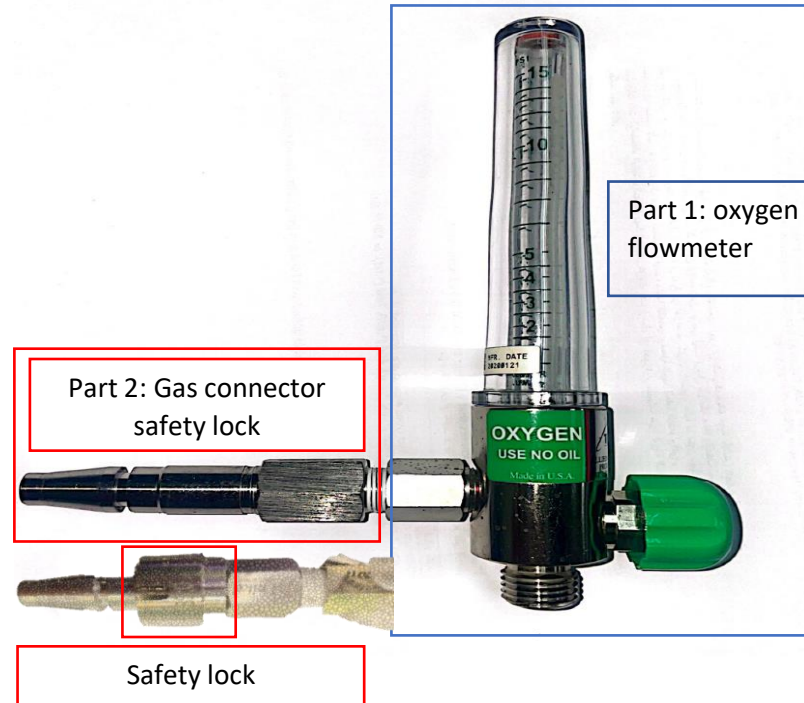
- SFDA received information on Oxygen flowmeter can be used in more than one medical air outlet.
- It was used on Nitrous oxide outlet instead of Oxygen outlet, which lead to health deterioration then patient admitted to ICU for further treatment.



Oxygen Flowmeter

■ Information discovered through Investigation:


- Device contain two parts
 - Part 1: oxygen flowmeter
 - Part2: Gas connector safety lock
- The safety lock not registered and some parts were supplied without the safety lock.



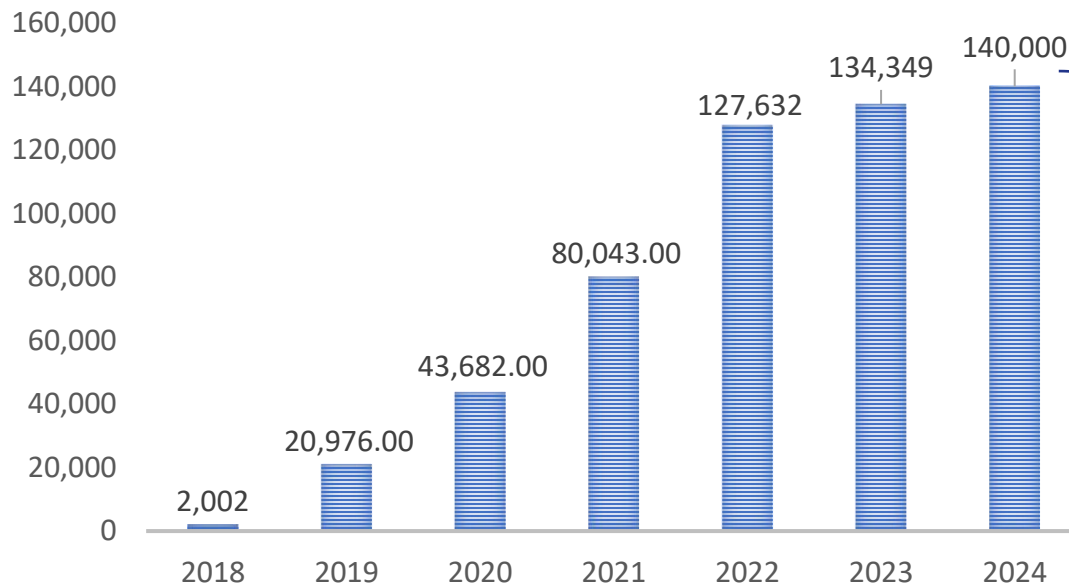
Oxygen Flowmeter

■ SFDA Action:

