

USER MANUAL

FRONT END USER

**MEDICAL DEVICE CENTRALIZED REPORTING SYSTEM
(MeDCReSt)**

DISEDIAKAN OLEH :



Version 1.0

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1 INTRODUCTION

This user manual is prepared for the purpose of the operational function of the Post Market Online Reporting System.

Medical Device Centralized Reporting System (MeDCReSt) is developed using a web-based method in which it utilises the internet access via internet server. In order to access this system, user has to key in the URL address onto the internet server as followed:

<https://medcrest.mda.gov.my>


The screen below shows the expected webpage after the address has been keyed In.




The user manual contains important information on operating the online reporting system, correctly and efficiently. Following this user manual helps establishments to carry out responsibilities of post market requirements under Medical Device Act 2012, Act 737, Medical Device (Duties and Obligation of Establishments) Regulation 2019 and its respective guidance documents conveniently, quick and easy as possible.

2 GENERAL


2.1 LOGIN

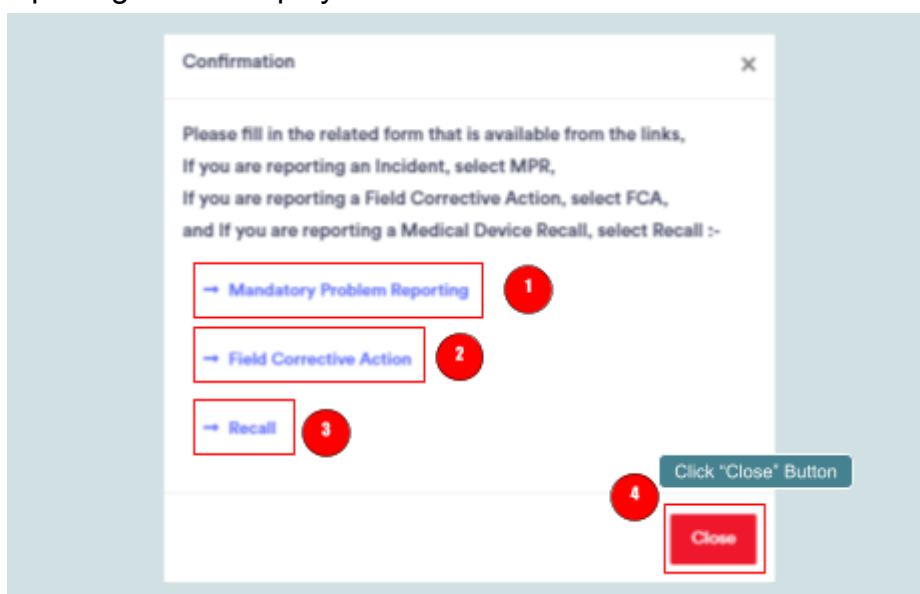
- a. The Login page will be displayed as above and the user required to fill the information needed (***Please use your MeDC@St 2.0+ log in information (Main Account) for the first-time user.***):
1. Please enter the User username.
 2. Please enter the User password.
 3. Click the  button.
 4. The pop-up below will be displayed:


5. If the device registered with MDA are available in Malaysian market

click  button and the system will redirect the user to the Dashboard (Refer to [2.3 DASHBOARD](#)).

6. If the device registered with MDA are not available in Malaysian

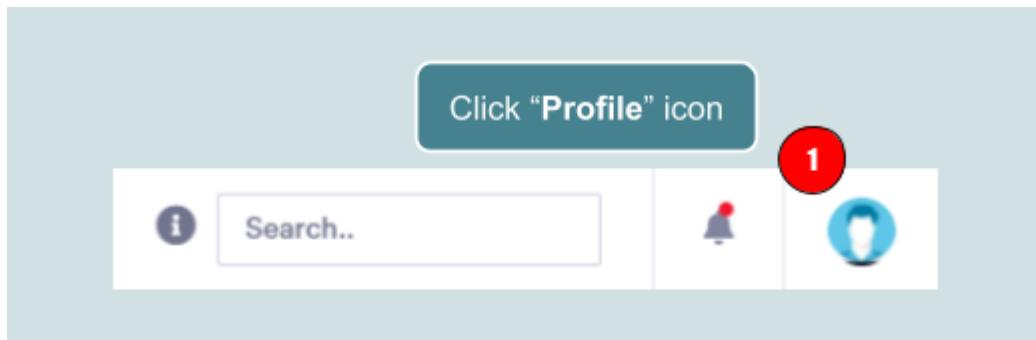
market click  button and the pop-up instruction for manual reporting will be displayed as below.





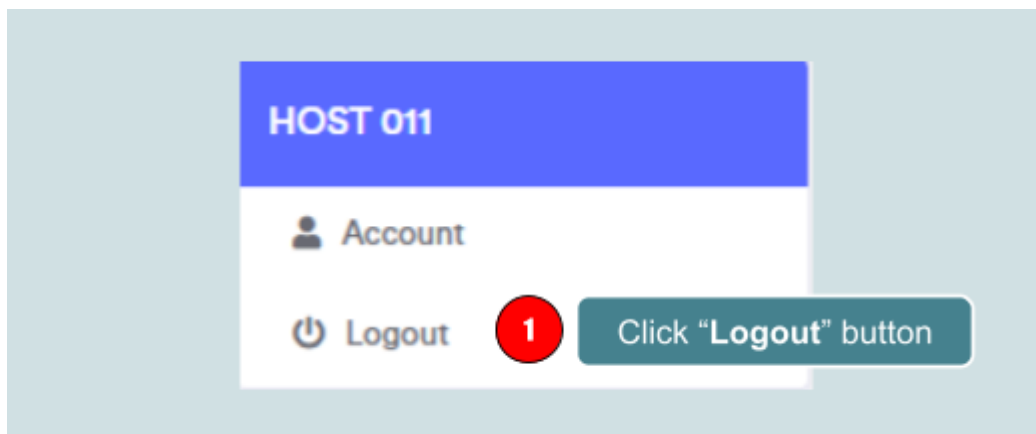
- I. If the user wants to make a report of an Incident, please click the “**Mandatory Problem Reporting**” link.
- II. If the user wants to make a report of Field Corrective Action, please click the “**Field Corrective Action**” link.
- III. If the user wants to make a report of Recall, please click the “**Recall**” link.
- IV. If the user wants to cancel, please click the  button.


- b. The user needs to log in to the system using the same username and password as the MeDC@St 2.0+ account.
- c. If the user wants to reset their password, please click the “**Forgot Your Password ?**” button.
- d. If the user wants to view the FAQ, please click the “**FAQ**” button.
- e. If the user wants to view the User Manual, please click the “**User Manual**” button.
- f. If the user wants to view the Public View Listing, please click the “**Public View Listing**” button.
- g. If the user wants to view the Helpdesk, please click the “**Helpdesk**” button.

2.2 LOGOUT

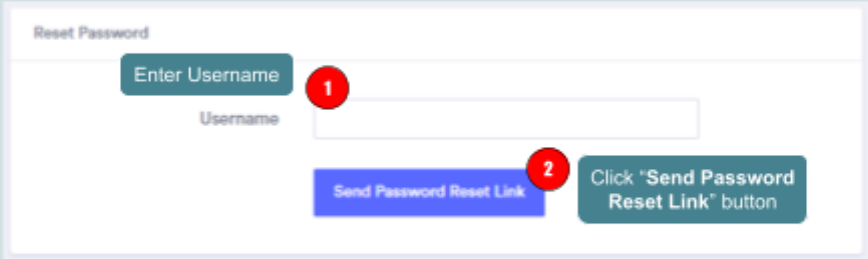


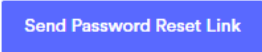
- a. The  icon button is located at the navigation bar. Click the  icon button and the system will display the sub-menu:

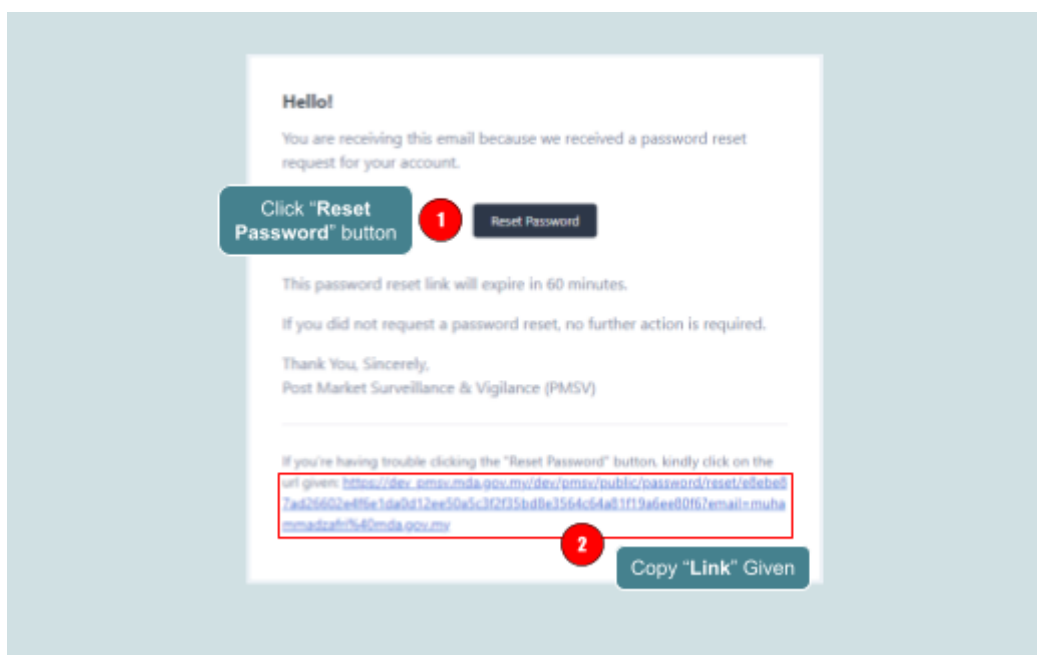


- b. Click  Logout button.
c. The system will end the user session and will redirect the user to the login page.

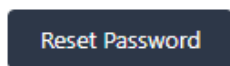
2.3 FORGET PASSWORD



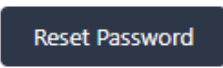
- a. The Forget password page will be displayed as above and the user required to fill the information needed:
 1. Please enter the User username.
 2. Click the  button and the system will send an email.
- b. The user will received an email as below:



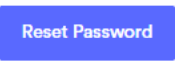
1. To continue with reset password, User need to click the



button or copy the “**Link**” given in the email.

- c. After click the  button or open the “**Link**” given, the system will displayed as below to proceed for the next step:

A screenshot of a web form titled "Reset Password". At the top, there is a yellow "Notes" box with a list of password requirements: "Please do not enter the same password as previous", "Your password should contain the Following:", "Atleast 1 Uppercase letters (A-Z)", "Atleast 1 Lowercase letters (a-z)", "Atleast 1 Number (0-9)", and "Atleast 1 special character (e.g. '!@#%*^&*()_+*)". Below the notes are three input fields: "Username", "New Password", and "Confirm Password". Each input field has a dark blue label above it: "Enter Username", "Enter New Password", and "Enter Confirm Password". Red circles with numbers 1, 2, and 3 are placed over the input fields. At the bottom, there is a blue "Reset Password" button and a dark blue button with the text "Click 'Reset Password' button" and a red circle with the number 4.

1. Please enter the username.
2. Please enter the new password.
3. Please enter the confirm password.
4. Click the  button. If the reset password is successful the system will redirect the user to the Dashboard (Refer to [2.3 DASHBOARD](#)).

2.4 DASHBOARD

1 Establishment details

2 Table list of Users

No	Name	Username	Role
1	HOST 011	host011@test	Superuser

Showing 1 of 1 entries.

3 Report Counter

MPR Reporting Form		FCA Reporting Form		Recall Reporting Form	
Current	Completed	Current	Completed	Current	Completed
47	0	17	1	23	0

Total application form is : 88

4 Latest of MPR

5 Latest of FCA

6 Latest of Recall

No.	Reference No.	Type Of Report	Medical Device Name	Date (dd/mm/yy)	Status	Action
1	MDA/MPR/P0316-73777966-2022	Reporting		24/03/2022	Draft	View
2	MDA/MPR/P0315-56866970-2022	Reporting		24/03/2022	Draft	View
3	MDA/MPR/P0314-59244598-2022	Reporting	MEDICAL TEST01D	17/03/2022	Submitted	View
4	MDA/MPR/P0312-57933226-2022	Reporting		16/03/2022	Submitted	View
5	MDA/MPR/P0311-91450907-2022	Reporting	MEDICAL TEST01B	17/03/2022	Submitted	View
6	MDA/MPR/P0309-96339876-2022	Reporting		16/03/2022	Submitted	View
7	MDA/MPR/P0308-9844815-2022	Reporting	MEDICAL TEST01B	22/03/2022	Draft	View
8	MDA/MPR/P0307-24919272-2022	Reporting		23/03/2022	Draft	View
9	MDA/MPR/P0306-22920596-2022	Reporting	MEDICAL TEST01D	30/03/2022	Submitted	View
10	MDA/MPR/P0305-42640543-2022	Reporting		23/03/2022	Draft	View

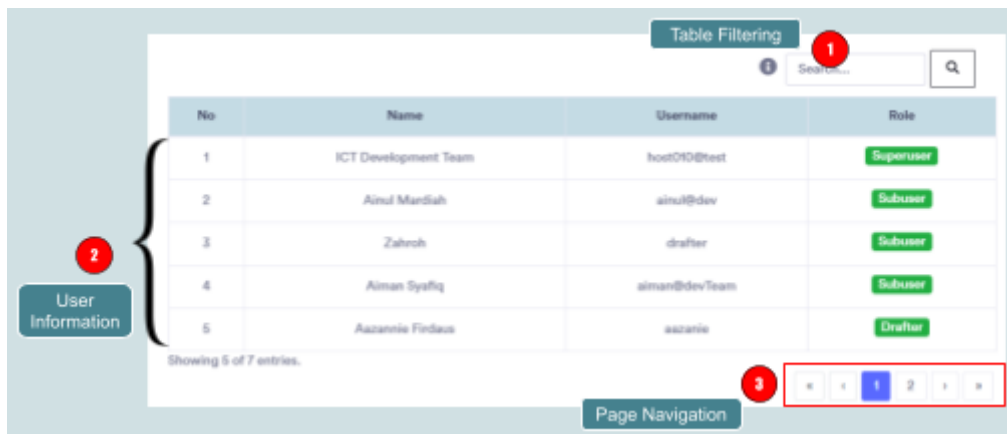
- a. The Dashboard page will be displayed as above:
1. Establishment Details (Refer to [2.3.1 Establishment Details](#)).
 2. Table list of Users (Refer to [2.3.2 Table list of Users](#)).
 3. Report Counter (Refer to [2.3.3 Report Counter](#)).
 4. Latest of MPR (Refer to [2.3.4 Latest of MPR](#)).
 5. Latest of FCA (Refer to [2.3.5 Latest of FCA](#)).
 6. Latest of Recall (Refer to [2.3.6 Latest of Recall](#)).

2.4.1 Establishment Details

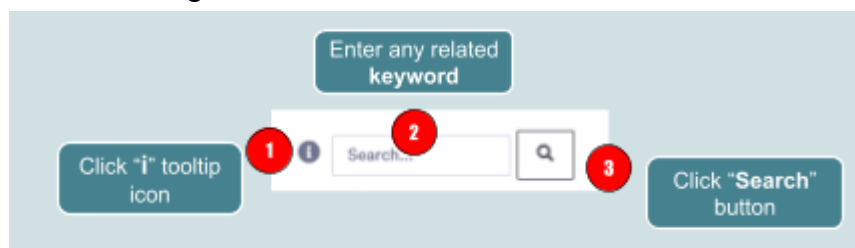


- a. This section will display establishment details that consist of:
1. Establishment Name
 2. Establishment Licence Number
 3. Person Responsible Name

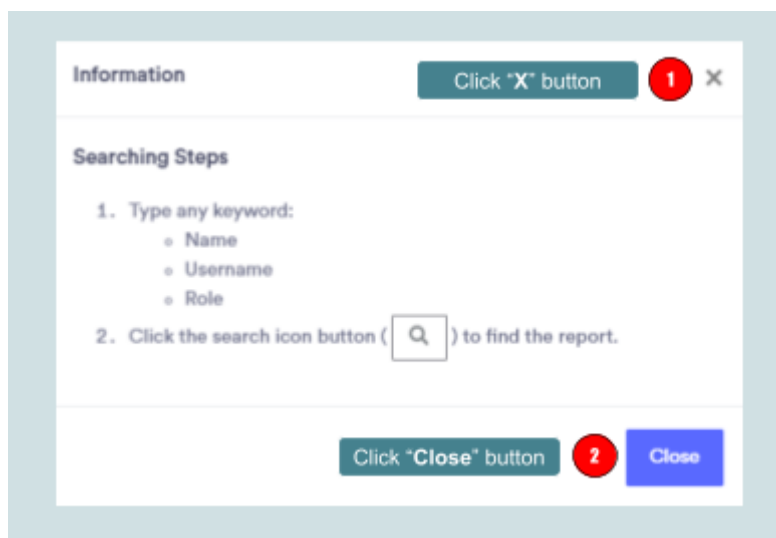
2.4.2 Table list of Users



- a. This section will display list of user :
1. Table Filtering



- I. User can click **i** icon and the pop-up information related to table filtering will display as below:



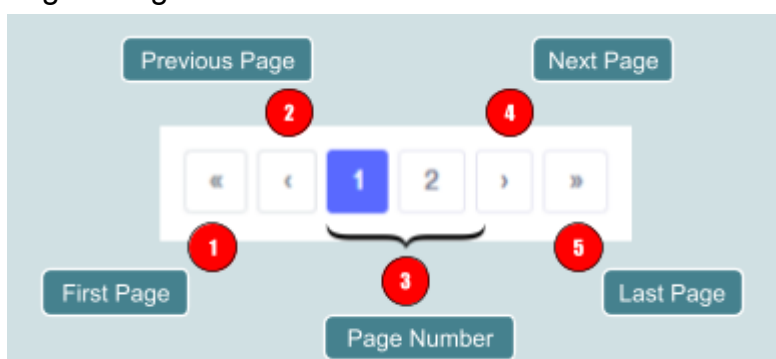
➤ Click **X** button or **Close** button to close the pop-up.

- II. Enter any related keyword (based on information given).
- III. Click **[Q]** icon and the system will display the result.


2. User Information that consist of:

- I. Name
- II. Username
- III. Role

3. Page Navigation



- I. Button **«** is to navigate to the first page.
- II. Button **◀** is to navigate to the previous page.
- III. Button **1** **2** is the page number.
- IV. Button **▶** is to navigate to the next page.

V. Button  is to navigate to the last page.

2.4.3 Report Counter



a. Dashboard have three (3) report counter that will be displayed as above:

1. **MPR Reporting Form** - This counter displays the number of Current MPR reports that are in process and MPR reports that are Completed.
2. **FCA Reporting Form** - This counter displays the number of Current FCA reports that are in process and reports FCA that are Completed.
3. **Recall Reporting Form** - This counter displays the number of Current Recall reports that are in process and Recall reports that are Completed.
4. **Total Application Form** - This counter displays the total number of reports that are in process and reports that are completed for all modules (MPR, FCA, Recall).

2.4.4 Latest of MPR

No.	Reference No.	Type Of Report	Medical Device Name	Date (dd/mm/yy)	Status	Action
1	MDA/MPR/P0259-96870981-2022	Reporting	MEDICAL TEST00D	17/02/2022	Draft	View
2	MDA/MPR/P0234-2173803-2022	Reporting	MEDICAL TEST00B	08/03/2022	Draft	View
3	MDA/MPR/P0223-33879036-2022	Reporting	MEDICAL TEST00B	25/01/2022	Submitted	View
4	MDA/MPR/P0222-4952856-2022	Reporting	MEDICAL TEST00B	25/01/2022	Submitted	View
5	MDA/MPR/P0221-0732789-2022	Reporting	MEDICAL TEST00A	25/01/2022	Submitted	View
6	MDA/MPR/P0220-6400075-2022	Reporting	MEDICAL TEST00A	25/01/2022	Submitted	View
7	MDA/MPR/P0219-37999336-2022	Reporting	MEDICAL TEST00C	25/01/2022	Submitted	View
8	MDA/MPR/P0218-26822802-2022	Reporting	MEDICAL TEST00B	25/01/2022	Submitted	View
9	MDA/MPR/P0217-62944335-2022	Reporting	MEDICAL TEST00D	25/01/2022	Submitted	View
10	MDA/MPR/P0216-67567978-2022	Reporting	MEDICAL TEST00C	25/01/2022	Submitted	View


a. Latest of MPR will be displayed as above:

1. **List of Report** - This table will display ten (10) latest reports of MPR.
2. Click [View](#) button and the system will display the report. (Refer to [3.5 VIEW](#)).

2.4.5 Latest of FCA

Sl	Reference no.	Medical Device Name	Date Submission (dd/mm/yy)	Date to be Completed (dd/mm/yy)	Type of Report	Status	Action
1	MDA/FCA/F93330-34542833-2022	MEDICAL TEST00D		24/02/2022	Notification	Overdue	View
2	MDA/FCA/F93329-32890630-2022	MEDICAL TEST00B		20/02/2022	Notification	Overdue	View
3	MDA/FCA/F93328-84408992-2022	MEDICAL TEST00A		20/02/2022	Notification	Overdue	View
4	MDA/FCA/F93326-70647883-2022	MEDICAL TEST00D		20/02/2022	Notification	Overdue	View
5	MDA/FCA/F93326-4207807-2022	MEDICAL TEST00A		20/02/2022	Notification	Overdue	View
6	MDA/FCA/F93326-54260762-2022	MEDICAL TEST00C		20/02/2022	Notification	Overdue	View
7	MDA/FCA/F93324-79833073-2022	MEDICAL TEST00B		20/02/2022	Notification	Overdue	View
8	MDA/FCA/F93320-40990529-2022	MEDICAL TEST00C		20/02/2022	Notification	Overdue	View
9	MDA/FCA/F93299-7042523-2022	MEDICAL TEST00D		20/02/2022	Notification	Overdue	View

a. Latest of FCA will be displayed as above:


1. **List of Report** - This table will display ten (10) latest reports of FCA.
2. Click  **View** button and the system will display the report. (Refer to [4.4 VIEW REPORTING](#))

2.4.6 Latest of Recall



ID	Recall Reference no.	Medical Device Name	Date of Reporting (dd/mm/yy)	Due Date (dd/mm/yy)	Reporting Stage	Status	Action
1	MDA/Recall/P0263-7247738-2022	MEDICAL TESTOHC	30/03/2022	-	Notification	Draft	
2	MDA/Recall/P0205-6300490-2022	MEDICAL TESTOHA	30/03/2022	-	Notification	Draft	
3	MDA/Recall/P0204-6301427-2022		30/03/2022	-	Notification	Draft	
4	MDA/Recall/P0209-7677290-2022		30/03/2022	-	Notification	Draft	
5	MDA/Recall/P0208-7686699-2022	MEDICAL TESTOHB	30/03/2022	16/04/2022	Notification	Draft	
6	MDA/Recall/P0207-80467572-2022	MEDICAL TESTOHD	24/03/2022	-	Notification	Draft	
7	MDA/Recall/P0206-84700680-2022	MEDICAL TESTOHE	03/03/2022	-	Notification	Draft	
8	MDA/Recall/P0205-07366994-2022		30/03/2022	-	Notification	Draft	
9	MDA/Recall/P0204-19068040-2022		30/03/2022	-	Notification	Draft	

a. Latest of Recall will be displayed as above:

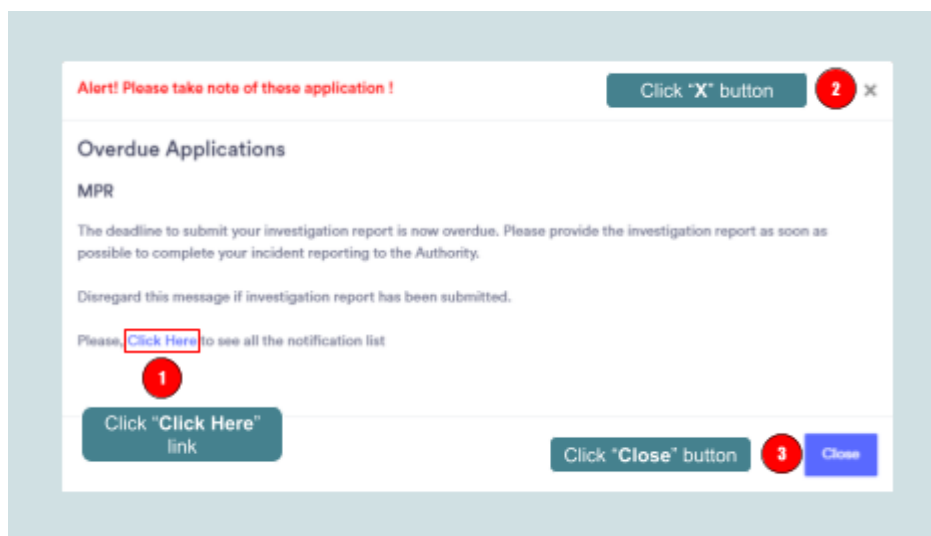
1. **List of Report** - This table will display ten (10) latest reports of Recall.
2. Click  **View** button and the system will display the report. (Refer to [5.4 VIEW RECALL REPORT](#))

2.5 SYSTEM NOTIFICATION

- a. System notification only focuses on reports with Overdue and almost Overdue status.
- b. There two (2) type of System Notification:

1. Notification Pop-up

- I. Notification pop-up is to notify the user that there are report with Almost Overdue and Overdue status:




- II. Notification pop-up will appear at the Dashboard (Refer to [2.3 Dashboard](#)) and will be displayed as above:

- Click [Click Here](#) link and the system will redirect to the list of Notification as below:

No.	Ref No.	Modal	Status	Action
1	MDA/NFR/P0275-700393-0002	MFR	Almost Overdue	View
2	MDA/NFR/P0274-6007073-0002	MFR	Almost Overdue	View
3	MDA/FCA/P0387-400086-0002	FCA	Almost Overdue	View
4	MDA/FCA/P0388-9006988-0002	FCA	Almost Overdue	View
5	MDA/NFR/P0273-200300-0002	MFR	Overdue	View


○ **Unread Notification tab**

No	Ref No	Model	Status	Actions
1	MDA/MPR/PCD/1700049-2022	MPR	Almost Overdue	View
2	MDA/MPR/PCD/1807071-2022	MPR	Almost Overdue	View
3	MDA/FCA/PCD/1402036-2022	FCA	Almost Overdue	View
4	MDA/FCA/PCD/1406038-2022	FCA	Almost Overdue	View
5	MDA/MPR/PCD/1403033-2022	MPR	Overdue	View

- **List of Notifications** - This table will display a list of unread notifications for the report with Almost Overdue and Overdue status.
- Click  button and the system will display the report:
 - MPR (Refer to [3.5 VIEW](#)).
 - FCA (Refer to [4.4 VIEW REPORTING](#)).
 - Recall (Refer to [5.4 VIEW RECALL REPORT](#)).

○ **Read Notification tab**



No	Ref No	Model	Status	Actions
1	MDA/FCA/PCD/420947-2021	FCA	Overdue	View
2	MDA/FCA/PCD/420947-2021	FCA	Almost Overdue	View
3	MDA/FCA/PCD/420947-2021	FCA	Overdue	View

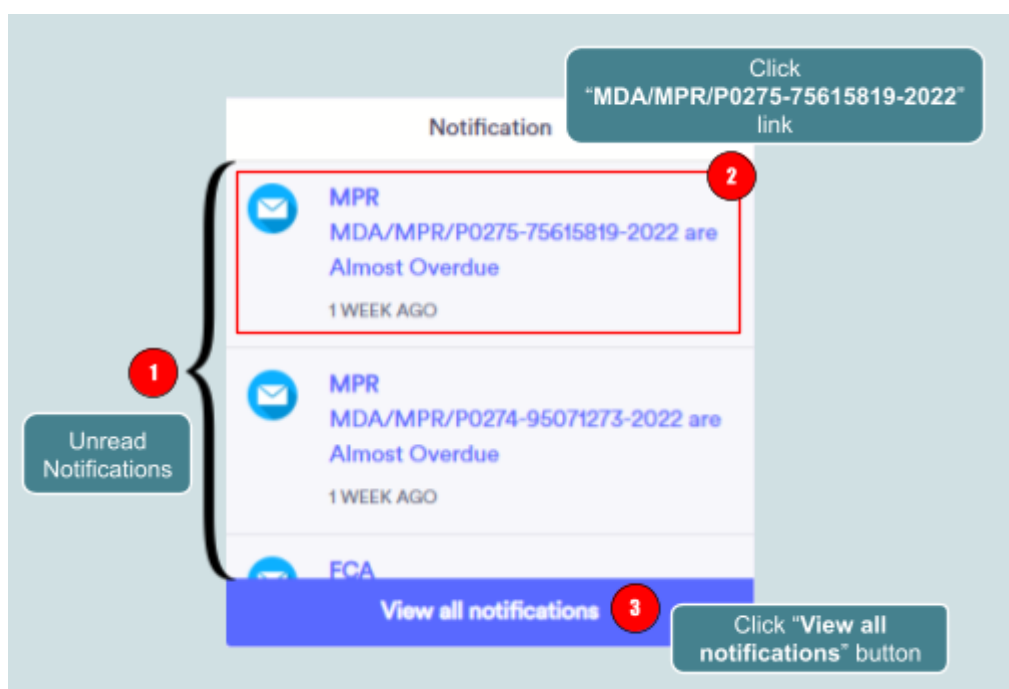
- **List of Notifications** - This table will display a list of read notifications for the report with Almost Overdue and Overdue status.
- Click  button and the system will display the report:
 - MPR (Refer to [3.5 VIEW](#)).
 - FCA (Refer to [4.4 VIEW REPORTING](#)).
 - Recall (Refer to [5.4 VIEW RECALL REPORT](#)).

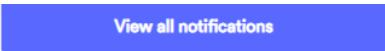
➤ Click  button or  button to close the pop-up.

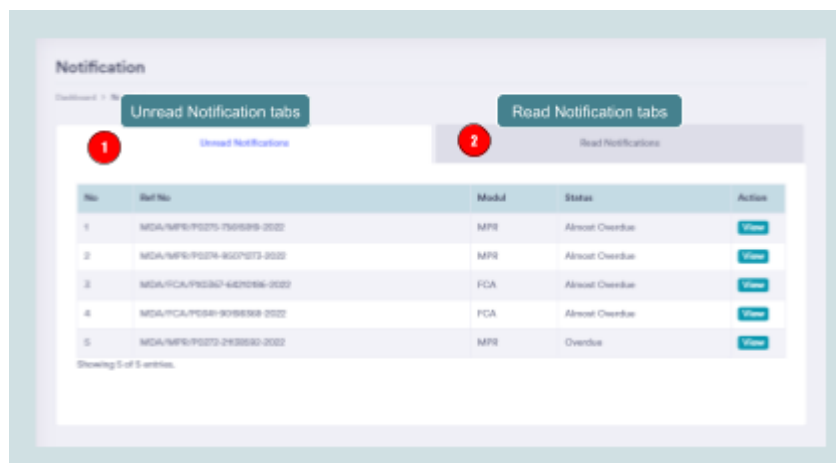
2. Notification Bell



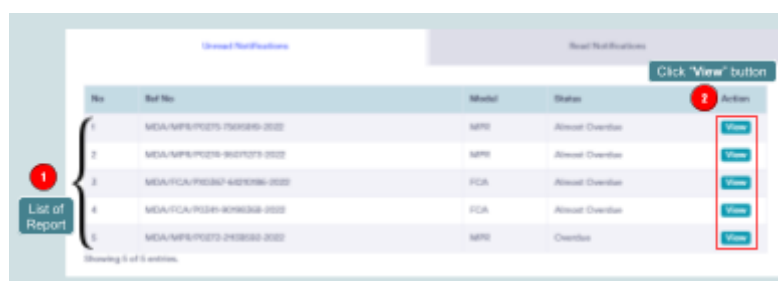
- I.  icon button is located at the navigation bar
- II. Click  icon button and the system will display a list of Unread Notification as below:




- **Unread Notifications** are the list of unread Notifications for the report with Almost Overdue and Overdue status.
- Click the “MDA/MPR/P0275-75615819-2022” link to view the report and the system will open the view page:
 - MPR (Refer to **3.5 VIEW**).
 - FCA (Refer to **4.4 VIEW REPORTING**).
 - Recall (Refer to **5.4 VIEW RECALL REPORT**).
- Click  button and the system will redirect to the list of Notification as below

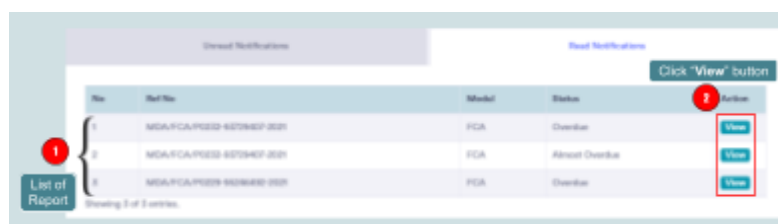


○ **Unread Notification tab**




- **List of Report** - This table will display a list of unread reports that are Almost Overdue and Overdue.
- Click  **View** button and the system will display the report:
 - MPR (Refer to [3.5 VIEW](#)).
 - FCA (Refer to [4.4 VIEW REPORTING](#)).
 - Recall (Refer to [5.4 VIEW RECALL REPORT](#)).

○ **Read Notification tab**



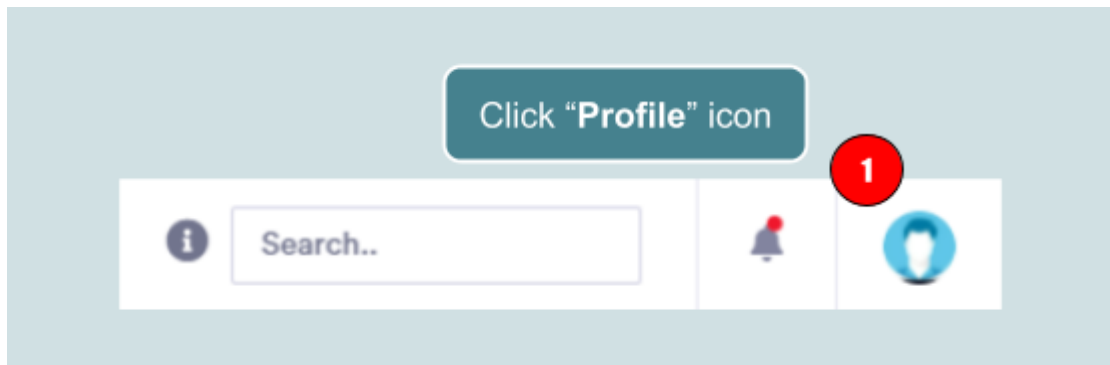
- **List of Report** - This table will display ten (10) latest reports of Recall.



➤ Click  button and the system will display the report:

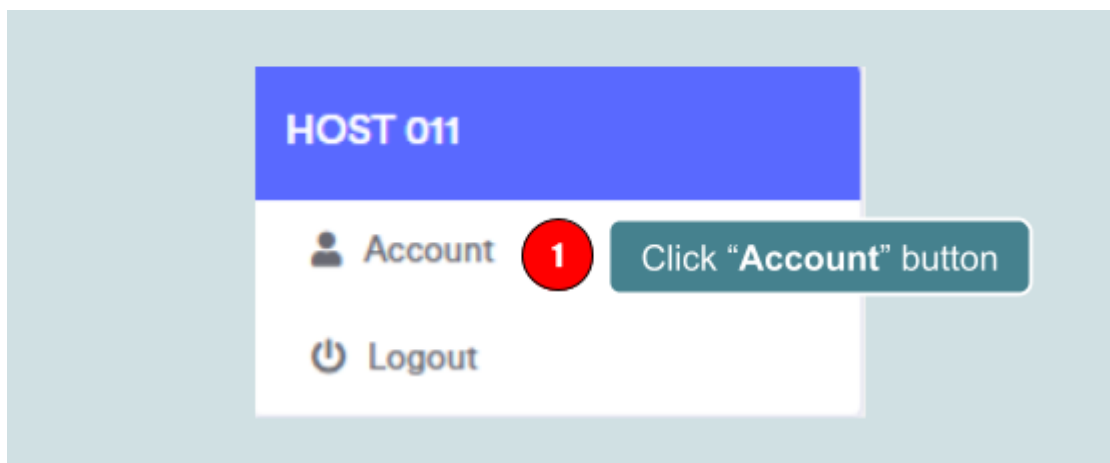
- MPR (Refer to [3.5 VIEW](#)).
- FCA (Refer to [4.4 VIEW REPORTING](#)).
- Recall (Refer to [5.4 VIEW RECALL REPORT](#)).


➤ Click  button or  button to close the pop-up.

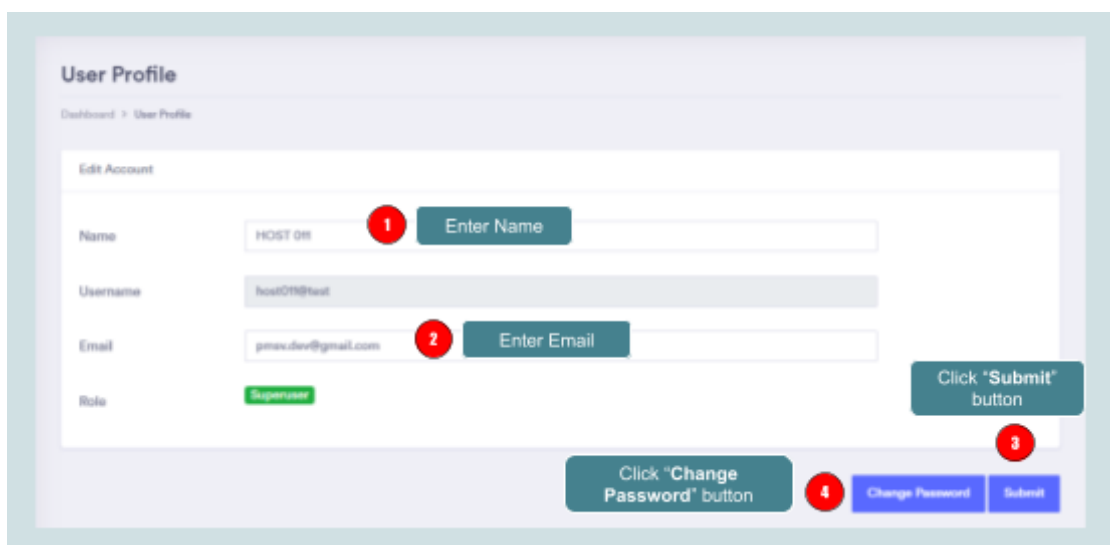
2.6 USER PROFILE



- a. The  icon button is located at the navigation bar. Click  icon button and the system will display the sub-menu:





- b. The list of sub-menus will be displayed as above. Click  **Account** button and the system will open the user profile page.

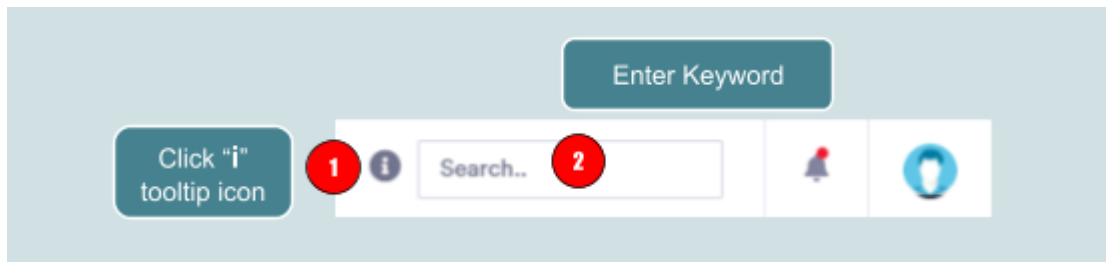


c. The User Profile page will be displayed as above and the user required to fill the updated information:


1. Please Enter the Updated Name.
2. Please Enter the Updated Email.
3. Click **Submit** button and the user information are updated.
4. Click **Change Password** button and the system will display the change password pop-up as below:

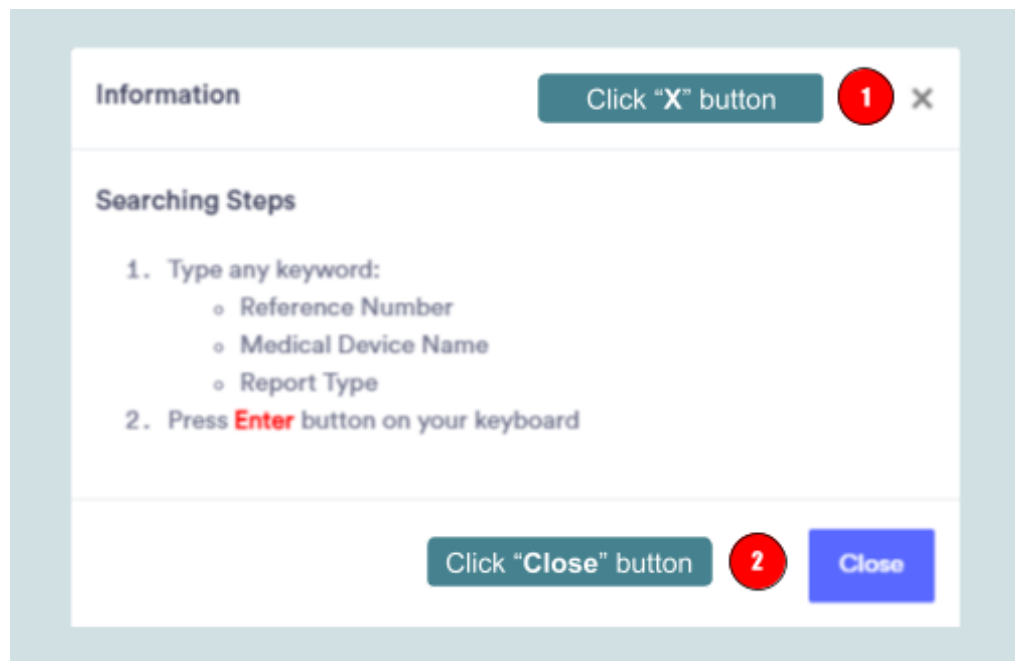
- I. Please Enter the Current Password.
- II. Please Enter the New Password.
- III. Please Enter the Confirm Password.
- IV. Click  icon button, to view the password that you enter.
- V. Click the **Submit** button and the password is updated.
- VI. Click the  button or **Close** button to close the pop-up.



2.7 SEARCH

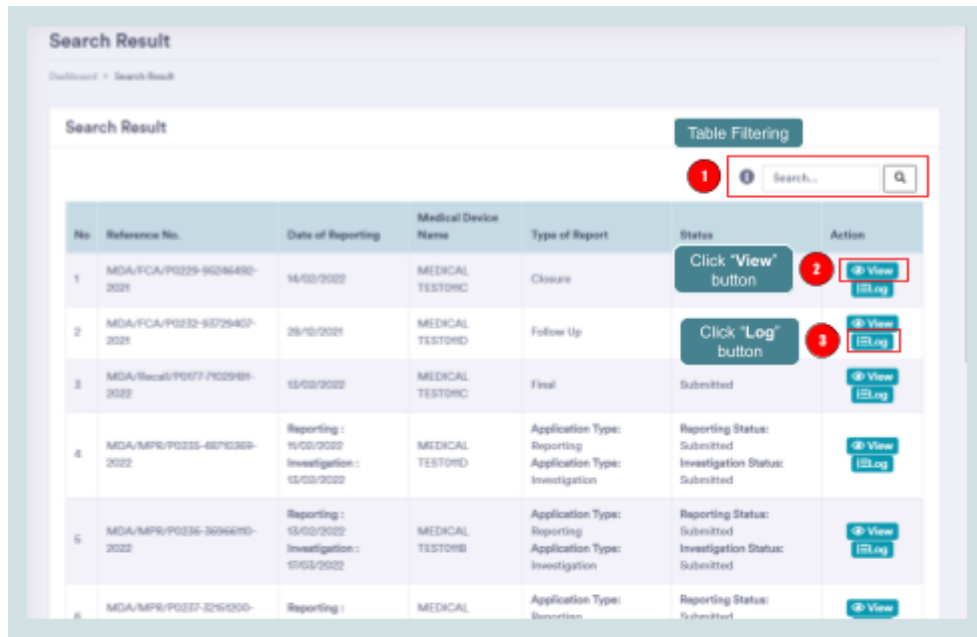


a. The search box (input field) is located at the navigation bar as above:

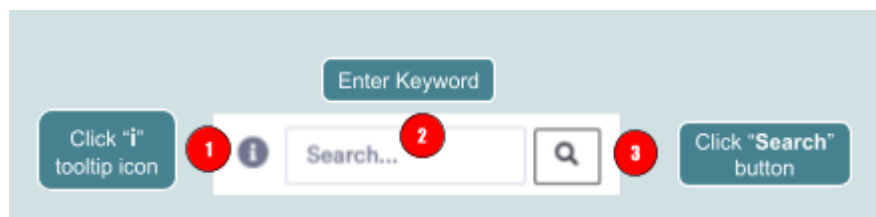
1. User can click  icon and the pop-up information related to search will display as below:



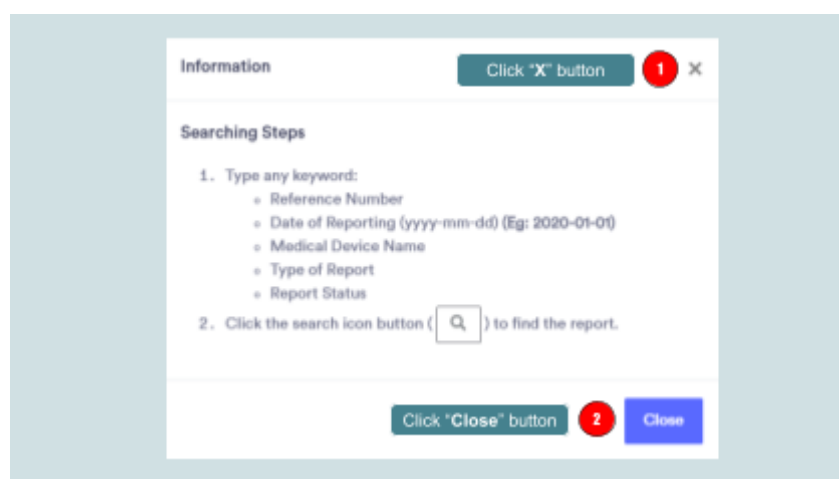
- I. Click  button or  button to close the pop-up.
2. Enter any related keyword (based on information given).
3. Press the **“Enter”** key on the keyboard and the system will display the result as below:






I. Table Filtering

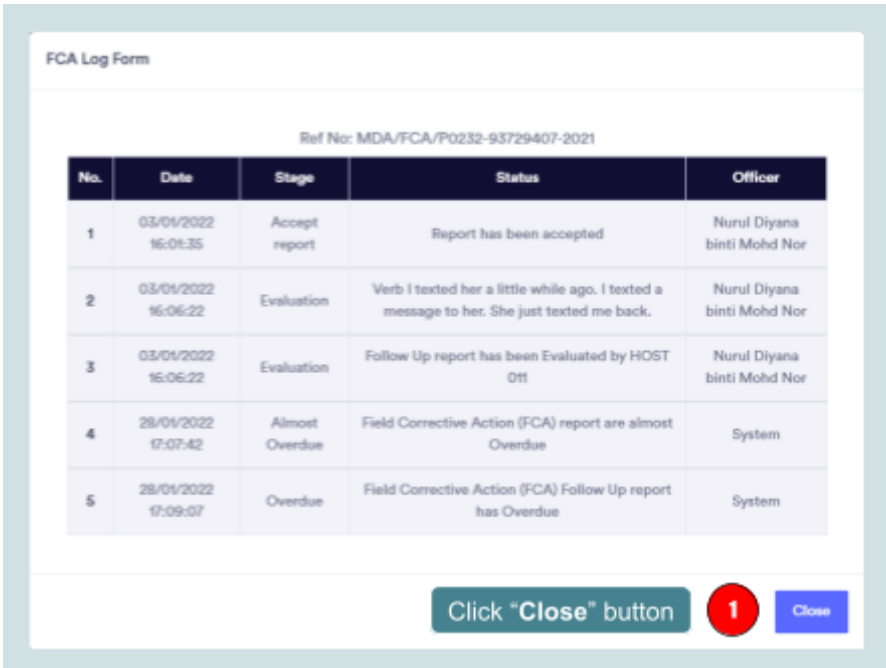


- User can click **i** icon and the pop-up information related to table filtering will display as below:



- Click **X** button or **Close** button to close the pop-up.

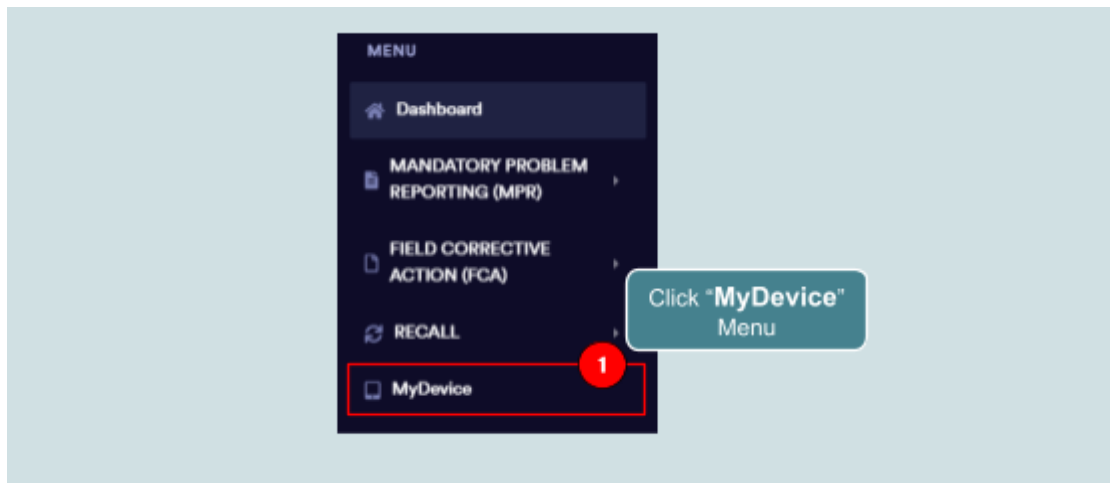
- Enter any related keyword (based on information given).
 - Click  icon and the system will display the result.
- II. Click  button and the system will display the report:
- MPR (Refer to [3.5 VIEW](#)).
 - FCA (Refer to [4.5 VIEW REPORTING](#)).
 - Recall (Refer to [5.4 VIEW](#)).
- III. Click  button and the system will display the pop-up list of Log as below:



No.	Date	Stage	Status	Officer
1	03/01/2022 16:01:35	Accept report	Report has been accepted	Nurul Diyana binti Mohd Nor
2	03/01/2022 16:06:22	Evaluation	Verb I texted her a little while ago. I texted a message to her. She just texted me back.	Nurul Diyana binti Mohd Nor
3	03/01/2022 16:06:22	Evaluation	Follow Up report has been Evaluated by HOST 011	Nurul Diyana binti Mohd Nor
4	28/01/2022 17:07:42	Almost Overdue	Field Corrective Action (FCA) report are almost Overdue	System
5	28/01/2022 17:09:07	Overdue	Field Corrective Action (FCA) Follow Up report has Overdue	System

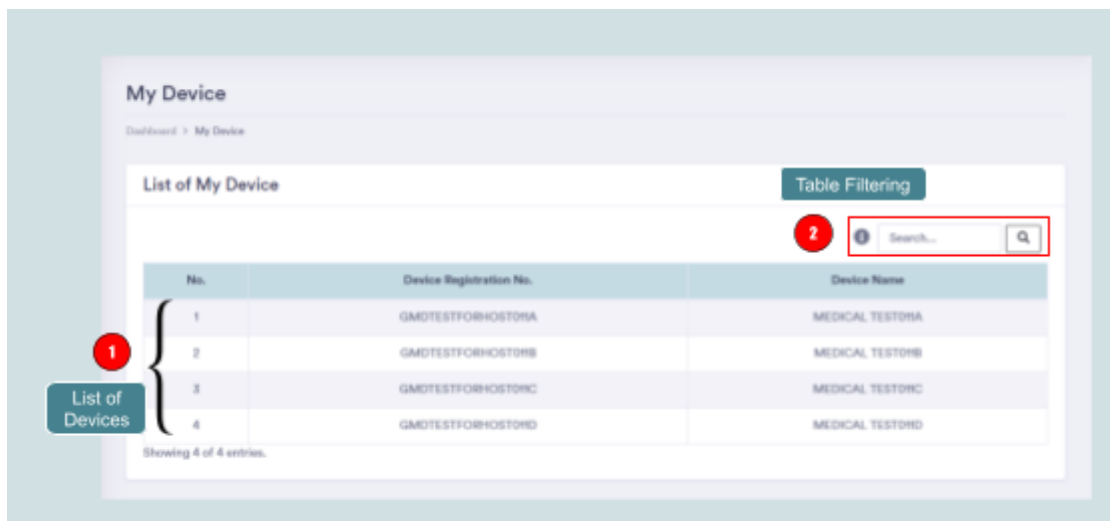
- Click  button to close the pop-up.

2.8 MY DEVICE



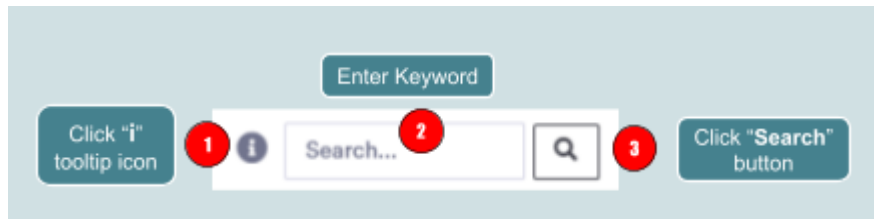
a. The Sidebar Menu will be displayed as above:


1. Click **MyDevice** menu and the system will redirect users and display the list of devices.

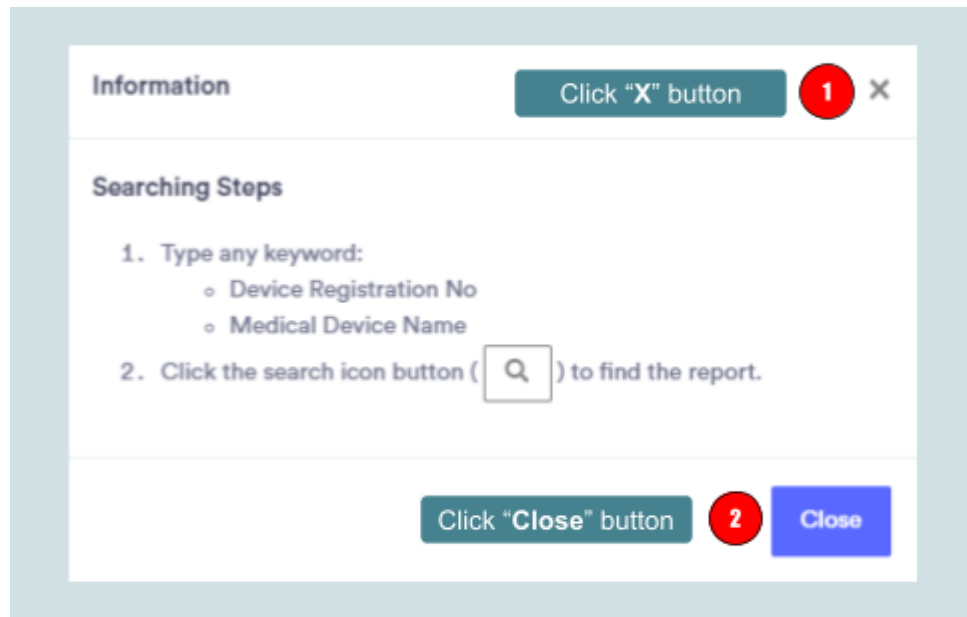


b. Page of My Device will be displayed as above:


1. **List of Devices** are the list of registered devices from Medcast 2.0.
2. **Table Filtering**



- I. User can click  icon and the pop-up information related to table filtering will display as below:



- Click  button or  button to close the pop-up.

- II. Enter any related keyword (based on information given).
- III. Click  icon and the system will display the result.

3 MANDATORY PROBLEM REPORTING (MPR)

3.1 MANDATORY PROBLEM REPORTING (MPR) SIDEBAR

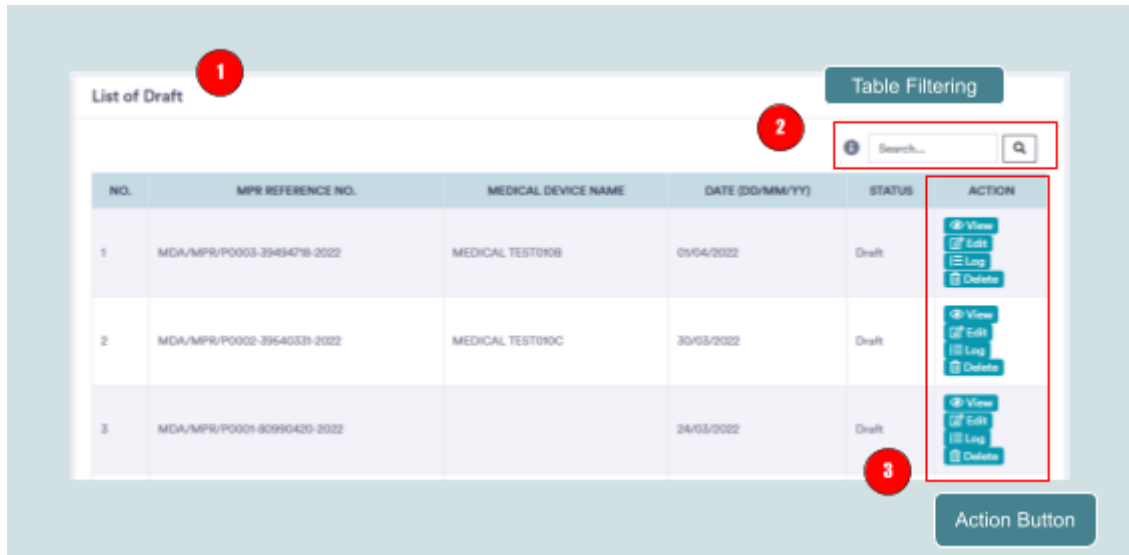


a. Mandatory Problem Reporting (MPR) sidebar will be displayed as above:

- 1. Create New Reporting** : Display the new create page for Reporting. (Refer to [3.3 CREATE NEW REPORTING](#))
- 2. Draft Reporting** : Display the Reporting with a 'Draft' status. (Refer to [3.2.1 Draft Reporting](#))
- 3. Status of Submission Reporting** : Display the list of reporting that have been submitted by the user. (Refer to [3.10.1 Status of Submission Reporting](#))
- 4. Investigation Dashboard** : Display the Investigation main dashboard. (Refer to [3.2.2 Investigation Dashboard](#))
- 5. Status of Submission Investigation** : Display the list of investigation reports that have been submitted by the user. (Refer to [3.10.2 Status of Submission Investigation](#))

3.2 DASHBOARD

3.2.1 Draft Reporting

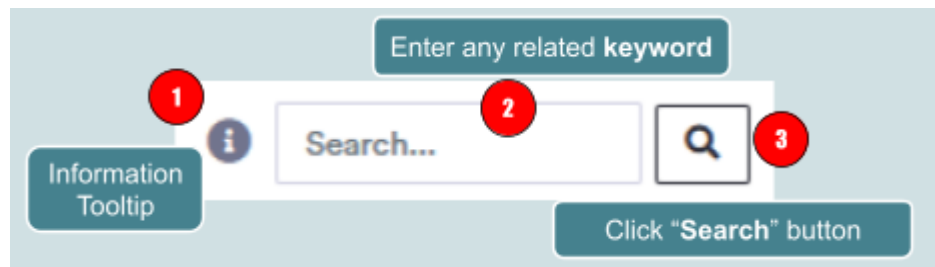



a. The Draft Reporting page will be displayed as above:

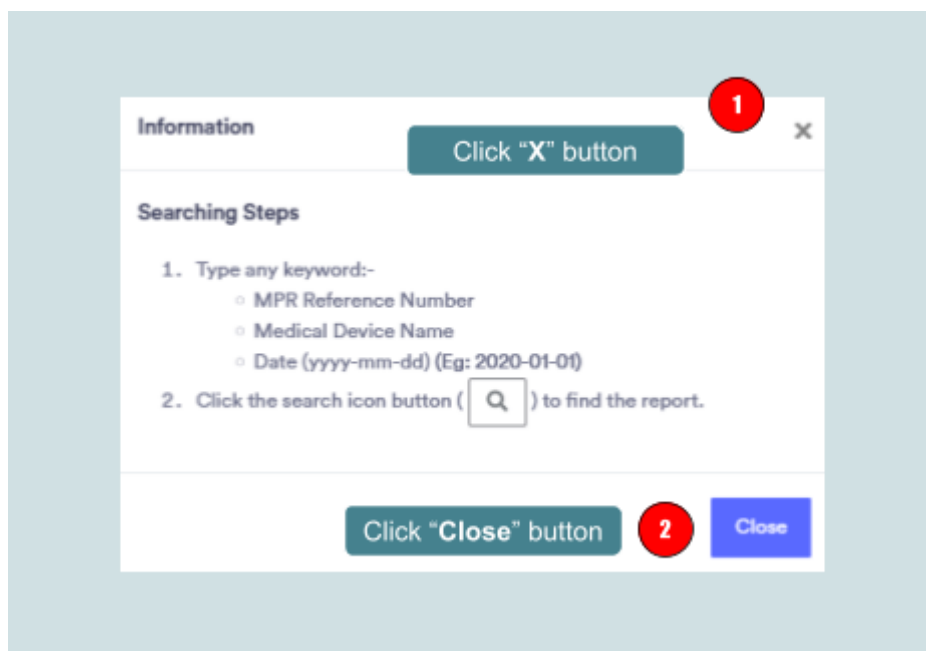
1. List of Draft




- I. List of Draft will display the list of reporting that has been saved as draft.

2. Table Filtering






- I. Click  icon to get more information related to table filtering and the pop-up will be displayed as below :



- Click  button or  button to close the pop-up.
- II. Enter any related keyword (based on information given).
- III. Click  icon and the system will display the result.

3. Action Button

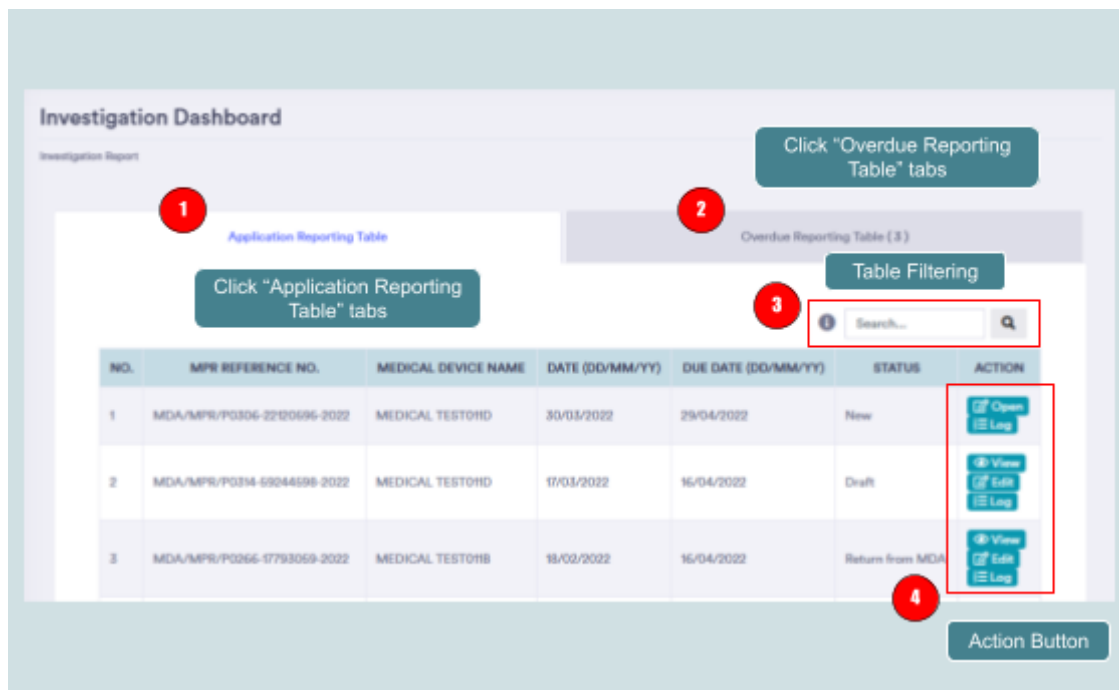
- I. Click  **View** button to view the reporting that has been saved as draft and the view page (Refer to [3.5.1 View Mandatory Problem Reporting](#))
- II. Click  **Edit** button to update the reporting. (Refer to [3.7.1 Edit Mandatory Problem Reporting](#))
- III. Click  **Log** button to view the reporting log and the pop-up will be displayed as below :



➤ Click **X** button or **Close** button to close the pop-up.

- IV. Click **Delete** button to delete the reporting. (Refer to **3.8 DELETE MANDATORY PROBLEM REPORTING**)

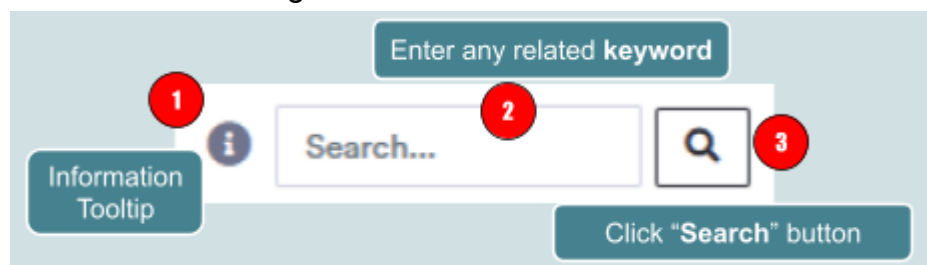
3.2.2 Investigation Dashboard




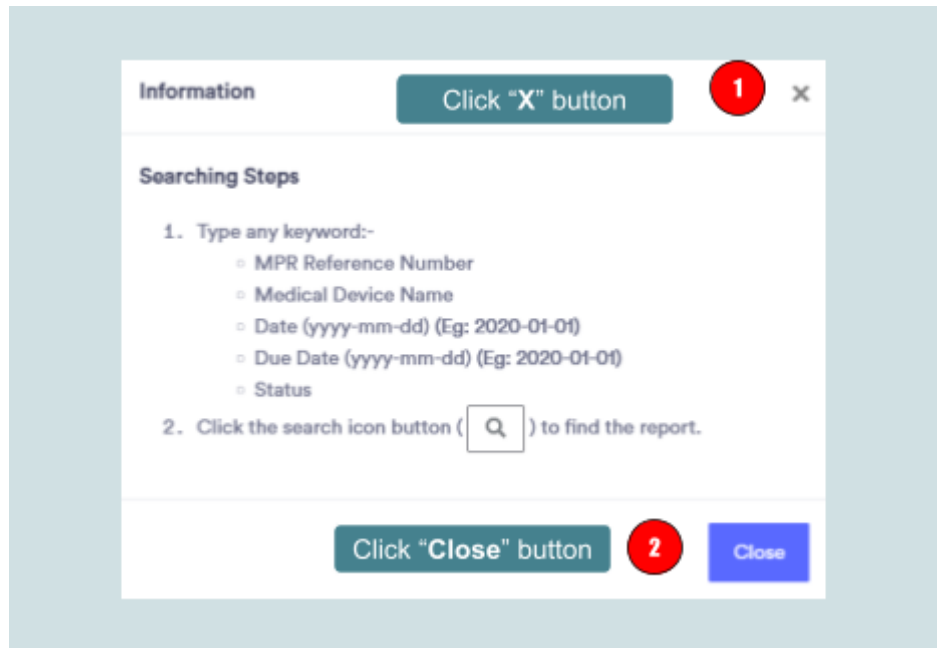
a. The Investigation Dashboard page will be displayed as above:

1. "Application Reporting Table" tabs
 - I. "Application Reporting Table" tabs will display the investigation report with the status of New, Draft and Return from MDA.
2. "Overdue Reporting Table" tabs
 - I. "Overdue Reporting Table" tabs will display the investigation report with the status of Almost Overdue, Overdue and Extend Date. (Refer to [3.9 OVERDUE REPORTING TABLE](#))

3. Table Filtering



- I. Click  icon to get more information related to table filtering and the pop-up will be displayed as below :



➤ Click **X** button or **Close** button to close the pop-up.

II. Enter any related keyword (based on information given).

III. Click **[Q]** icon and the system will display the result.

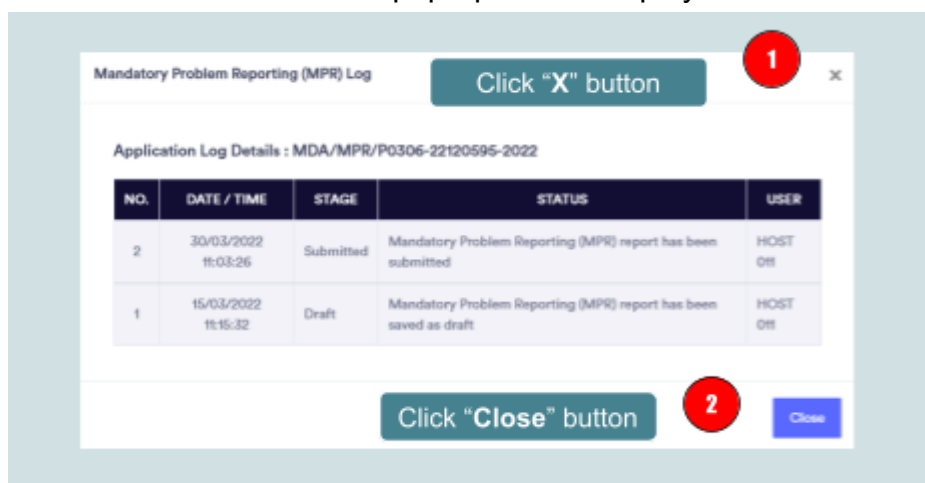
4. Action Button



I. Action button in the Investigation Dashboard will be displayed based on statuses as shown below :

STATUS	ACTION
New	Open Log
Draft	View Edit Log
Return from MDA	View Edit Log




➤ Status New : New investigation report that has not yet been opened and has not yet been filled out by the user.

- Click  **Open** button to create investigation report. (Refer to [3.4 CREATE INVESTIGATION REPORT](#))
- Click  **Log** button to view the investigation report log and the pop-up will be displayed as below :








- Click  button or  button to close the pop-up.

➤ Status Draft : Investigation report that has been opened but has not yet been submitted by the user.

- Click  **View** button to view the investigation report. (Refer to [3.5.2 View Investigation Report](#))
- Click  **Edit** button to update the investigation report (Refer to [3.7.2 Edit Investigation Report](#))
- Click  **Log** button to view the investigation report log and the pop-up will be displayed as below :



- Click  button or  button to close the pop-up.

- Status Return From MDA : Investigation report that has been returned by the MDA for the user to update an incomplete report or there are corrections that need to be updated.
 - Click  **View** button to view the investigation report that has been returned from MDA. (Refer to [3.5.3 View Return From MDA](#))
 - Click  **Edit** button to update the investigation report that has been returned from MDA. (Refer to [3.7.3 Edit Return From MDA](#))
 - Click  **Log** button to view the investigation report that has been return from MDA log and the pop-up will be displayed as below :

Mandatory Problem Reporting (MPR) Log



Click "X" button

Application Log Details : MDA/MPR/P0266-17793059-2022

NO.	DATE / TIME	STAGE	STATUS	USER
5	17/03/2022 12:30:48	Evaluation	The Investigation Report has been returned to Establishment for further action	Nur Syazila binti Hamzah
4	16/02/2022 09:55:13	Submitted	Investigation Report has been submitted	HOST 0H
3	16/02/2022 09:26:23	Enforcement	Enforcement action is Potential	System
2	16/02/2022 09:26:23	Submitted	Mandatory Problem Reporting (MPR) report has been submitted	HOST 0H
1	16/02/2022 08:46:41	Draft	Mandatory Problem Reporting (MPR) report has been saved as draft	HOST 0H

Click "Close" button

Close

- Click  button or  button to close the pop-up.

3.3 CREATE NEW REPORTING

Figure X shows flow-chart of the steps to be taken by user before making submission for Mandatory Problem Reporting under Section 40 of Act 737

Mandatory Problem Reporting (MPR)

Mandatory Problem Reporting Form

MANDATORY PROBLEM REPORTING FORM
Medical Device Act 2012 (ACT 737)
Section 40, Act 737 and Regulation 5 Medical Device (Duties and Obligations of Establishment) Regulations 2019

(*) -required

This page DOES NOT HAVE AN AUTO SAVE FUNCTION. Please click the BACK BUTTON at the bottom of the page and click the SAVE AS DRAFT in the confirmation box.

MPR Reference No. MDA/MPR/P0003-294947B-2022 **1** MPR Reference Number

Section A: Location of Incident **2** Section A: Location of Incident

Section B: Background Information **3** Section B: Background Information

Section C: Device Information **4** Section C: Device Information

Section D: Incident Information **5** Section D: Incident Information

6 Declaration

I hereby attest that the information and attachment provided on this reporting is / are correct, completed and current to this date.*

I understand and acknowledge that it is an offence under Section 76 of Act 737, to make sign or furnish any declaration, or other document which is untrue, inaccurate or misleading.*

Person Responsible for the Establishment HOST DR

Job Title MANAGER

Telephone 023466799

Email Address hostdr@sebang.com

7 Button Section

Back Clear Previous PDF Submit

a. The Create New Reporting page will be displayed as above :

1. MPR Reference Number


I. MPR Reference Number will be displayed as below :

MPR Reference No. MDA/MPR/P0003-294947B-2022

II. MPR Reference Number is auto-generated by the system.

2. Section A : Location of Incident

I. Section A will be displayed as below :

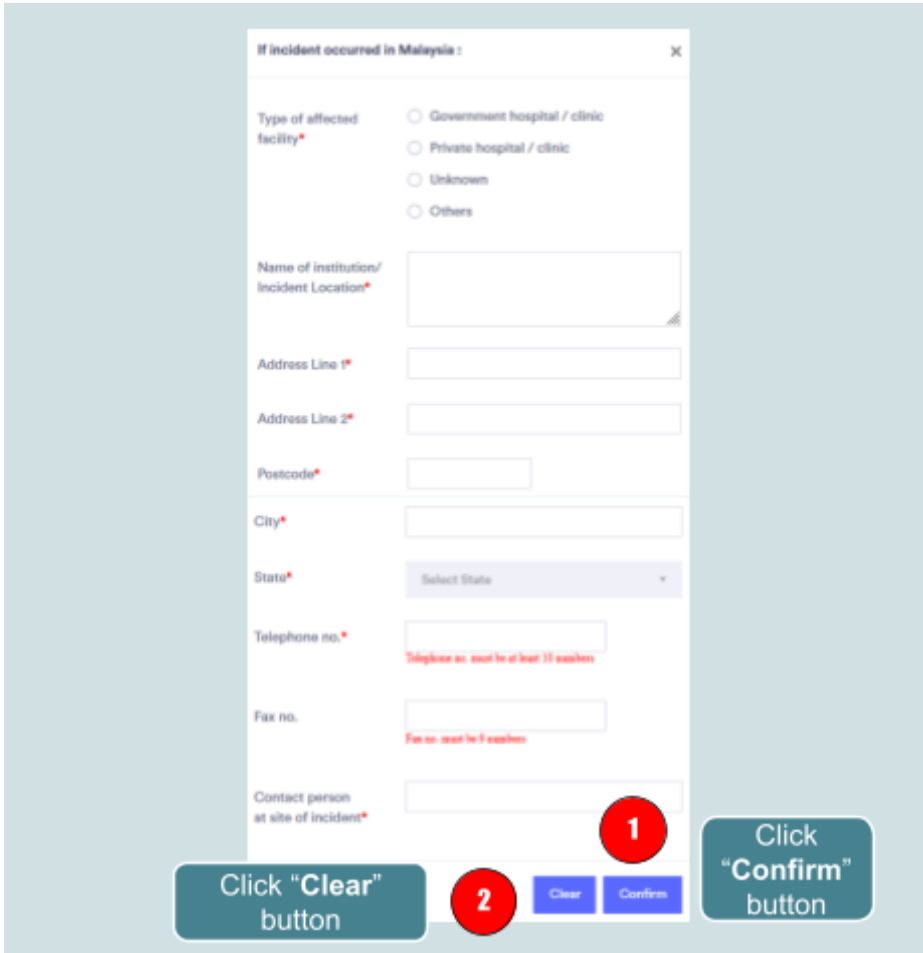


The screenshot shows a form titled "Section A : Location of Incident". It contains a section labeled "Where the incident occurred*" with two radio button options: "In Malaysia" and "Outside Malaysia".

II. User must select one of the radio button whether the location of the incident is in Malaysia (In Malaysia) or outside Malaysia (Outside Malaysia).

III. If the user select In Malaysia

➤ The pop-up will be displayed as below :




The screenshot shows a pop-up form titled "If incident occurred in Malaysia :". It contains several fields and buttons:

- Type of affected facility* (radio buttons): Government hospital / clinic, Private hospital / clinic, Unknown, Others
- Name of institution/ Incident Location* (text input)
- Address Line 1* (text input)
- Address Line 2* (text input)
- Postcode* (text input)
- City* (text input)
- State* (dropdown menu: Select State)
- Telephone no.* (text input, note: Telephone no. must be at least 10 numbers)
- Fax no. (text input, note: Fax no. must be 9 numbers)
- Contact person at site of incident* (text input)
- Buttons: "Clear" (with a red circle '2' next to it), "Confirm" (with a red circle '1' next to it), and a large "Click 'Confirm' button" button.


➤ User are required to fill in all fields that marked with an asterisk (*). User can choose to fill or not in the fields that not marked with an asterisk (*).

➤ Click button to close the pop-up.

- Click  button to clear the form in the pop-up.

IV. If the user select Outside Malaysia

- The pop-up will be displayed as below :




- User are required to select the name of the country where the incident occurred in the dropdown button.

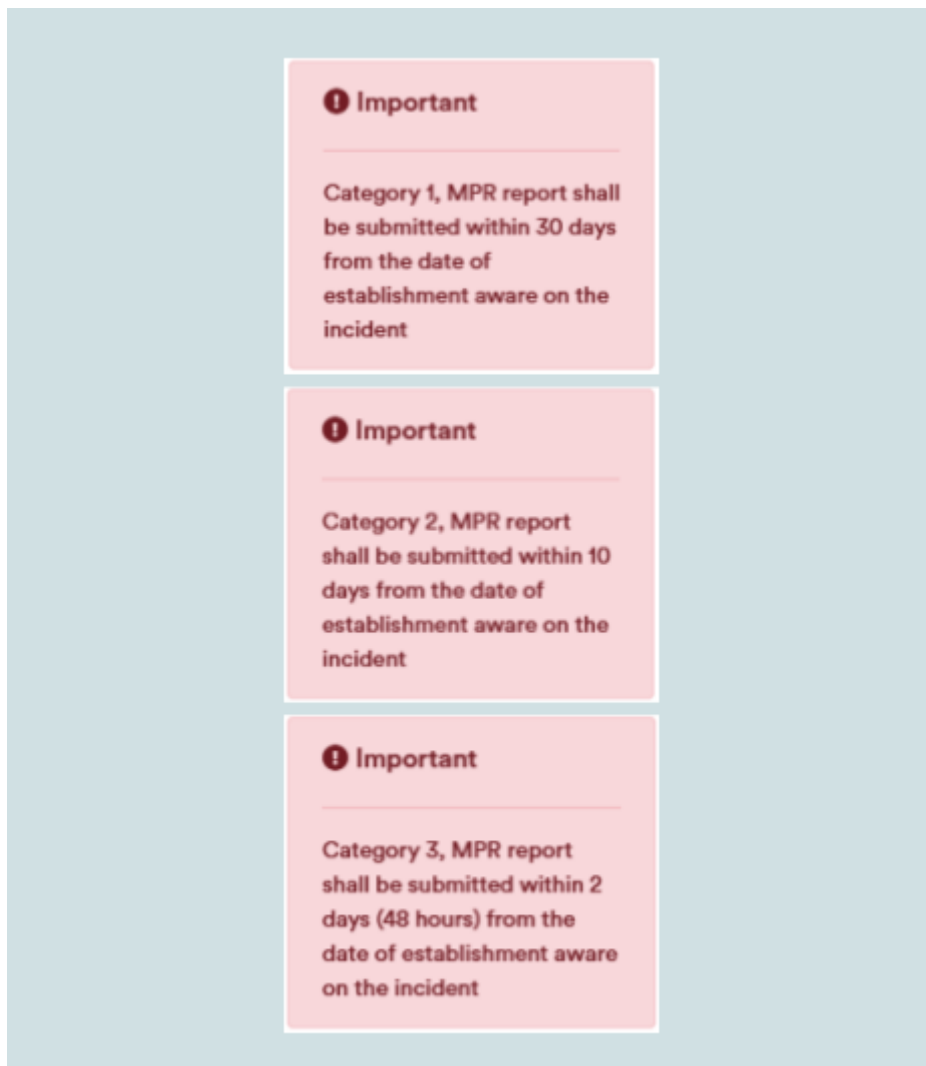
- Click  button to close the pop-up.

3. Section B : Background Information

I. Section B will be displayed as below :



- II. User are required to fill in all fields that marked with an asterisk (*). For question Number 1 (Date of Reporting) will fill in automatically based on current date.
- III. Important notice will be displayed as below based on the radio button category that has been selected in question Number 3 (Report Category).



- IV. For question Number 5 (Time period of reporting from the date of incident), the system will fill in automatically once the user selects the date on question Number 2 (Date of Incident). This time period indicates the period of how many days the user took to report from the Date of Incident. Question Number 5 will be displayed as below :



- V. If the user select the date on question Number 4 (Date of establishment aware on the incident) more than the specified period from the date on question Number 1 (Date of Reporting), the Justification text area will be displayed as below :

The screenshot displays the 'Section B: Background Information' form. It includes the following fields and options:

- 1. Date of Reporting: 30/05/2022
- 2. Date of Incident: 24/05/2022
- 3. Report Category: Category 3 (Selected), with sub-options for Category 1 (Non death / Non injury), Category 2, and Category 3 (Serious threat to public health).
- 4. Date of establishment aware on the incident: 28/05/2022
- 5. Time period of reporting from the date of incident: 7 days

A red 'Important' warning box is displayed, stating: 'Category 3, MFR report shall be submitted within 2 days (48 hours) from the date of establishment aware on the incident'. Below this, a text area is shown with the message: 'This field is required. Minimum 40 characters.' and a red error message: 'Under the Act 733, your reporting has been exceeded the specified reporting timeframe. Therefore please state your justification.'

- VI. User need to fill in the text area to justify the delay of the period that has been set according to the act. The minimum number of characters for this field is 40 characters. If user does not fill in more than 40 characters, user will not be able to submit the reporting.
4. Section C : Device Information
- I. Section C will be displayed as below :

The screenshot displays the 'Section C : Device Information' form with the following fields:

- Medical Device Registration No. (Dropdown menu with placeholder text: 'Select Medical Device Registration No.')
- Device Name (Text input field)
- Brand Name (Text input field)
- Class of Device (Text input field)
- Manufacturer Name (Text input field)

Below the form is a 'Table of Affected Devices' table with the following columns: NO., BATCH NO., LOT NO., SERIAL NO., and EXPIRY DATE. The table currently shows 'No list to display'.

A red circle with the number '1' highlights the 'Add Details of Affected Devices' button. A callout box points to this button with the text: 'Click "Add Details of Affected Devices" button'.

- II. User are not required to fill in this field because the field for Section C is not mandatory for reporting.
- III. Click the dropdown button to select Medical Device Registration No.
- IV. All questions will be automatically filled by the system according to the Medical Device Registration No. that the user has been selected except for Table of Affected Devices.
- V. **Add Details of Affected Devices** button will be enabled after the user fills in the Medical Device Registration No. in Question 1.
- VI. By clicking **Add Details of Affected Devices** button, the system will display Details of Affected Devices page shown as below :

Mandatory Problem Reporting (MPR)

Dashboard > Mandatory Problem Reporting Form > Details of Affected Devices

1 Click "Add Details" button

2 Action Button

NO.	BATCH NO.	LOT NO.	SERIAL NO.	EXPIRY DATE	ACTION
1	A4560				[Edit] [Delete]
2				30/03/2022	[Edit] [Delete]

3 Supporting Document

(Establishment may download the template excel file & upload at given file section)

4 Template: Template for Table of Affected Device.xlsx

Supporting Document for Table of Affected Devices

5 • MPR_Table of Affected Device(2) (MOA_MPR_P0001_30494718_2022) (1c8f2b716).xlsx

6 Next to edit

- Click **Add Details** button to add the details of the affected devices and the pop-up will be displayed as below :

Add details of affected devices

1 Please fill in one (1) information from the four (4) elements displayed

Batch no.

Lot no.

Serial no.