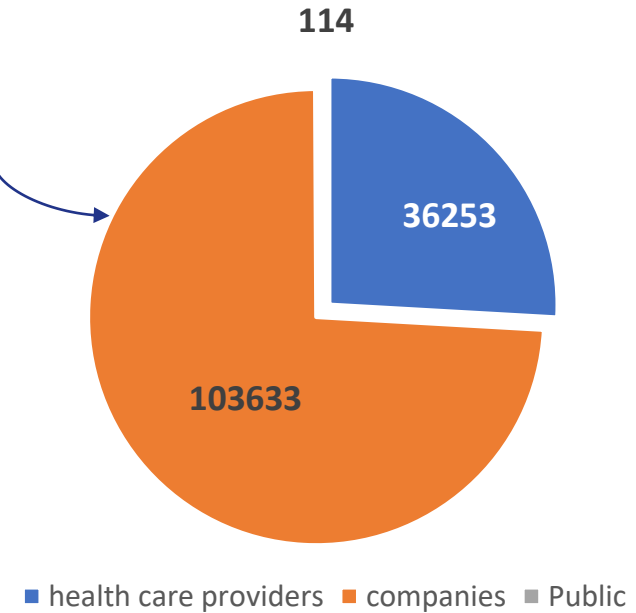
- Published Field safety corrective action to recall all affected products.
- SFDA took the necessary measures with the responsible supplier/ manufacturer of part2.

Manufacturer:	[REDACTED]
Device Type:	[REDACTED] Flowmeter
Description:	Air Flowmeter
Medical Device Identifier:	Any [REDACTED] equipped with the unauthorized connector. (please refer to the attached pictures)
Reason of Field Safety Corrective Action:	<p>- A report of [REDACTED] due to using a [REDACTED] Flowmeter with a noncompliance Connector; the Connector doesn't contain a security piece that allows it to be used with other medical gas outlets.</p> <p>- Also, The Connector fixed with [REDACTED] flowmeter is not authorized by SFDA (does not have MDMA), Therefore, can't ensure the safety, efficacy and performance of it.</p>
Remedy Action:	<p>- Remove all affected items from the healthcare providers.</p> <p>- Recommendations for the departments of biomedical engineering and medical supply to ensure all medical devices are authorized for marketing by SFDA (having medical devices marketing authorization (MDMA)), and ensure the devices comply with the users' specifications and the medical purpose specified by the healthcare provider.</p> <p>- Recommendations for health practitioners/users to read the instructions for use (IFU) for the medical device, and to ensure that it complies with the intended purpose of use by healthcare provider.</p>
Athorized Representative/Importer/Distributor:	[REDACTED]
Report Source:	SFDA
Source Ref. Number:	[REDACTED]
SFDA Comments:	SFDA urges all healthcare providers that have devices subjected to this safety alert to contact the company.
Attachments:	 Safety Alert - Flowmeter.pdf
View History	