Expiry Date

1 Click "Add" button

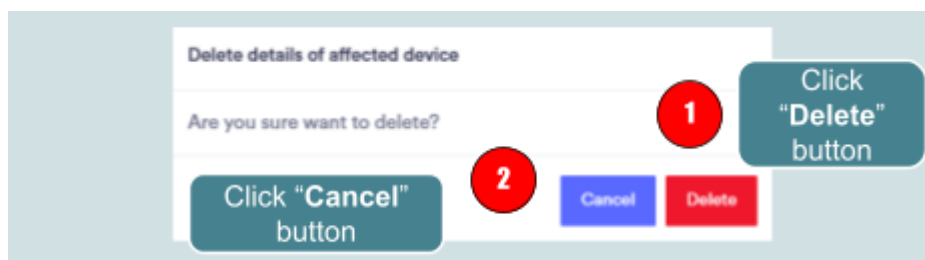
2 Click "Clear" button



Clear Add

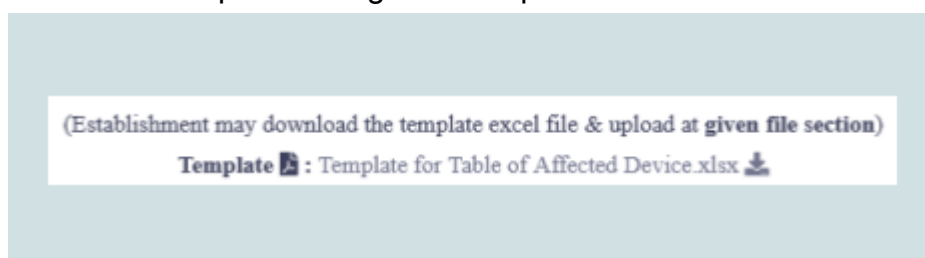
- User can fill in only one (1) information from the four (4) elements displayed.

- After user fill in the field, click **Add** button to store the information into the Table of Affected Devices.
- Click **Clear** button to clear the form in the pop-up.
- If user wants to fill in the next details, user need to click **Add Details** button again.
- In the Action column, there are two (2) buttons that user can use which is :
 - Click **Edit** button to update the details of affected devices in the table. The pop-up will be displayed as below :

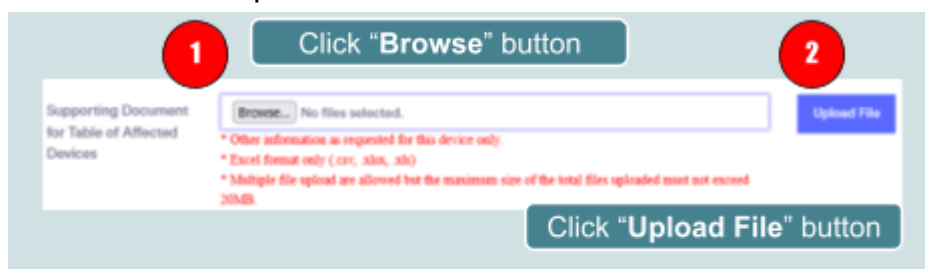
- Click **Update** button to update the details.
- Click **Clear** button to clear the form in the pop-up.
- Click **Delete** button to delete the details from the table. The pop-up will be displayed as below :

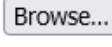



- Click  button to delete the details.
 - Click  button to cancel and delete the details.
- User may download the template excel file and upload at a given file upload section.

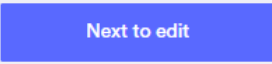


- For Supporting Document for Table of Affected Devices, user are not required to upload the file because this section is not mandatory. User are allowed to upload excel files only and are allowed to upload more than one file.



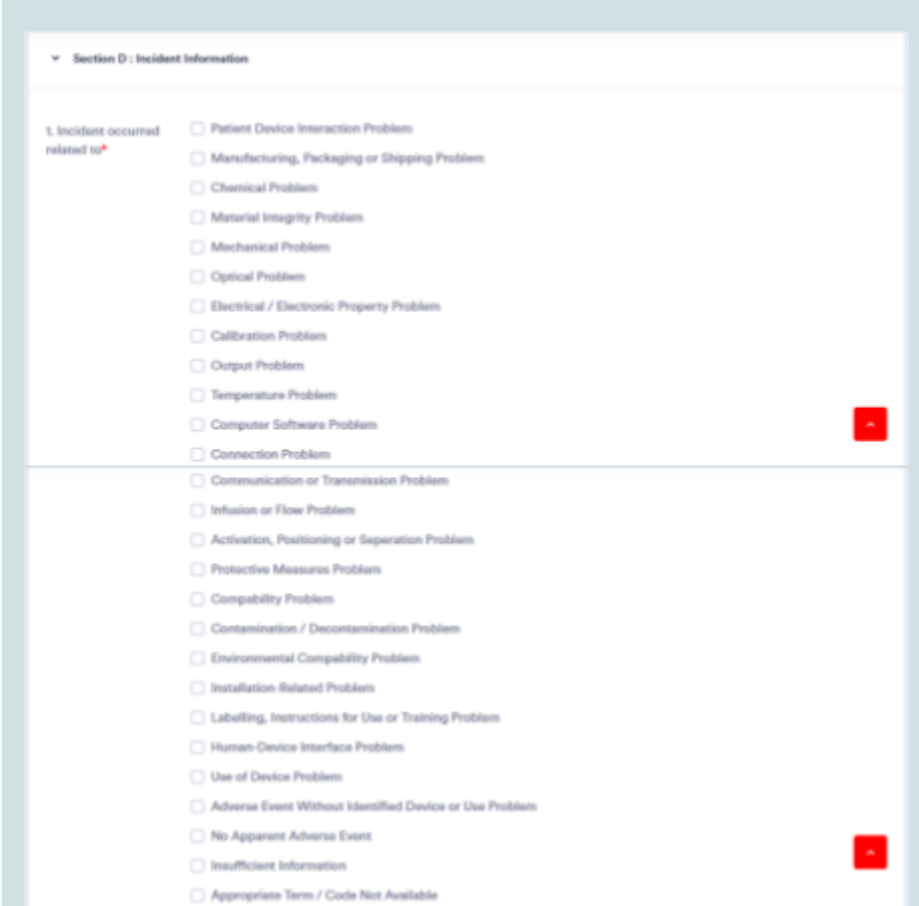
- User can choose the file that needs to be uploaded by clicking on  button. Then click  button to upload the file.
- Under the supporting document upload file section, it will display the file uploaded by the user.

• MPR_Table of Affected Device(2) (MDA_MPR_P0003_39494718_2022)
(LcBF2UTd).xlsx

➤ Click  button to continue to the next question for Section D.

5. Section D : Incident Information

I. Section D will be displayed as below :



The screenshot shows a web form titled "Section D : Incident Information". The form contains a list of 25 radio button options for selecting the cause of an incident. The options are:

- Patient Device Interaction Problem
- Manufacturing, Packaging or Shipping Problem
- Chemical Problem
- Material Integrity Problem
- Mechanical Problem
- Optical Problem
- Electrical / Electronic Property Problem
- Calibration Problem
- Output Problem
- Temperature Problem
- Computer Software Problem
- Connection Problem
- Communication or Transmission Problem
- Infusion or Flow Problem
- Activation, Positioning or Separation Problem
- Protective Measures Problem
- Compatibility Problem
- Contamination / Decontamination Problem
- Environmental Compatibility Problem
- Installation-Related Problem
- Labelling, Instructions for Use or Training Problem
- Human-Device Interface Problem
- Use of Device Problem
- Adverse Event Without Identified Device or Use Problem
- No Apparent Adverse Event
- Insufficient Information
- Appropriate Term / Code Not Available

There are two red square buttons with a white minus sign on the right side of the form, one at the end of the first group of options and one at the end of the second group of options.

The screenshot displays a web form for reporting a medical device incident. It is divided into several sections:

- 2. Description of incident***: A large text input field.
- 3. Device operator during time of incident**: Radio button options for Healthcare Professional, Patients, and Others.
- 4. Usage of device***: A red note says "Please select two (2)". Radio button options include Initial Use, Single Use / Disposables, Reuse of Single Use, Reuse of Reusable, Re-serviced / Refurbished, and Others.
- 5. Current location of the device**: A red note says "Note: Submission on state of device is at the time of the report". Radio button options include Remain implanted, Explanted, Disposed, Quarantined at user's site, Quarantined at establishment's site, Returned to manufacturer, and Others.
- 6. List of other devices involved in the incident (if applicable)**: A text input field.
- 7. Immediate Action taken by the establishment during incident**: A text input field.
- 8. Submission of Investigation Report***: Radio button options for Within 30 days after submission and Request for extension time.

Red square icons are visible on the right side of sections 4 and 8.

- II. User are required to fill in all fields that marked with an asterisk (*). User can choose to fill or not in the fields that not marked with an asterisk (*).

6. Declaration

- I. Declaration will be displayed as below :

The screenshot shows the Declaration section of the form. It includes:

- Two checkboxes: "I hereby attest that the information and attachment provided on this reporting is / are correct, completed and current to this date.*" and "I understand and acknowledge that it is an offence under Section 76 of Act 733, to make sign or furnish any declaration, or other document which is untrue, inaccurate or misleading.*".
- Fields for: Person Responsible for the Establishment (HDST DR), Job Title (MANAGER), Telephone (023454789), and Email Address (hst01@hdbunbung.com).


- II. User are required to tick the checkbox that marked with an asterisk (*).
- III. In this section, the system will display person responsible details which are :
 - Name of Reporting Person

- Job Title
- Telephone
- Email Address

7. Button Section



I. Button section will be displayed as below :








II. Click  button to go back to the previous page. There will be two (2) types of pop-up that will be displayed as below :



➤ Back Confirmation Pop-up

- If the question Table of Affected Devices in Section C has been filled, this Back Confirmation pop-up will be displayed.
- Click the  button to go back to the previous page.
- Click the  button to stay on the same page.



- Draft Confirmation Pop-up
 - If the question Table of Affected Devices in Section C has not been filled, this Draft Confirmation pop-up will be displayed.
 - Click  button to save the reporting as draft.
 - Click the  button to delete the reporting.
- III. Click  button to clear all the information in the reporting except the default value.
- IV. Click  button to preview the reporting in Portable Document Format (PDF) format. (Refer to [3.6.1 Preview PDF Mandatory Problem Reporting](#))
- V. Click  button to submit the reporting. This button will be enabled once the user tick both of the checkboxes in the Declaration section.

3.4 CREATE INVESTIGATION REPORT

Figure X shows flow-chart of the steps to be taken by user before making submission for Investigation Report under Section 40 of Act 737

INVESTIGATION FORM
Medical Device Act 2012 (ACT 737)
Section 40, Act 737 and Regulation 5 Medical Device (Duties and Obligations of Establishment) Regulations 2019

(*)--required
This page has an **AUTO SAVE FUNCTION**. Your form would be saved automatically as you make progress on the browser. Please be cautious with your case details.

MPR Reference No. MDA/MPR/P0314-59244598-2022 **1** MPR Reference Number

Section A : Device Information **2** Section A : Device Information

Section B : Results of Manufacturer Investigation **3** Section B : Results of Manufacturer Investigation

Section C : Patient Information **4** Section C : Patient Information

5 Declaration

I hereby attest that the information and attachment provided on this reporting is / are correct, completed and current to this date.*
 I understand and acknowledge that is an offence under Section 76 of Act 737, to make sign or furnish any declaration, or other document which is untrue, inaccurate or misleading.*

Person Responsible for the Establishment: HOST 01
Job Title: MANAGER
Telephone: 0123456789
Email Address: host01@webbung.com

Button Section

Back Clear Preview PDF Submit **6**

a. The Create Investigation Report page will be displayed as above :

1. MPR Reference Number

I. MPR Reference Number will be displayed as below :

MPR Reference No. MDA/MPR/P0314-59244598-2022

- II. MPR Reference Number is auto-generated by the system.

2. Section A : Device Information

- I. Section A will be displayed as below :

Section C : Device Information

Medical Device Registration No.

Device Name

Brand Name

Class of Device

Manufacturer Name

Table of Affected Devices*

NO.	BATCH NO.	LOT NO.	SERIAL NO.	EXPIRY DATE
No list to display				

Click "Edit / Add Details of Affected Devices" button

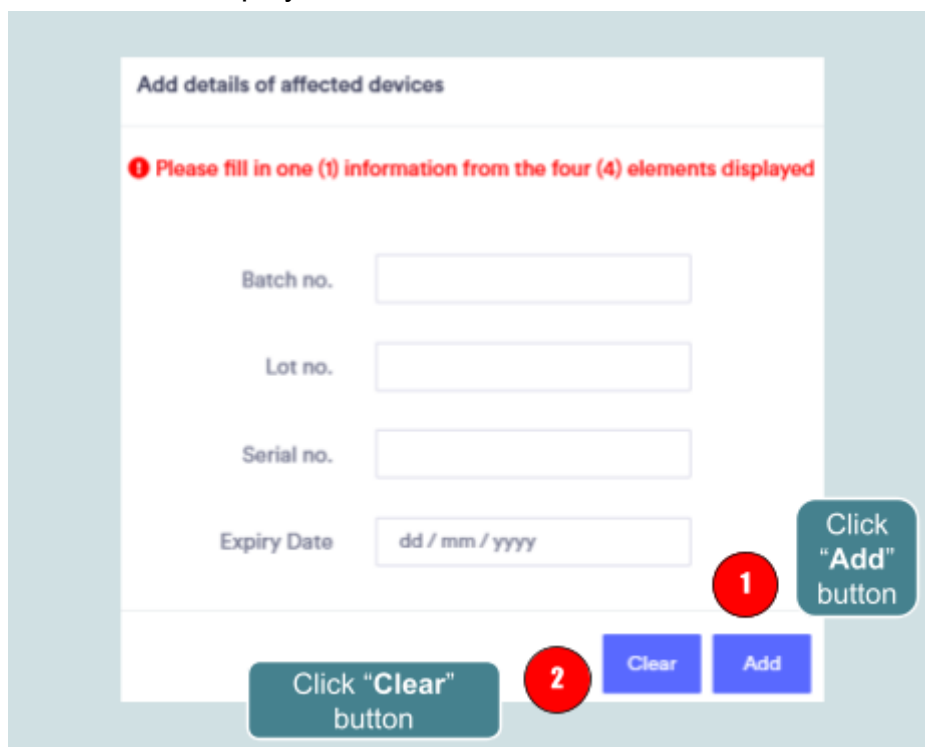
1

Edit / Add Details of Affected Devices

- II. User are required to fill in this field because the field for Section A in the Investigation Report is mandatory. If user already fills in Device Information in Mandatory Problem Reporting (MPR), the data will be displayed in this section.
- III. Click the dropdown button to select Medical Device Registration No.
- IV. All questions will be automatically filled by the system according to the Medical Device Registration No. that the user has been selected except for Table of Affected Devices.
- V. button will be enabled after the user fills in the Medical Device Registration No. in Question 1.
- VI. By clicking button, the system will display Details of Affected Devices page shown as below :



- Click **Add Details** button to add the details of the affected devices and the pop-up will be displayed as below :



- User can fill in only one (1) information from the four (4) elements displayed.

- After user fill in the field, click **Add** button to store the information into the Table of Affected Devices.
- Click **Clear** button to clear the form in the pop-up.
- If user wants to fill in the next details, user need to click **Add Details** button again.
- In the Action column, there are two (2) buttons that user can user which is :
 - Click **Edit** button to update the details of affected devices in the table. The pop-up will be displayed as below :

Update details of affected devices

Batch no. A4560

Lot no.

Serial no.

Expiry Date dd / mm / yyyy

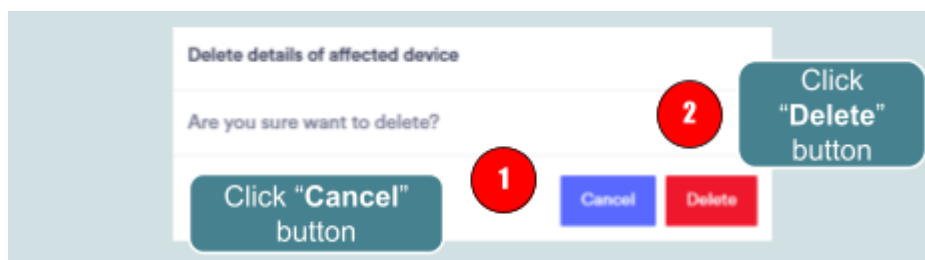
Click "Clear" button



2

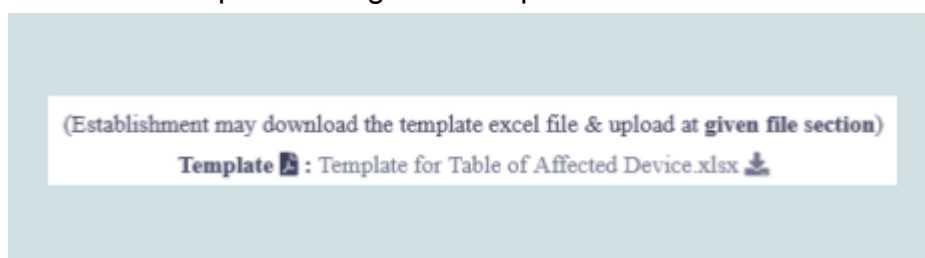
1

Click "Update" button

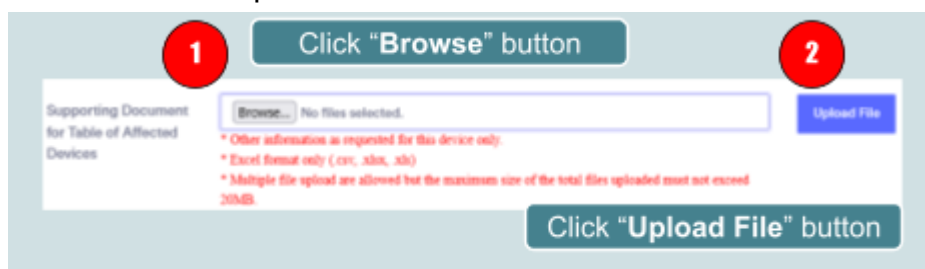
- Click **Update** button to update the details.
- Click **Clear** button to clear the form in the pop-up.
- Click **Delete** button to delete the details from the table. The pop-up will be displayed as below :

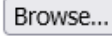



- Click  button to delete the details.
 - Click  button to cancel and delete the details.
- User may download the template excel file and upload at a given file upload section.

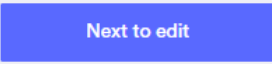


- For Supporting Document for Table of Affected Devices, user are not required to upload the file because this section is not mandatory. User are allowed to upload excel files only and are allowed to upload more than one file.




- User can choose the file that needs to be uploaded by clicking on  button. Then click  button to upload the file.
- Under the supporting document upload file section, it will display the file uploaded by the user.

• MPR_Table of Affected Device(2) (MDA_MPR_P0003_39494718_2022)
(LcBF2UTd).xlsx

➤ Click  button to continue to the next question for Section D.

3. Section B : Results of Manufacturer Investigation

I. Section B will be displayed as below :



Section B : Results of Manufacturer Investigation

1. Investigation findings*

- Biological Problem Identified
- Electrical Problem Identified
- Electromagnetic Compatibility Problem Identified
- Interoperability Problem Identified
- Labelling and Instructions for Use / Maintenance
- Material and / or Chemical Problem Identified
- Mechanical Problem Identified
- Optical Problem Identified
- Clinical Imaging Problem Identified
- Software Problem Identified
- Thermal Problem
- Protective System Problem Identified

2. Root cause of the incident*

3. Corrective Action and Preventive Action has been taken by the manufacturer? Yes No

4. In Malaysia, this MPR leads to FCA and Recall Action? Yes No action required

5. Investigation report provided? No files selected.
* If upload files will delete all previous files
* Multiple file upload are allowed but the maximum size of the total files uploaded must not exceed 20MB.

6. Was this incident reported to other Regulatory Authorities? Yes No

7. Submission Date of Investigation Report 29/04/2022

- II. User are required to fill in all fields that marked with an asterisk (*). User can choose to fill or not in the fields that not marked with an asterisk (*).
- III. For question Number 4 (In Malaysia, this MPR leads to FCA and Recall Action?), when user select 'Yes' in the radio button, a checkbox will be displayed as below :

4. In Malaysia, this MPR leads to FCA and Recall Action? Yes



FCA

Recall

No action required

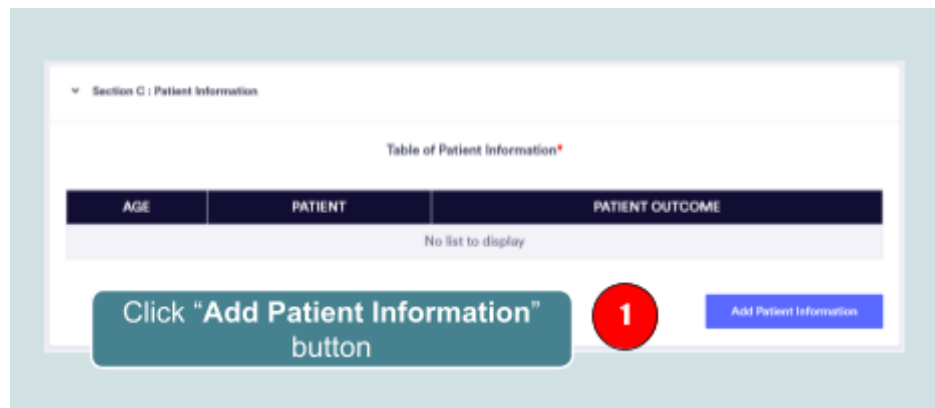
- IV. User need to choose whether to open a report for FCA only, Recall only or both FCA and Recall from the investigation report.
- V. The FCA and Recall will be automatically opened through the investigation report after user submits the investigation report.
- VI. Click button to get more information about multiple file upload. The pop-up will be displayed as below:



➤ Click  button or  button to close the pop-up.

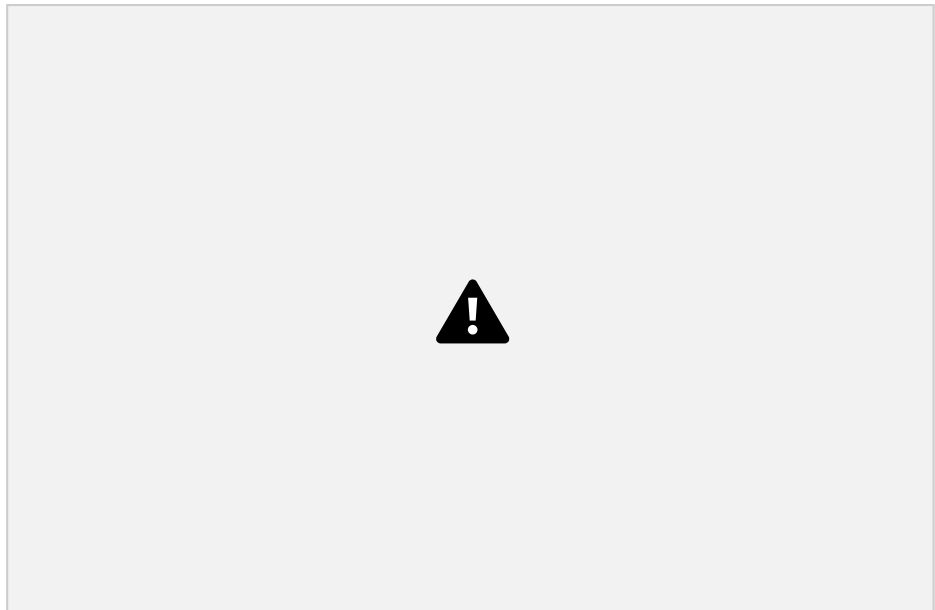
4. Section C : Patient Information

I. Section C will be displayed as below :



II. Section C will be appeared when user chooses based on the situation as below in Mandatory Problem Reporting (MPR) :

➤ Situation 1



➤ Situation 2

Type of affected facility*

Government hospital / clinic

Private hospital / clinic

Unknown

Others

5. Current location of the device

Note : Information on state of device is at the time of the report

Remain implanted

Explanted


Disposed

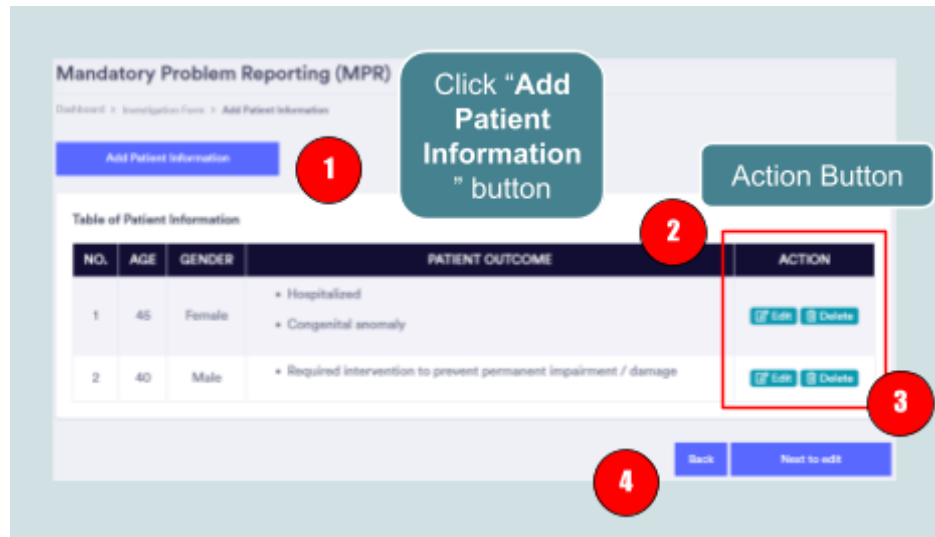
Quarantined at user's site


Quarantined at establishment's site

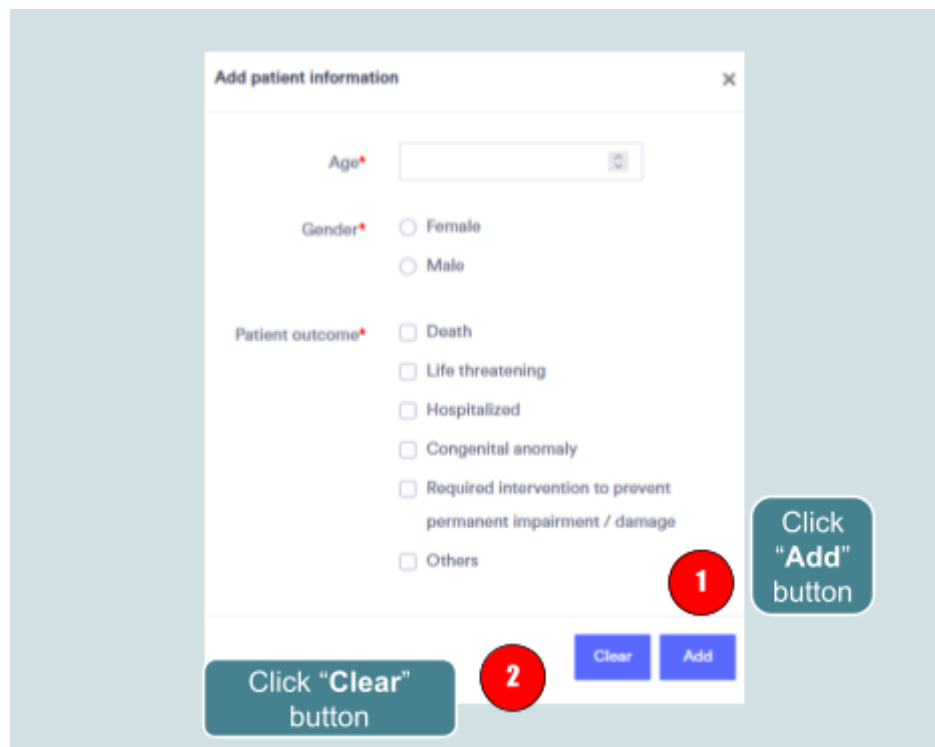
Returned to manufacturer


Others




- III. If user does not select one of the elements based on the situation as above, the Section C display will not be displayed on the investigation report.
- IV. By clicking  button, the system will display Patient Information page shows as below :

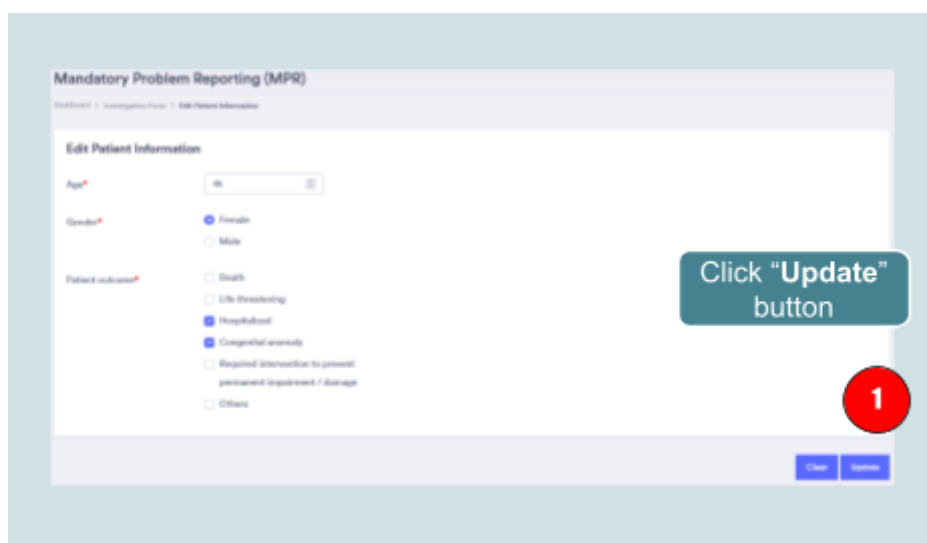




- Click  button to add patient information and the pop-up will be displayed as below :

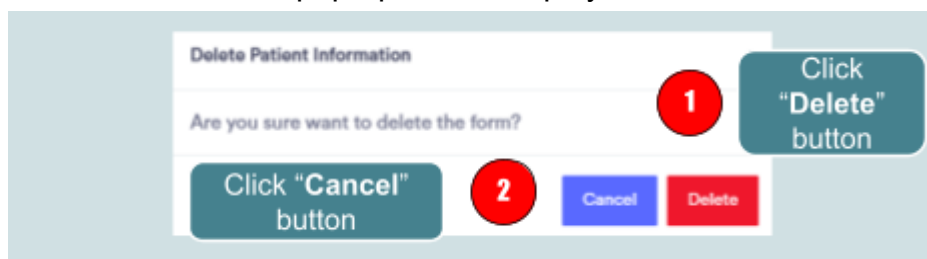


- User are required to fill in all fields that marked with an asterisk (*).
- After user fill in the field, click  button to store the information into the Table of Patient Information.

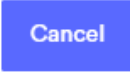
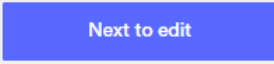
- Click  button to clear the form in the pop-up.
- If user wants to fill in the next details, user need to click  button again.
- In the Action column, there are two (2) buttons that user can use which is :
 - Click  button to update the details of patient information in the table. The edit patient information page will be displayed as below :



- Click  button to update the patient information.
- Click  button to delete the details of patient information from the table. The pop-up will be displayed as below :

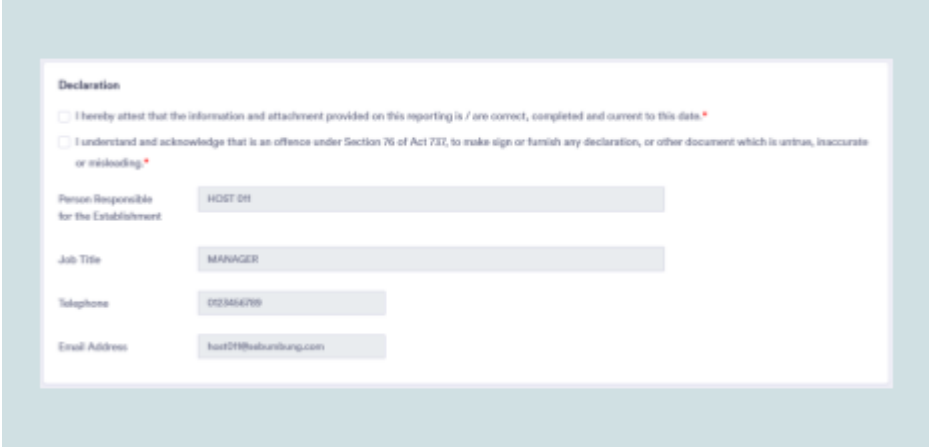


- Click  button to delete the details

- Click  button to cancel and delete the details.
- Click  button to return to the investigation report page

5. Declaration

I. Declaration will be displayed below :




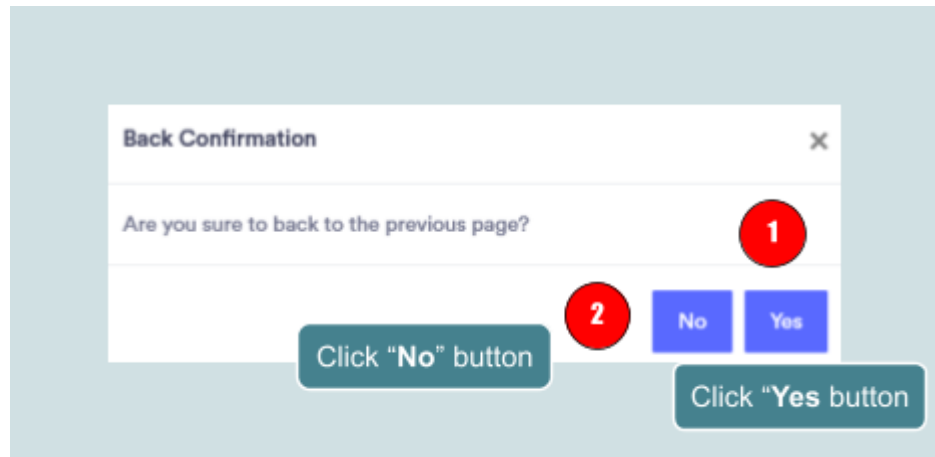
- II. User are required to tick the checkbox that marked with an asterisk (*).
- III. In this section, the system will display person responsible details which are :
 - Name of Reporting Person
 - Job Title
 - Telephone
 - Email Address




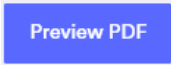
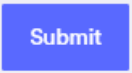
6. Button Section

I. Button section will be displayed as below :




- II. Click  button to go back to the previous page and the confirmation pop-up message will be displayed as below :



- Click the  button to go back to the previous page.
 - Click the  button to stay on the same page.
- III. Click  button to clear all the information in the investigation report except the default value.
- IV. Click  button to preview the investigation report in Portable Document Format (PDF) format. (Refer to [3.6.2 Preview PDF Investigation Report](#))
- V. Click  button to submit the investigation report. This button will be enabled once the user tick both of the checkboxes in the Declaration section.

3.5 VIEW

3.5.1 View Mandatory Problem Reporting (MPR)

- a. Click  button to view the reporting and the view page will be displayed as below :

Mandatory Problem Reporting (MPR)

View Mandatory Problem Reporting Form

MANDATORY PROBLEM REPORTING FORM

Medical Device Act 2012 (ACT 737)

Section 40, Act 737 and Regulation 5 Medical Device (Duties and Obligations of Establishment) Regulations 2019

MPR Reference No.	MDA/MPR/P0306-22/20595-2022
-------------------	-----------------------------

Section A : Location of Incident

Where the incident occurred	Outside Malaysia
Name of country where the incident occurred	Australia

Section B : Background Information

1. Date of reporting	30/03/2022
2. Date of incident	22/03/2022
3. Report category	Category 1 <ul style="list-style-type: none"> Failure of device effectiveness; Deterioration of device effectiveness; Inadequacy in labelling or IFU.
4. Date of establishment aware about the incident	23/03/2022
5. Time period of reporting from the date of incident	8 days

Section C : Device Information

1. Medical device registration no.	GMDTESTFORHOSTRD								
2. Device name	MEDICAL TESTRD								
3. Brand name	TESTRD								
4. Class of device	D								
5. Manufacturer name	MANUFACTURER 011								
6. Details of affected devices	<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 25%;">BATCH NO.</th> <th style="width: 25%;">LOT NO.</th> <th style="width: 25%;">SERIAL NO.</th> <th style="width: 25%;">EXPIRY DATE</th> </tr> </thead> <tbody> <tr> <td colspan="4" style="text-align: center;">No list to display</td> </tr> </tbody> </table>	BATCH NO.	LOT NO.	SERIAL NO.	EXPIRY DATE	No list to display			
BATCH NO.	LOT NO.	SERIAL NO.	EXPIRY DATE						
No list to display									
7. Supporting Document for Table of Affected Devices	<ul style="list-style-type: none"> MPR_Table of Affected Device(1) (MDA_MPR_P0306_22/20595_2022) (pAA2)(1).xlsx 								

Section D : Incident Information	
1. Incident occurred related to	<ul style="list-style-type: none"> • Connection Problem • Activation, Positioning or Separation Problem • Installation-Related Problem • Adverse Event Without Identified Device or Use Problem
2. Description of incident	Process output for establishment license for 2015 KPI – 21 working days with complete application
3. Device operator during time of incident	Healthcare Professional
4. Usage of device	<ul style="list-style-type: none"> • Single Use / Disposable • Reuse of Reusable
5. Device disposition / current location	Disposed
6. List of other devices involved in the accident	-
7. Immediate action taken by the establishment during incident	-
8. Submission of Investigation Report	Within 30 days after submission

Declaration

I hereby attest that the information and attachment provided on this reporting is / are correct, completed and current to this date.

I understand and acknowledge that it is an offence under Section 76 of Act 732, to make sign or furnish any declaration, or other document which is untrue, inaccurate or misleading.

Person Responsible for the Establishment:

Job Title:

Telephone:

Email Address:

Click "Preview PDF" button

Click "Back" button

Back Preview PDF

1. Click [Preview PDF](#) button to preview the reporting and the system will generate the Portable Document Format (PDF) format. (Refer to [3.6.1 Preview PDF Mandatory Problem Reporting](#))
2. Click [Back](#) button to return to the previous page.

3.5.2 View Investigation Report

- a. Click [View](#) button to view the investigation report and the view page will be displayed as below :

Mandatory Problem Reporting (MPR)
View Investigation Form

INVESTIGATION FORM
Medical Device Act 2012 (ACT 737)
Section 40, Act 737 and Regulation 6 Medical Device (Duties and Obligations of Establishment) Regulations 2019

MPR Reference No.	MDA/MPR/P0235-4879388-2022
-------------------	----------------------------

Section A : Device Information

1. Medical device registration no.	QMOTESTFORH0ST0HD
2. Device name	MEDICAL TEST0HD
3. Brand name	TEST0HD
4. Class of device	D
5. Manufacturer name	MANUFACTURER 0H

6. Details of affected devices

BATCH NO.	LOT NO.	SERIAL NO.	EXPIRY DATE
450-500			01/03/2022

7. Supporting Document for Table of Affected Devices
+ No file attached

Section B : Results of Manufacturer Investigation

1. Investigation findings	<ul style="list-style-type: none"> + Optical Problem Identified + Software Problem Identified + Operational Problem Identified + Environment Problem Identified
2. Root cause of the incident	Corrective Action and Preventive Action has been taken by the manufacturer
3. Corrective Action and Preventive Action has been taken by the manufacturer	Yes
4. In Malaysia, this MPR leads to FCA and Recall Action?	Yes <ul style="list-style-type: none"> + FCA + Recall
5. Investigation report provided?	+ 3DR0 (MDA_MPR_P0235_4879388_2022) (IC)36492.pdf
6. Was the incident reported to other Regulatory Authorities?	Yes <ul style="list-style-type: none"> + Australia + Canada
7. Submission Date of Investigation Report	15/05/2022

Declaration

I hereby attest that the information and attachment provided on this reporting is / are correct, completed and current to this date.

I understand and acknowledge that it is an offence under Section 76 of Act 733, to make sign or furnish any declaration, or other document which is untrue, inaccurate or misleading.

Person Responsible for the Establishment: HOET OR

Job Title: MANAGER



Telephone: 023466795

Email Address: hoetor@subumburg.com


Click "Preview PDF" button

Click "Back" button

Back Preview PDF

1. Click  button to preview the investigation report and the system will generate the Portable Document Format (PDF) format. (Refer to [3.6.2 Preview PDF Investigation Report](#))
2. Click  button to return to the previous page.

3.5.3 View Return From MDA

- a. Click  button to view the investigation report that has been returned from MDA.
 1. The view page for status Return from MDA is the combination of the view page of Mandatory Problem Reporting (MPR) (Refer to [3.5.1 View Mandatory Problem Reporting](#)) and the view page of Investigation Report (Refer to [3.5.2 View Investigation Report](#)).

3.6 PREVIEW PDF

3.6.1 Preview PDF Mandatory Problem Reporting (MPR)

- a. There are two (2) types of Preview PDF :
 1. Preview PDF for Draft Report will be shown as below :

	
MANDATORY PROBLEM REPORTING FORM Medical Device Act 2012 (ACT 737) Section 40, Act 737 and Regulation 5 Medical Device (Duties and Obligations of Establishment) Regulations 2019	
MPR Reference No.	MDA/MPR/P0316-73777966-2022
Section A : Location of Incident	
Where the incident occurred	


Section B : Background Information	
1. Date of reporting	01/04/2022
2. Date of incident	16/03/2022
3. Report category	Category 1 <ul style="list-style-type: none">• Failure of device effectiveness;• Deterioration of device effectiveness;• Inadequacy in labelling or IFU.
4. Date of establishment aware about the incident	
5. Time period of reporting from the date of incident	8 days

Section C : Device Information									
1. Medical device registration no.									
2. Device name									
3. Brand name									
4. Class of device									
5. Manufacturer name									
6. Details of affected devices	<table border="1"> <thead> <tr> <th>Batch no.</th> <th>Lot no.</th> <th>Serial no.</th> <th>Expiry date</th> </tr> </thead> <tbody> <tr> <td colspan="4" style="text-align: center;">No list to display</td> </tr> </tbody> </table>	Batch no.	Lot no.	Serial no.	Expiry date	No list to display			
Batch no.	Lot no.	Serial no.	Expiry date						
No list to display									
7. Supporting Document for Table of Affected Devices	<ul style="list-style-type: none"> No file attached 								

Section D : Incident Information	
1. Incident occurred related to	
2. Description of incident	
3. Device operator during time of incident	
4. Usage of device	
5. Device disposition / current location	
6. List of other devices involved in the accident	
7. Immediate action taken by the establishment during incident	
8. Submission of Investigation Report	

I. The Declaration section will not be included in the Preview PDF for Draft Report.

2. Preview PDF for Submitted Report will be shown as below :

	
MANDATORY PROBLEM REPORTING FORM Medical Device Act 2012 (ACT 737) Section 40, Act 737 and Regulation 5 Medical Device (Duties and Obligations of Establishment) Regulations 2019	
MPR Reference No.	MDA/MPR/P0306-22120595-2022
Section A : Location of Incident	
Where the incident occurred	Outside Malaysia
Name of country where the incident occurred	Australia
Section B : Background Information	
1. Date of reporting	30/03/2022
2. Date of incident	22/03/2022
3. Report category	Category 1 <ul style="list-style-type: none">• Failure of device effectiveness;• Deterioration of device effectiveness;• Inadequacy in labelling or IFU.
4. Date of establishment aware about the incident	23/03/2022
5. Time period of reporting from the date of incident	8 days

Section C : Device Information									
1. Medical device registration no.	GMDTESTFORHOST011D								
2. Device name	MEDICAL TEST011D								
3. Brand name	TEST011D								
4. Class of device	D								
5. Manufacturer name	MANUFACTURER 011								
6. Details of affected devices	<table border="1"> <thead> <tr> <th>Batch no.</th> <th>Lot no.</th> <th>Serial no.</th> <th>Expiry date</th> </tr> </thead> <tbody> <tr> <td colspan="4" style="text-align: center;">No list to display</td> </tr> </tbody> </table>	Batch no.	Lot no.	Serial no.	Expiry date	No list to display			
Batch no.	Lot no.	Serial no.	Expiry date						
No list to display									
7. Supporting Document for Table of Affected Devices	<ul style="list-style-type: none"> MPR_Table of Affected Device(t) (MDA_MPR_P0306_22120595_2022) (gAAj8jth).xlsx 								


Section D : Incident Information	
1. Incident occurred related to	<ul style="list-style-type: none"> • Connection Problem • Activation, Positioning or Separation Problem • Installation-Related Problem • Adverse Event Without Identified Device or Use Problem
2. Description of incident	Process output for establishment license for 2015 KPI – 21 working days with complete application
3. Device operator during time of incident	Healthcare Professional
4. Usage of device	<ul style="list-style-type: none"> • Single Use / Disposables • Reuse of Reusable
5. Device disposition / current location	Disposed

6. List of other devices involved in the accident	-
7. Immediate action taken by the establishment during incident	-
8. Submission of Investigation Report	Within 30 days after submission

Declaration	
Person Responsible for the Establishment	HOST 011
Job Title	MANAGER
Telephone Number	0123456789
Email Address	host011@sebung.com

3.6.2 Preview PDF Investigation Report

- a. There are two (2) types of Preview PDF :
 1. Preview PDF for Draft Report will be shown as below :



INVESTIGATION FORM
Medical Device Act 2012 (ACT 737)
Section 40, Act 737 and Regulation 5 Medical Device (Duties and Obligations of Establishment) Regulations 2019

MPR Reference No.	MDA/MPR/P0314-59244598-2022
-------------------	-----------------------------

Section A : Device Information	
1. Medical device registration no.	GMDTESTFORHOST011D
2. Device name	MEDICAL TEST011D
3. Brand name	TEST011D
4. Class of device	

Draft


5. Manufacturer name	MANUFACTURER SITI								
6. Details of affected devices	<table border="1"> <thead> <tr> <th>Batch no.</th> <th>Lot no.</th> <th>Serial no.</th> <th>Expiry date</th> </tr> </thead> <tbody> <tr> <td colspan="4" style="text-align: center;">No list to display</td> </tr> </tbody> </table>	Batch no.	Lot no.	Serial no.	Expiry date	No list to display			
Batch no.	Lot no.	Serial no.	Expiry date						
No list to display									
7. Supporting Document for Table of Affected Devices	<ul style="list-style-type: none"> No file attached 								

Section B : Results of Manufacturer Investigation	
1. Investigation finding	<ul style="list-style-type: none"> Clinical Imaging Problem Identified Operational Problem Identified
2. Root cause of the incident	
3. Corrective Action and Proventive Action has been taken by the manufacturer	
4. This MPR leads to FCA and Recall Action?	
5. Investigation report provided?	
6. Was the incident reported to other Regulatory Authorities?	
7. Submission Date of Investigation Report	16/04/2017

Section C : Patient Information		
Age	Patient	Patient Outcome
No list to display		

- I. The Declaration section will not be included in the Preview PDF for Draft Report.

2. Preview PDF for Submitted Report will be shown as below :

													
INVESTIGATION FORM Medical Device Act 2012 (ACT 737) Section 40, Act 737 and Regulation 5 Medical Device (Duties and Obligations of Establishment) Regulations 2019													
MPR Reference No.	MDA/MPR/P0235-48710369-2022												
Section A : Device Information													
1. Medical device registration no.	GMDTESTFORHOST011D												
2. Device name	MEDICAL TEST011D												
3. Brand name	TEST011D												
4. Class of device	D												
5. Manufacturer name	MANUFACTURER 011												
6. Details of affected devices	<table border="1"> <thead> <tr> <th>Batch no.</th> <th>Lot no.</th> <th>Serial no.</th> <th>Expiry date</th> </tr> </thead> <tbody> <tr> <td>450-500</td> <td></td> <td></td> <td></td> </tr> <tr> <td></td> <td></td> <td></td> <td>01/02/2022</td> </tr> </tbody> </table>	Batch no.	Lot no.	Serial no.	Expiry date	450-500							01/02/2022
	Batch no.	Lot no.	Serial no.	Expiry date									
	450-500												
			01/02/2022										
7. Supporting Document for Table of Affected Devices	<ul style="list-style-type: none"> No file attached 												

Section B : Results of Manufacturer Investigation	
1. Investigation finding	<ul style="list-style-type: none"> • Optical Problem Identified • Software Problem Identified • Operational Problem Identified • Environment Problem Identified
2. Root cause of the incident	Corrective Action and Preventive Action has been taken by the manufacturer
3. Corrective Action and Proventive Action has been taken by the manufacturer	Yes
4. This MPR leads to FCA and Recall Action?	Yes <ul style="list-style-type: none"> • FCA • Recall

5. Investigation report provided?	<ul style="list-style-type: none"> • 3010 (MDA_MPR_P0235_48710369_2022) (IO3jduqS).pdf
6. Was the incident reported to other Regulatory Authorities?	Yes <ul style="list-style-type: none"> • Australia • Canada
7. Submission Date of Investigation Report	13/03/2022

Declaration	
Person Responsible for the Establishment	HOST 011
Job Title	MANAGER
Telephone Number	0123456789
Email Address	host011@sebung.com

3.7 EDIT

3.7.1 Edit Mandatory Problem Reporting (MPR)

- a. A part of the Edit Mandatory Problem Reporting (MPR) page will be displayed as below :

5. Current location of the device
Note : Information on state of device is at the time of the report

Remain implanted
 Explanted
 Disposed
 Quarantined at user's site
 Quarantined at establishment's site
 Returned to manufacturer
 Others

6. List of other devices involved in the incident (if applicable)

7. Immediate Action taken by the establishment during incident

8. Submission of Investigation Report*

Within 30 days after submission
 Request for extension time:

1. Users can update all information in this report.
2. The process to submit the updated reporting will be the same as submitting a new report. (Refer to [3.3 CREATE NEW REPORTING](#))

3.7.2 Edit Investigation Report

- a. A part of the Edit Investigation Report page will be displayed as below:

2. Root cause of the incident*

3. Corrective Action and Preventive Action has been taken by the manufacturer*

4. In Malaysia, this MPR leads to FCA and Recall Action**

5. Investigation report provided**

*** Re-upload files will delete all previous files**
**** Multiple file upload are allowed but the maximum size of the total files uploaded must not exceed 20MB.**


1. Users can update all information in this investigation report.

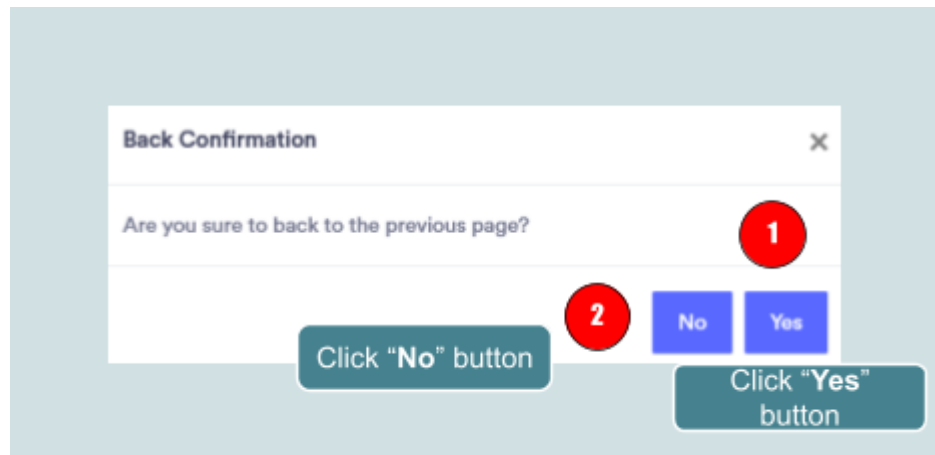
2. The process to submit the updated investigation report will be the same as submitting a new investigation report. (Refer to **3.4 CREATE INVESTIGATION REPORT**)





3.7.3 Edit Return From MDA

- a. A part of the Edit Return From MDA page will be displayed as below :


1. Users can only update the information that has 'No' remark in this report.
2. Button Section
 - I. Button section will be displayed as below :

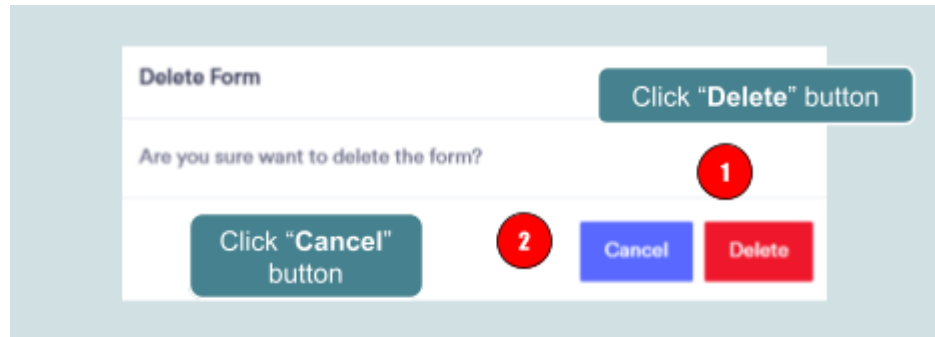
- II. Click  button to go back to the previous page and the confirmation pop-up message will be displayed as below :





- Click the  button to go back to the previous page.
 - Click the  button to stay on the same page.
- III. Click  button to preview the investigation report in Portable Document Format (PDF) format.
- IV. Click  button to submit the investigation report.

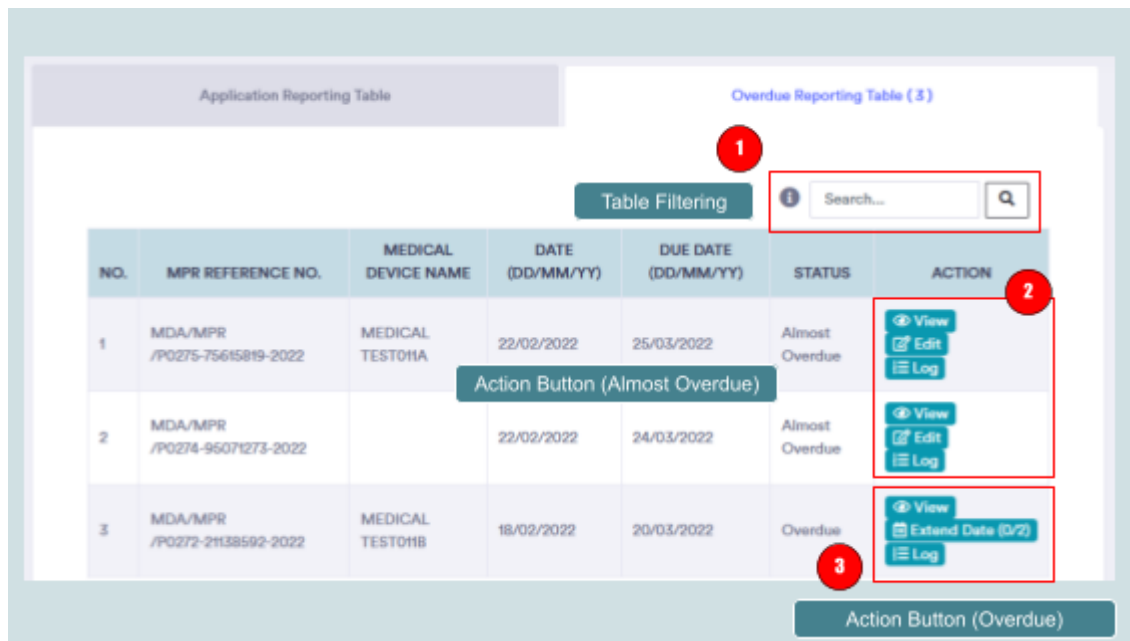
3.8 DELETE MANDATORY PROBLEM REPORTING (MPR)

- a. Click  button to delete the reporting and the pop-up will be displayed as below :



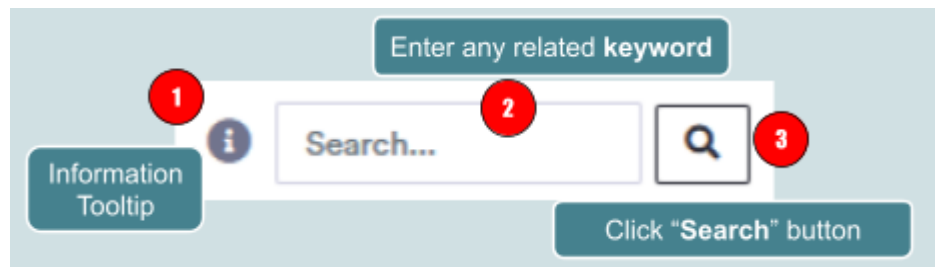
1. Click  button to delete the Mandatory Problem Reporting (MPR).
2. Click  button to close the delete pop-up.


3.9 OVERDUE REPORTING TABLE

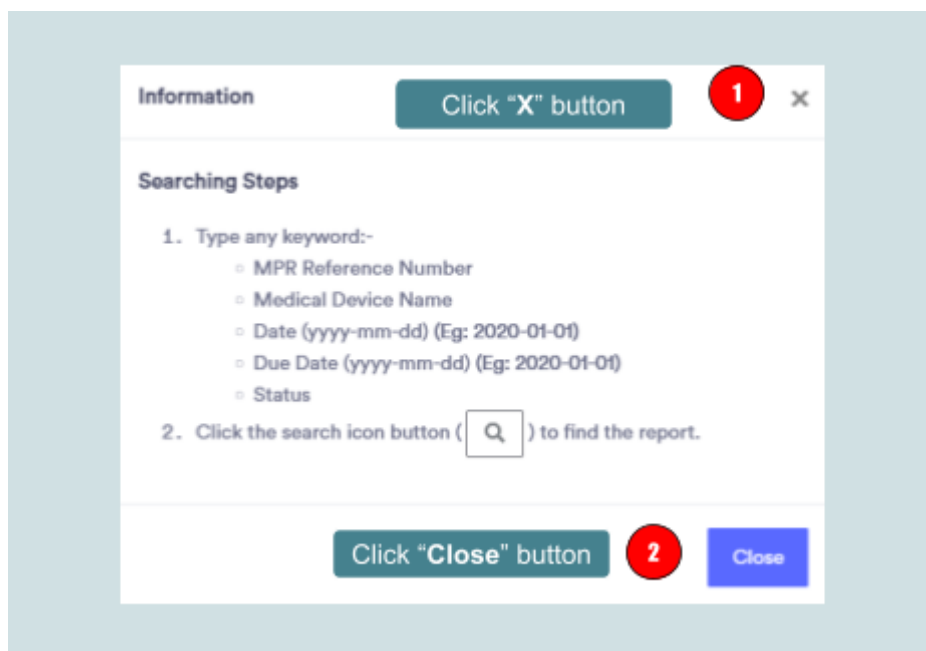





a. The Overdue Reporting Table tabs page will be displayed as above:

1. Table Filtering






- I. Click  icon to get more information related to table filtering and the pop-up will be displayed as below :



- Click  button or  button to close the pop-up.
- II. Enter any related keyword (based on information given).
- III. Click  icon and the system will display the result.

2. Action Button for Almost Overdue Status

- I. Click  button to view the investigation report that has been almost overdue. (Refer to [3.5.2 View Investigation Report](#))
- II. Click  button to continue updating the investigation report and submit the investigation report before overdue. (Refer to [3.7.2 Edit Investigation Report](#))
- III. Click  button to view the investigation report log and the pop-up will be displayed as below :

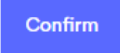




➤ Click **X** button or **Close** button to close the pop-up.


3. Action Button for Overdue Status

- I. Click **View** button to view the investigation report that has been overdue. (Refer to [3.5.2 View Investigation Report](#))
- II. Click **Extend Date (0/2)** button to request extension time and the pop-up will be displayed as below :



- Click  button to submit the request for extension time.
- Click  button to close the pop-up.

III. Click  button to view the investigation report log and the pop-up will be displayed as below :



Mandatory Problem Reporting (MPR) Log

Click "X" button

Application Log Details : MDA/MPR/P0272-21138592-2022

NO.	DATE / TIME	STAGE	STATUS	USER
3	21/03/2022 08:51:33	Overdue	This report has exceeded the timeframe required	System
2	18/02/2022 11:44:21	Submitted	Mandatory Problem Reporting (MPR) report has been submitted	HOST OH
1	18/02/2022 11:42:06	Draft	Mandatory Problem Reporting (MPR) report has been saved as draft	HOST OH

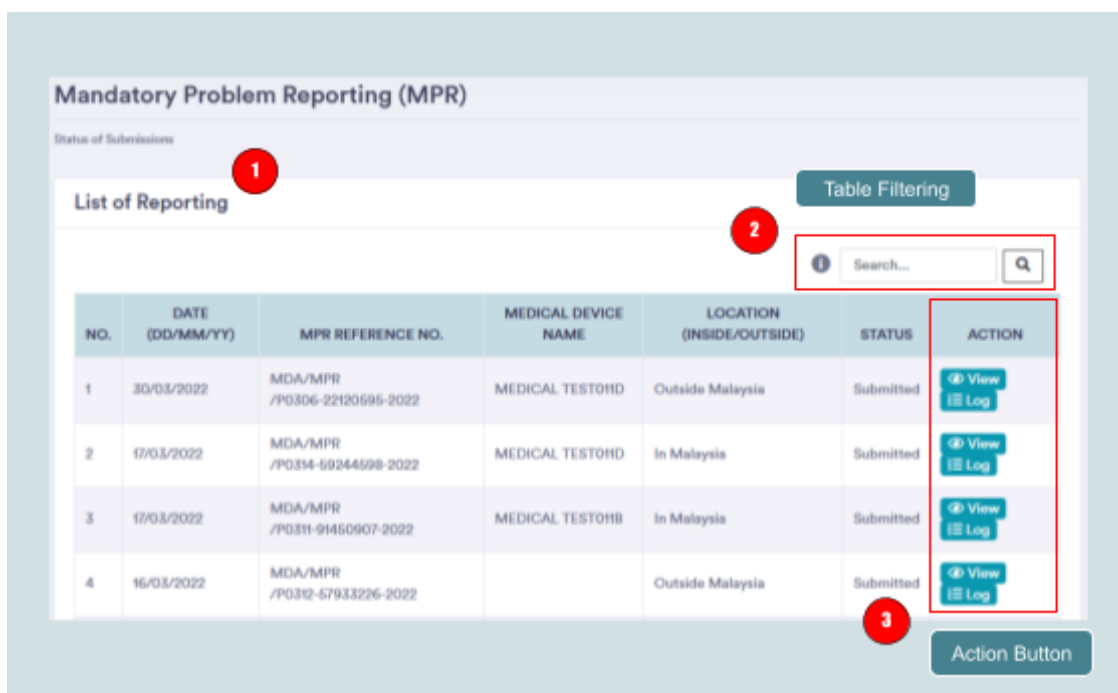
Click "Close" button

Close

- Click  button or  button to close the pop-up.

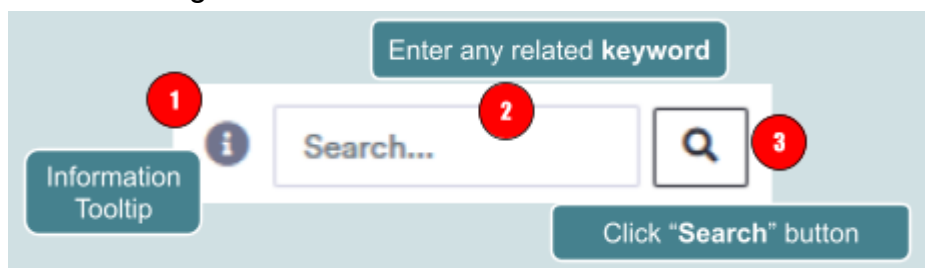
3.10 STATUS OF SUBMISSION INVESTIGATION


3.10.1 Status of Submission Reporting

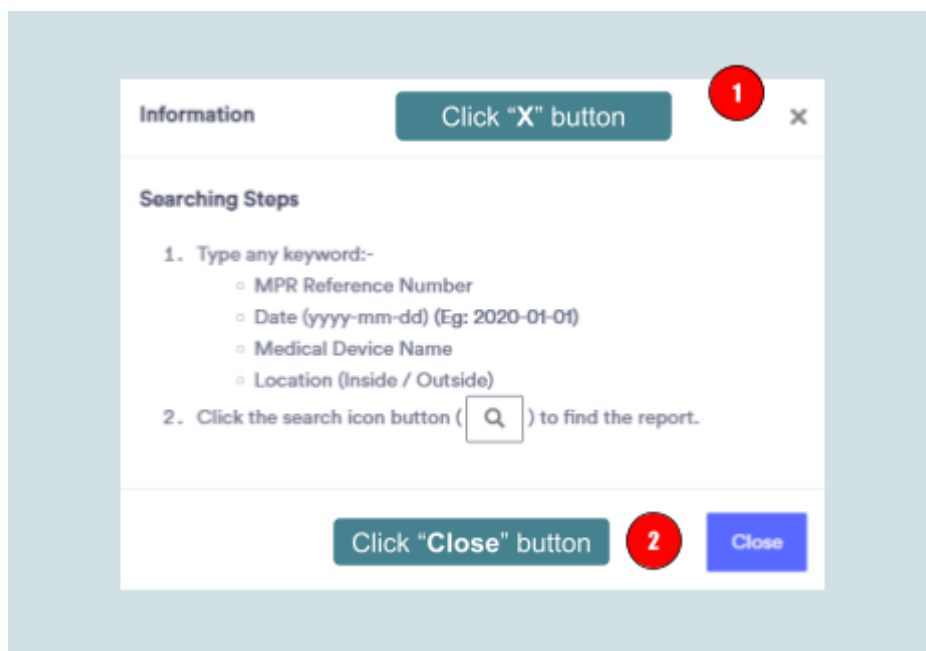


a. The Status of Submission Reporting page will be displayed as above :

1. List of Reporting
 - I. List of Reporting will display the list that has been submitted by the user.
2. Table Filtering



- I. Click  icon to get more information related to table filtering and the pop-up will be displayed as below :



➤ Click **X** button or **Close** button to close the pop-up.

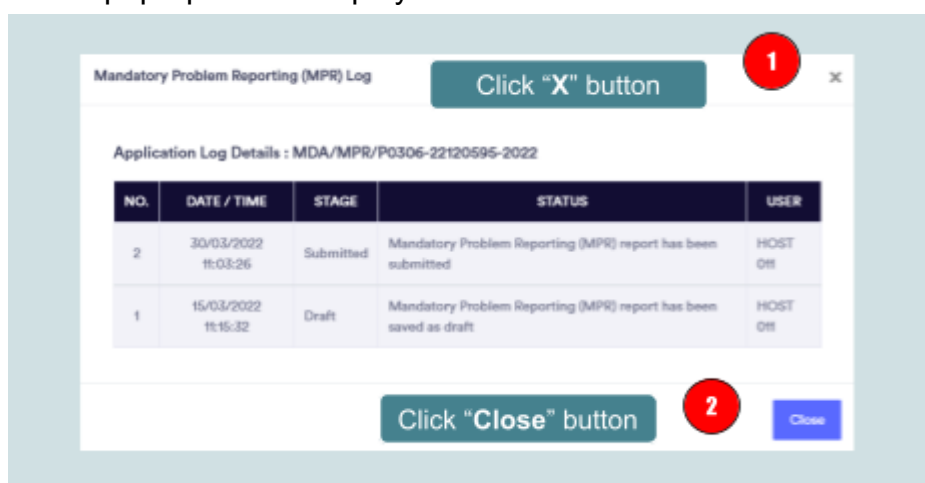
II. Enter any related keyword (based on information given).

III. Click **[Q]** icon and the system will display the result.

3. Action Button

I. Click **View** button to view the submitted reporting and the view page. (Refer to [3.5.1 View Mandatory Problem Reporting](#))

II. Click **Log** button to view the reporting log and the pop-up will be displayed as below :



➤ Click **X** button or **Close** button to close the pop-up.

3.10.2 Status of Submission Investigation

Investigation Report 1 Investigation Report Counter

Status of Submission

Case Submission	Under Processing	Total Case Running	Completed
4	0	4	0

List of Final Report 2

Table Filtering 3

Search...

NO.	DATE (DD/MM/YY)	MPR REFERENCE NO.	MEDICAL DEVICE NAME	LOCATION (INSIDE/OUTSIDE)	STATUS	ACTION
1	11/03/2022	MDA/MPR/P0236-3096610-2022	MEDICAL TEST01B	Outside Malaysia	Submitted	View Log
2	11/03/2022	MDA/MPR/P0266-17793059-2022	MEDICAL TEST01B	Outside Malaysia	Submitted	View Log
3	11/03/2022	MDA/MPR/P0311-91450907-2022	MEDICAL TEST01B	In Malaysia	Submitted	View Log

Action Button 4

a. The Status of Submission Investigation page will be displayed as above :

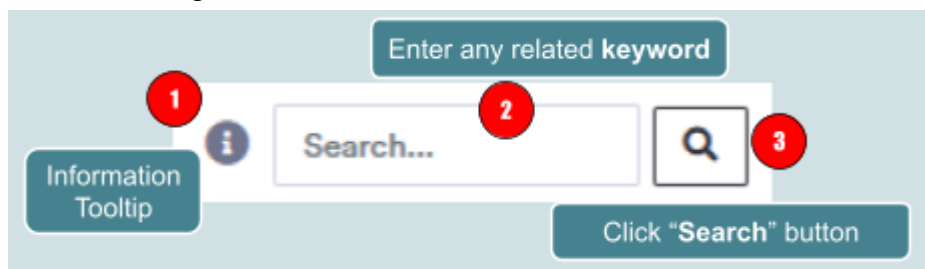
1. Investigation Report Counter


- I. There are four (4) types of reports counter will be displayed :
 - Case Submission : The total of investigation reports that have been submitted by the user.
 - Under Processing : The total of investigation reports that are in the process of evaluation by the Evaluation Officer.
 - Total Case Running : The combined total for Case Submission and Under Processing.
 - Completed : The total for the investigation report that has been approved by the Approval Officer.

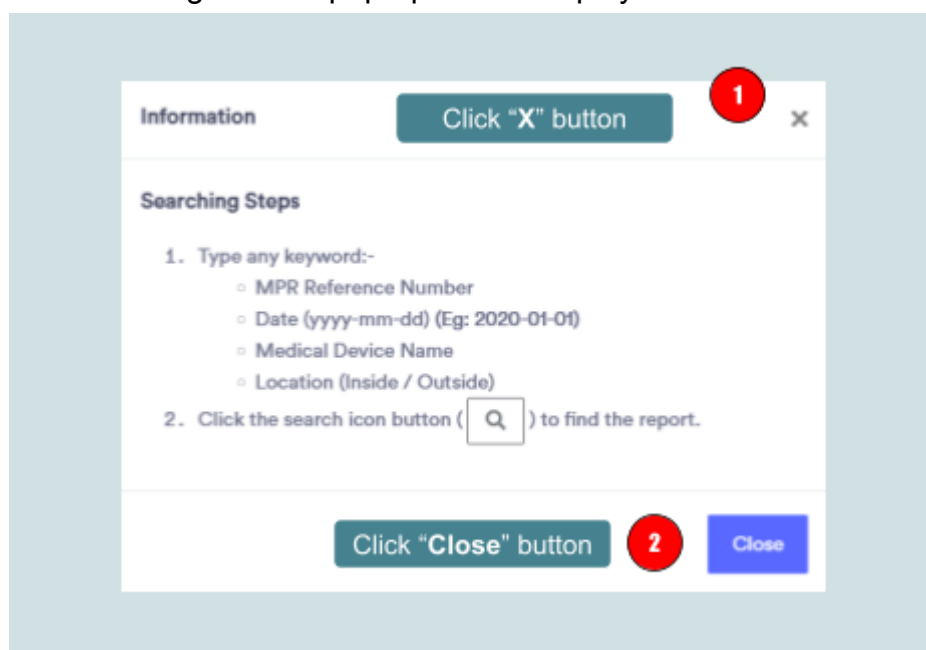
2. List of Final Report




- I. List of Final Report will display the list that has been submitted by the user.

3. Table Filtering





- I. Click  icon to get more information related to table filtering and the pop-up will be displayed as below :



- Click  button or  button to close the pop-up.
- II. Enter any related keyword (based on information given).
- III. Click  icon and the system will display the result.

4. Action Button

- I. Click  button to view the completed and submitted investigation report (Refer to [3.5.2 View Investigation Report](#))
- II. Click  button to view the investigation report log and the pop-up will be displayed as below :



- Click  button or  button to close the pop-up.

4 FIELD CORRECTIVE ACTION (FCA)

4.1 FIELD CORRECTIVE ACTION (FCA) SIDEBAR



a. Field Corrective Action (FCA) Sidebar will be displayed as above:

1. Create New Notification Report
 - I. Create New Notification Report will display the create page for Notification report. (Refer to [4.3.1 Create New Notification Report](#))
2. FCA Dashboard
 - I. FCA Dashboard will display Field Corrective Action (FCA) main dashboard. (Refer to [4.2 FCA DASHBOARD](#))
3. FCA Report Overdue
 - I. FCA Report Overdue will display the list of FCA reports that are overdue. (Refer to [4.8 FCA REPORT OVERDUE](#))

4. FCA Report Completed
 - I. FCA Report Completed will display the list of FCA reports that are completed. (Refer to **4.9 FCA REPORT COMPLETED**)

4.2 FCA DASHBOARD

The screenshot displays the FCA Dashboard interface. At the top, there is a 'FCA Report Counter' section (1) containing three report categories: Notification Report, Follow Up Report, and Closure Report. Each category shows counts for 'Draft / Submitted' and 'Return from MDA'. Below the counter is a 'Total FCA Report: 1' indicator. A 'Create New Notification Report' button (2) is located below the counter. The main section is the 'List of FCA Report' table (3), which includes a search bar (4) and 'Table Filtering' options. The table contains one entry with the following details:

No.	Ref No.	Medical Device Name	Date FCA To Be Communicated To User	Date Submission	Date Proposed Completion	Type of Report	Status	Action
1	MDA/FCA/P0000-63N7737-2022	MEDICAL TEST/DXA	Yes (14/03/2022)	24/03/2022	06/09/2022	Notification	Submitted	View, Log, Follow Up

a. Field Corrective Action (FCA) Dashboard page will be displayed as above:

1. FCA Report Counter.
2. Click the **Create New Notification Report** button.
3. List of FCA Report Table.
4. Table Filtering.

4.2.1 FCA Report Counter

The screenshot shows the FCA Report Counter section. It features three distinct report counter boxes: 1. Notification Report Counter, 2. Follow Up Report Counter, and 3. Closure Report Counter. Each counter displays the number of reports in 'Draft / Submitted' and 'Return from MDA' status. Below these counters, a 'Total FCA Report' section (4) indicates 'Total FCA Report: 1'.

a. FCA have three (3) report counter that will be displayed as above:

1. **Notification Report Counter** - This counter displays the number of Notification reports with Draft/Submitted status and reports that are Returned From MDA.

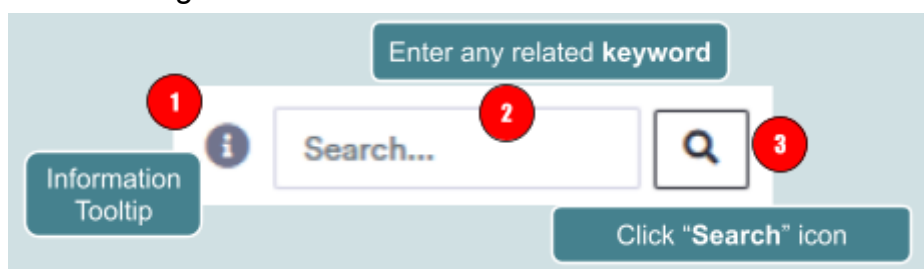
2. **Follow Up Report Counter** - This counter displays the number of Follow Up reports with Draft/Submitted status and reports that are Returned From MDA.
3. **Closure Report Counter** - This counter displays the number of Closure reports with Draft/Submitted status and reports that are Returned From MDA.
4. Total FCA Report.

- b. User can click on Draft / Submitted to view the list of all reports with Draft and Submitted status according to the report type. Table below shows the list for the Notification Report.

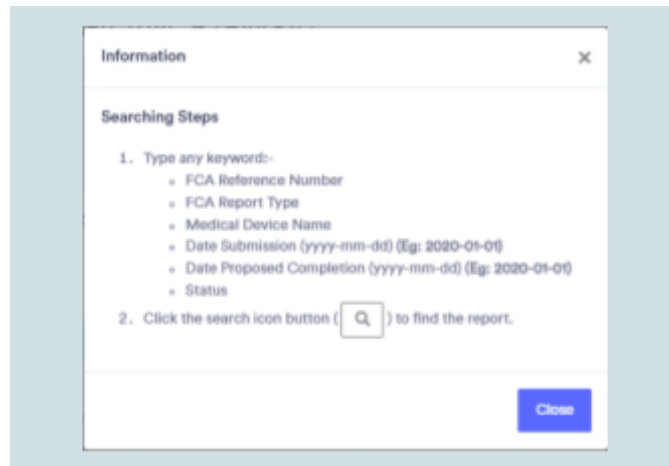
No.	Ref No.	Medical Device Name	Date Submission	Date Proposed Completion	Type of Report	Status	Action
1	MDA/FCA/P0000-4320737-2022	MEDICAL TESTING	24/03/2022	04/09/2022	Notification	Submitted	View, Log, Follow Up, Close
2	MDA/FCA/P0001-4029676-2022	MEDICAL TESTING			Notification	Draft	View, Log, Edit, Delete
3	MDA/FCA/P0004-4403927-2022	MEDICAL TESTING			Notification	Draft	View, Log, Edit, Delete

Showing 3 of 3 entries.

- a. Table Filtering shown as below:




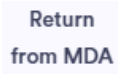
- I. User can click the i icon to get more information related to table filtering and the pop-up will be displayed as below:









➤ Click the **X** button or **Close** button to close the pop-up.

II. Enter any related keyword (based on information given).

III. Click the  icon and the system will display the result.

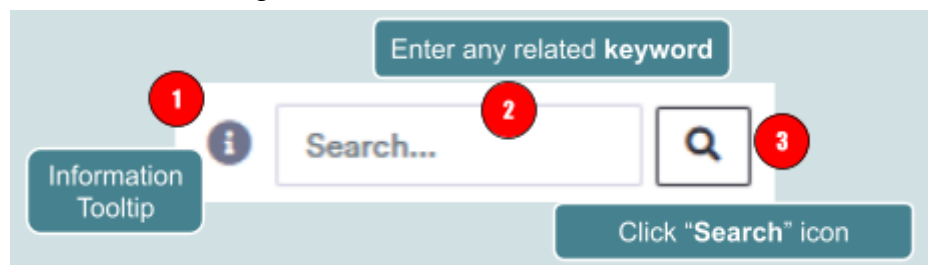
c. User can click on  to view the list of all reports with Return from MDA status according to the report type. Table below shows the list for the Follow Up Report.


List of FCA Follow Up: Return from MDA Report

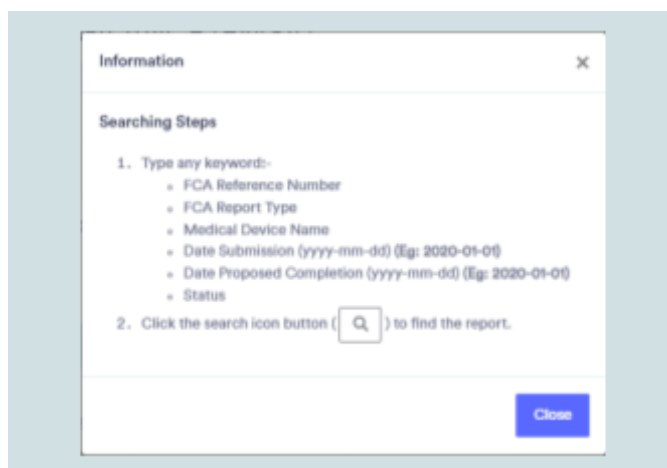
No.	Ref No.	Medical Device Name	Date Submission	Date Proposed Completion	Type of Report	Status	Action
1	MDA/FCA/POSD-2567046-2022	MEDICAL TESTING	25/03/2022	16/04/2022	Additional Follow Up	Return from MDA	  
2	MDA/FCA/POSD-4788033-2022	MEDICAL TESTING	16/03/2022	10/04/2022	Follow Up	Return from MDA	  

Showing 2 of 2 entries.

1. Table Filtering shown as below:



I. User can click the  icon to get more information related to table filtering and the pop-up will be displayed as below:



- Click the **X** button or **Close** button to close the pop-up.
- II. Enter any related keyword (based on information given).
- III. Click the **Q** icon and the system will display the result.

d. Total FCA report will display the sum of all numbers on the counter.

4.2.2 Create New Notification Report

a. Please refer to [4.3.1 Create New Notification Report](#).

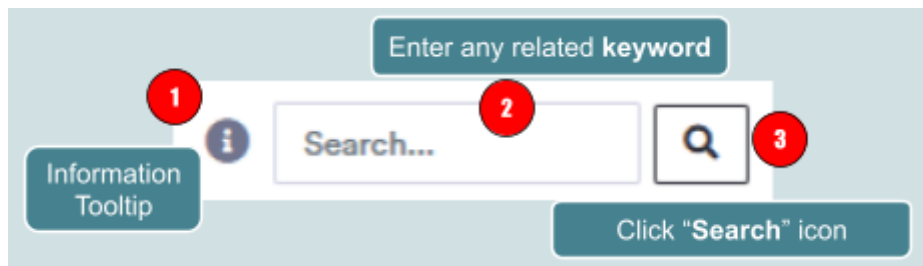
4.2.3 List of FCA Report Table


a. List of FCA Report table will be shown as below:

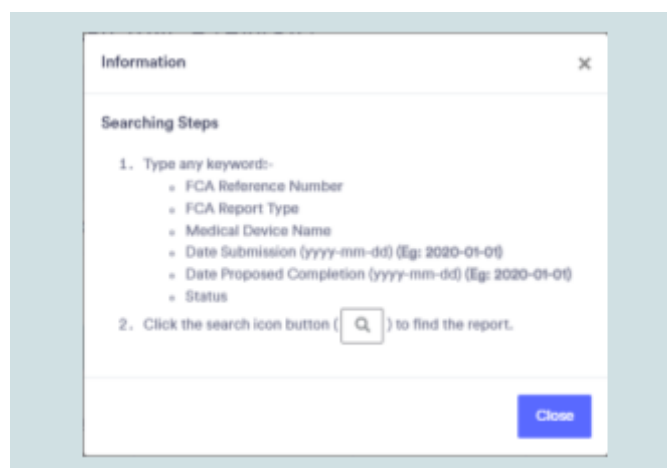
No.	Ref No.	Medical Device Name	Date FCA To Be Communicated To User	Date Submission	Date Proposed Completion	Type of Report	Status	Action
1	MDA/FCA/PX0375-44094838-2022	MEDICAL TESTDHS				Notification	Draft	View Log Edit
2	MDA/FCA/PG370-89395360-2022	MEDICAL TESTDHS	Yes (28/03/2022)	06/04/2022	26/08/2022	Notification	Submitted	View Log Follow Up
3	MDA/FCA/PX0366-43263645-2022	MEDICAL TESTDHS	Yes (21/03/2022)	14/03/2022	24/03/2022	Closure	Submitted	View Log
4	MDA/FCA/PG365-67482433-2022	MEDICAL TESTDHS	Yes (07/02/2022)	06/04/2022	10/04/2022	Follow Up	Return from MDA	View Log Edit Selected
5	MDA/FCA/PG363-49523478-2022	MEDICAL TESTDHS	Yes (07/02/2022)	29/03/2022	31/03/2022	Closure	Submitted	View Log



Showing 5 of 10 entries.


1. The List of FCA Report table shows the list of all report types (Notification, Follow Up, Additional Follow Up, Closure) with Draft, Submitted, and Return from MDA status.
2. Table Filtering shown as below:





- I. User can click the  icon to get more information related to table filtering and the pop-up will be displayed as below:



- I. > Click the  button or  button to close the pop-up.









- II. Enter any related keyword (based on information given).
- III. Click the  icon and the system will display the result.

3. Action Button:

- I. Click the  button to view the report. (Refer to [4.4.1 View Field Corrective Action \(FCA\) Report](#))
- II. Click the  button to view the reporting log and the pop-up will be displayed as below:

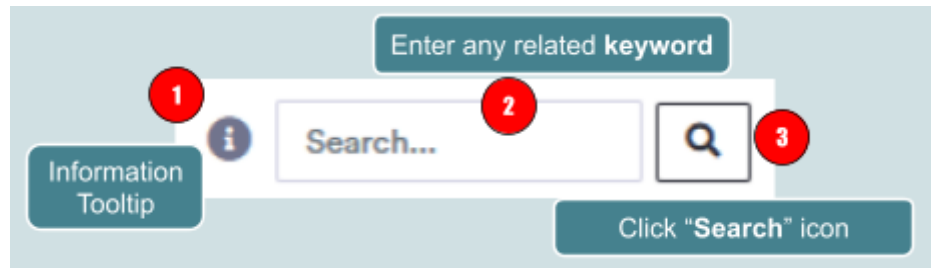



➤ Click the  button to close the pop-up.

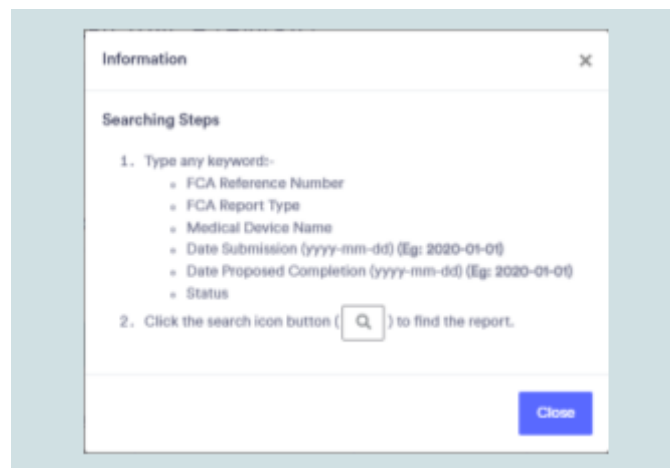
- III. Click the  button to create a new Follow Up report. (Refer to [4.3.2 Create New Follow Up Report](#))
- IV. Click the  button to create a new Additional Follow Up report. (Refer to [4.3.3 Create New Additional Follow Up Report](#))
- V. Click the  button to create a new Closure report. (Refer to [4.3.4 Create New Closure Report](#))
- VI. Click the  button to update the Notification report. (Refer to [4.6.1 Edit Notification Report](#))
- VII. Click the  button to update the Follow Up report. (Refer to [4.6.2 Edit Follow Up Report](#))
- VIII. Click the  button to update the Return from MDA report. (Refer to [4.6.3 Edit Return from MDA Report](#))
- IX. Click the  button to delete the Notification report. (Refer to [4.7.1 Delete Notification Report](#))
- X. Click the  button to delete the Follow Up report. (Refer to [4.7.2 Delete Follow Up Report](#))




4.2.4 Table Filtering

- a. Table Filtering will be shown as below:



- I. User can click the  icon to get more information related to table filtering and the pop-up will be displayed as below:



- Click the  button or  button to close the pop-up.
- II. Enter any related keyword (based on information given).
- III. Click the  icon and the system will display the result.