NUMBER OF REPORTD CASES

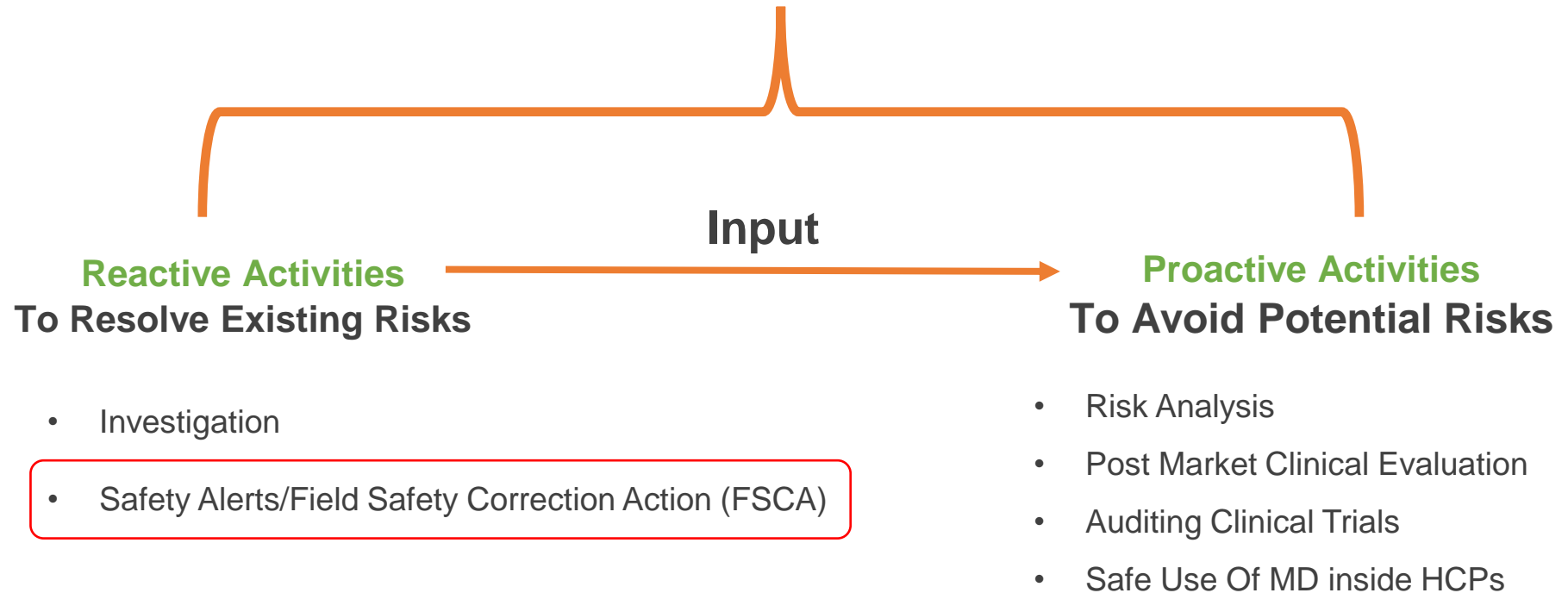


Type of reporters 2024





Post-Market Surveillance Activities



What is a Field Safety Corrective Action?



Safety Alert:

A notice issued by the NCMDR indicating the risk associated with a medical device or supply and the corrective actions required to avoid such risk.



Field Safety Corrective Action:

An action taken by the manufacturer to limit or reduce the risks compromising the safety of a medical device or supply.



Acknowledgment Letter:

A document proves the user has viewed the information and the corrective actions mentioned in the safety alerts letter.

Stages of Field Safety Corrective Actions (FSCA)

1 Reporting FSCA to SFDA or Receiving an Inquiry from the SFDA

2 Notifying the Affected Users

3 Corrective Action Plan

4 Implementing Corrective Actions

5 Closure

Stages of Field Safety Corrective Actions

Stage 1: Reporting FSCA to NCMDR or Receiving an Inquiry from SFDA

The manufacturer or authorized representative shall report to the NCMDR about FSCAs affecting KSA within (2 days) from the issuing date or FSCA letter, and attached the FSCA letter including all the information.

When receiving inquiries from the NCMDR about FSCA, the manufacturer or authorized representative shall respond within (5 days) through The Saudi Vigilance (NCMDR).