4.3 CREATE REPORTING

4.3.1 Create New Notification Report

Field Corrective Action

FCA Dashboard > FCA Notifications

MEDICAL DEVICE FIELD CORRECTIVE ACTION REPORT

(*) - required

This page DOES NOT HAVE AN AUTO SAVE FUNCTION! Please use the BACK BUTTON at the bottom of the page and click the SAVE AS DRAFT in the confirmation box.

FCA Reference No. MDA/FCA/P0001-0067010-2022 **1** FCA Reference Number

- 2** Section A: Field Corrective Action Report
- 3** Section B: Establishment Particular
- 4** Section C: Affected Medical Device Details
- 5** Section D: FCA Proposed Plan and Action
- 6** Section E: FCA Information
- 7** Section F: Follow Up
- 8** Section G: Closure Information Report (Only opened in Closure Report)
- 9** Section H: Others Information

10 Declaration

I hereby attest that the information and attachment provided on this reporting is / are correct, completed and current to this date.*

I understand and acknowledge that it is an offence under Section 76 of Act 737, to make sign or furnish any declaration, or other document which is untrue, inaccurate or misleading.*

Person Responsible for the Establishment: Ivan Anjan Bani Azman

Job Title: MANAGER

Telephone: 603-9641067

Email Address: gmnulm@gmail.com

11 Button Section

Back Close Preview PDF Submit Notification

Copyright © 2020 Concept. All rights reserved. Dashboard by MDA_MCS

a. Creating New Notification report will be display as above:

1. FCA Reference Number.
 - I. FCA Reference Number is auto-generated by the system.
2. Section A: Field Corrective Action Report.
 - I. Section A will be display as below:

Type of Report Notification Follow Up Closure

1. Title of FCA*

2. Type of Field Corrective Action (FCA)*

Return

Modification

Exchange

Specific Advice

Destruction

II. User are required to fill in all fields that marked with an asterisk (*).

3. Section B: Establishment Particular.

I. Section B will be display as below:

1. Name of Company Medical Device Authority Development Team (ICT)

2. Company Address 26 JALAN PRIMA 9

3. Contact Person Name Azzannie Firdaus Bin Azali

4. Job Title MANAGER

5. Telephone Number 603-96541267

6. Email Address unijayatest01@nada.email

II. All information in this section will be auto-filled by the system.

4. Section C: Affected Medical Device Details.

I. Section C will be display as below:

1. Medical Device Name* Please choose one of the options

2. MDA Registration Number

3. Device intended use

4. Device Classification

5. Device Risk Type

6. Medical Device Category

7. GMDN

7.1 List of GMDN Please choose one of the options

Table of Affected Device Details*

(Establishment may download the template excel file & upload at given below file section)

1. [Example](#) Example for Table of Affected Device Details (PCA).xls

2. [Template](#) Template for Table of Affected Device Details (PCA).xls

No.	Product / Catalogue / Identifier Number	Serial Number / UDI Code (if applicable)	Batch Number	Lot Number	Quantity
No affected device details to be display					
					Total
					0

[Add Details of Affected Devices](#)

9. Accessories / Associated medical devices affected (if any)

10. Manufacturer name

11. Manufacturer address

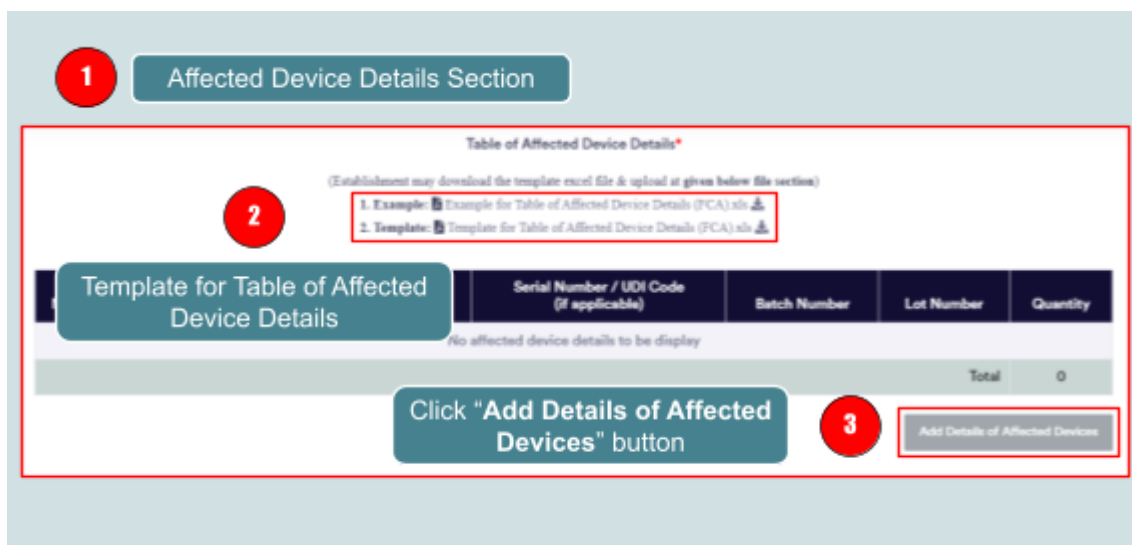
12. AR Name*

13. Distributor Name*

14. Importer Name*

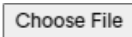
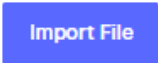


15. CAB Name

- II. User are required to fill in all fields that marked with an asterisk (*).
- III. Click the dropdown button to choose one Medical Device Name for Question 1.
- IV. All questions will be automatically filled by the system according to the Medical Device Name that the user chose except for Question 7.1, 9, 12, 13, 14, and Table of Affected Device Details.
- V. Table of Affected Device Details Section


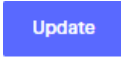



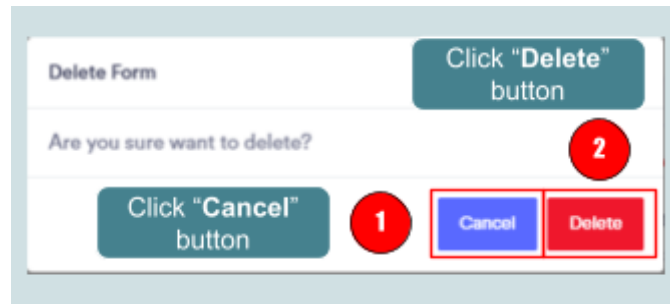
- Table of Affected Device Details will be displayed as above.
- There are two (2) template for Table of Affected Device Details that user can download which are:
 - Example for Table of Affected Device Details
 - Template for Table of Affected Device Details
- Users are required to use the template provided to upload it in the table.
- **Add Details of Affected Devices** button will be enabled after the user fills in the Medical Device Name in Question 1.
- By clicking **Add Details of Affected Devices** button, the system will display Details of Affected Devices page shown as below:






- In the Upload File Section, users can choose the file that needs to be uploaded by clicking  button and  button will be enabled after the user chooses the file. Then click  button to import the file in the table.
- In the Uploaded File Section, it will display the file that the user uploads.
- In the Action column, it has two (2) button that user can use:
 - User can click  button to update the affected devices details in the table and the system will display the popup to update the details of affected devices shown as below:



- Click the  button to clear all the information.
- Click the  button to update the information.
- User can click the  button to delete the information from the table.



- I. Click the  button to go back to the previous page.
 - II. Click the  button to delete the affected device details.
- Click the  button to continue to the next question in section C.

5. Section D: FCA Proposed Plan and Action.

- I. Section D will be display as below:

- II. User are required to fill in all fields that marked with an asterisk (*).

6. Section E: FCA Information.

- I. Section E will be displayed as below:

**** This information is generated as "No" automatically if based on the Dashboard: Problem Reporting (as previously) submitted and awaiting PTCA as a case control action. Otherwise it generated as "Yes" automatically if not stated in Dashboard: Problem Reporting**

1. Did the FCA arise due to an incident? Yes No

2. Did this incident occur in Malaysia? Yes No

3. If yes, has the incident been reported to MDA? Yes No

4. Evaluation of the risk associated with affected medical device (Health Hazard Evaluation Report)

No file chosen

To upload files ->2. Select all previous files.
Multiple file upload are allowed for the maximum size of the total files uploaded must not exceed 20MB.

5. Background information and reason for the FCA?

6. Root Cause?

** The root cause is based on what is stated under the reason to initiate the PTCA. Usually, the root cause is identified first before any corrective action is taken.

7. FCA plan and action to be taken (corrective action)?

8. Advice on actions to be taken by the distributor and the user?

9. Number and name of affected units supplied to each consignee?

Template: [Template for Name of Affected Consignee.xlsx](#)

No file chosen

To upload files ->2. Advice all previous files.
Multiple file upload are allowed for the maximum size of the total files uploaded must not exceed 20MB.
** Please upload any document that contain information of name of affected consignee with its quantity and date.

10. Has the FCA been communicated to all consignees? Yes No

Date sent:

Expected date to be sent:

11. No. of affected units and the period that affected units are manufactured / imported / supplied in Malaysia*

	Quantity Affected <small>(Required)</small>	From <small>(Optional)</small>	Until <small>(Optional)</small>
11.1 Manufactured in Malaysia*	<input type="text" value="Enter Unit..."/>	<input type="text" value="dd/mm/yyyy"/>	<input type="text" value="dd/mm/yyyy"/>
11.2 Imported into Malaysia*	<input type="text" value="Enter Unit..."/>	<input type="text" value="dd/mm/yyyy"/>	<input type="text" value="dd/mm/yyyy"/>
11.3 Supplied in Malaysia*	<input type="text" value="Enter Unit..."/>	<input type="text" value="dd/mm/yyyy"/>	<input type="text" value="dd/mm/yyyy"/>
11.4 Expected shipment to Malaysia*	<input type="text" value="Enter Unit..."/>	<input type="text" value="dd/mm/yyyy"/>	<input type="text" value="dd/mm/yyyy"/>

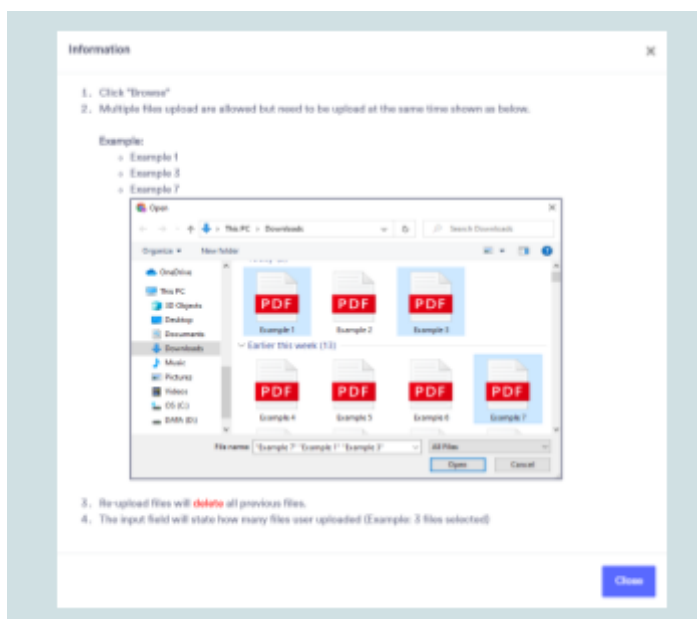
12. Date of commencement of FCA by manufacturer?


13. Date of commencement of FCA in Malaysia?

14. Proposed date of completion of FCA in Malaysia?

II. Users are required to fill in all fields that marked with an asterisk (*).

III. User can click the button to get more information about multiple file upload. The pop-up will be displayed as below:



➤ Click the  button to go back to the previous page.

7. Section F: Follow Up.


- I. The Follow Up section will only be opened in the Follow Up Report.

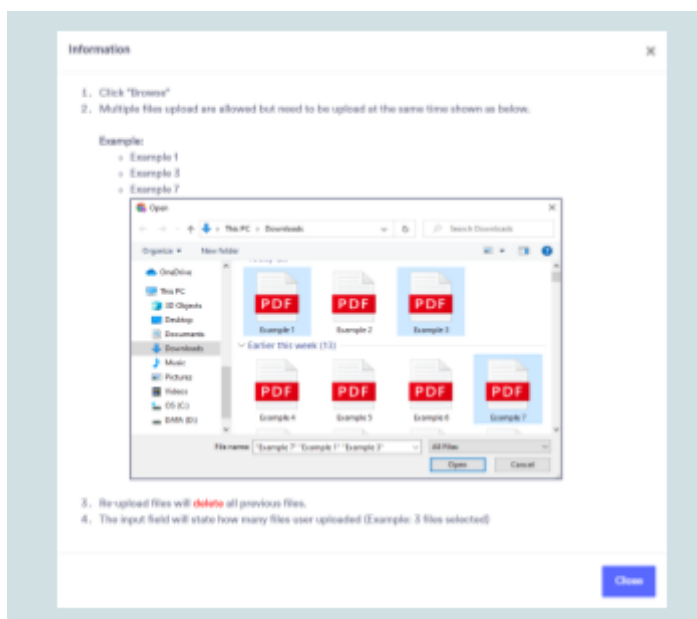
8. Section G: Closure Information Report.


- I. The Closure section will only be opened in the Closure Report.

9. Section H: Others Information.

- I. Section H will be displayed as below:

- II. Users are required to fill in all fields that marked with an asterisk (*).
- III. User can click the  button to get more information about multiple file upload. The pop-up will be displayed as below:



- Click the  button to go back to the previous page.

10. Declaration.


- I. The Declaration section will be displayed as below:

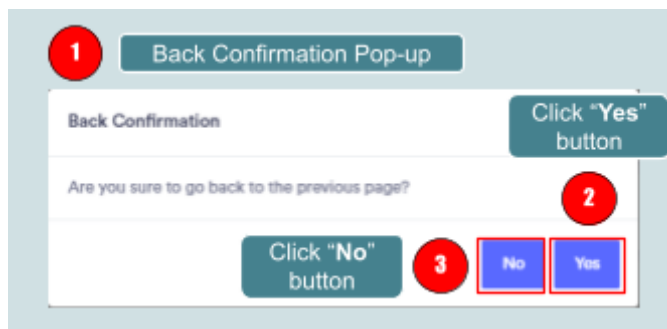
- II. Users are required to tick the checkbox that marked with an asterisk (*).
- III. In this section, the system will display person responsible details which are:
 - Name of Reporting Person
 - Job Title
 - Telephone
 - Email Address



11. Button Section.

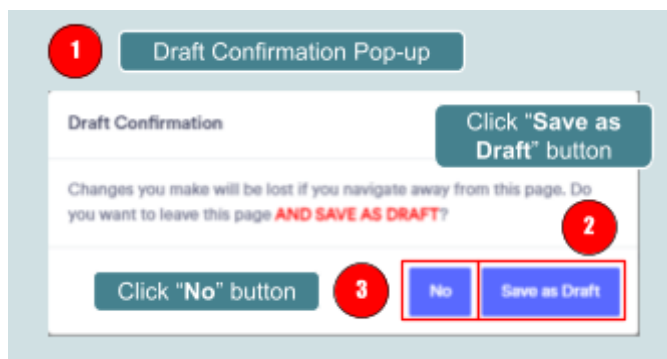
- I. This section displays all buttons in the Notification Report.






- II. Click  button to go back to the previous page. There will be two (2) types of pop-up that will be displayed as below:



- Back Confirmation Pop-up.
 - If the question Table of Affected Device Details in Section C has been filled, this Back Confirmation pop-up will be displayed.
 - Click the  button to go back to the next page.
 - Click the  button to stay on the same page.



- Draft Confirmation Pop-up
 - If the question Table of Affected Device Details in Section C has not been filled, this Draft Confirmation pop-up will be displayed.
 - Click the  button to save the report as draft.
 - Click the  button to delete the report.

- III. Click the  button to clear all the information in the report except the default value. The pop-up will be displayed as below:



➤ Clear Confirmation Pop-up.

- Click the **Clear** button to clear all the information.
 - Click the **No** button to stay on the same page.
- IV. Click the **Preview PDF** button to view the report in Portable Document Format (PDF) format. (Refer to **4.5.1 Preview PDF Field Corrective Action (FCA) Report**)
- V. Click the **Submit Notification** button to submit the Notification report. This button will be enabled if the user tick the checkbox in the Declaration section.

4.3.2 Create New Follow Up Report

Field Corrective Action

Main Dashboard > FCA Dashboard > FCA Follow Up

This page HAS AN AUTO SAVE FUNCTION. Your form would be saved automatically as you make progress on the browser. Please be cautious with your case details.

1 Notification Section **Field Corrective Action (FCA) Report Follow Up Form**

Section A: Field Corrective Action Report

1. MDA FCA Reference Number	MDA/FCA/PX0345-79741604-2022
1.1 MDA MPR Reference Number	MDA/MPR/P0235-48710369-2022
2. Type of Report	Notification
3. Title of FCA	etret
4. Type of Field Corrective Action (FCA)	Return

Section B: Establishment Particulars

1. Name of Company	Medical Device Authority Development Team (ICT)
2. Company Address	011, JALAN CYBERIA 1, CYBERJAYA
3. Contact Person Name	HOST 011
4. Job Title	MANAGER

2 Section F: Follow Up

3 Section G: Closure Information Report

4 Section H: Others Information

5 Declaration

I hereby attest that the information and attachment provided on this reporting is / are correct, completed and current to this date.*

I understand and acknowledge that it is an offence under Section 76 of Act 737, to make sign or furnish any declaration, or other document which is untrue, inaccurate or misleading.*

Person Responsible for the Establishment:

Job Title:

Telephone:

Email Address:

6 Button Section

a. Creating New Follow Up report will be display as above:

1. Notification Section.

I. Users can view the Notification section in this Follow Up report.

2. Section F: Follow Up.

I. Section F will be display as below:

The screenshot shows a form titled "Section F: Follow Up". It contains two main sections:

- 1. Follow Up (Progress of FCA, together with reconciliation status and/or effectiveness check and its method)***: A large empty text area for input.
- 2. Has the FCA able to completed within the proposed timeline***: Two radio buttons labeled "Yes" and "No". Below them is a date input field with a placeholder "dd/mm/yyyy" and a calendar icon.

II. User are required to fill in all fields that marked with an asterisk (*).

3. Section G: Closure Information Report.

I. The Closure section will only be opened in the Closure Report.

4. Section H: Others Information.

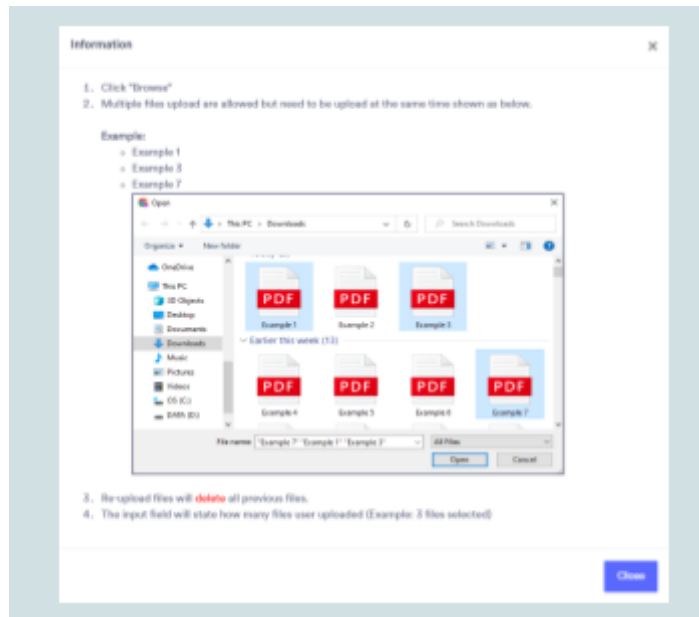
I. Section H will be display as below:


The screenshot shows a form titled "Section H: Others Information". It contains three main sections:

- 1. Copy of official manufacturer Field Safety Notice (FSN) ⓘ**: A "Choose Files" button with "No file chosen" text. Below it, a red error message reads: "File upload size will exceed all previous files. Multiple file upload are allowed for the maximum size of the total files uploaded must not exceed 20 MB." A file named "TEMPLATE (MDA_FCA_PD370_89295360_2022) (kxHLGqHe).pdf" is listed below.
- 2. Other supporting documents ⓘ**: A "Choose Files" button with "No file chosen" text. Below it, the same red error message is displayed.
- 3. Remark**: A large empty text area for input.

II. Users can update the information in this section.

III. User can click the ⓘ button to get more information about multiple file upload. The pop-up will be displayed as below:



- Click the  button to go back to the previous page.

5. Declaration.

I. The Declaration section will be display as below:

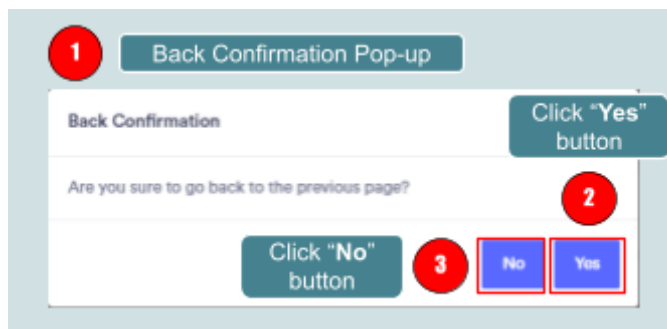
- II. Users are required to tick the checkbox that marked with an asterisk (*).
- III. In this section, the system will display person responsible details which are:
 - Name of Reporting Person
 - Job Title
 - Telephone
 - Email Address

6. Button Section.

I. This section displays all buttons in the Follow Up Report.



- II. Click **Back** button to go back to the previous page. The pop-up that will be displayed as below:



➤ Back Confirmation Pop-up.

- Click the **Yes** button to go back to the next page.
- Click the **No** button to stay on the same page.

- III. Click the **Clear** button to clear all the information in the report except the default value. The pop-up will be displayed as below:



➤ Clear Confirmation Pop-up.

- Click the **Clear** button to clear all the information.
- Click the **No** button to stay on the same page.

- IV. Click the **Preview PDF** button to view the report in Portable Document Format (PDF) format. (Refer to [4.5.1 Preview PDF Field Corrective Action \(FCA\) Report](#))

- V. Click the **Submit Follow Up** button to submit the Follow Up report. This button will be enabled if the user tick the checkbox in the Declaration section.

4.3.3 Create New Additional Follow Up Report

Field Corrective Action

Main Dashboard > FCA Dashboard > FCA Follow Up

This page DOES NOT HAVE AN AUTO SAVE FUNCTION.

1 Notification Section

2 Section A: Field Corrective Action Report

1. MDA FCA Reference Number	MDA/FCA/P0356-99616777-2022
2. Type of Report	Follow Up
3. Title of FCA	Lorem Ipsum is simply dummy text of the printing and typesetting industry.
4. Type of Field Corrective Action (FCA)	Exchange

3 Section B: Establishment Particulars

1. Name of Company	Medical Device Authority Development Team (ICT)
2. Company Address	011, JALAN CYBERIA 1, CYBERJAYA
3. Contact Person Name	HOST 011
4. Job Title	MANAGER
5. Telephone Number	0123456789

4 Section Additional Follow Up

5 Section G: Closure Information Report

6 Section Additional Others Information

7 Declaration

I hereby attest that the information and attachment provided on this reporting is / are correct, completed and current to this date.*

I understand and acknowledge that is an offence under Section 76 of Act 737, to make sign or furnish any declaration, or other document which is untrue, inaccurate or misleading.*

Person Responsible for the Establishment: HOST 011

Job Title: MANAGER

Telephone: 0123456789

Email Address: host011@webbung.com

6 Button Section

Back Clear Submit Additional Follow Up

a. Creating New Additional Follow Up report will be display as above:

1. Notification Section.

I. Users can view the Notification section in this Additional Follow Up report.

2. Section Additional Follow Up.

I. Section Additional Follow Up will be displayed as below:

Additional Follow Up

1. Follow Up (Progress of FCA, together with reconciliation status and / or effectiveness check and its method)*

2. Has the FCA able to completed within the proposed timeline?*

Yes

No

dd/mm/yyyy

II. Users are required to fill in all fields that marked with an asterisk (*).

3. Section G: Closure Information Report.

I. The Closure section will only be opened in the Closure Report.

4. Section Additional Others Information.

I. Section Additional Others Information will be display as below:

Additional Others Information

1. Copy of official manufacturer Field Safety Notice (FSN) ⓘ

Choose Files No file chosen

No upload files will delete all previous files.
Multiple file upload are allowed but the maximum size of the total files uploaded must not exceed 20MB.

2. Manufacturer / Local Authorized Representative Field Safety Notice (FSN), List Affected Customer/User, or Others information ⓘ

Choose Files No file chosen

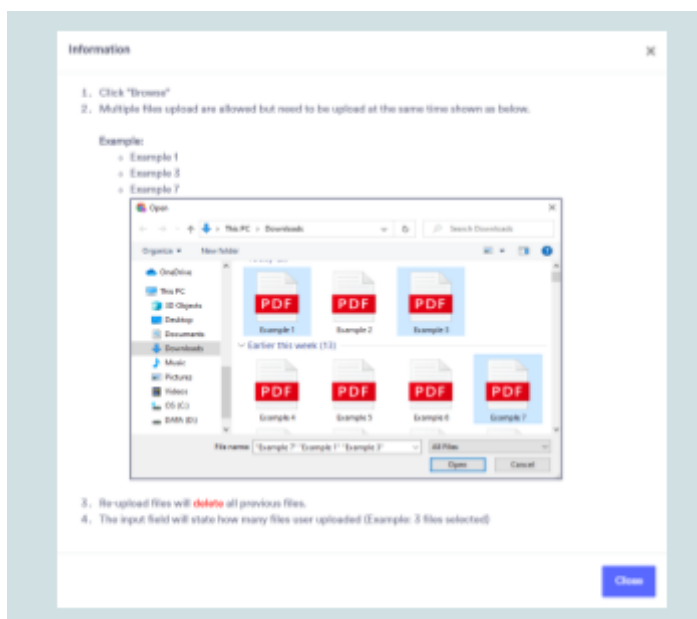
No upload files will delete all previous files.
Multiple file upload are allowed but the maximum size of the total files uploaded must not exceed 20MB.


3. Remark

Enter any remark...

II. Users can fill in this section if needed.

III. User can click the ⓘ button to get more information about multiple file upload. The pop-up will be displayed as below:



- Click the  button to go back to the previous page.

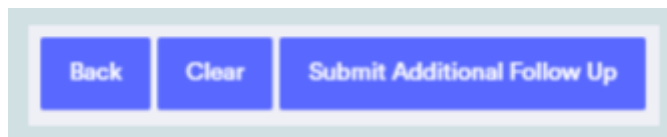
5. Declaration.


I. The Declaration section will be display as below:

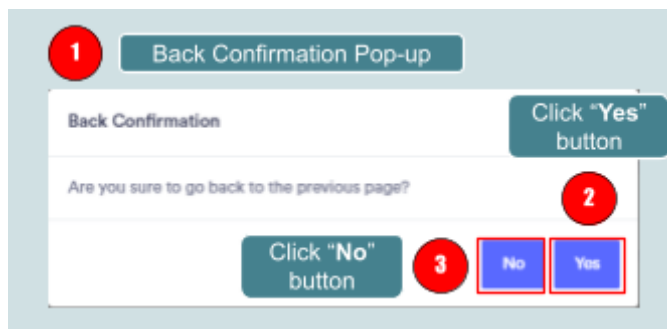
- II. Users are required to tick the checkbox that marked with an asterisk (*).
- III. In this section, the system will display person responsible details which are:
 - Name of Reporting Person
 - Job Title
 - Telephone
 - Email Address

6. Button Section.



- I. This section displays all buttons in the Additional Follow Up Report.




- II. Click  button to go back to the previous page. The pop-up that will be displayed as below:





➤ Back Confirmation Pop-up.

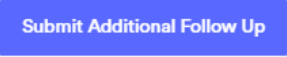
- Click the  button to go back to the next page.
- Click the  button to stay on the same page.

- III. Click the  button to clear all the information in the report except the default value. The pop-up will be displayed as below:



➤ Clear Confirmation Pop-up.

- Click the  button to clear all the information.
- Click the  button to stay on the same page.

- IV. Click the  button to submit the Additional Follow Up report. This button will be enabled if the user tick the checkbox in the Declaration section.

4.3.4 Create New Closure Report

Field Corrective Action

Main Dashboard > FCA Dashboard > FCA Closure

This page HAS AN AUTO SAVE FUNCTION. Your form would be saved automatically as you make progress on the browser. Please be cautious with your case details.

1 Notification Section **Field Corrective Action (FCA) Report Closure Form**

Section A: Field Corrective Action Report Form

1. MDA FCA Reference Number	MDA/FCA/PX0345-79741604-2022
1.1 MDA MPR Reference Number	MDA/MPR/P0235-48710369-2022
2. Type of Report	Notification
3. Type of Field Corrective Action (FCA)	etret
4. Type of Field Corrective Action (FCA)	Return

Section B: Establishment Particulars

1. Name of Company	Medical Device Authority Development Team (ICT)
2. Company Address	011, JALAN CYBERIA 1, CYBERJAYA
3. Contact Person Name	HOST 011
4. Job Title	MANAGER

Section G: Closure Information Report **2** Section G: Closure Information Report

Section H: Others Information **3** Section H: Others Information

Declaration **4** Declaration

I hereby attest that the information and attachment provided on this reporting is / are correct, completed and current to this date.*

I understand and acknowledge that is an offence under Section 76 of Act 737, to make sign or furnish any declaration, or other document which is untrue, inaccurate or misleading.*

Person Responsible for the Establishment: HOST 011

Job Title: MANAGER

Telephone: 0123456789

Email Address: host011@webbung.com

5 Button Section

Back Clear Submit Closure

a. Creating New Closure report will be displayed as above:

1. Notification Section.


I. Users can view the Notification section in this Follow Up report.

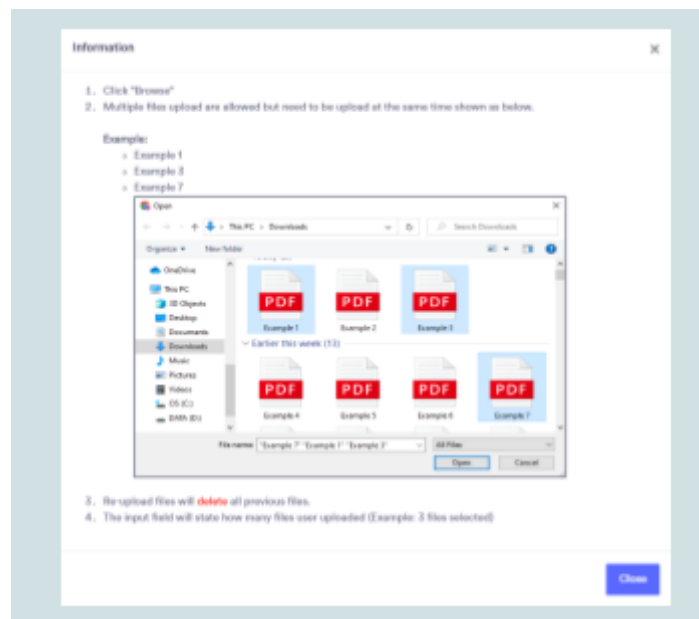
2. Section G: Closure Information Report.

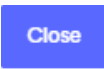
I. Section G will be displayed as below:

The screenshot shows a web form titled "Section G : Closure Information Report". It contains three main sections:

- 1. Status completion FCA of each affected medical device***: A text input field with the placeholder "Enter any remark...".
- 2. Copy of acknowledgement receipt by the affected users on completion of the FCA***: A "Choose Files" button next to the text "No file chosen". Below this, there is a red warning message: "Re-uploaded files will delete all previous files. Multiple file upload are allowed but the maximum size of the total files uploaded must not exceed 20MB." To the right of the "Choose Files" button is a small information icon (i).
- 3. Proposed action to prevent recurrence of the problem (Preventive Action)***: A text input field with the placeholder "Enter any remark...".

- II. Users are required to fill in all fields that marked with an asterisk (*).
- III. User can click the  button to get more information about multiple file upload. The pop-up will be displayed as below:



- Click the  button to go back to the previous page.

3. Section H: Others Information.

- I. Section H will be displayed as below:

Section II : Others Information

1. Copy of official manufacturer Field Safety Notice (FSN) ?

Choose Files No file chosen

No upload files will delete all previous files.
Multiple file upload are allowed for the maximum size of the total files uploaded must not exceed 200MB

- TEMPLATE (MDA_FCA_FGZ70_89395360_2022) (k4HLGqtlc).pdf

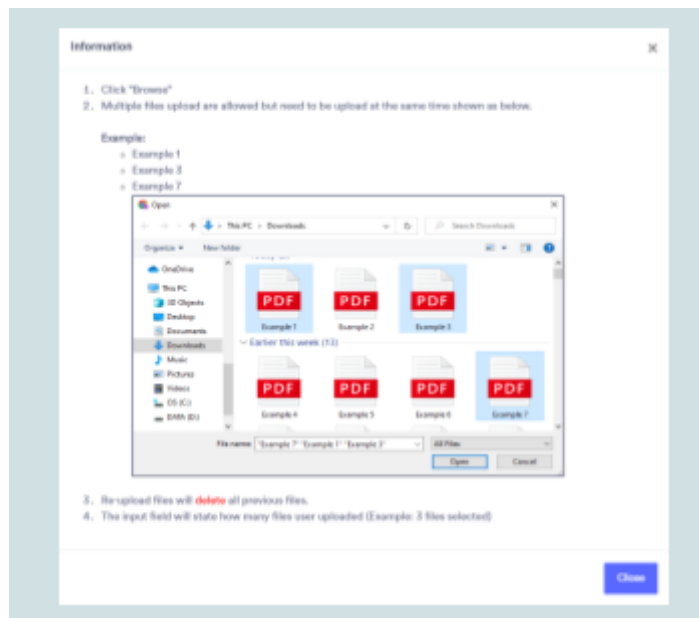
2. Other supporting documents ?

Choose Files No file chosen

No upload files will delete all previous files.
Multiple file upload are allowed for the maximum size of the total files uploaded must not exceed 200MB

3. Remark

- II. Users can update the information in this section.
- III. User can click the ? button to get more information about multiple file upload. The pop-up will be displayed as below:



- Click the Close button to go back to the previous page.

4. Declaration.

- I. The Declaration section will be display as below:

Declaration

I hereby attest that the information and attachment provided on this reporting is / are correct, completed and current to this date.*

I understand and acknowledge that is an offence under Section 76 of Act 737, to make sign or furnish any declaration, or other document which is untrue, inaccurate or misleading.*

Person Responsible for the Establishment: Iman Atiqah Binti Arman

Job Title: MANAGER

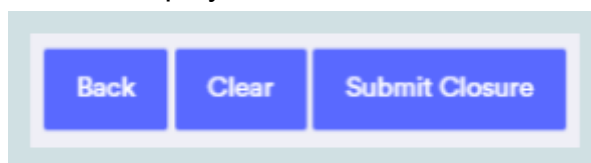
Telephone: 603-96541267


Email Address: pmv.dev@gmail.com

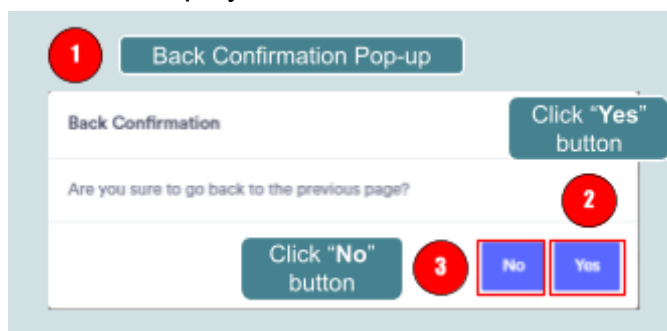
- II. Users are required to tick the checkbox that marked with an asterisk (*).
- III. In this section, the system will displayed person responsible details which are:
 - Name of Reporting Person
 - Job Title
 - Telephone
 - Email Address

5. Button Section.



- I. This section displays all buttons in the Follow Up Report.




- II. Click  button to go back to the previous page. The pop-up that will be displayed as below:





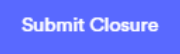
- Back Confirmation Pop-up.

- Click the  button to go back to the next page.
- Click the  button to stay on the same page.

- III. Click the  button to clear all the information in the report except the default value. The pop-up will be displayed as below:




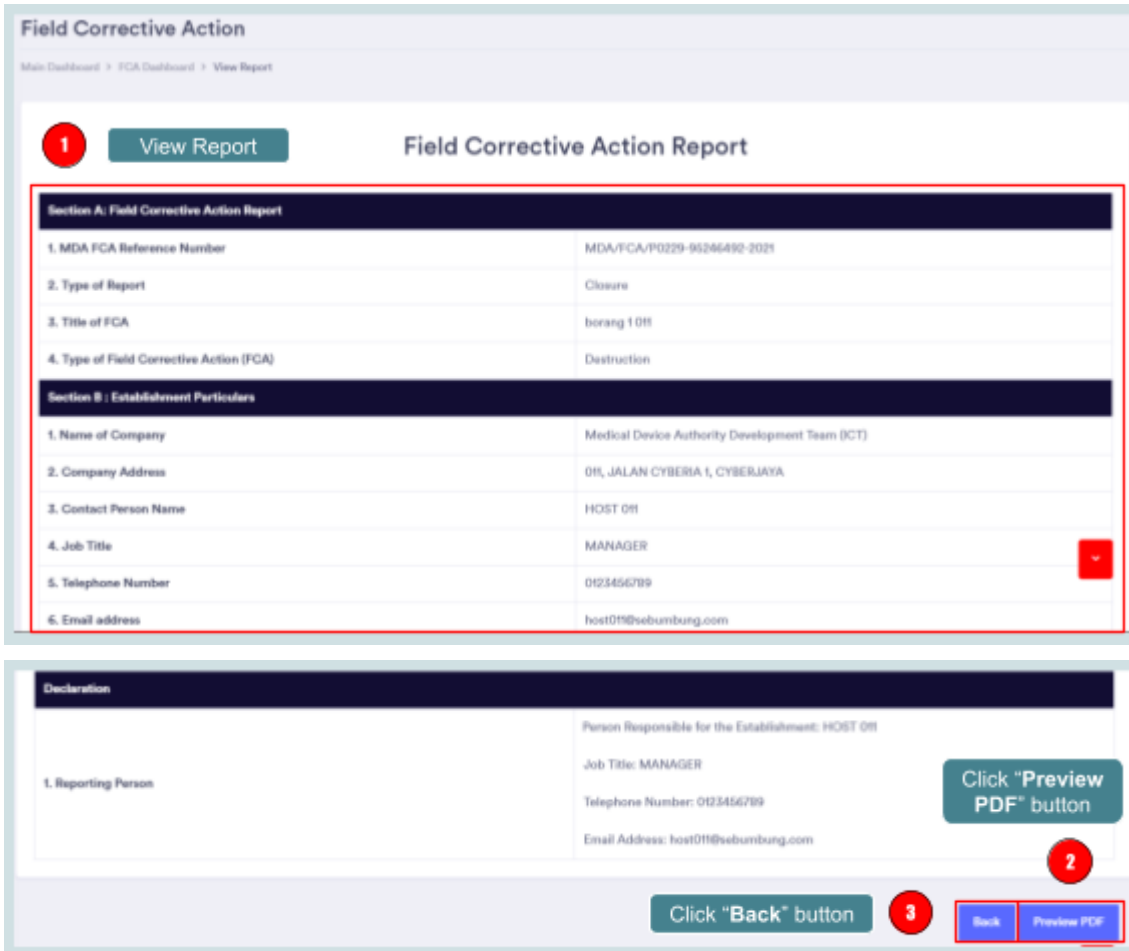
- Clear Confirmation Pop-up.

- Click the  button to clear all the information.
 - Click the  button to stay on the same page.
- IV. Click the  button to submit the Closure report. This button will be enabled if the user tick the checkbox in the Declaration section.

4.4 VIEW REPORTING


4.4.1 View Field Corrective Action (FCA) Report

- a. Click the  button to view the reporting and a part of the view page will be shown as below:



Field Corrective Action

Main Dashboard > FCA Dashboard > View Report

1  **Field Corrective Action Report**

Section A: Field Corrective Action Report

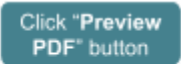
1. MDA FCA Reference Number	MDA/FCA/P0229-95246492-2021
2. Type of Report	Closure
3. Title of FCA	bersang 10H
4. Type of Field Corrective Action (FCA)	Destruction




Section B : Establishment Particulars



1. Name of Company	Medical Device Authority Development Team (ICT)
2. Company Address	0H, JALAN CYBERA 1, CYBERJAYA
3. Contact Person Name	HOST 0H
4. Job Title	MANAGER
5. Telephone Number	0123456789
6. Email address	host0H@sebung.com

Declaration

1. Reporting Person	Person Responsible for the Establishment: HOST 0H Job Title: MANAGER Telephone Number: 0123456789 Email Address: host0H@sebung.com
---------------------	---

2 

3   

1. All sections will be shown in this report.
2. Click the  button to go back to the previous page.
3. Click the  button to view the report in Portable Document Format (PDF) format. (Refer to [4.5.1 Preview PDF Field Corrective Action \(FCA\) Report](#))

4.5 PREVIEW PDF

4.5.1 Preview PDF Field Corrective Action (FCA) Report

- a. There are two (2) types of Preview PDF:
 1. A part of Preview PDF for Draft Report will be shown below.





Field Corrective Action Report Follow Up

Section A : Field Corrective Action Report	
1. MDA FCA Reference Number	MDA/FCA/PX0345-79741604-2022
1.1 MDA MPR Reference Number	MDA/MPR/P0235-48710369-2022
2. Type of Report	Follow Up
3. Title of Field Corrective Action (FCA)	etret
4. Type of Field	Return

Section B : Establishment Particulars	
1. Name of Company	Medical Device Authority Development Team (ICT)
2. Company Address	011, JALAN CYBERIA 1, CYBERJAYA
3. Contact Person Name	HOST 011
4. Job Title	MANAGER
5. Telephone Number	0123456789
6. Email address	host011@sebung.com

- I. The Declaration Section will not be included in the Preview PDF for Draft Report.

2. A part of Preview PDF for Submitted Report will be shown below.



Field Corrective Action Report Notification

Section A : Field Corrective Action Report	
1. MDA FCA Reference Number	MDA/FCA/PX0345-79741604-2022
1.1 MDA MPR Reference Number	MDA/MPR/P0235-48710369-2022
2. Type of Report	Notification
3. Title of Field Corrective Action (FCA)	etret
4. Type of Field	Return

Section B : Establishment Particulars	
1. Name of Company	Medical Device Authority Development Team (JCT)
2. Company Address	011, JALAN CYBERIA 1, CYBERJAYA
3. Contact Person Name	HOST 011
4. Job Title	MANAGER
5. Telephone Number	0123456789
6. Email address	host011@sebung.com

4.6 EDIT REPORTING

4.6.1 Edit Notification Report

a. A part of the edit Notification Report page will be shown below.

4. Evaluation of the risk associated with affected medical device (Health Hazard Evaluation Report) ⓘ

Choose Files No file chosen

File upload size will delete all previous files.
Multiple file upload are allowed but the maximum size of the total file uploaded must not exceed 20MB.

5. Background information and reason for the FCA?*

6. Root Cause?*

** The root cause is based on what is actual cause the reason to initiated the FCA. Usually, the root cause is identified first before any corrective action is taken.

7. FCA plan and action to be taken (corrective action)?*

8. Advice on actions to be taken by the distributor and the user?*

1. Users can update all information in this report.
2. The process to submit the updated report will be the same as submitting a new report. (Refer to [4.3.1 Create New Notification Report](#))

4.6.2 Edit Follow Up Report

a. A part of the edit Follow Up Report page will be shown below.

Section F : Follow Up

1. Follow Up (Progress of FCA, together with reconciliation status and/or effectiveness check and its method)?*

2. Has the FCA able to completed within the proposed timeline?*

Yes

No

dd/mm/yyyy

1. Users can update all information for this section in this report.
2. The process to submit the updated report will be the same as submitting a new report. (Refer to [4.3.2 Create New Follow Up Report](#))

4.6.3 Edit Return from MDA Report

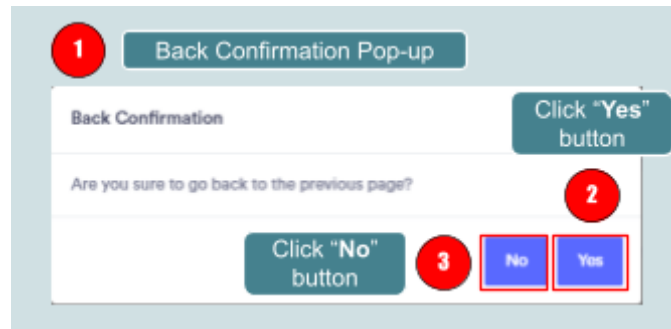
a. A part of the edit Return from MDA Report page will be shown below.

The screenshot displays the 'Edit Return from MDA Report' interface. It is divided into two main sections: Section D (FCA Proposed Plan and Action) and Section E (FCA Information). Section D includes a text area for 'FCA Planned by Establishment' with a red box highlighting the 'Satisfied: No' and 'Comment' options. Section E contains several questions with 'No' responses, including 'Did this incident occur in Malaysia?'. A red circle with the number '1' is placed over the 'No' response. A blue box labeled 'Remark section' is placed over the 'Evaluation of the risk' field. At the bottom, a 'Declaration' section is visible, followed by a 'Button Section' containing 'Back', 'Preview PDF', and 'Submit' buttons. A red circle with the number '2' is placed over the 'Button Section' label, and a red box highlights the buttons.

1. Users can only update the information that has a 'No' remark in this report.
2. Button section.
 - I. This section displays all buttons in the Notification Report.



- II. Click [Back](#) button to go back to the previous page. The pop-up will be display as below:




- Back Confirmation Pop-up.
 - Click the **Yes** button to go back to the previous page.
 - Click the **No** button to stay on the same page.

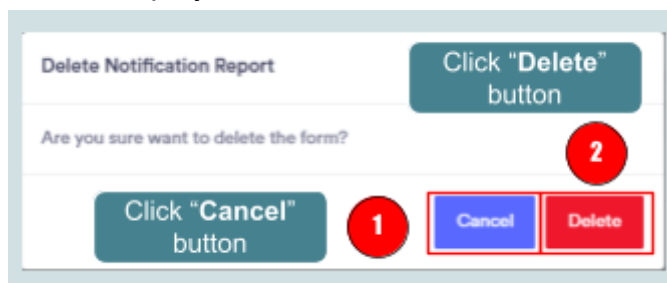
- III. Click the **Preview PDF** button to view the report in Portable Document Format (PDF) format. (Refer to [4.5.1 Preview PDF Field Corrective Action \(FCA\) Report](#))



- IV. Click the **Submit** button to submit the updated report. This button will be enabled if the user tick the checkbox in the Declaration section.

4.7 DELETE REPORTING


4.7.1 Delete Notification Report

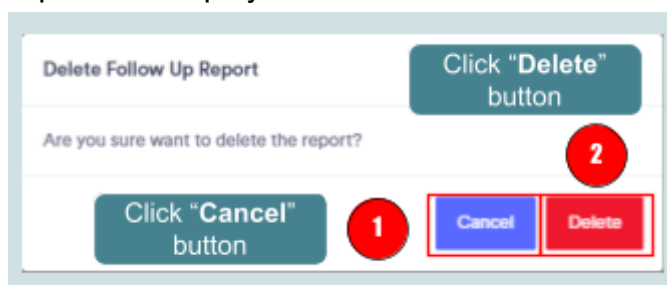
- a. Click the  **Delete** button to delete the Notification report and the pop-up will be displayed as below:





- I. Click the  **Cancel** button to close the delete pop-up.
- II. Click the  **Delete** button to delete the Notification report.

4.7.2 Delete Follow Up Report

- a. Click the  **Delete Follow Up** button to delete the Follow Up report and the pop-up will be displayed as below:



- I. Click the  **Cancel** button to close the delete pop-up.
- II. Click the  **Delete** button to delete the Follow Up report.

4.8 FCA REPORT OVERDUE

Field Corrective Action

Dashboard > FCA Dashboard > FCA Overdue Report

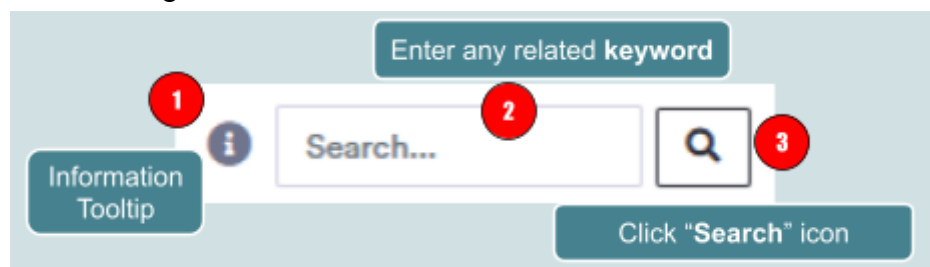
List of FCA Overdue Reports


No.	Ref No.	Medical Device Name	Date Submission	Date Proposed Completion	Type of Report	Status	Action
1	MDA/FCA/P0232-94729407-2021	MEDICAL TESTORD	26/10/2021	07/01/2022	Follow Up	Overdue	View, Log, Extend Date (30)
2	MDA/FCA/P0341-90196368-2022	MEDICAL TESTORA	01/03/2022	24/03/2022	Closure	Overdue	View, Log, Extend Date (30)
3	MDA/FCA/PX0367-6429086-2022	MEDICAL TESTORA	25/02/2022	27/03/2022	Follow Up	Overdue	View, Log, Extend Date (30)
4	MDA/FCA/P0371-63370451-2022	MEDICAL TESTORA	14/03/2022	06/04/2022	Follow Up	Almost Overdue	View, Log, Follow Up, Extend Date (30)

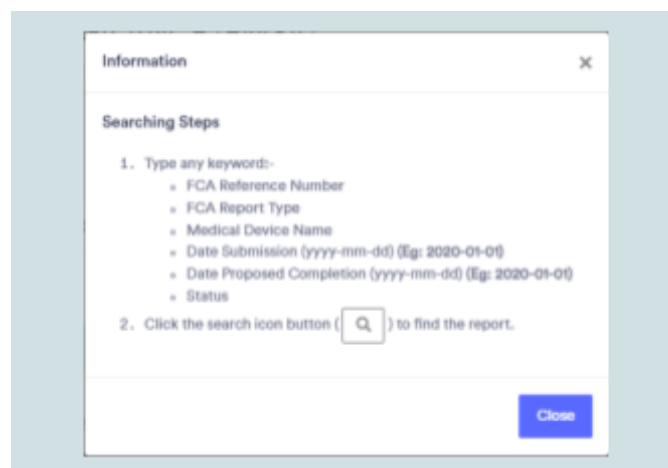
Showing 4 of 4 entries.



a. List of FCA Overdue Report will be displayed as above:

1. Table Filtering shown as below:





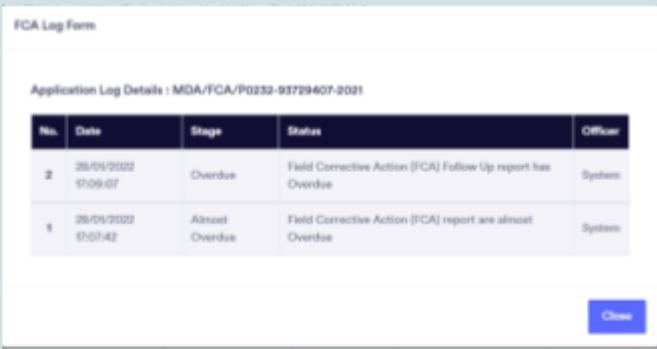
- I. User can click the  icon to get more information related to table filtering and the pop-up will be displayed as below:



- Click the  button to close the pop-up.
- II. Enter any related keyword (based on information given).
- III. Click the  icon and the system will display the result.


2. Action Button for Overdue Status:

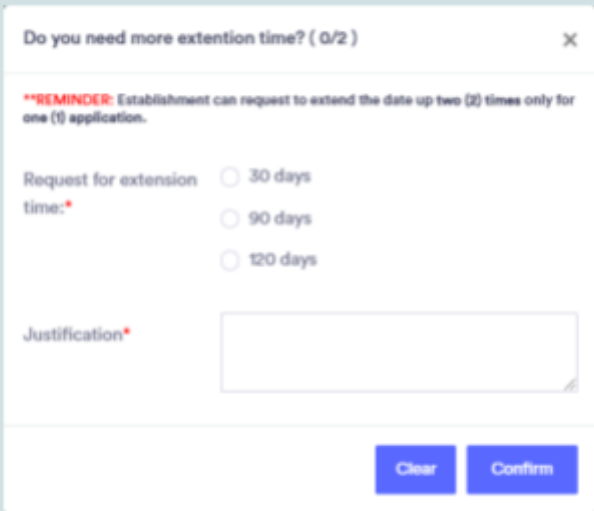
- I. Click the  button to view the report. (Refer to [4.4.1 View Field Corrective Action \(FCA\) Report](#))
- II. Click the  button to view the reporting log and the pop-up will be displayed as below:



No.	Date	Stage	Status	Officer
2	28/01/2022 17:09:07	Overdue	Field Corrective Action (FCA) Follow Up report has Overdue	System
1	28/01/2022 17:07:42	Almost Overdue	Field Corrective Action (FCA) report are almost Overdue	System

- Click the  button to close the pop-up.

- IV. Click the  button to request extension time and the pop-up will be displayed as below:



Do you need more extension time? (0/2)

****REMINDER:** Establishment can request to extend the date up two (2) times only for one (1) application.


Request for extension time:*


30 days

90 days



120 days

Justification*

- Click the  button to clear all the information.

- Click the  button to submit the request for extension time.



3. Action Button for Almost Overdue Status:

- I. Click the  button to view the report. (Refer to [4.4.1 View Field Corrective Action \(FCA\) Report](#))
- II. Click the  button to view the reporting log and the pop-up will be displayed as below:



- Click the  button to close the pop-up.

III. If the report status is Almost Overdue, user have two (2) actions to choose which are:

- Click the  button to continue the report and submit the report before Overdue. (Refer to [4.3.2 Create New Follow Up Report](#))
- Click the  button to request extension time and the pop-up will be displayed as below:

Do you need more extension time? (0/2)

****REMINDER:** Establishment can request to extend the date up two (2) times only for one (1) application.

Request for extension time:*

30 days

90 days

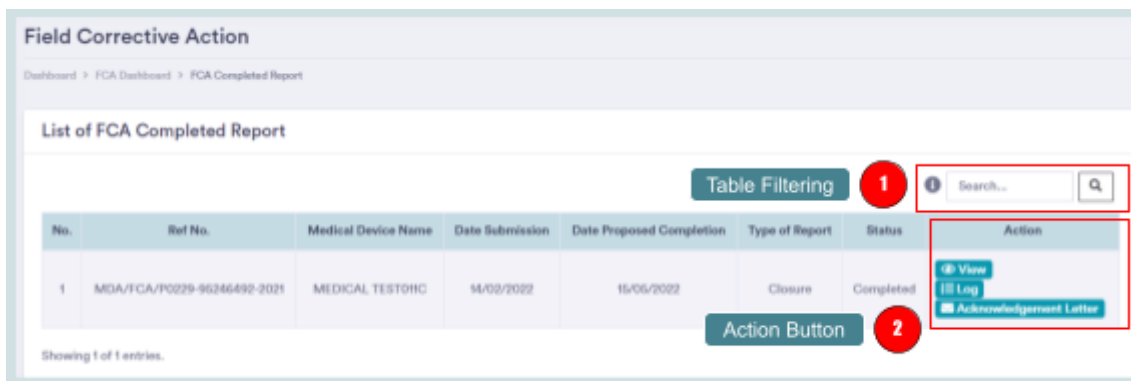
120 days

Justification*

Clear Confirm

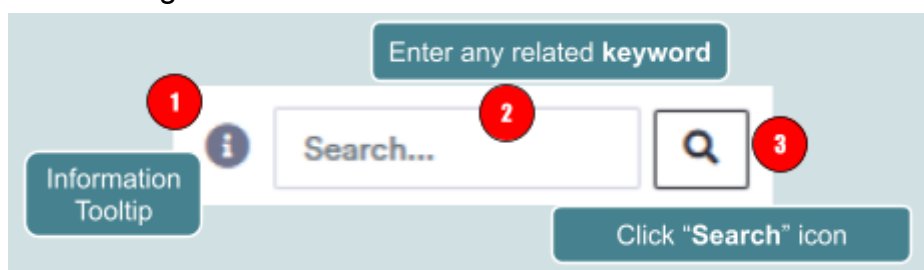
- Click the **Clear** button to clear all the information.
- Click the **Confirm** button to submit the request for extension time.


4.9 FCA REPORT COMPLETED

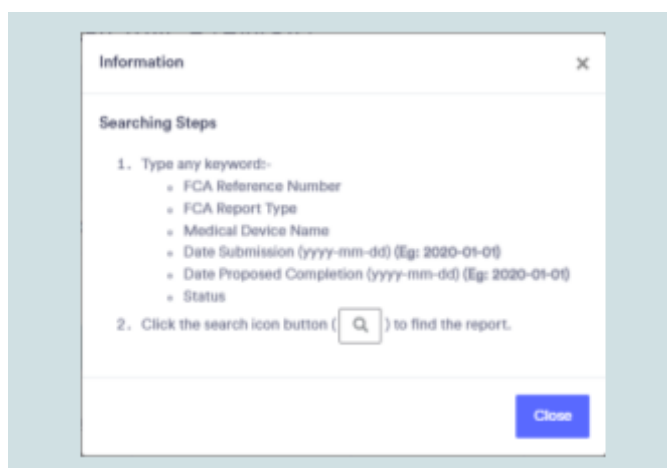




a. List of FCA Completed Report will be displayed as above:

1. Table Filtering shown as below:




II. User can click the  icon to get more information related to table filtering and the pop-up will be displayed as below:





➤ Click the  button or  button to close the pop-up.

IV. Enter any related keyword (based on information given).

V. Click the  icon and the system will display the result.

2. Action Button:


- XI. Click the  button to view the report. (Refer to [4.4.1 View Field Corrective Action \(FCA\) Report](#))
- XII. Click the  button to view the reporting log and the pop-up will be displayed as below:

FCA Log Form

No.	Date	Stage	Status	Officer
1	14/02/2022 01:27:36	Submitted	Field Corrective Action (FCA) Closure report has been Submitted	HOIST 08
2	14/02/2022 01:21:30	Extend Date	The report to extend new completion date has been approved.	Nurul Diyana binti Muzid Nur
3	14/02/2022 01:20:52	Extend Date	Field Corrective Action (FCA) application has been request for Extend Date	HOIST 08
4	25/01/2022 16:56:44	Overdue	Field Corrective Action (FCA) Additional Follow Up report has Overdue	System

[Close](#)

- Click the  button to close the pop-up.

- XIII. Click the  button to view the acknowledgement letter that the system will generate for the user. The acknowledgement letter will be displayed as below:


PERKARA BERSEKUTUAN PERHAKIM
 PERHAKIM-DA
 Medical Device Authority
 450007/PERHAKIM-DA/0001/PERHAKIM-DA
 Ministry of Health Malaysia
 Jalan 6, Tower 6, Pusat Perkhidmatan,
 Blok 604, Persiaran PRTS,
 46000 Cyberjaya,
 Malaysia.

Tel: 1-800-88-1100
 Email: perh@mda.gov.my
 Email: perh@mda.gov.my


Our Reference Number : MDA/FCA/P0229-6026490-0021
 Date : 04/04/2022

HOIST 08
 Medical Device Authority Development Team (CT)
 071, JALAN CYBERJAYA 1, CYBERJAYA

Su/Mediam,

Acknowledgement Receipt of Field Corrective Action Report Closure.

With reference to the above, we acknowledge the receipt of the following Field Safety Notification communication from your company:

MDA FCA Ref. Number : MDA/FCA/P0229-6026490-0021
Report Type : Destruction
Title : Barring 1 (B)
Device Name : MEDICAL TEST/SHC
MDA Registration Number : H082101
Initial Date : 04/04/2022
Closure Date : 16/05/2022
CAB Name : CAB 01K

3. Please be advised to monitor closely the effectiveness of the corrective actions mentioned above.

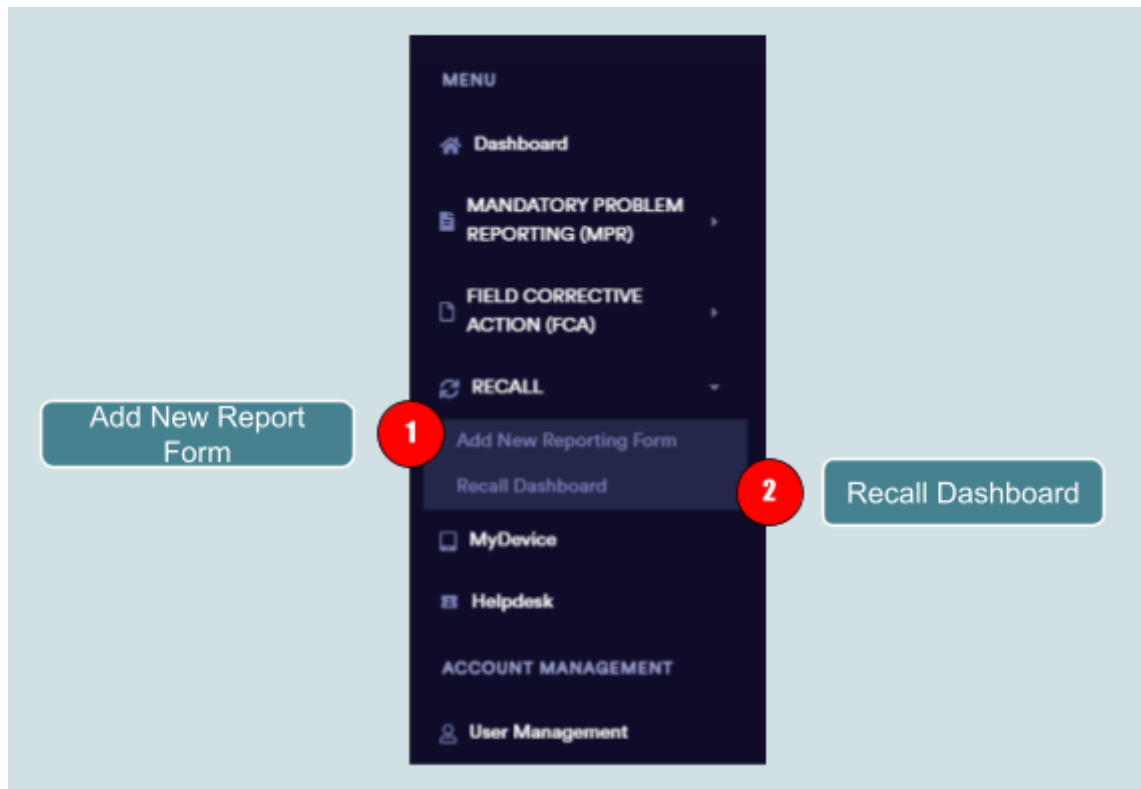
Thank you.

Director
 Registration, Licensing and Enforcement Division
 Medical Device Authority
 Ministry of Health Malaysia

This is a computer-generated document. No signature is required.

5 RECALL

5.1 RECALL SIDEBAR



- a. Recall Sidebar will be displayed as above:
 1. Create New Notification Report
 - I. Create New Notification Report will display the create page for Notification report.
 2. Recall Dashboard
 - I. Recall Dashboard will display Recall main dashboard.

5.2 RECALL DASHBOARD

The screenshot shows the Recall Dashboard with the following components and callouts:

- 1** Recall Report Counter (highlighted in a red box)
- 2** Add New Reporting Form button (highlighted in a blue box)
- 3** Reporting Table tabs (highlighted in a blue box)
- 4** Overdue Reporting Table (5) tabs (highlighted in a blue box)
- 5** Closure Reporting Table (0) tabs (highlighted in a blue box)
- 6** Table with columns: No., Ref No., Medical Device Name, Date of Reporting (dd/mm/yy), Due Date for Next Reporting (dd/mm/yy), Reporting Stage, Status, Action.

No.	Ref No.	Medical Device Name	Date of Reporting (dd/mm/yy)	Due Date for Next Reporting (dd/mm/yy)	Reporting Stage	Status	Action
1	MDA/Recall /P020-45298529-2022	MEDICAL TESTOTIC			Final	Draft	Log View Edit
2	MDA/Recall	MEDICAL	18/03/2022		Notification	Draft	Log View Edit

a. The Recall Dashboard page will be displayed as above:

1. Recall Report Counter (Refer to [5.2.1 Recall Report Counter](#)).
2. Click the **Add New Reporting Form** button to open a new report Notification (Refer to [5.3.1 Notification Report](#)).
3. “Reporting Table” tabs (Refer to [5.2.3 Reporting Table](#)).
4. “Overdue Reporting Table” tabs (Refer to [5.8 OVERDUE REPORTING](#)).
5. “Closure Reporting Table” tabs (Refer to [5.9 CLOSURE REPORTING](#)).

5.2.1 Recall Report Counter

The close-up screenshot shows the Recall Report Counter section with the following components and callouts:

- 1** Notification Report Counter
- 2** Follow-Up Report Counter
- 3** Final Report Counter
- 4** Total reporting form counter

Notification Report	Follow-Up Report	Final Report
Total of Reporting: 12	Total of Reporting: 2	Total of Reporting: 3
Return from MDA: 0	Return from MDA: 0	Return from MDA: 1

Total reporting form is : 18

a. There are three types of reports counter will be displayed as above:

1. **Notification Report** - Counter Statistic for Notification Report.
2. **Follow-Up Report** - Counter Statistic for Follow -Up Report.
3. **Final Report** - Counter Statistics for Final Report.
4. Total reporting form.

b. Users are allowed to click on the counter number to see a list of reports running at each report stage:

1. **List of Total Reporting** - Displays a list of all reports at the reporting stages (Notification, Follow-Up,Final) with Draft and Submitted status.
 - I. A part of the total reporting list will be shown below.

Final Total of Reporting

Main Dashboard > Final Total of Reporting Table

Final Total of Reporting

Table Filtering



Search...

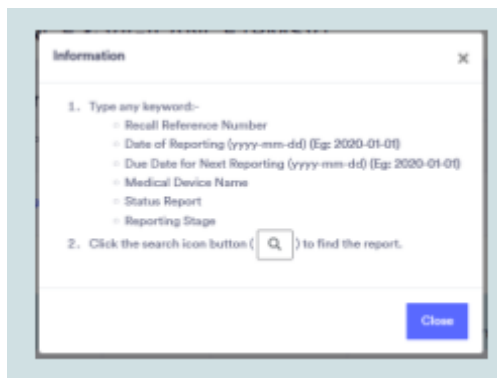
No.	Ref No.	Medical Device Name	Date of Reporting (dd/mm/yy)	Due Date for Next Reporting (dd/mm/yy)	Reporting Stage	Status	Action
1	MDA/Recall /P026-6238329-2022	MEDICAL TEST08C		-	Final	Draft	Log, View, Edit
2	MDA/Recall /P0177-7029881-2022	MEDICAL TEST08C	11/02/2022	-	Final	Submitted	Log, View, Acknowledgement Letter
3	MDA/Recall /P0160-92660132-2022	MEDICAL TEST08B	18/02/2022	-	Final	Submitted	Log, View

Showing 3 of 3 entries.


Action buttons

➤ Table Filtering




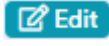



- Users can fill in the 'Search...' field to find the reporting that the user wants to search. User need to click  button to find the reporting.
- User can click  button to get more information about filter tables.
- The information pop-up below will be displayed :



➤ Action buttons

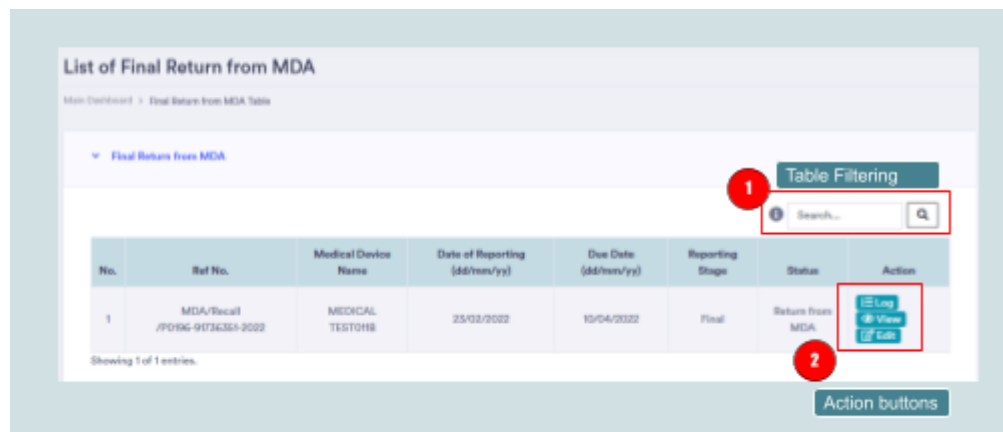
- Click  button to view report Log Details.
 - Log details will be display as below:




- Report Reference Number.
- Report log details.
- Click  button or  button to close the pop-up.
- Click  button to view the report (Refer to [5.4 VIEW RECALL REPORT](#)).
- Click  button to update all information in the report (Refer to [5.6 EDIT REPORT](#)).
- Click  button to open Follow - Up Report (Refer to [5.3.2 Follow-Up Report](#)).
- Click  button to open Final Report (Refer to [5.3.3. Final Report](#)).
- Click  button to view and print acknowledgement letters.
 - Acknowledgement letters will be display as below:




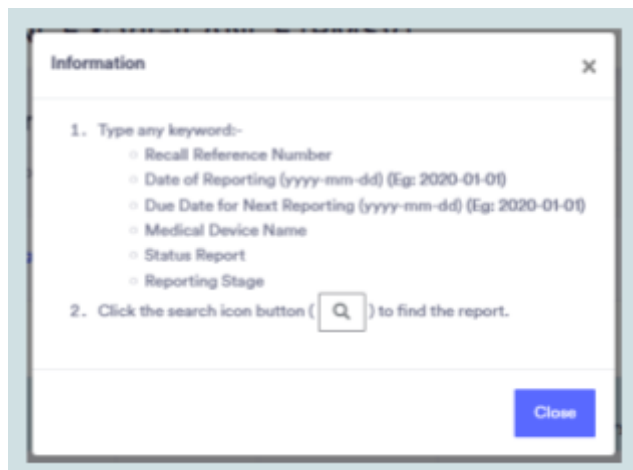
2. **List of Return from MDA** - Displays a list of all reports at the reporting stages (Notification, Follow-Up, Final) with Return from MDA status.
 - I. A part of the return from MDA LIST will be shown below.




➤ **Table Filtering**

- Users can fill in the 'Search...' field to find the reporting that the user wants to search. User need to click  button to find the reporting.





- User can click  button to get more information about filter tables.
- The information pop-up below will be displayed :



➤ Action buttons

- Click  button to view report Log Details.
 - Log details will be display as below:



- Report Reference Number.
 - Report log details.
 - Click  button or  button to close the pop-up.
- Click  button to view the report (Refer to [5.4 VIEW RECALL REPORT](#)).
 - Click  button to update all information in the report (Refer to [3.7.3 Edit Return From MDA](#)).

5.2.2 Open New report (Notification)

- a. The Recall new report page will be as shown (Refer to [5.3.1 Notification Report](#)):



5.2.3 Reporting Table

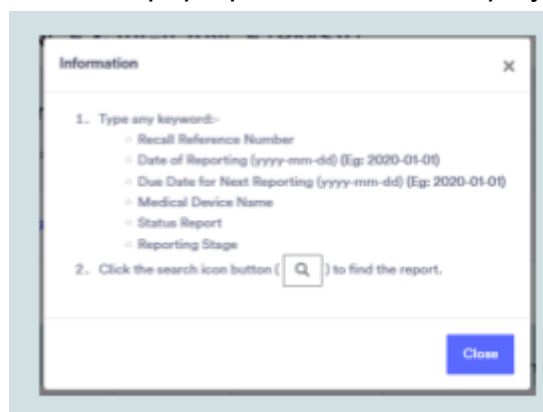
a. The Reporting Table tabs will be shown as below:

No.	Ref No.	Medical Device Name	Date of Reporting (dd/mm/yy)	Due Date for Next Reporting (dd/mm/yy)	Reporting Stage	Status	Action
1.	MDA/Recall /P023-6320460-2022	MEDICAL TESTORA	21/01/2022		Notification	Draft	Log, View, Link
2.	MDA/Recall /P023-6327690-2022	MEDICAL TESTORIC	20/03/2022	06/04/2022	Follow Up	Submitted	Log, View, Link, Final Report
3.	MDA/Recall /P026-0440010-2022	MEDICAL TESTORD	20/03/2022	03/04/2022	Notification	Submitted	Log, View, Link, Follow Up Report
4.	MDA/Recall /P024-4528826-2022	MEDICAL TESTORA	25/02/2022	28/02/2022	Follow Up	Return from MDA	Log, View, Link
5.	MDA/Recall /P021-6228228-2022	MEDICAL TESTORIC			Final	Draft	Log, View, Link


1. **Reporting Table Tabs** - Display a list of all reporting stages (Notification, Follow-Up, Final) with Draft, Submitted, and Return from MDA status.

I. Table Filtering

- Users can fill in the 'Search...' field to find the reporting that the user wants to search. User need to click  button to find the reporting.
- User can click  button to get more information about filter tables.
- The information pop-up below will be displayed :



II. Action Button

- Click  button to view report Log Details.
 - Log details will be display as below:



- Report Reference Number.
 - Report log details.
 - Click **×** button or **Close** button to close the pop-up.
-
- Click **View** button to view the report (Refer to [5.4 VIEW RECALL REPORT](#)).
 - Click **Edit** button to update all information in the report (Refer to [5.6 EDIT](#)).
 - Click **Follow-Up Report** button to open Follow - Up Report (Refer to [5.3.2 Follow-Up Report](#)).
 - Click **Final Report** button to open Final Report (Refer to [5.3.3. Final Report](#)).
 - Click **Acknowledgement Letter** button to view and print acknowledgement letters.
 - Acknowledgement letter will be display as below:

5.2.4 Overdue Reporting Table

- The Overdue Reporting Table will be as shown (Refer to [5.8 OVERDUE REPORTING](#)):

5.2.5 Closure Reporting Table

- The Closure Reporting Table will be as shown (Refer to [5.9 CLOSURE REPORTING](#)):

5.3 CREATE RECALL REPORT

5.3.1 Notification Report

- Click the [Add New Reporting Form](#) button to create Notification report and the Notification page will be displayed as below:

1. Recall Reference Number.

- I. Recall Reference Number is auto-generated by the system.
2. Click the Section A: Medical Device Recall Report Form.
 - I. Section A will be display as below:

Section A : Medical Device Recall Report Form

1. Recall Initiated by *

Establishment (Voluntary Recall)

Authority (Mandatory Recall)

2. Type Of Report

Notification / Preliminary Report

Follow Up Report

Final Report

- II. User are required to fill in all fields that marked with an asterisk (*).
- III. Question 2 is autofill by system based on report type.

3. Click the Section B : Establishment Details

- I. Section B will be display as below:

Section B : Establishment Details

1. MDA Establishment License No. * KP-HOST01

2. Name of Establishment * Medical Device Authority Development Team (ICT)

3. Establishment Address * 01, JALAN CYBERIA 1, CYBERJAYA3000, SELANGOR

4. Contact Person Name * HOST 01

5. Job Title * MANAGER

6. Tel No. * 0123456789 7. Fax No. * 0123456789

8. Email Address * host01@seabumbug.com

9. CAB Name * CARE CERTIFICATION INTERNATIONALMS SDN.BHD

- II. All information in this section will be auto-filled by the system

4. Click the Section C : Affected Medical Device Details.

- I. Section C will be display as below:

Section C : Affected Medical Device Details

1. MDA Device Registration No. *

2. Affected Device Name *

3. Device intended use *

4. Class of Device *

5. Device Risk *

Table of Device Details*

(Establishment may download the template excel file & upload at given file section)

1. [Template](#) : Template for Table of Affected Device Details.xls

2. [Example](#) : Example for Table of Affected Device Details.xls

Product No. / Catalogue No. / Identifier No.	Lot / Batch No.	Serial Number / UDI Code (If applicable)	Quantity
No Table of Device Details to display			
			Total 0

[Add Details of Affected Devices](#)

7. Accessories/ Associated Devices Affected * (Max)

8. Manufacturer Name

9. Manufacturer Address

- II. Click the dropdown button on MDA Device Registration No.(Question 1) to choose a registered device number.
- III. All information in this section will be auto-filled by the system based on the chosen MDA Device Registration number except Table of Device Details and question 7.
- IV. Table of Device Details:

1 Affected Device Details Section

2 [Template](#) : Template for Table of Affected Device Details.xls

Template for Table of Affected Device Details

Product No. / Catalogue No. / Identifier No.	Lot / Batch No.	Serial Number / UDI Code (If applicable)	Quantity
No Table of Device Details to display			
			Total 0


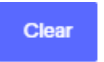
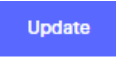


Click "Add Details of Affected Devices" button

3 [Add Details of Affected Devices](#)

- Table of Device Details will be displayed as above.
- There are two (2) template for Table of Affected Device Details that user can download which are:
 - Example for Table of Device Details
 - Template for Table of Device Details
- Users are required to use the template provided to upload it in the table.
- The **Add Details of Affected Devices** button will be enabled after the user chooses any MDA Device Registration number as shown below:
- By clicking **Add Details of Affected Devices** button, the system will display Details of Affected Devices page shown as below:



- In the Upload File Section, users can choose the file that needs to be uploaded by clicking **Choose File** button and **Import File** button will be enabled after the user chooses the file. Then click **Import File** button to import the file in the table.
- In the Uploaded File Section, it will display the file that the user uploads.
- In the Action column, it has two (2) button that user can use:
 - User can click **Edit** button to update the affected devices details in the table and the system will display the popup to update the details of affected devices shown as below:

- Click the  button to close the popup.
 - Click the  button to clear all the information.
 - Click the  button to update the information.
- User can click the  button to delete the information from the table.
- Click the  button to back to the previous page section C.

V. The updated Table of Device Details will be displayed in Section C as shown below:

6. Table of Device Details*

(Establishment may download the template excel file & upload at given file section)

1. **Template**  : [Template for Table of Affected Device Details.xls](#)

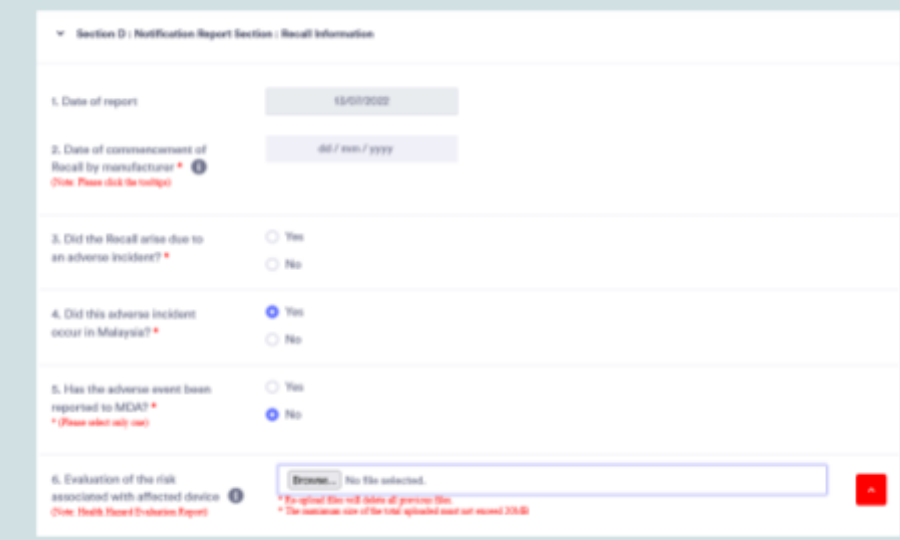
2. **Example**  : [Example for Table of Affected Device Details.xls](#)

No.	Product No. / Catalogue No. / Identifier No.	Lot / Batch No.	Serial Number / UDI Code (if applicable)	Quantity
1.	AIMB-28-70	10222636, 10238909, 10245880, 10250361, 10250362, 10250363, 10262545, 10262546, 10269483	n/a	100
Total				100

[Edit / Add Details of Affected Devices](#)

VI. Click  button if users want to edit add details of affected devices.

5. Click the Section D : Notification Report Section: Recall Information.
 - I. Section D will be display as below:



Section D : Notification Report Section : Recall Information

1. Date of report

2. Date of commencement of Recall by manufacturer *
(Note: Please click the tooltip)

3. Did the Recall arise due to an adverse incident? * Yes No

4. Did this adverse incident occur in Malaysia? * Yes No

5. Has the adverse event been reported to MDA? * Yes No
* (Please select only one)

6. Evaluation of the risk associated with affected device *
(Note: Health Recall Evaluation Report)
* To input file will show at previous step
* The maximum size of the total uploaded must not exceed 20MB



7. Reason for Recall *

- A01: Patient Device Interaction Problem
- A02: Manufacturing, Packaging or Shipping Problem
- A03: Chemical Problem
- A04: Material Integrity Problem
- A05: Mechanical Problem
- A06: Optical Problem
- A07: Electrical / Electronic Property Problem
- A08: Calibration Problem
- A09: Output Problem
- A10: Temperature Problem
- A11: Computer Software Problem
- A12: Connection Problem
- A13: Communication or Transmission Problem
- A14: Infusion or Flow Problem
- A15: Activation, Positioning or Separation Problem
- A16: Protective Measures Problem
- A17: Compatibility Problem
- A18: Contamination / decontamination Problem
- A19: Environmental Compatibility Problem
- A20: Installation-Related Problem
- A21: Labelling, Instructions for Use or Training Problem
- A22: Human Device Interface Problem
- A23: Use of Device Problem
- A24: Adverse Event Without Identified Device or Use Problem
- A25: No Apparent Adverse Event
- A26: Insufficient Information
- A27: Appropriate Term/Code Not Available

8. Recall Class *

Class I :High Risk
 Class II :Moderate Risk
 Class III :Low Risk

9. Recall Strategy and action to be taken *

10. Action to be taken by the Customer/User *

11. Date of recall initiation *
*(Expected date of first notification to affected customer)

dd / mm / yyyy

12. Extension timeline for notification affected customers if required.*
 Yes
 No

13. Estimated Date to complete recall*
dd / mm / yyyy

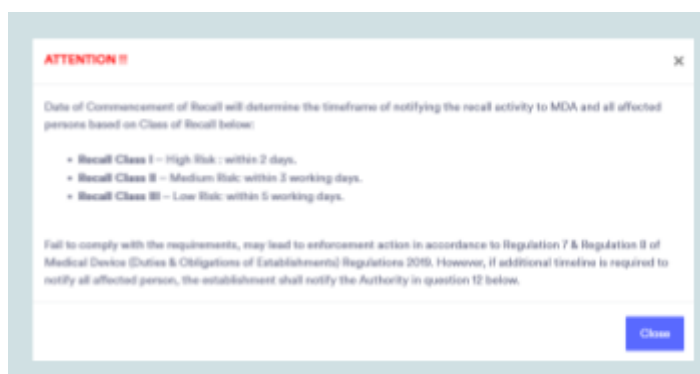
14. Expected date to submit follow-up report*
dd / mm / yyyy

Supporting Document ⓘ

15. Copy of official Recall Communication *

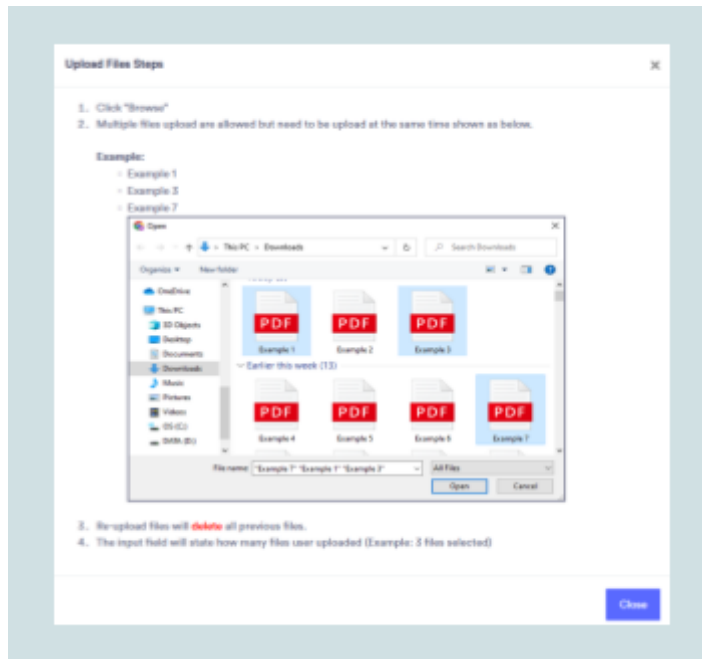
Browse... No files selected.
* Upload files will delete all previous files.
* Multiple files upload are allowed but the maximum size of the total uploaded must not exceed 20MB

- II. User are required to fill in all fields that marked with an asterisk (*).
- III. User need to click the ⓘ button on question 2 to read about the attention of the Date of commencement of Recall by manufacturer. The pop-up will be displayed as below:

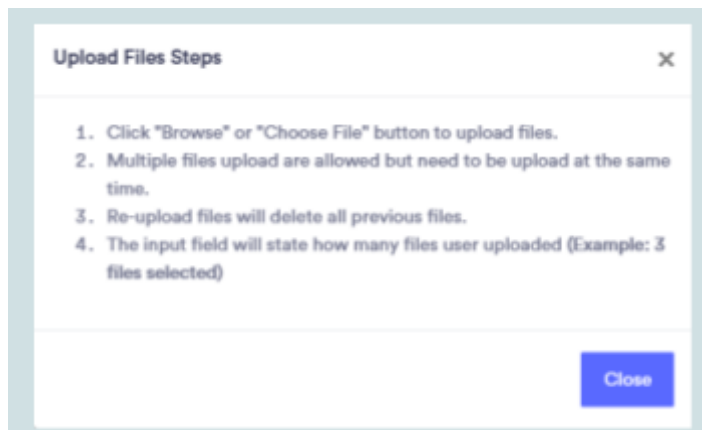


- IV. User can click the ⓘ button to get more information about multiple or single file upload. The pop-up will be displayed as below:

➤ Multiple upload files steps



➤ Single upload file steps



6. Declaration

I. Declaration section will be display as below:

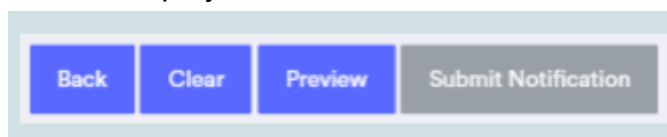
The screenshot shows a "Declaration" section with two radio button options:


- I hereby attest that the information and attachment provided on this reporting is / are correct, completed and current to this date. *
- I understand and acknowledge that is an offence under Section 76 of Act 732, to make sign or furnish any declaration, or other document which is untrue, inaccurate or misleading. *

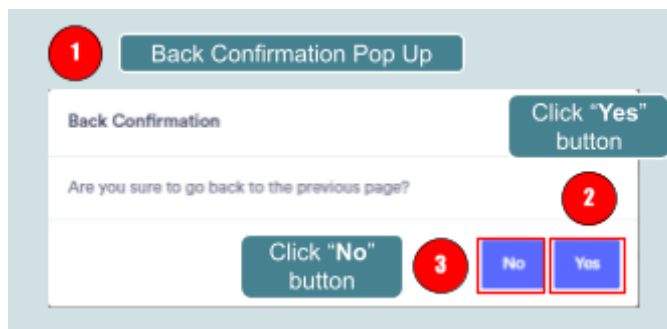
Below the options are input fields for the following information:



- Person Responsible for the Establishment: HOSTON
- Job Title: MANAGER
- Telephone: 0123456789
- Email Address: host01@weburl.com

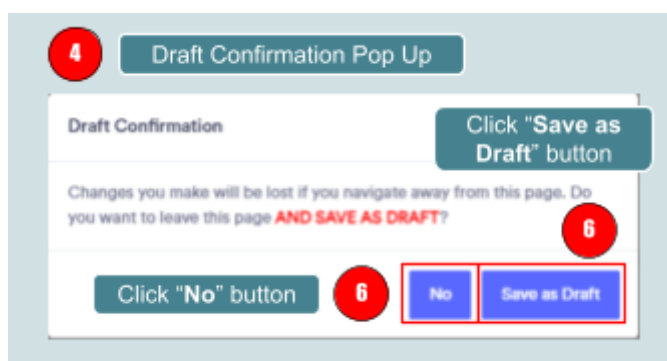
- II. User are required to tick the checkbox that marked with an asterisk (*) before submitting the report.
 - III. In this section, the system will display person responsible details which are:
 - Person Responsible for the Establishment
 - Job Title
 - Telephone
 - Email Address
7. Button Section.
- I. This section displays all buttons in the Notification Report.