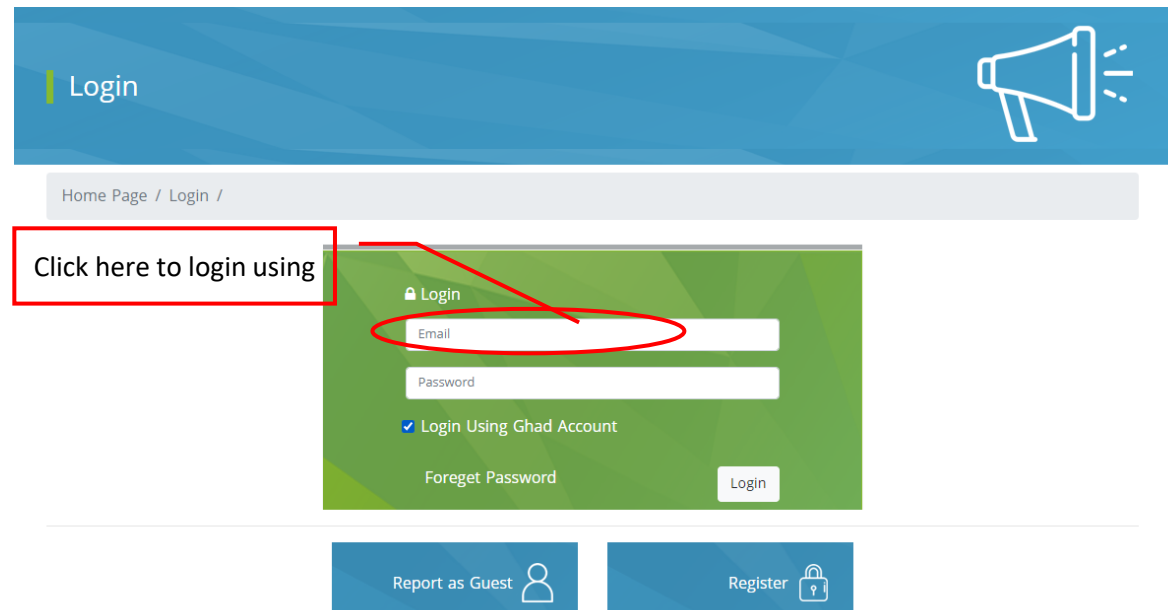
Stage 1

Annex (1) Required information for field safety corrective action (FSCA) Letter

- The subject in bold (**URGENT FIELD SAFETY CORRECTIVE ACTION OR FIELD SAFETY NOTICE**) mentioning the name of the affected medical device.
- **Safety alert reference number.**
- **Attention to the user:** (establishment/user/healthcare provider's information).
- **Purpose of safety alert:**
 - o Purpose of field safety corrective action (FSCA).
 - o If any deaths or serious injuries has been occurred or could occur, they shall be mentioned along with the probability of its occurrence.
- **Affected medical devices:**
 - o Mentioning all affected medical devices.
 - o How to identify the affected medical devices.
- **Cause of the field safety corrective action (FSCA):**
 - o Simplified overview of the medical device and how it works.
 - o Description of the problem, which was the cause to issue the safety alert.
 - o Frequency of malfunction and complaints.
 - o If the device malfunction could result injuries or treatment delay, or may require surgical intervention, such effect shall be clarified.
 - o How the user can identify that the medical device malfunctioned or subject to malfunction – if possible-
- **Actions to be taken by the user:**
 - o Description of the action required to be taken (e.g. isolating the affected medical devices, returning, following instructions, etc.).
 - o The time limit for implementing the required actions.
 - o Notifying the users about the safety alert or advising to review the patients' previous results - if recommended -.
 - o In case that Acknowledgment letter has been attached with the field safety corrective action (FSCA) letter, the time limit to respond with acknowledgment.
- **Field safety corrective action (FSCA):**
 - o Description of the actions going to be taken by the manufacturer (e.g. withdrawing, modifying, providing instructions for use, updating software).
 - o Specifying the time period to complete implementation of field safety corrective action (FSCA).
- **Contact information of the manufacturer/authorized representative:**
 - o Name of authorized person.
 - o Email.
 - o Phone number.
 - o National address.

Unified Electronic System (GHAD)

The leading regional regularity authority for food, drugs and medical devices with professional and excellent services that contributes to the protection and advancement of the health in Saudi Arabia.



The screenshot shows the login interface of the Unified Electronic System (GHAD). At the top, there is a blue header with the word "Login" and a megaphone icon. Below the header is a breadcrumb trail: "Home Page / Login /". The main content area has a green background and contains a "Login" form. The form includes an "Email" input field, a "Password" input field, a checked checkbox for "Login Using Ghad Account", a "Foreget Password" link, and a "Login" button. A red box highlights the "Email" input field, and a red arrow points from a text box to it. The text box contains the text "Click here to login using". At the bottom of the page, there are two buttons: "Report as Guest" with a person icon and "Register" with a padlock icon.

Login

Home Page / Login /

Click here to login using

Login

Email

Password

Login Using Ghad Account

Foreget Password Login

Report as Guest

Register

List of Safety Alerts (FSCA) and Inquires


Safety Alert Requests [24]		Inquiries From SFDA [14]		Medical Device Reports [8]		Reports from SFDA [10]	
No.	Reference Number	Status	Source of FSCA	Manufacturer	Create Date	View Request	
1	ISA-22-08-23-29	Affected by the Safety Alert	TEST	test	8/22/2023 6:28:27 AM	View Request	
2	ISA-21-08-23-28	NOT Affected by the Safety Alert	test	test	8/21/2023 9:07:16 AM	View Request	

[About](#)[Search for Product](#)[Report](#)[FAQ](#)[Contact Us](#)[عربي](#)






Safety Alert Requests [24] Inquiries From SFDA [14] Medical Device Reports [8] Reports from SFDA [10]

No.	Reference Number	Request Status	Device Name	Create Date	Last Update	View Request	Comment
1	SA-23-08-23-62	Report Received		8/23/2023 8:57:05 AM	8/23/2023 2:20:27 PM		
2	SA-23-08-23-61	Report Received		8/23/2023 8:39:49 AM			
3	SA-22-08-23-60	Case Under Evaluation		8/22/2023 6:31:06 AM	8/22/2023 5:16:40 PM		

Adding a New Safety Alert

Add New Safety Alert 

Medical Device Info

Authorization Type	Other
Device List	--Other--
Medical Device Name	Test
Medical Device Identifier	Test
Model	Test
Manufacturer	Test
Add Another Device	
Risks	Test  
Reason of Problem	Test
Action	Test  

Stages of Field Safety Corrective Actions

Stage 2: Notifying the Affected Users

Notify all affected customers / users within 5 days.

The manufacture or authorized representative shall keep records of communication with the importers, distributors, healthcare providers and users which proves they have notified them by the Field Safety Notice.



Stage 2

Annex (2) Required information for acknowledgment letter

-Safety alert information:

- Safety alert reference number.
- Issuing date.
- Name of affected medical device.
- Labeling information of affected medical device.

-User information:

- Name of (establishment/healthcare provider/user).
- National address.
- Name and job title (for healthcare providers).
- Email.
- Phone number.

-Actions to be taken by the user:

- The Statement “*I acknowledged that I have received the safety alert and read and understood its content*”.
- The Statement “*I took all actions mentioned in the safety alert*”.
- The Statement “*I (disposed/isolated/returned) the mentioned devices (quantity and identifier)*”.
- Or
- The Statement “*The mentioned devices are not available (out of service or missing) (quantity and identifier)*”.

-Contact information of the authorized person:

- Name.
- Email.
- Phone number.
- Date.
- Signature.

-Contact information of the manufacturer/authorized representative:

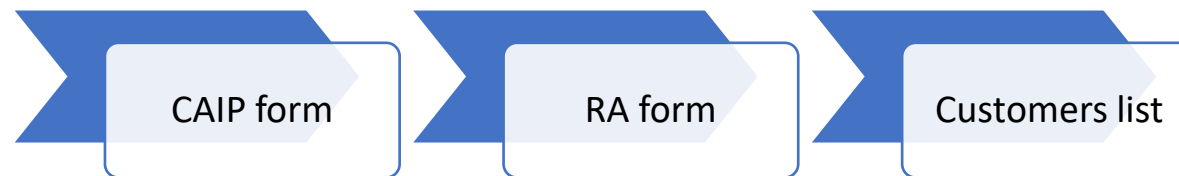
- Name of authorized person.
- Email.
- Phone number.
- National address.

-The time limit to respond with acknowledgment.

Stage 3: FSCA Implementation Plan

The manufacturer or authorized representative shall submit FSCA implementation plan within (5 days) from the date of reporting to the NCMDR, or from the date of responding to NCMDR inquiry indicating that KSA affected by the safety alert, through NCMDR portal.

The plan consist of:





Corrective Action Implementation Plan form



Corrective Action Implementation Plan form

FSCA Reference:	
Medical Device Name:	
Manufacturer:	
MDMA Authorization Numbers/ Low Risk Device Number	