- II. Click  button to go back to the previous page. There will be two (2) types of pop-up that will be display as below:

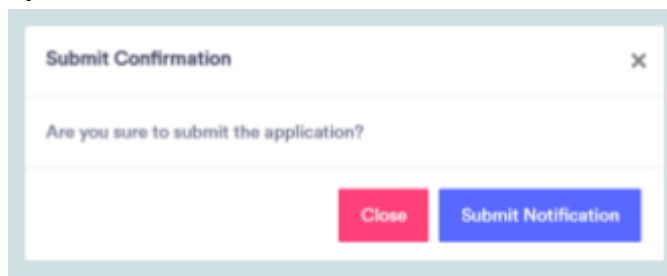


- Back Confirmation pop-up.
 - If the question Table of Affected Device Details in Section C has been filled, this Back Confirmation pop-up will be displayed.
 - Click the  button to go back to the next page.
 - Click the  button to stay on the same page.




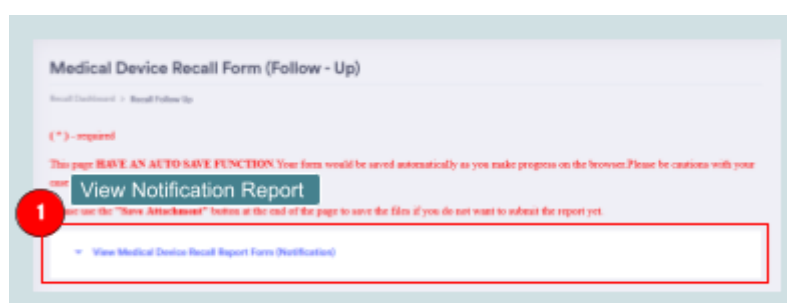
- Draft Confirmation pop-up

- If the question Table of Affected Device Details in Section C is still not filled, this Draft Confirmation pop-up will be displayed.
- III. Click the  button to clear all the information in the report except the default value.
 - IV. Click the  button to view the report in Portable Document Format (PDF) format.
 - V. Click the  button to submit the notification report. This button will be enabled if the user tick the checkbox in the Declaration section. Double confirmation pop-up that will be display as below:



5.3.2 Follow-Up Report

- a. Click the  button to create Follow-Up report and the Follow-Up page will be displayed as below:



Section E : Follow-Up Report Section

1. Has the Recall communication been sent to all affected person? Yes No

2. Table of Affected Person*

(Establishment may download the template word file to update or give file word)

1. [Template](#) : Template for Table of Affected Person.docx

2. [Example](#) : Example for Table of Affected Person.docx

No.	Affected Person/ Customer/ User	Quantity Affected
No Table of Affected Person to display		
Total		0

[Edit / Add Details of Affected Person](#)

Declaration

I hereby attest that the information and attachment provided on this reporting is / are correct, completed and current to this date *

I understand and acknowledge that in an offence under Section 76 of Act 732, to make sign or furnish any declaration, or other documents which is untrue, inaccurate or misleading *

Person Responsible for the Establishment:

Job Title:

Telephone:

Email Address:

4 **Button Section**

[Back](#) [Clear](#) [Previous PCR](#) [Submit Follow-Up](#)

1. View Notification Report

- I. Click [View Medical Device Recall Report Form \(Notification\)](#) to display the submitted Notification Report.

2. Click the Section E : Follow-Up Report Section

- I. Section E will be display as below:

The screenshot displays a form with the following sections:

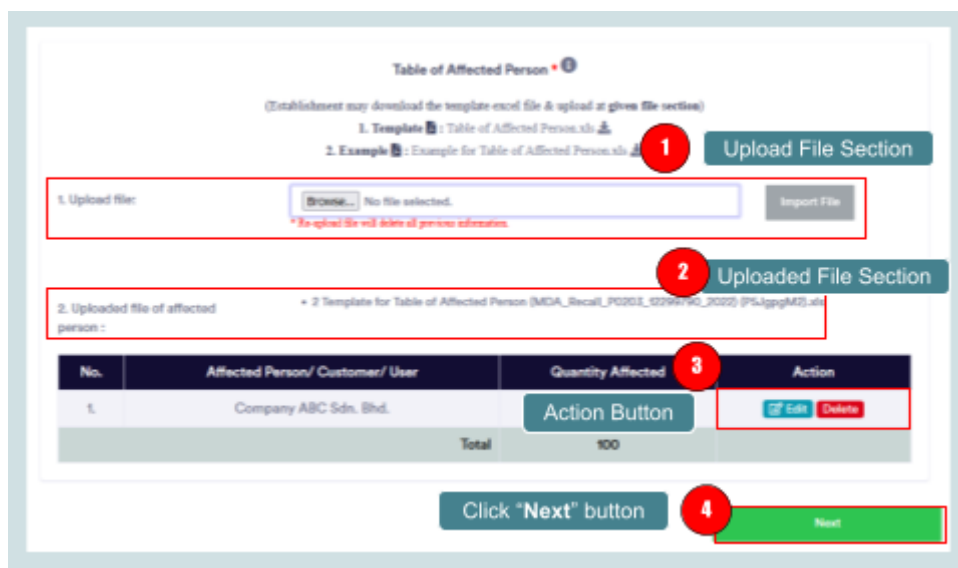
- 3. List of inspected countries:** A dropdown menu currently showing "Nothing selected".
- 4. Proposed date of completion of Recall in Malaysia:** A date input field with "dd / mm / yyyy" format.
- 5. Expected date to submit final report to the Authority:** A date input field with "dd / mm / yyyy" format.
- 6. The method of quarantine and segregation of recalled products:** A large text area for detailed input.
- Supporting Document:** A section with two file upload fields:
 - 7. Copy of acknowledgment receipt on the product recall by the affected customers:** Includes a "Browse" button and a note: "No file selected. *Upload file in table of person file. *Upload file upload on allowed for the maximum size of the total upload must not exceed 20MB"
 - 8. Evidence of quarantine / segregation area and tagging:** Includes a "Browse" button and a note: "No file selected. *Upload file in table of person file. *Upload file upload on allowed for the maximum size of the total upload must not exceed 20MB"

- II. User are required to fill in all fields that marked with an asterisk (*).
- III. Table of Affected Person:

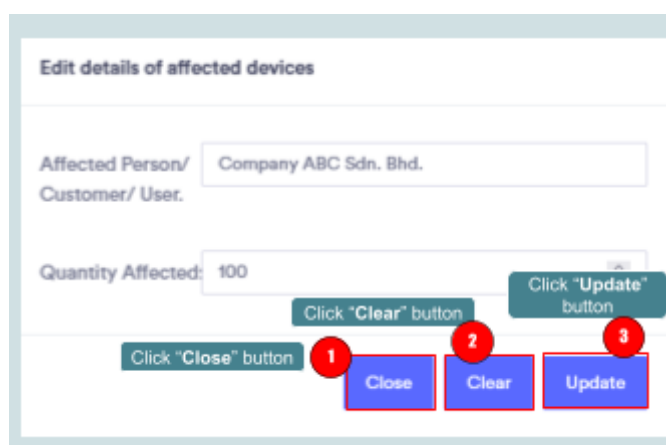
The screenshot shows the "2. Table of Affected Person" section. It includes a note: "(Establishment may download the template excel file & upload at given file name)". Below this, there are two links: "1. Template" and "2. Example". A callout box labeled "2" points to these links with the text "Template for Table of Affected Person". A callout box labeled "1" points to the section title "Affected Person Section". A callout box labeled "3" points to a blue button at the bottom right that says "Edit / Add Details of Affected Person".

No.	Affected Person/ Customer/ User	Quantity Affected
No Table of Affected Person to display		
Total		0


- The Table of Affected Person will be displayed as above.
- There are two (2) template for Table of Affected Person that user can download which are:
 - Example for Table of Affected Person
 - Template for Table of Affected Person
- Users are required to use the template provided to upload it in the table.
- By clicking Edit / Add Details of Affected Person button, the system will display Details of Affected Person page shown as below:




- In the Upload File Section, users can choose the file that needs to be uploaded by clicking **Choose File** button and **Import File** button will be enabled after the user chooses the file. Then click **Import File** button to import the file in the table.
- In the Uploaded File Section, it will display the file that the user uploads.
- In the Action column, it has two (2) button that user can use:
 - User can click **Edit** button to update the affected person in the table and the system will display the popup to update the details of affected person shown as below:



- Click the **Close** button to close the popup.
- Click the **Clear** button to clear all the information.



- Click the  button to update the information.
- User can click the  button to delete the information from the table.
- Click the  button to back to the previous page section E.


VI. The updated Table of Device Details will be displayed in Section E as shown below:




2. Table of Affected Person*



(Establishment may download the template excel file & upload at given file section)

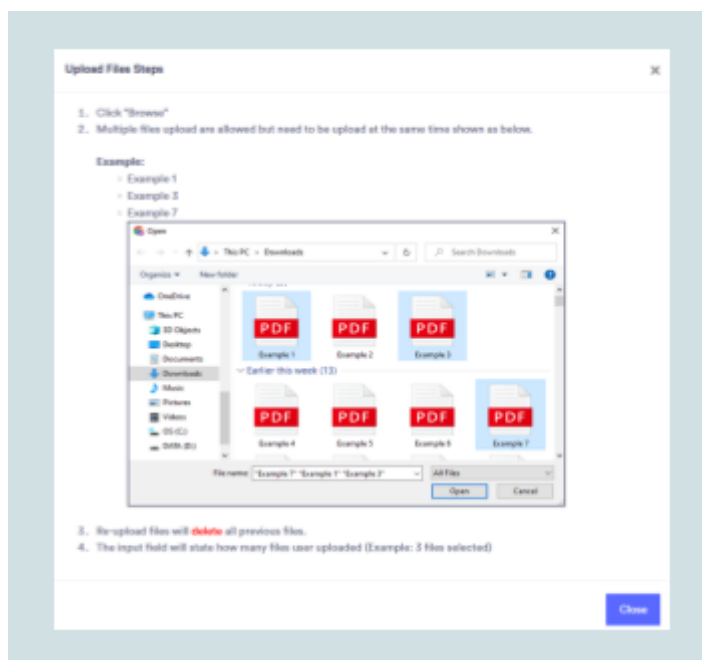
1. **Template**  : Template for Table of Affected Person.xls 

2. **Example**  : Example for Table of Affected Person.xls 

No.	Affected Person/ Customer/ User	Quantity Affected
1.	Company ABC Sdn. Bhd.	100
Total		100



- VII. Click  button if users want to edit add details of the affected person.
- VIII. User can click the  button to get more information about multiple or single file upload. The pop-up will be displayed as below:
- Multiple upload files steps



3. Declaration

I. Declaration section will be display as below:

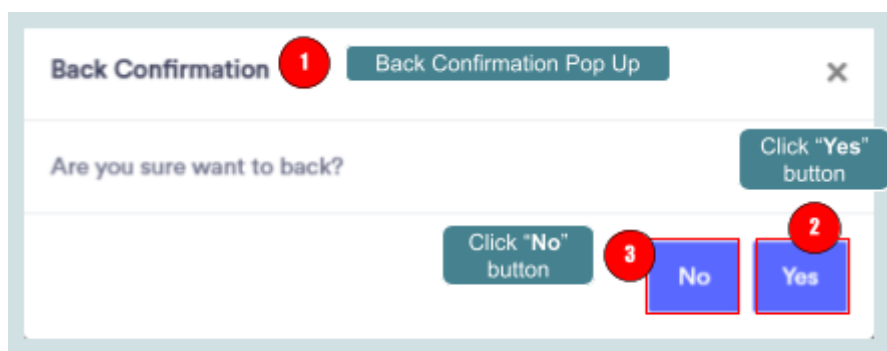
- II. User are required to tick the checkbox that marked with an asterisk (*) before submitting the report.
- III. In this section, the system will display person responsible details which are:
 - a. Person Responsible for the Establishment
 - b. Job Title
 - c. Telephone
 - d. Email Address

4. Button Section

I. This section displays all buttons in the Follow-Up Report.

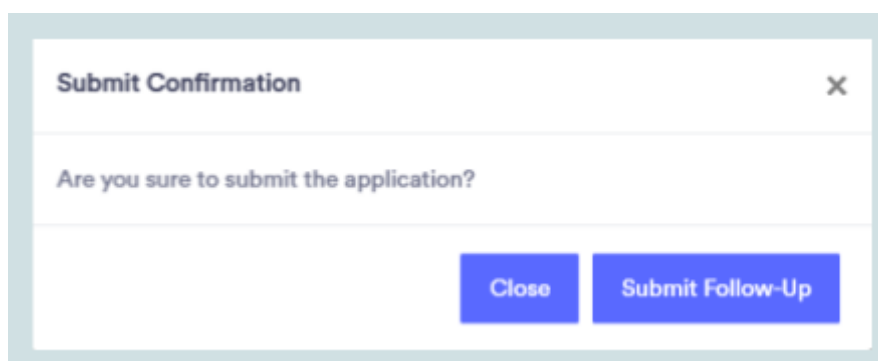


- II. Click **Back** button to go back to the previous page that will be display as below:




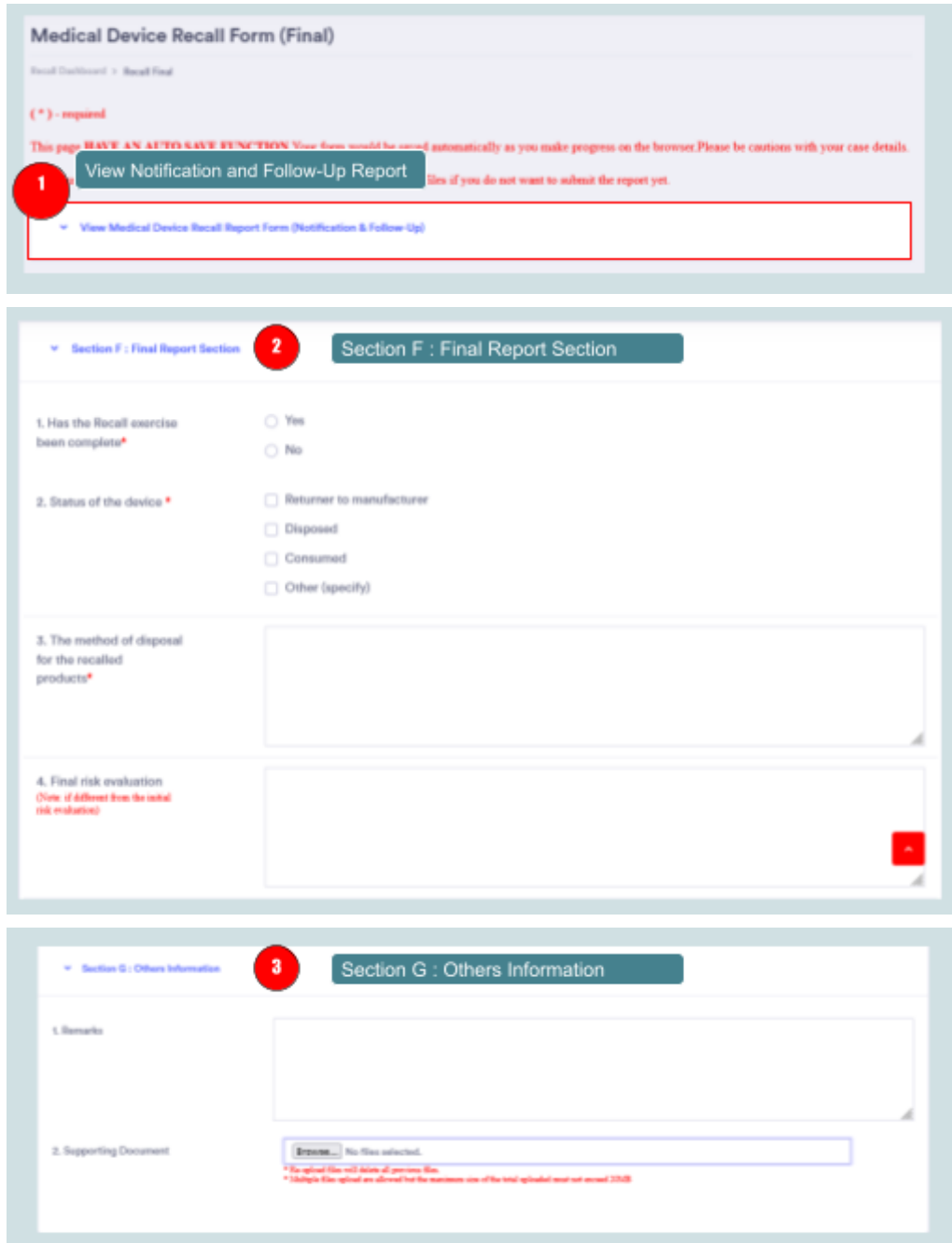
➤ Back Confirmation pop-up.

- Click the **Yes** button to go back to the next page.
 - Click the **No** button to stay on the same page.
- III. Click the **Clear** button to clear all the information in the report except the default value.
- IV. Click the **Preview PDF** button to view the report in Portable Document Format (PDF) format.
- V. Click the **Submit Follow-Up** button to submit the follow-up report. This button will be enabled if the user tick the checkbox in the Declaration section. Double confirmation pop-up that will be display as below:



5.3.3 Final Report

- a. Click the  button to create Final report and the Final page will be displayed as below:



Medical Device Recall Form (Final)

Recall Dashboard > Recall Final

(*) - required

This page **HAVE AN AUTO SAVE FUNCTION** Your form would be saved automatically as you make progress on the browser. Please be cautious with your case details.
Click if you do not want to submit the report yet.

1 [View Notification and Follow-Up Report](#)

[View Medical Device Recall Report Form \(Notification & Follow-Up\)](#)

2 **Section F : Final Report Section**

1. Has the Recall exercise been complete* Yes No

2. Status of the device * Returner to manufacturer Disposed Consumed Other (specify)

3. The method of disposal for the recalled products*

4. Final risk evaluation
(Note: if different from the initial risk evaluation)

3 **Section G : Others Information**

1. Remarks

2. Supporting Document
* To upload file will show all previous files.
** Multiple files upload are allowed but the maximum size of the total uploaded must not exceed 25MB

Declaration 4

Declaration

I hereby attest that the information and attachment provided on this reporting is / are correct, completed and current to this date.*

I understand and acknowledge that it is an offence under Section 76 of Act 732, to make sign or furnish any declaration, or other document which is untrue, inaccurate or misleading.*

Name of Reporting Person: HCST 01

Job Title: MANAGER

Telephone: 0123456789

Email Address: hsst01@webbank.com

5 **Button Section**

Back Clear Preview PDF Submit Final

1. View Notification and Final Report

- I. Click [Section A : Medical Device Recall Report Form](#) to display the submitted Notification and Follow-Up Report.

2. Section F : Final Report Section

- I. Section F will be display as below:

Section F : Final Report Section

1. Has the Recall exercise been complete* Yes No

2. Status of the device * Returner to manufacturer Disposed Consumed Other (specify)

3. The method of disposal for the recalled products*

4. Final risk evaluation (Note: if different from the initial risk evaluation)

5. Proposed action(s) to prevent recurrence of the problem*

Table of Final Device Status
($x + a) = (p + q + r)$)

(Establishment may download the template excel file & upload at given file section)

1. **Template** Template for Table of Final Device Status.xls [Download](#)
2. **Example** Example for Table of Final Device Status.xls [Download](#)

No.	Product Number / Catalogue Number	Lot / Batch No.	Total affected unit ($x = x+y$)	Quantity remaining in warehouse (x)	Quantity Sold ($y = a+b+c$)	Quantity Recalled (a)	Quantity consumed by customers (b)	Quantity Unidentified (c)	Quantity Disposed (p)	Quantity Returned (q)	Quantity Recycled (r)
No Table of Final Device Status to display											
Total			0	0	0	0	0	0	0	0	0

Add Final Device Status

7. Justification on total quantity of unidentified device
(Only if applicable)

Supporting Document

8. Evidence of returning affected device to the manufacturer

Browse... No files selected.

* No upload file will delete all previous files.
 * Multiple files upload are allowed but the maximum size of the total uploaded must not exceed 10MB.

9. Evidence of disposal process

Browse... No files selected.

* No upload file will delete all previous files.
 * Multiple files upload are allowed but the maximum size of the total uploaded must not exceed 10MB.

10. Evidence of device consumed

Browse... No files selected.

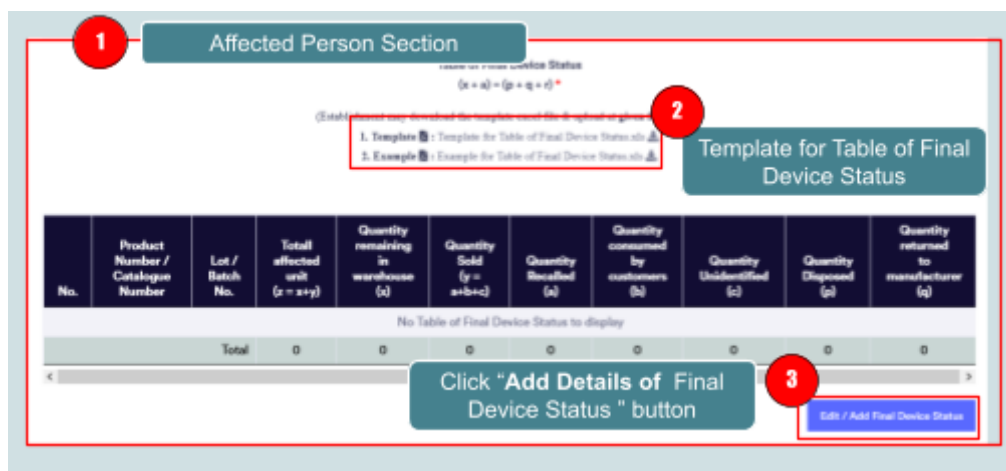
* No upload file will delete all previous files.
 * Multiple files upload are allowed but the maximum size of the total uploaded must not exceed 10MB.

11. Health risk assessment report
(Only if different from the actual risk evaluation)

Browse... No files selected.

* No upload file will delete all previous files.
 * Multiple files upload are allowed but the maximum size of the total uploaded must not exceed 10MB.

- II. User are required to fill in all fields that marked with an asterisk (*).
- III. Table of Final Device Status:

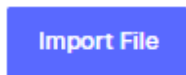


- The Table of Final Device Status will be displayed as above.
- There are two (2) template for Table of Final Device Status that user can download which are:
 - Example for Table of Final Device Status
 - Template for Table of Final Device Status
- Users are required to use the template provided to upload it in the table.
- By clicking **Edit / Add Final Device Status** button, the system will display Details of Final Device Status page shown as below:





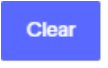
- In the Upload File Section, users can choose the file that needs to be uploaded by clicking **Choose File** button and **Import File**

button will be enabled after the user chooses the file. Then click



button to import the file in the table.

- In the Uploaded File Section, it will display the file that the user uploads.
- In the Action column, it has two (2) button that user can use:
 - User can click  button to update the affected person in the table and the system will display the popup to update the device detail status shown as below:

- Click the  button to close the popup.
- Click the  button to clear all the information.

- Click the **Update** button to update the information.
- User can click the **Delete** button to delete the information from the table.
- Click the **Next** button to back to the previous page section F.

IV. The updated Table of Final Device Status will be displayed in Section F as shown below:

Table of Final Device Status
 $(x + y) = (p + q + r)$ *

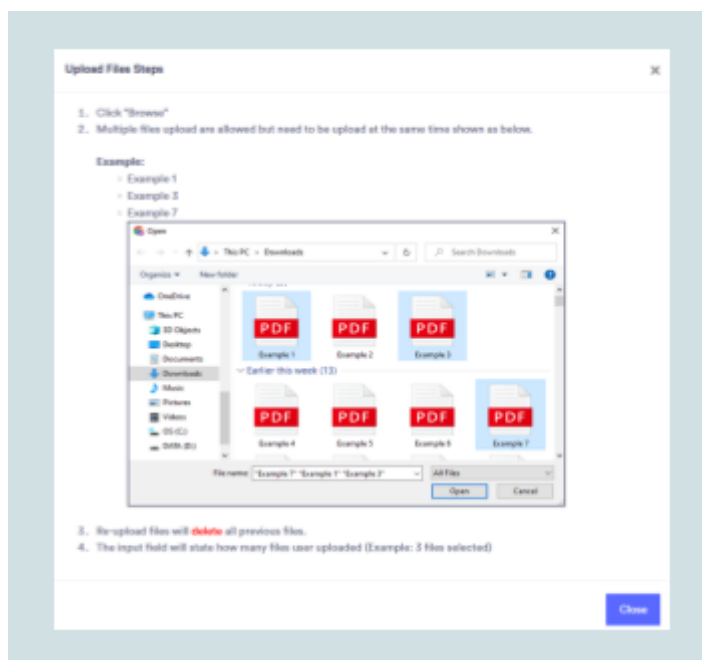
(Establishment may download the template excel file & upload at given file section)

1. **Template** Template for Table of Final Device Status.xls
2. **Example** Example for Table of Final Device Status.xls

No.	Product Number / Catalogue Number	Lot / Batch No.	Total affected unit (x+y)	Quantity remaining in warehouse (x)	Quantity Sold (y = a+b+c)	Quantity Recalled (a)	Quantity consumed by customers (b)	Quantity Unidentified (c)	Quantity Disposed (d)
1.	AIMB-26-028	1025804, 10255109	100	30	70	50	20	0	80
Total			100	30	70	50	20	0	80

Edit / Add Final Device Status

- V. Click **Edit / Add Final Device Status** button if users want to edit add details of the affected person.
- VI. User can click the button to get more information about multiple or single file upload. The pop-up will be displayed as below:
 - Multiple upload files steps



3. Declaration

I. Declaration section will be display as below:

Declaration

I hereby attest that the information and attachment provided on this reporting is / are correct, completed and current to this date. *

I understand and acknowledge that is an offence under Section 76 of Act 732, to make signs or furnish any declaration, or other document which is untrue, inaccurate or misleading. *

Person Responsible for the Establishment: HOST GH

Job Title: MANAGER

Telephone: 0123456789

Email Address: hostGH@webunbung.com

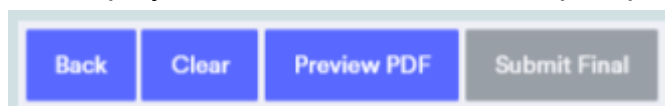
II. User are required to tick the checkbox that marked with an asterisk (*) before submitting the report.


III. In this section, the system will display person responsible details which are:

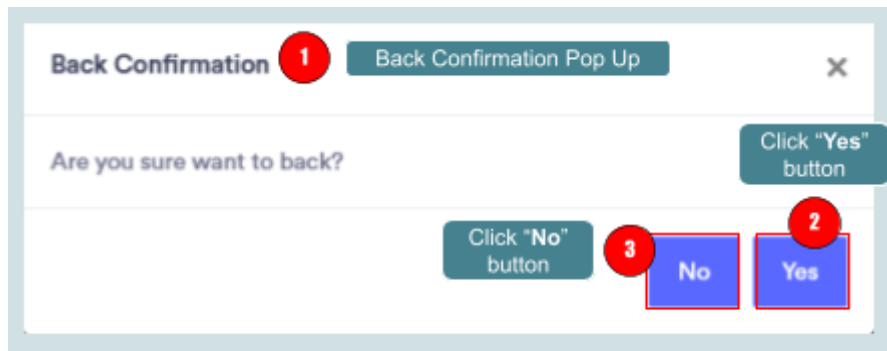
- Person Responsible for the Establishment
- Job Title
- Telephone
- Email Address

4. Button Section




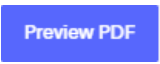

I. This section displays all buttons in the Follow-Up Report.

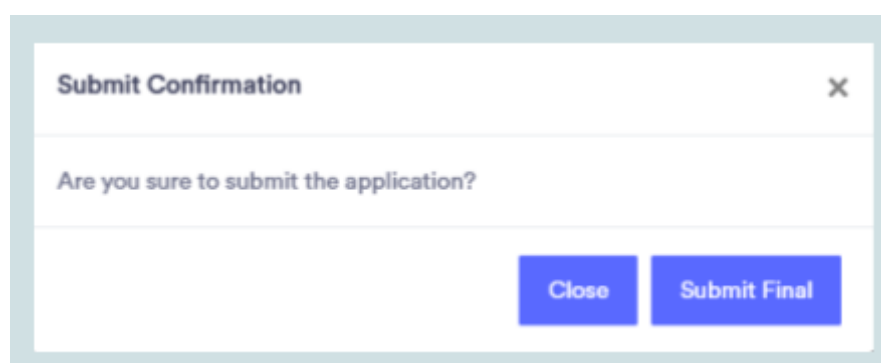


- II. Click  button to go back to the previous page that will be display as below:




➤ Back Confirmation pop-up.

- Click the  button to go back to the next page.
 - Click the  button to stay on the same page.
- III. Click the  button to clear all the information in the report except the default value.
- IV. Click the  button to view the report in Portable Document Format (PDF) format.
- V. Click the  button to submit the follow-up report. This button will be enabled if the user tick the checkbox in the Declaration section. Double confirmation pop-up that will be display as below:



5.4 VIEW RECALL REPORT

- a. Click the  button to view the reporting and the view page will be displayed as below:

1 View Report

Medical Device Recall Form

Section A: Medical Device Recall Report Form

1. MDA Recall Reference Number	MDA/Recall/P02H-66238329-2022
2. Recall Initiated by	Authority (Mandatory Recall) • MDA Ref No: try auto save • 3f920560-06ab-42b3-be20-872898aaa03c (MDA_Recall_P02H_66238329_2022) [Pw780qj].pdf
3. Type of Report	Final

Section B: Establishment Details

1. MDA Establishment License No.	KP-HOST011
2. Name of establishment	Medical Device Authority Development Team (ICT)
3. Establishment Address	011, JALAN CYBERIA 1, CYBERJAYA63000, SELANGOR
4. Contact Person Name	HOST 011
5. Job Title	MANAGER
6. Tel No.	0123456789
7. Fax No.	0123456789
8. Email Address	host011@wbumbung.com
9. CAB Name	CARE CERTIFICATION INTERNATIONAL(M) SDN.BHD

Declaration

I hereby attest that the information and attachment provided on this reporting is / are correct, completed and current to this date .

I understand and acknowledge that it is an offence under Section 76 of Act 737, to make sign or furnish any declaration, or other document which is untrue, inaccurate or misleading.

Person Responsible for the Establishment: HOST 011

Job Title: MANAGER

Telephone: 0123456789

Email Address: host011@wbumbung.com

Click "Preview PDF" button

Click "Back" button

2 **3**

1. View the Recall Report.
2. Click the **Back** button to go back to the previous page.
3. Click the **Preview PDF** button to view the report in Portable Document Format (PDF) format (Refer to [5.5 PREVIEW PDF](#)).

5.5 PREVIEW PDF

5.5.1 Preview Recall Report

- a. There are two (2) types of Preview PDF:

1. Preview PDF for Draft Report is shown as below:

The screenshot shows a 'Medical Device Recall Report' form. At the top, there is a logo for the Medical Device Authority Malaysia. Below the logo, the title 'Medical Device Recall Report' is centered. A table at the top contains the 'MDA Recall Reference Number' as 'MDA/Recall/P0211-65238329-2022'. The form is divided into two main sections: 'Section A: Medical Device Recall Report Form' and 'Section B: Establishment Details'. Section A contains two rows: '1. Recall Initiated by' with details for an Authority (Mandatory Recall) and a file link, and '2. Type of Report' with the value 'Final'. Section B contains nine rows of establishment details, including license number, name, address, contact person, job title, and phone numbers. A large red 'Draft' watermark is overlaid diagonally across the entire form.

MDA Recall Reference Number.	
MDA/Recall/P0211-65238329-2022	
Section A: Medical Device Recall Report Form	
1. Recall Initiated by	Authority (Mandatory Recall) MDA Ref No: try auto save • 3f920560-06ab-42b3-ba20-672898aa01c (MDA_Recall_P0211-65238329_2022) (cPw: 10qb).pdf
2. Type of Report	Final
Section B : Establishment Details	
1. MDA Establishment License No.	KP-HOST011
2. Name of establishment	Medical Device Authority Development Team (ICT)
3. Establishment Address	011, JALAN CYBERIA 1, CYBERJAYA63000, SELANGOR
4. Contact Person Name	HOST 011
5. Job Title	MANAGER
6. Tel No.	0123456789
7. Fax No.	0123456789
8. Email Address	host011@sebung.com
9. CAB Name	CARE CERTIFICATION INTERNATIONAL(M) SDN.BHD

- I. The Declaration Section will not be included in the Preview PDF for Draft Report.

2. Preview PDF for Submitted Report.

Section A: Medical Device Recall Report Form	
1. Recall Initiated by	Establishment (Voluntary Recall)
2. Type of Report	Final

Section B: Establishment Details	
1. MDA Establishment License No.	KP-HOST011
2. Name of establishment	Medical Device Authority Development Team (ICT)
3. Establishment Address	011, JALAN CYBERIA 1, CYBERJAYA63000, SELANGOR
4. Contact Person Name	HOST 011
5. Job Title	MANAGER
6. Tel No.	0123456789
7. Fax No.	0123456789
8. Email Address	host011@sebumbung.com
9. CAI Name	CARE CERTIFICATION INTERNATIONAL(M) SDN.BHD

5.6 EDIT REPORT

5.6.1 Edit Notification Report

- a. A part of the edit Notification Report page will be shown below.

1. Users can update all information in this report.
2. The process to submit the updated report will be the same as submitting a new report. (Refer to [5.3.1 Notification Report](#)).

5.6.2 Edit Follow-Up Report

- a. A part of the edit Follow-Up Report page will be shown below.

The screenshot displays a form with the following sections:

- 3. List of impacted countries** (Note: If any and user may choose more than 1 country.)
Nothing selected
Selected countries:
 - Algeria
 - Barbados
 - Belarus
- 4. Proposed date of completion of Recall in Malaysia *** (Note: Complete retrieval product from the market)
22 / 04 / 2022
- 5. Expected date to submit final report to the Authority ***
dd / mm / yyyy
- 6. The method of quarantine and segregation of recalled products ***
[Empty text area]

1. Users can update all information in this report.
2. The process to submit the updated report will be the same as submitting a Follow-Up report. (Refer to [5.3.2 Follow-Up Report](#)).

5.6.3 Edit Final Report

- a. A part of the edit Final Report page will be shown below:

The screenshot displays a form with the following sections:

- 1. Has the Recall exercise been complete ***
 Yes
Date recall completed * 05 / 04 / 2022
 No
- 2. Status of the device ***
 Returner to manufacturer
 Disposed
 Consumed
 Other (specify)
- 3. The method of disposal for the recalled products ***
test

1. Users can update all information in this report.
2. The process to submit the updated report will be the same as submitting a Final report. (Refer to [5.3.3.Final Report](#)).

5.6.4 Return from MDA

- a. A part of the edit Return from MDA Report page will be shown below:

Section F : Final Report Section		
1. Has the Recall exercise been complete *	<input checked="" type="radio"/> Yes <input type="radio"/> No	• Remark: No
2. Status of the device *	<input checked="" type="checkbox"/> Returner to manufacturer <input checked="" type="checkbox"/> Disposed <input type="checkbox"/> Consumed <input type="checkbox"/> Other (specify)	• Remark: No
3. The method of disposal for the recalled products *	Testing	• Remark: No
4. Final risk evaluation <small>(Note: if different from the initial risk evaluation)</small>	N/A	• Remark: Yes
5. Proposed action(s) to prevent recurrence of the problem *	Testing	• Remark: Yes

Remark section

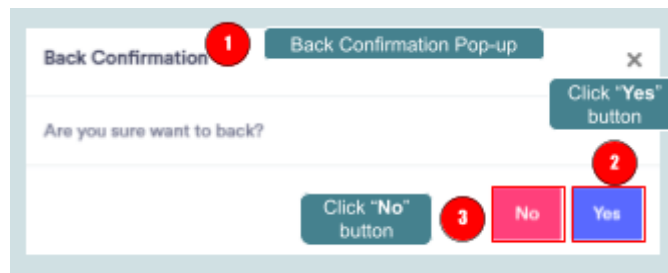
Declaration	
1. Attestation	<input type="checkbox"/> I hereby attest that the information and attachment provided on this reporting is / are correct, completed and current to this date. * <input type="checkbox"/> I understand and acknowledge that is an offence under Section 76 of Act 732, to make sign or furnish any declaration, or other document which is untrue, inaccurate or misleading. *
2. Person Responsible for the Establishment	HOST 011
3. Job Title	MANAGER
4. Telephone	0123456789
5. Email Address	host011@sebung.com

Button Section

1. Users can only update the information that has a 'No' remark in this report.
2. Button section.
 - I. This section displays all buttons in the Notification Report.

Back	Preview PDF	Submit Report
------	-------------	---------------

- II. Click **Back** button to go back to the previous page. The pop-up will be display as below:

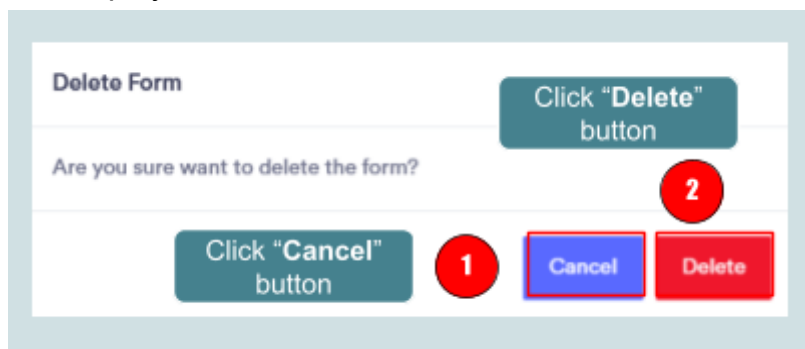


➤ Back Confirmation Pop-up.

- Click the **Yes** button to go back to the previous page.
 - Click the **No** button to stay on the same page.
- III. Click the **Preview PDF** button to view the report in Portable Document Format (PDF) format. (Refer to [4.5.1 Preview Recall Report](#))
- IV. Click the **Submit Report** button to submit the updated report. This button will be enabled if the user tick the checkbox in the Declaration section.

5.7 DELETE REPORT

- a. Delete report only can be made for Draft Notification Report .
- b. Click the **Delete** button to delete the Draft Notification report and the pop-up will be displayed as below:



1. Click the **Cancel** button to close the delete pop-up.
2. Click the **Delete** button to delete the Notification report.