Requirements	Comment
1 All affected customers notified	<input type="checkbox"/> Yes <input type="checkbox"/> No, Details: <input type="text"/>
2 Number of affected products (specify units, for example: Pieces, Box, Kits, etc.)	<input type="text"/>
3 Planned methods to be used when notifying the customers by the Field Safety Notice	<input type="checkbox"/> Phone, <input type="checkbox"/> Email, <input type="checkbox"/> Visit, <input type="checkbox"/> Registered Mail <input type="checkbox"/> Other: <input type="text"/>
4 Choose which remaining field actions to be implemented (other than notifying customers)	<input type="checkbox"/> Product Removal <input type="checkbox"/> On-site device modifications/inspection <input type="checkbox"/> Software upgrade <input type="checkbox"/> IFU or labelling change <input type="checkbox"/> None <input type="checkbox"/> Other: <input type="text"/>
5 Are there any future follow-up actions not mentioned in the Safety alert and can't be done in the meantime?	<input type="checkbox"/> No <input type="checkbox"/> Yes, Details: <input type="text"/>
6 Specify the deadline date to complete all corrective actions	<input type="text"/>
7 Justification for the proposed deadline to complete all corrective actions	<input type="text"/>
8 Choose progress reports period (if completion deadline is longer than 3 months), a progress report includes: <ul style="list-style-type: none">No. of notified customers with date and methods of communicationNo. of customers respondedNo. of corrected units per customer	<input type="checkbox"/> Every Week <input type="checkbox"/> Every 2 Weeks <input type="checkbox"/> Every Month <input type="checkbox"/> Every 2 Months <input type="checkbox"/> Every 3 Months <input type="checkbox"/> Other: <input type="text"/>
The following documents should be provided when submitting this form.	
9 List of affected customers provided? (Facility name, City, No. of products per customer)	<input type="checkbox"/> Yes, Number of affected customers: <input type="text"/> <input type="checkbox"/> No, Details: <input type="text"/>
10 Risk Assessment form provided?	<input type="checkbox"/> Yes <input type="checkbox"/> No, Details: <input type="text"/>

I hereby confirm that I am the authorized person from the company listed below, and I am aware of SFDA Safety Alerts requirements, and I have verified the information provided in this document.

Authorized Person Name:	
Company Name	
Date:	
Signature:	



Risk Assessment form

FSCA Reference:	
Medical Device Name:	
Manufacturer:	

Severity			Probability of harm		
Value	Level	Description	Value	Level	Description
5	Catastrophic	Loss of limb; life-threatening injury or death	5	Frequent	> 1 in 10
4	Critical	Severe; long-term injury; potential disability	4	Probable	1 in 11 to 100
3	Serious	Short-term injury or impairment requiring additional medical intervention to correct (e.g. Reoperation)	3	Occasional	1 in 101 to 10,000
2	Minor	Slight customer inconvenience; little to no effect on product performance, non-vital fault	2	Remote	1 in 10,001 to 1,000,000
1	Negligible	No or negligible risk to patient	1	Improbable	< 1 in 1,000,000

Risk Assessment Form

Fill the fields below:

Severity	Probability	Click here to calculate risk value	Risk Level	Value Range
Critical (4)	Frequent (5)	20	High	10 - 25
			Medium	5 - 9
			Low	1 - 4

Health Risk Index Table

Probability of harm x Severity	Negligible (1)	Minor (2)	Serious (3)	Critical (4)	Catastrophic (5)
Frequent (5)	5	10	15	20	25
Probable (4)	4	8	12	16	20
Occasional (3)	3	6	9	12	15
Remote (2)	2	4	6	8	10
Improbable (1)	1	2	3	4	5

I hereby confirm that I am the authorized person from the company listed below, and I am aware of SFDA Safety Alerts requirements, and I have verified the information provided in this document.

Authorized Person Name:	
Company Name	
Date:	
Signature:	

Stage 4: Implementing FSCA

The manufacturer or authorized representative shall:

Document the following information:

Safety alert reference number.

Model/Batch (LOT) Number/Serial Number of the affected medical devices.

Data of importers, distributors, healthcare providers and users for whom FSCA implemented on.

A detailed description of the action taken as required in FSCA letter

Shall record and document proof for implementing any action (e.g., withdrawal, software update, updating IFU, replacement, destruction).

In case, unable to comply with the expected date to complete implementation of FSCA, a request to extend the expected date shall be submitted to the NCMDR through email (ncmdr.md@sfd.gov.sa) with a justification and explanation of the remaining actions and their expected completion date.



Stage 5: Closure



Field Safety Corrective Action Closure Report form

FSCA Reference:	
Medical Device Name:	
Manufacturer:	
MDMA Authorization Numbers/ Low Risk Device Numbers	

Actions	Comment
1 The number of all affected customers	
2 Methods of communications used	<input type="checkbox"/> Phone, <input type="checkbox"/> Email, <input type="checkbox"/> Visit, <input type="checkbox"/> Registered Mail <input type="checkbox"/> Other: _____
3 All affected customers notified (reached) and are acknowledged (replied)?	All notified: <input type="checkbox"/> Yes, <input type="checkbox"/> No: number of not notified _____ All replied: <input type="checkbox"/> Yes, <input type="checkbox"/> No: number of not replied _____ <i>If you answer (NO), you must provide a list of the customers' names, city, contact details and communication history and whether they were not notified or not acknowledged</i>
4 The number of all affected products	
5 The number of used/consumed products	Consumed number: _____, or <input type="checkbox"/> N/A
6 The number of corrected/removed products	
7 The number of products that were not located (at healthcare facility premises)	Not located number: _____, or <input type="checkbox"/> N/A
8 Specify the action done for any recovered products	<input type="checkbox"/> Destroyed, <input type="checkbox"/> Shipped outside KSA, <input type="checkbox"/> N/A, <input type="checkbox"/> Other: _____
9 Choose which field actions were implemented (other than notifying customers)	<input type="checkbox"/> Product Removal <input type="checkbox"/> On-site device modifications/inspection <input type="checkbox"/> Software upgrade <input type="checkbox"/> IFU or labelling change <input type="checkbox"/> None <input type="checkbox"/> Other: _____

I hereby confirm that I am authorized from the company listed below, and I am aware of SFDA Safety Alerts requirements, and I have verified the information provided in this document.

Authorized Person Name:	
Company Name	
Date:	
Signature:	



نموذج "إفادة إتمام الإجراء التصحيحي لإنذار السلامة"

Confirmation Statement for Completing the Corrective Action in the Safety Alert

Dear National Center for Medical Devices Reporting at Medical Devices Sector/ Saudi Food and Drug Authority,

السادة/ المركز الوطني للإجهزة والمستلزمات الطبية بقطاع الأجهزة والمستلزمات الطبية في الهيئة العامة للغذاء والدواء المحترمين السلام عليكم ورحمة الله وبركاته...

We Name of Manufacturer or Authorized Representative emphasize to conduct

نحن اسم المصنِّع أو الممثل المتمد نؤكد قيامنا بتنفيذ جميع الإجراءات التصحيحية الموصى بها في إنذار السلامة للأجهزة والمستلزمات الطبية المتأثرة المشار إليه أدناه، كما نؤكد استيفائنا جميع المتطلبات المشار إليها في "متطلبات رقابة ما بعد التسويق للأجهزة والمستلزمات الطبية". ولتكرم بتقديمها فور طلبكم لذلك، وللهيئة اتخاذ الإجراءات المناسبة عند معالفة أي من ذلك. واستناداً على ما سبق نأمل منكم إغلاق إنذار السلامة أدناه.

recommended corrective actions in the below Safety Alert for the affected medical devices. We confirm the fulfillment of all requirements specified in SFDA's guidance document entitled "Requirement for Post-Market Surveillance of medical Device", and we are committed to provide them immediately upon SFDA request. The SFDA reserves the right to take the appropriate actions when any of these is violated. Therefore, we kindly request to close the below Safety Alert.

الرقم المرجعي Reference Number	اسم الجهاز/المستلزم الطبي Medical Device Name
Authorized Person Name:	اسم الشخص المفوض:
Signature:	التوقيع:
Date:	التاريخ:

Case study: Issuing safety alerts for medical devices

Case study 1: issuing safety alerts for medical devices

Manufacturer: **xxx** , AR: **xxx**


Medical device name: **3-Way Stopcock.** , Product codes: Model: **xxx**.

Reason: **Leakage in 3-way stopcock(due to manufacturing defect).**

Action: **Withdraw all affected devices.**

No of affected product: **xxx**.

Expected date to complete the corrective action: **November 25th, 2024.**

Details	
Reference Number	SA-09-10-24-621
Manufacturer Company	Saudi Mais Co. for Medical Products
Medical Device Name	3 way stopcock
Affected Devices	Model: 401-0010 Lot numbers: 240515 & 240606
Authorized Representative	SAUDI MAIS CO FOR MEDICAL PRODUCTS
Reason of Problem	Leakage issue from the connector.
Action	Stop using all affected products and return them to the manufacturer.
Attach Files	

Statistics

**2024
Safety Alert
Decisions**



393 / 15 issued by SFDA

**# Safety
Alerts**

26,812,666

**# Qty. of Medical
devices**

60

High
Risk

318

Medium
Risk

15

Low
Risk

**Closed 58%
Under Progress 42%**

┌ Thanks