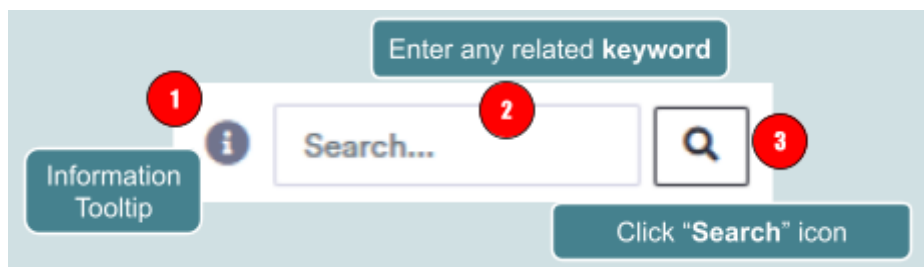
5.8 OVERDUE REPORTING


- a. List of Recall Overdue Reporting Table will be display as below:

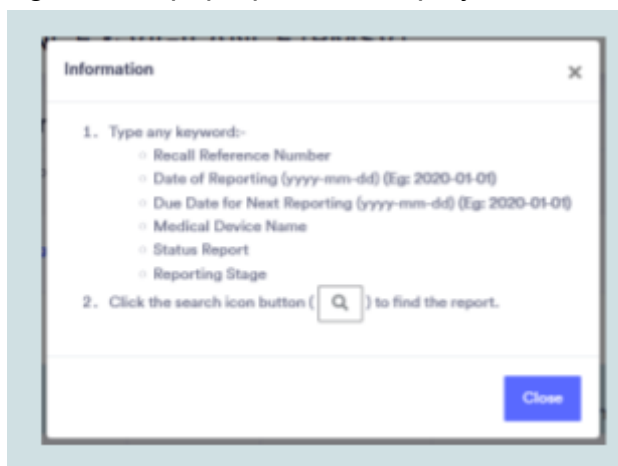
No.	Ref No.	Medical Device Name	Date of Reporting (dd/mm/yy)	Due Date (dd/mm/yy)	Reporting Status	Station	Action
1.	MDA/Recall /P0189-34156688-2022	MEDICAL TEST01B	-	18/03/2022	Final	Almost Overdue	Log, View, Edit, Extend Date (0/2)
2.	MDA/Recall /P0197-75458948-2022	MEDICAL TEST01C	-	26/02/2022	Follow Up	Overdue	Log, View, Extend Date (0/2)
3.	MDA/Recall /P0179-10699735-2022	MEDICAL TEST01D	13/02/2022 -	15/03/2022	Notification	Overdue	Log, View, Extend Date (0/2)
4.	MDA/Recall /P0188-98321595-2022	MEDICAL TEST01C	-	23/05/2022	Follow Up	Overdue	Log, View, Extend Date (1/2)




Showing 4 of 4 entries.

1. Table Filtering shown as below:





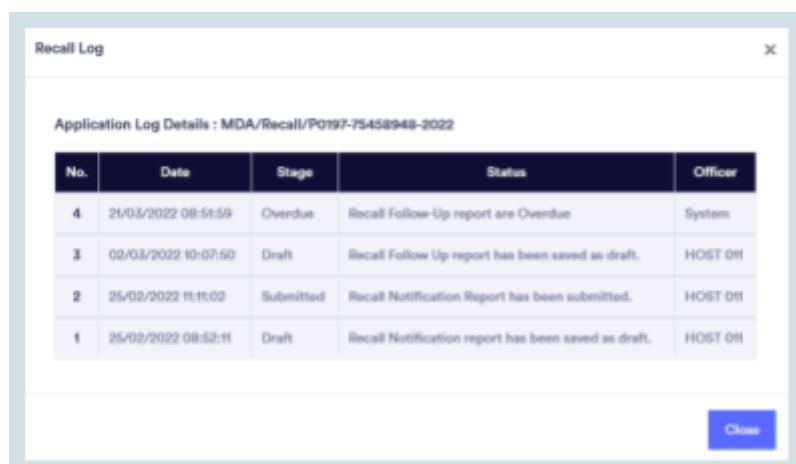
- I. User can click the  icon to get more information related to table filtering and the pop-up will be displayed as below:



- Click the  button or  button to close the pop-up.
- II. Enter any related keyword (based on information given).
- III. Click the  icon and the system will display the result.



2. Action Button for Overdue Status:

- I. Click the  button to view the report. (Refer to [5.4 VIEW RECALL REPORT](#))
- II. Click the  button to view the reporting log and the pop-up will be displayed as below:



The screenshot shows a 'Recall Log' window with a title bar containing 'Recall Log' and a close button. Below the title bar, the text 'Application Log Details : MDA/Recall/P0197-75458948-2022' is displayed. A table with five columns (No., Date, Stage, Status, Officer) contains four rows of data. A 'Close' button is located at the bottom right of the window.

No.	Date	Stage	Status	Officer
4	21/03/2022 08:51:59	Overdue	Recall Follow-Up report are Overdue	System
3	09/03/2022 10:07:50	Draft	Recall Follow Up report has been saved as draft.	HOST 011
2	25/02/2022 11:11:02	Submitted	Recall Notification Report has been submitted.	HOST 011
1	25/02/2022 08:52:11	Draft	Recall Notification report has been saved as draft.	HOST 011

- Click the  button to close the pop-up.
- III. Click the  button to request extension time and the pop-up will be displayed as below:



Do you need more extension time? (0/2)

****REMINDER:** Establishment can request to extend the date up two (2) times only for one (1) application.



Request for extension time:* 30 days
 90 days
 120 days

Justification*

Clear Confirm

- User are required to fill in all fields that marked with an asterisk (*).
- Click the  button to clear all the information.
- Click the  button to submit the request for extension time.

3. Action Button for Almost Overdue Status:

- Click the  button to view the report. (Refer to [5.4 VIEW RECALL REPORT](#))
- Click the  button to view the reporting log and the pop-up will be displayed as below:

Recall Log

Application Log Details : MDA/Recall/P0197-75458948-2022

No.	Date	Stage	Status	Officer
4	21/03/2022 08:51:59	Overdue	Recall Follow-Up report are Overdue	System
3	02/03/2022 10:07:50	Draft	Recall Follow Up report has been saved as draft.	HOST 011
2	25/02/2022 11:11:02	Submitted	Recall Notification Report has been submitted.	HOST 011
1	25/02/2022 08:52:11	Draft	Recall Notification report has been saved as draft.	HOST 011

Close

- Click the  button to close the pop-up.

III. If the report status is Almost Overdue, user have two (2) actions to choose which are:

- Click the **Edit** button to continue the report and submit the report before Overdue (Refer to [5.6 EDIT](#)).
- Click the **Extend Date (0/2)** button to request extension time and the pop-up will be displayed as below:

- User are required to fill in all fields that marked with an asterisk (*).
- Click the **Clear** button to clear all the information.
- Click the **Confirm** button to submit the request for extension time.

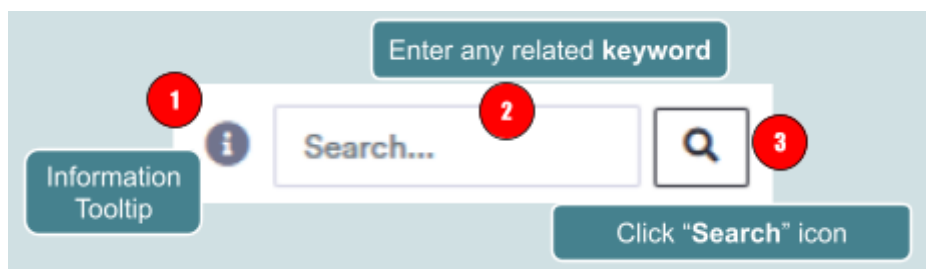
5.9 CLOSURE REPORTING


a. List of Recall Closure Reporting table will be display as above:

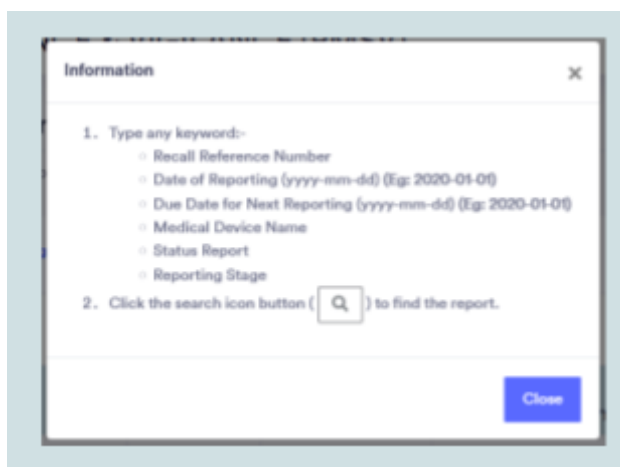
No.	Ref No.	Medical Device Name	Date of Reporting (dd/mm/yy)	Due Date (dd/mm/yy)	Reporting Stage	Status	Action
1.	MDA/Recall /PO177-71029181-2022	MEDICAL TESTONC	15/02/2022	24/03/2022	Final	Completed	<ul style="list-style-type: none"> Log View Acknowledgement Letter Closure Letter



Showing 1 of 1 entries.


1. Table Filtering shown as below:





- I. User can click the  icon to get more information related to table filtering and the pop-up will be displayed as below:



- Click the  button or  button to close the pop-up.

- II. Enter any related keyword (based on information given).
- III. Click the  icon and the system will display the result.

2. Action Button

- I. Click the  button to view the report. (Refer to [5.4 VIEW RECALL REPORT](#))
- II. Click the  button to view the reporting log and the pop-up will be displayed as below:


Recall Log

Application Log Details : MDA/Recall/P0177-71029181-2022

No.	Date	Stage	Status	Officer
9	13/02/2022 21:41:03	Submitted	Recall Final Report has been submitted.	HOST 011
8	13/02/2022 21:18:09	Draft	Recall Final report has been saved as draft.	HOST 011
7	13/02/2022 21:14:51	Draft	Recall Final report has been saved as draft.	HOST 011
6	13/02/2022 21:05:42	Draft	Recall Final report has been saved as draft.	HOST 011
5	13/02/2022 20:17:47	Draft	Recall Final report has been saved as draft.	HOST 011
4	13/02/2022 20:15:40	Submitted	Recall Follow Up report has been submitted.	HOST 011
3	13/02/2022 20:14:24	Draft	Recall Follow Up report has been saved as draft.	HOST 011
2	13/02/2022 20:09:07	Submitted	Recall Notification Report has been submitted.	HOST 011
1	10/02/2022 14:21:31	Draft	Recall Notification report has been saved as draft.	HOST 011

Close

➤ Click the  button to close the pop-up.

III. Click the  button to view the acknowledgement letter that the system will generate for the user. The acknowledgement letter will be displayed as below:


 Pejabat Bersekutu Peranan
PELUBANG
 Medical Device Authority
 (Majlis/Divisi Pengawasan MALAYSIA)
 Ministry of Health Malaysia
 Area 6, Prima 6, Prima Avenue 6,
 Blok S&T, Pavilion APTC,
 40000 Cyberjaya,
 Malaysia.

Tel: 03-89593000-03000
 Faks: 03-89593000-03000
 Portal: www.mda.gov.my
 Email: mda@mda.gov.my


Our Reference Number : MDA/Recall/P0177-71029181-2022
 Date : 05/04/2022

HOST 011
 Medical Device Authority Development Team (ICT)
 011, JALAN CYBERIA 1, CYBERJAYA.

Sir/Madam,

Acknowledgement of Medical Device Recall.

With reference to the above, please be informed that our office has received a final on the following Medical Device Recall by your company on 13/02/2022.

MDA Recall Ref.No : MDA/Recall/P0177-71029181-2022
 Device Name : MEDICAL TEST0HC
 Product No : GMDTESTFORHOST0HC
 Lot No : 10199454, 10199470, 10203866, 10216004, 10222621, 10225098, 10225099,
 10236496, 10248988, 10248989, 10261154, 10262338, 10262339, 10262340,
 10266633X
 Recall Class : Final
 MDA Registration Number : HOST011


2. We hope that your company will monitor closely the effectiveness of the product recall and the communication to your affected customers.
 3. We appreciate your effort in order to comply with the requirements of Act 737 and its regulations.

Your cooperation I end with thanks.

Regards

Thank you.

Director
 Registration, Licensing and Enforcement Division
 Medical Device Authority
 Ministry of Health Malaysia
 this is a computer generated. no signature required

- IV. Click the  button to view the closure letter that the system will generate for the user. The closure letter will be displayed as below:



PIRASA BERSEKUTUA PERANI
PERUBATAN
Medical Device Authority
KEMENTERIAN KESEHATAN MALAYSIA
Ministry of Health Malaysia
Ave 5, Prima S, Prima Avenue II,
80000 Johor Bahru, JPD,
80000 Johor Bahru,
Malaysia.

Tel: (+60)6033 0200
Faks: (+60)6033 0205
Portal Rasmi: www.mda.gov.my
Email: mda@mda.gov.my

Medical Device
Malaysia

Our Reference Number : MDA/Recall/PO17-7029181-2022
Date : 2022-04-05

HGSTD01
Medical Device Authority Development Team (DCT)
011, JALAN CYBERA 1, CYBERJAYA

Sir/Madam,

Acknowledgement of Medical Device Recall Closure

With reference to the above, we acknowledge the following report for recall closure by your company.

MDA Recall Ref.No : MDA/Recall/PO17-7029181-2022
Device Name : MEDICAL TESTONIC
Product No : GMDTESTFORHSTONIC
Lot No : 10199414, 10199410, 10208416, 10216004, 10222421, 10228098, 10230189,
10234491, 10244188, 10248189, 10261154, 10262338, 10262339, 10262340,
10206533X
Recall Class : Final
MDA Registration Number : HGSTD01

2. We understand that Medical Device Authority Development Team (DCT) has recalled the above affected device in between 15/02/2022 to 24/03/2022.

3. We would like to inform Medical Device Authority Development Team (DCT) that the action taken in this recall is appropriately done based on the level of risk that have been identified.

Your cooperation is end with thanks.

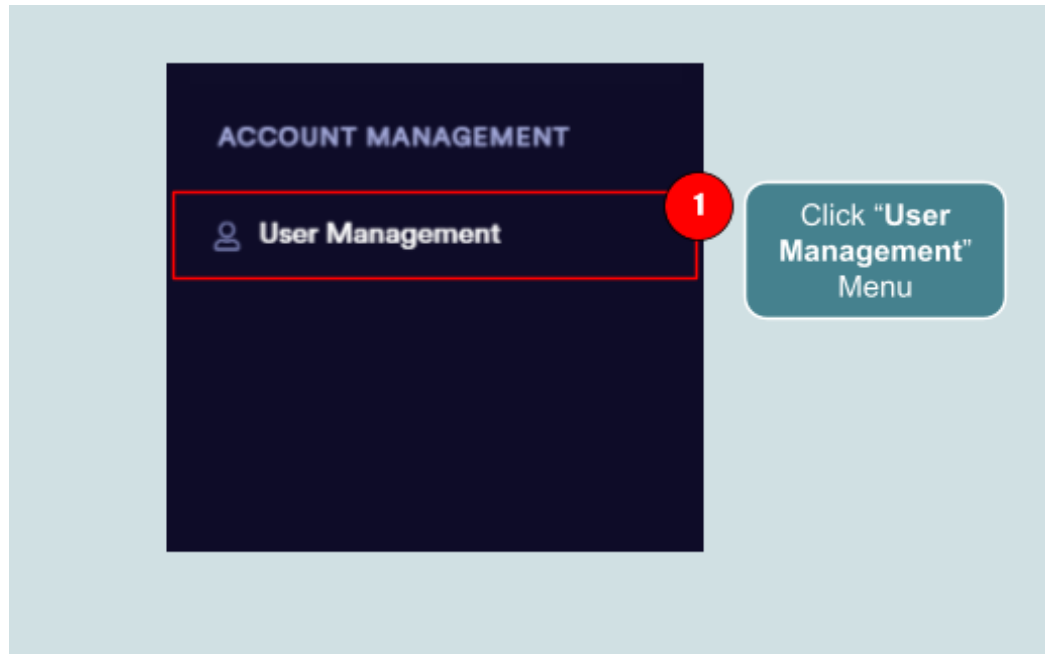
Regards
Thank you.

Director
Registration, Licensing and Enforcement Division
Medical Device Authority
Ministry of Health Malaysia

This is a computer generated document. No signature is required

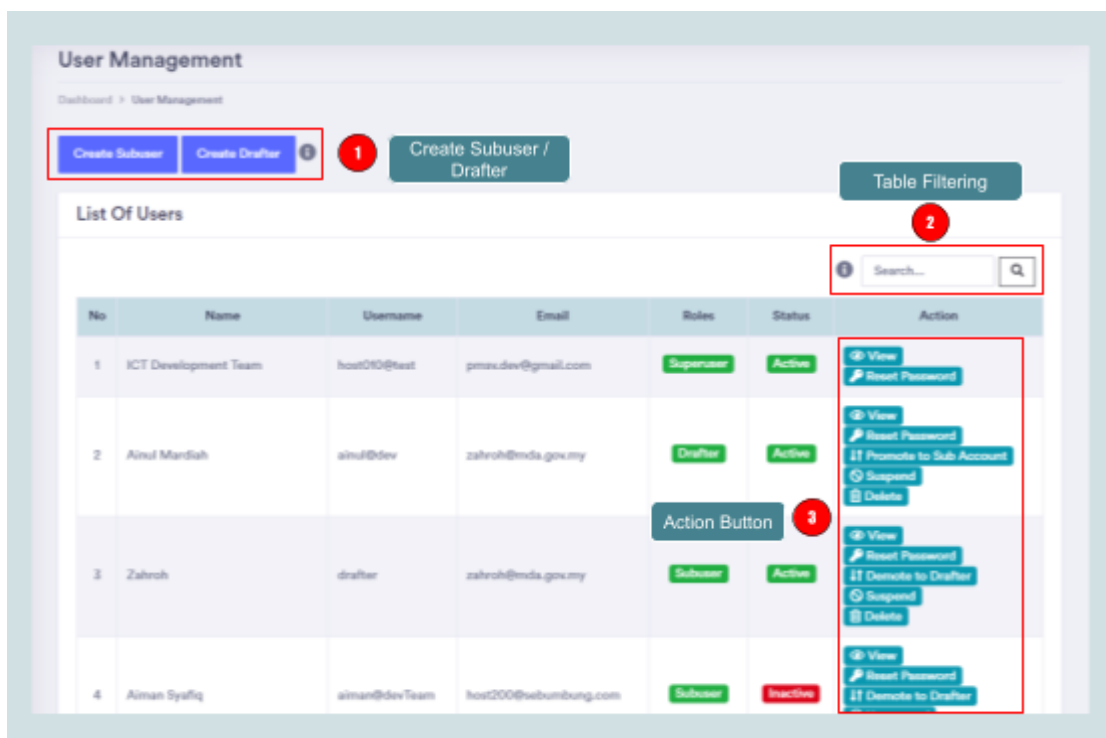
6 ADMIN








6.1 USER MANAGEMENT



a. The Sidebar Menu will be displayed as above:

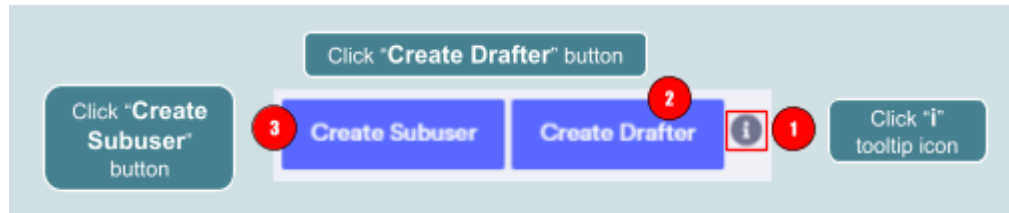
1. Click **User Management** menu and the system will redirect users and display the user management page.



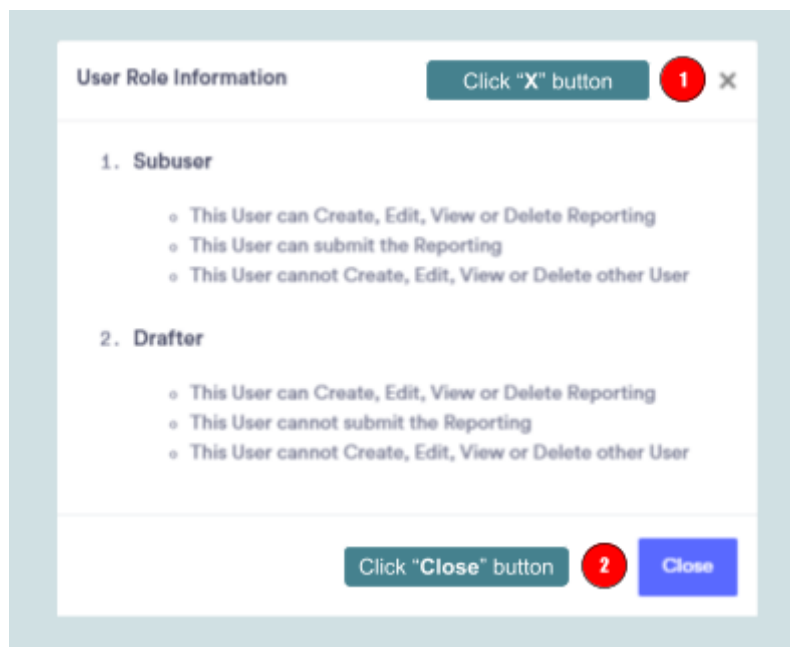
- b. The User Management page will be displayed as above:
1. Create Subuser / Drafter. (Refer to [6.1.1 Create User](#))
 2. Table Filtering. (Refer to [6.1.2 Table Filtering](#))
 3. Action button
 - I. Click the  **View** button to view the user information. (Refer to [6.1.3 View](#))
 - II. Click the  **Reset Password** button to reset the password. (Refer to [6.1.4 Reset Password](#))
 - III. Click the  **Demote to Drafter** button to demote to drafter. (Refer to [6.1.5 Demote to Drafter](#))
 - IV. Click the  **Promote to Sub Account** button to promote to subuser. (Refer to [6.1.6 Promote to Subuser](#))
 - V. Click the  **Suspend** button to Suspend the user. (Refer to [6.1.7 Suspend](#))
 - VI. Click the  **Unsuspend** button to Unsuspend the user. (Refer to [6.1.8 Unsuspend](#))
 - VII. Click the  **Delete** button to remove / Delete the user. (Refer to [6.1.9 Delete](#))
-

6.1.1 Create User

- a. There are two type of user which is Subuser and Drafter

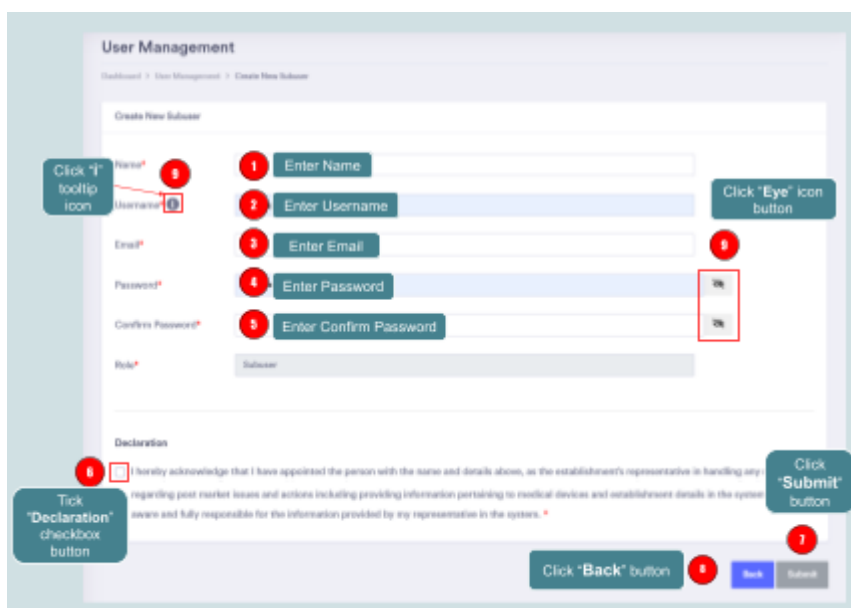



1. User can click **i** icon and the pop-up information related to search will display as below:

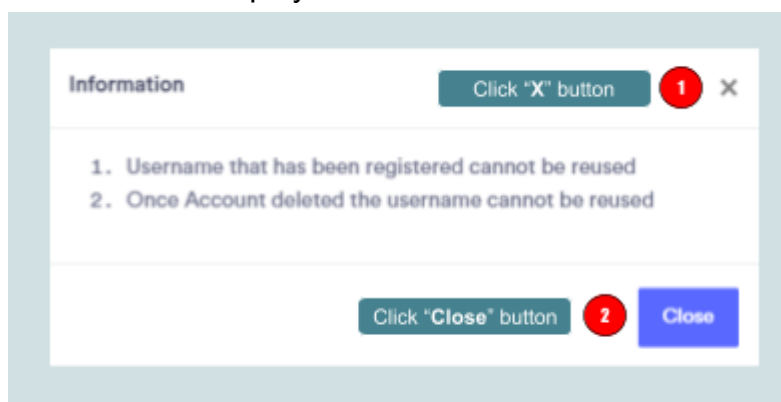


- I. Click **X** button or **Close** button to close the pop-up.


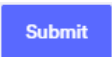
2. Create Subuser




- I. Please enter the Name.
- II. Please enter the Username.
- III. User can click  icon and the pop-up information related to the username will display as below:

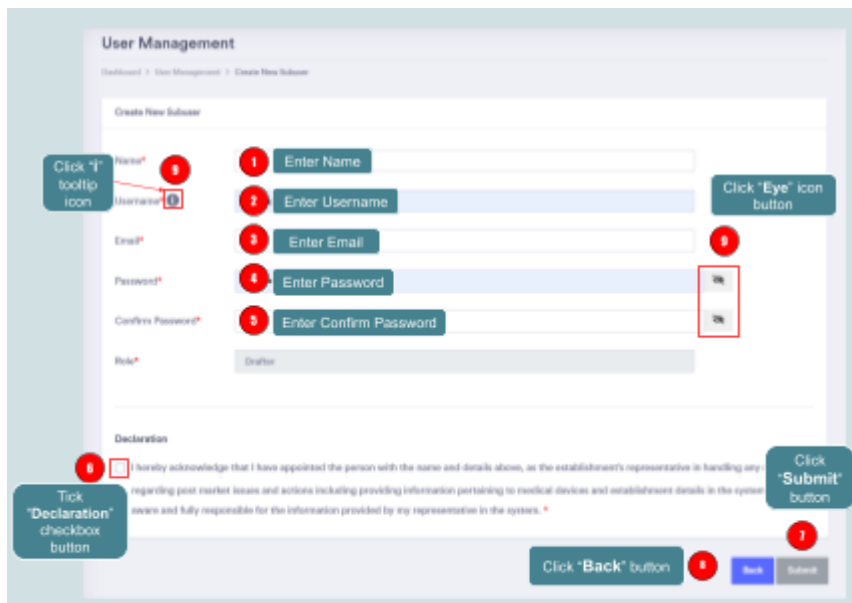



➤ Click  button or  button to close the pop-up.

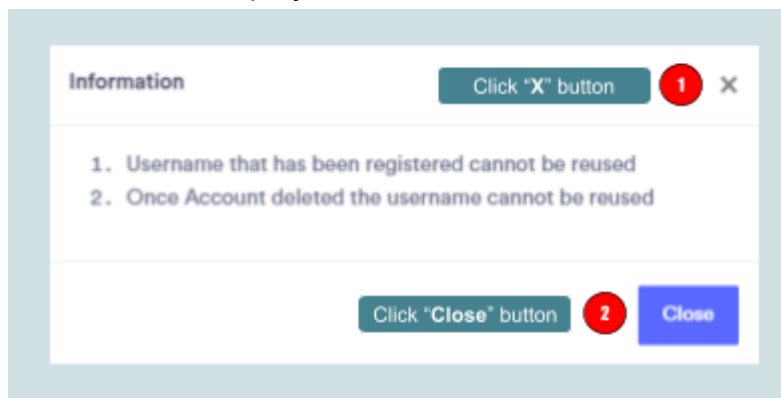
- IV. Please enter the Email.
- V. Please enter the Password.
- VI. Please enter the Confirm Password.
- VII. Click  icon button, to view the password that you enter.
- VIII. Tick declaration checkbox button and the submit button will enable.
- IX. Click the  button and the system will create a User.

- X. Click the  button to go back to the previous page.


3. Create Drafter

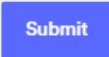



- I. Please enter the Name.
- II. Please enter the Username.
- III. User can click  icon and the pop-up information related to the username will display as below:




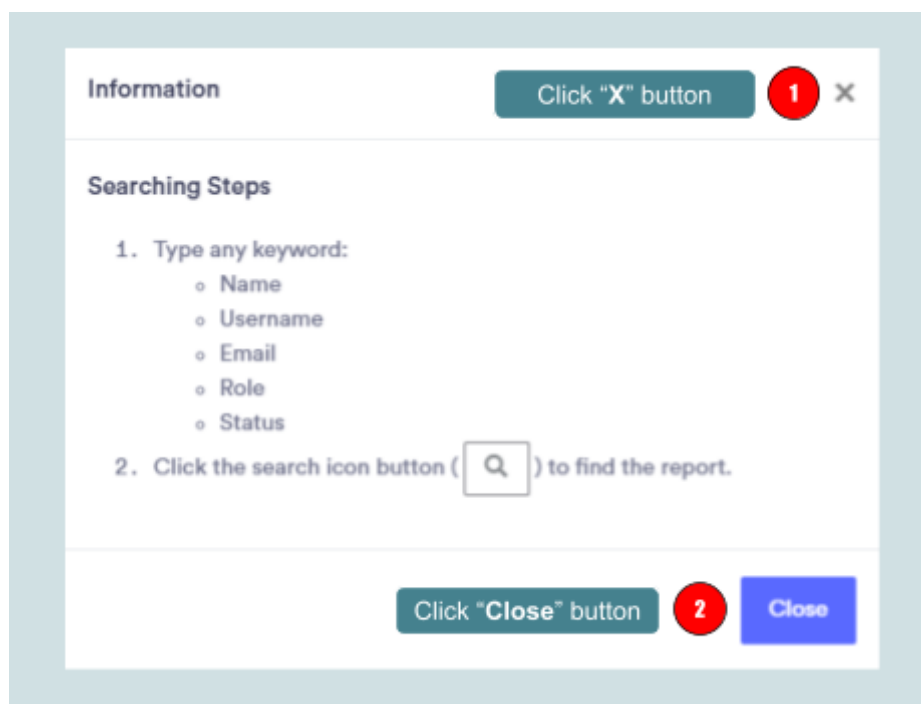
- Click  button or  button to close the pop-up.




- IV. Please enter the Email.
- V. Please enter the Password.
- VI. Please enter the Confirm Password.
- VII. Click  icon button, to view the password that you enter.

- VIII. Click the  button and the system will create a User.
- IX. Tick declaration checkbox button and the submit button will enable.
- X. Click the  button to go back to the previous page.


6.1.2 Table Filtering

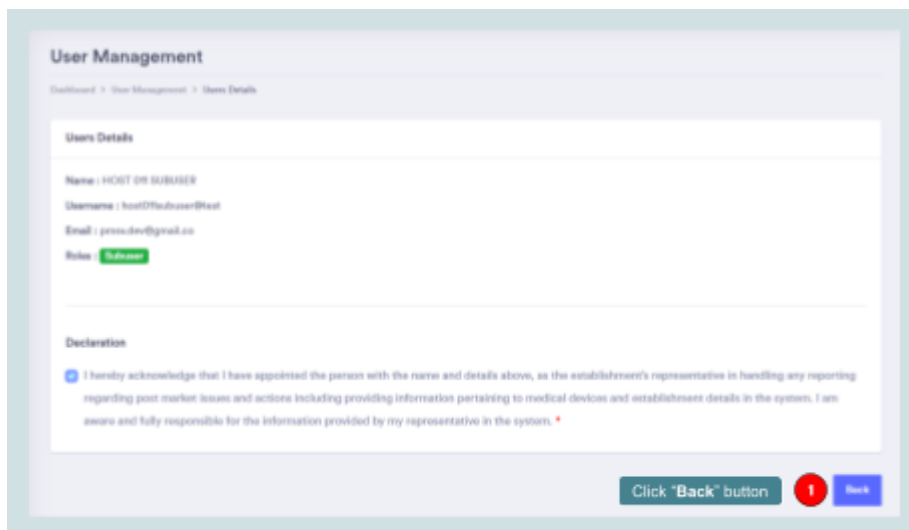
- a. User can click  icon and the pop-up information related to table filtering will display as below:




- 1. Click  button or  button to close the pop-up.
- b. Enter any related keyword (based on information given).
- c. Click  icon and the system will display the result.


6.1.3 View

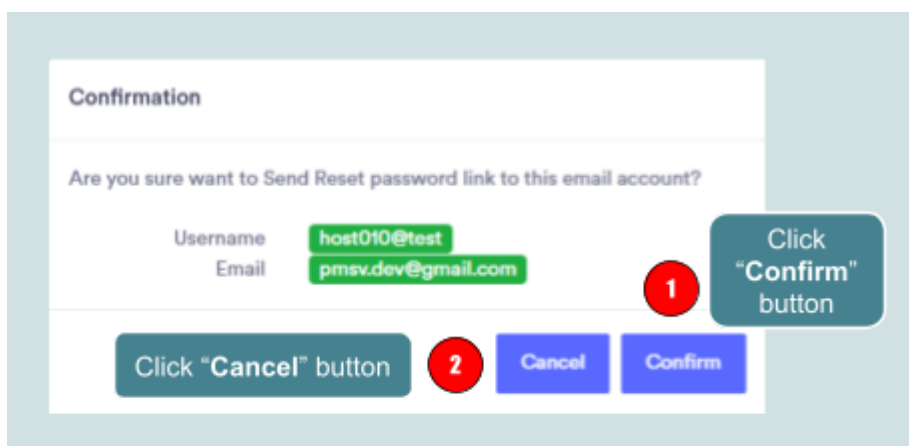
- a. Click the  button to view the User Information and the view page will be shown as below:


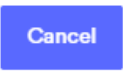


- b. Click  button to go back to the previous page.

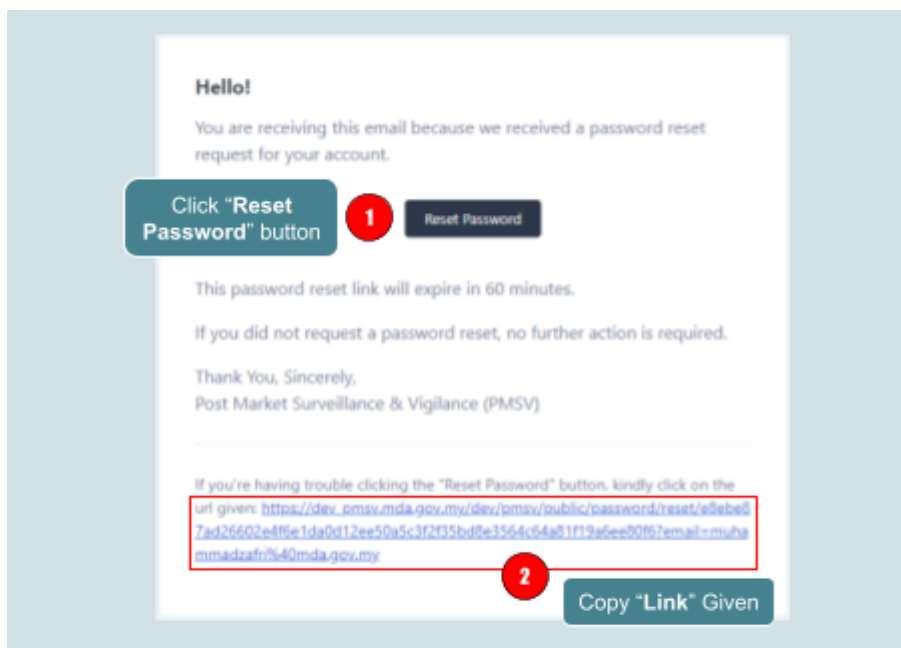
6.1.4 Reset Password

- a. Click the  button to reset the password and a pop-up confirmation will appear as shown below:

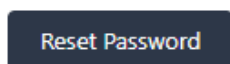


1. Click  button to reset password
2. Click  button to cancel the process and close the pop-up.

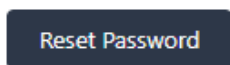
b. The user will received an email as below:



1. To continue with reset password, User need to click the



button or copy the “**Link**” given in the email.



c. After click the button or open the “**Link**” given, the system will displayed as below to proceed for the next step:

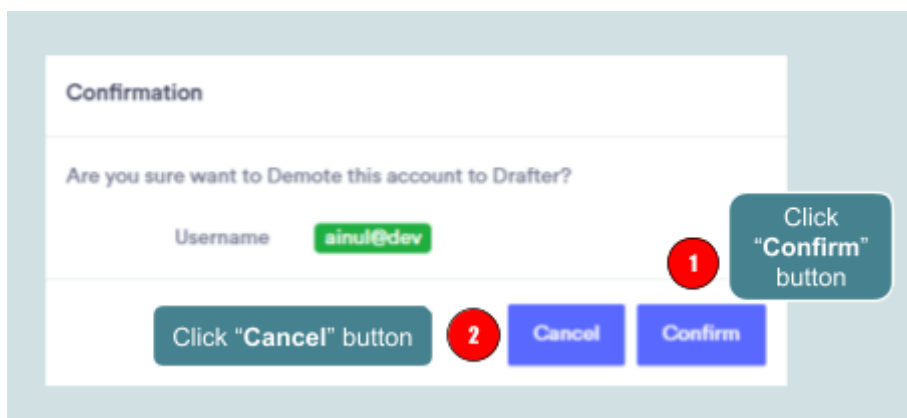


1. Please enter the username.
2. Please enter the new password.
3. Please enter the confirm password.

4. Click the **Reset Password** button. If the reset password is successful the system will redirect the user to the Dashboard (Refer to [2.3 DASHBOARD](#)).

6.1.5 Demote to Drafter

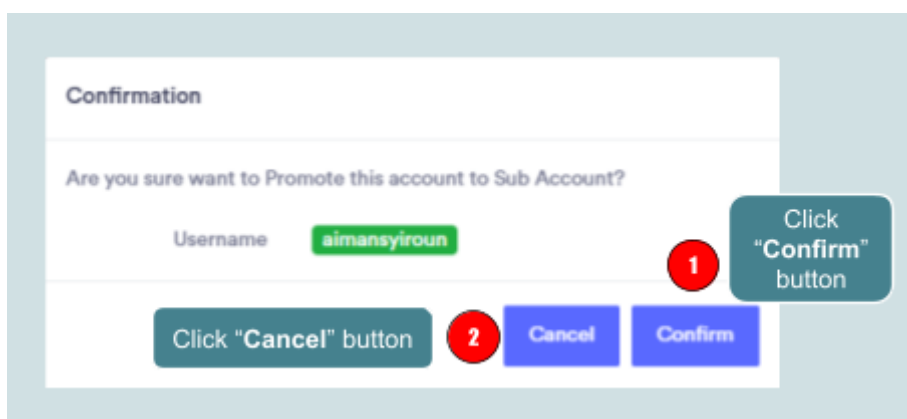
- a. Click the **Demote to Drafter** button to demote the user role from subuser to drafter and The system will show a pop-up confirmation as below:


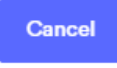


1. Click **Confirm** button to demote the user role from subuser to drafter.
2. Click **Cancel** button to cancel the process and close the pop-up.


6.1.6 Promote to Subuser

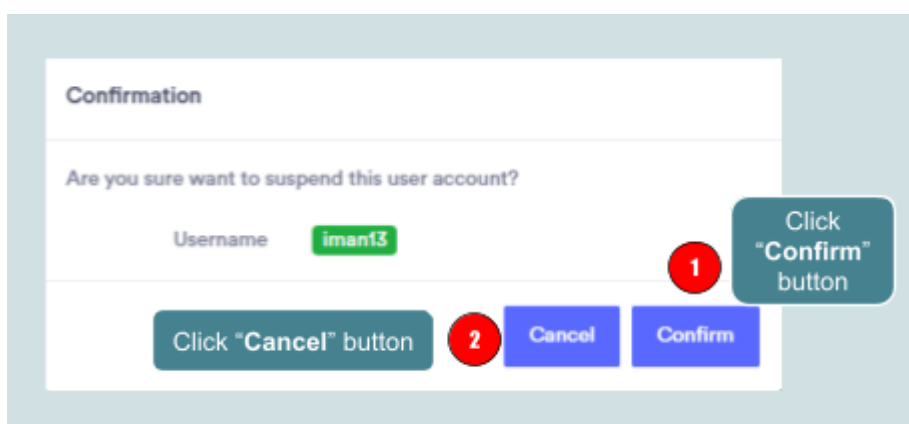
- a. Click the **Promote to Sub Account** button to promote the user role from drafter to subuser and The system will show a pop-up confirmation as below:


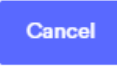


1. Click  button to promote the user role from drafter to subuser.
2. Click  button to cancel the process and close the pop-up.


6.1.7 Suspend

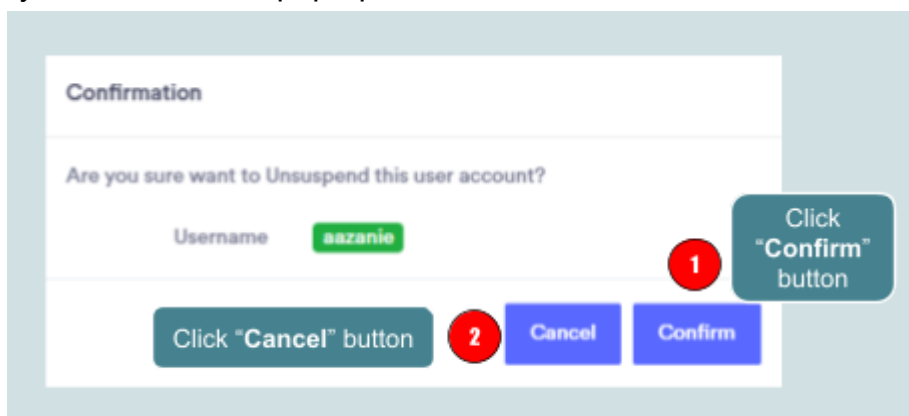
- a. Click the  button to suspend the user account and The system will show a pop-up confirmation as below:


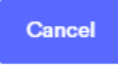


1. Click  button to suspend the user account.
2. Click  button to cancel the process and close the pop-up.


6.1.8 Unsuspend

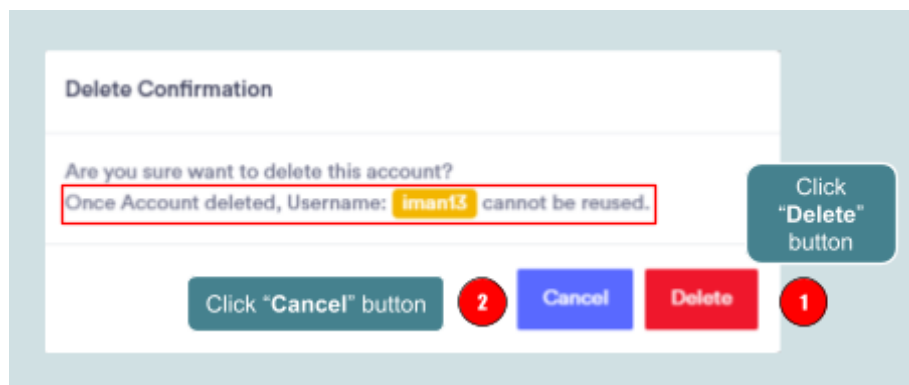
- a. Click the  button to unsuspend the user account and The system will show a pop-up confirmation as below:





1. Click  button to unsuspend the user account.
2. Click  button to cancel the process and close the pop-up.

6.1.9 Delete

- a. Click the  button to remove / Delete the user and The system will show a pop-up confirmation as below:



1. Click  button to unsuspend the user account.
2. Click  button to cancel the process and close the pop-up.