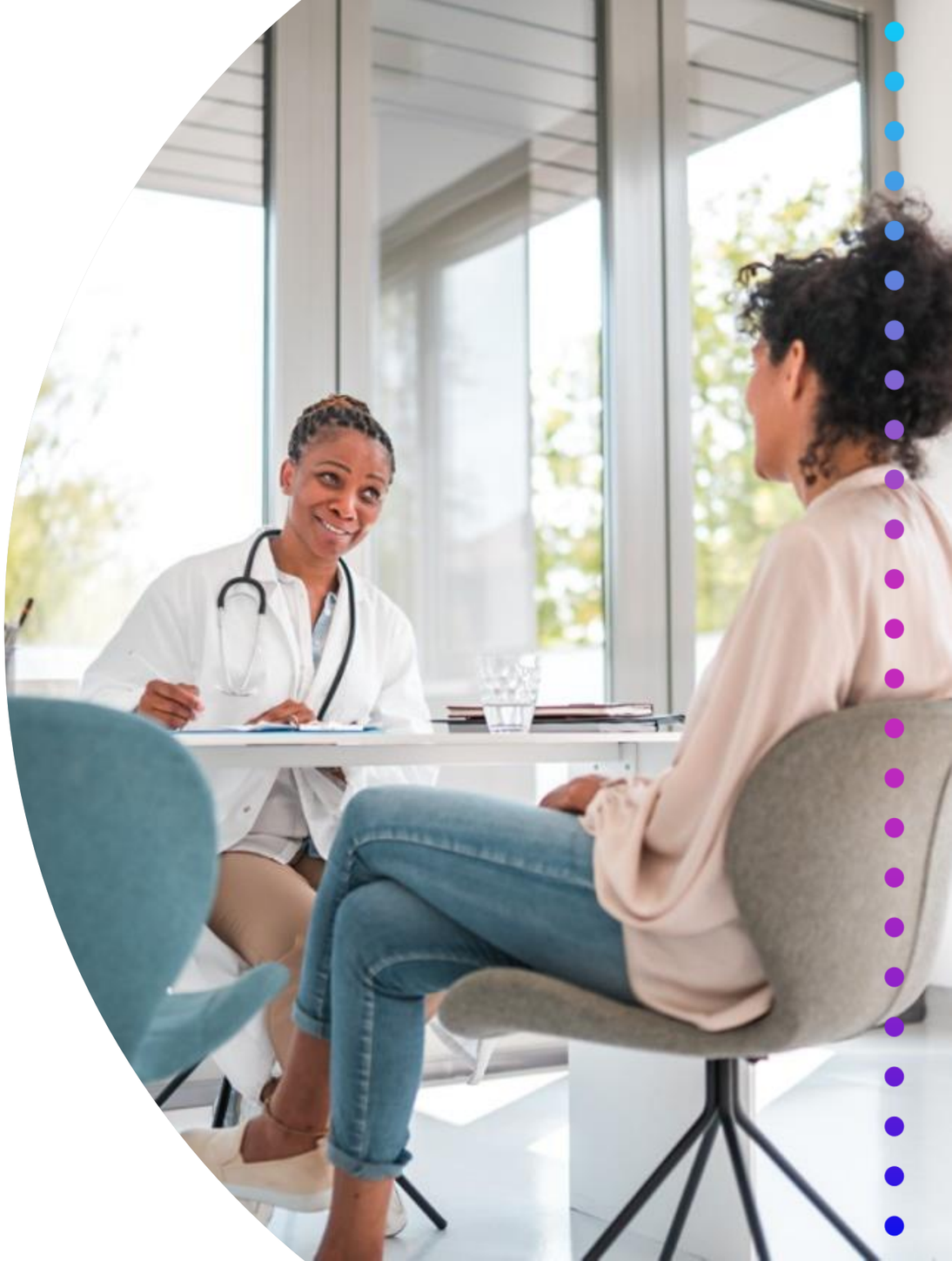
Medtronic

Engineering the extraordinary

Distributors of Medtronic Quality Training and Regulatory Matters



Supplier Team

REGULATORY AND QUALITY CONTRACTUAL REQUIREMENTS

Note: This training provides overall principles related to quality and regulatory contracts. There may be specific requirements in individual contracts for distributors. The requirements in distributor contracts supersede this training material in the event of conflict

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Quality & Regulatory contracts requirements

Basic concepts

Regulatory Documents/Assistance in Regulatory Affairs

- At Medtronic's request and in the name of Medtronic or any designee of Medtronic, DISTRIBUTOR shall make such filings with, and shall use its best efforts to obtain such authorizations and/or consents from any Governmental Authority in the Territory as may be necessary to permit the lawful import, distribution, sale and use of Products in the Territory, including Product registrations and all import licenses and remittance (collectively "Licenses").

- All rights in any License shall, to the extent permitted by Applicable Laws, belong to and be vested exclusively in Medtronic or any Medtronic designee.

- DISTRIBUTOR shall make available to Medtronic all documents provided to any Governmental Authority used to obtain Licenses and shall provide status reports of submission dates and expected and actual approval dates.

- DISTRIBUTOR shall comply with any vigilance requirements under Applicable Law. DISTRIBUTOR shall assist Medtronic in fulfilling vigilance requirements including vigilance reporting if requested by Medtronic.

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Quality & Regulatory contracts requirements

Basic concepts

Regulatory Documents

- DISTRIBUTOR must provide to Medtronic all relevant documentation regarding product complaints and/or a copy of any submitted vigilance report(s) in a timely manner and not later than the time of submission to the regulatory authority. Medtronic reserves the right to request to review the report before submission and DISTRIBUTOR shall take this into account in order to ensure timely submission. Any questions or inquiries from the regulatory authority relating to complaints, vigilance or field actions concerning the Products must be forwarded immediately to Medtronic.

- DISTRIBUTOR shall provide Medtronic with any assistance and information necessary or desirable in Medtronic's opinion to create, improve or preserve the most favorable regulatory environment in the Territory for the distribution of Products, or to communicate with the relevant authorities in the Territory regarding actual or potential individual measures or decisions affecting the distribution of Products.

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Quality & Regulatory contracts requirements

Basic concepts

Minimum Resources, Knowledgeable Representatives

- DISTRIBUTOR shall maintain for the entire forecasted lifetime (as defined in the IFUs) of all Products distributed by DISTRIBUTOR, sufficient qualified human resources, facilities and equipment to fulfill all legal and contractual requirements concerning quality or regulatory aspects of the Products which are or may become applicable to such Products.

- DISTRIBUTOR shall ensure that any representative providing information or instructions concerning Medtronic products to third parties is sufficiently trained and qualified.

- DISTRIBUTOR shall maintain records of training/qualification for each representative for a period of twenty (20) years.

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Quality & Regulatory contracts requirements

Basic concepts

Product Labeling of IFU

- DISTRIBUTOR shall ensure at all times that Products are accompanied by labeling and Instructions For Use (jointly "IFUs") in the language required by Applicable Law in the Territory and shall inform Medtronic of such local language requirements. Where such IFUs are not supplied by Medtronic in the local language, and when required by Applicable Law,

- DISTRIBUTOR shall, at its sole cost and responsibility, ensure that the English language versions of the same provided by Medtronic are translated by a Qualified Technical Translator into the language required by Applicable Law.

- Medtronic shall have the right to the copyright in such translations

- Medtronic shall provide to DISTRIBUTOR such graphic files of IFUs or other electronic text as may be required

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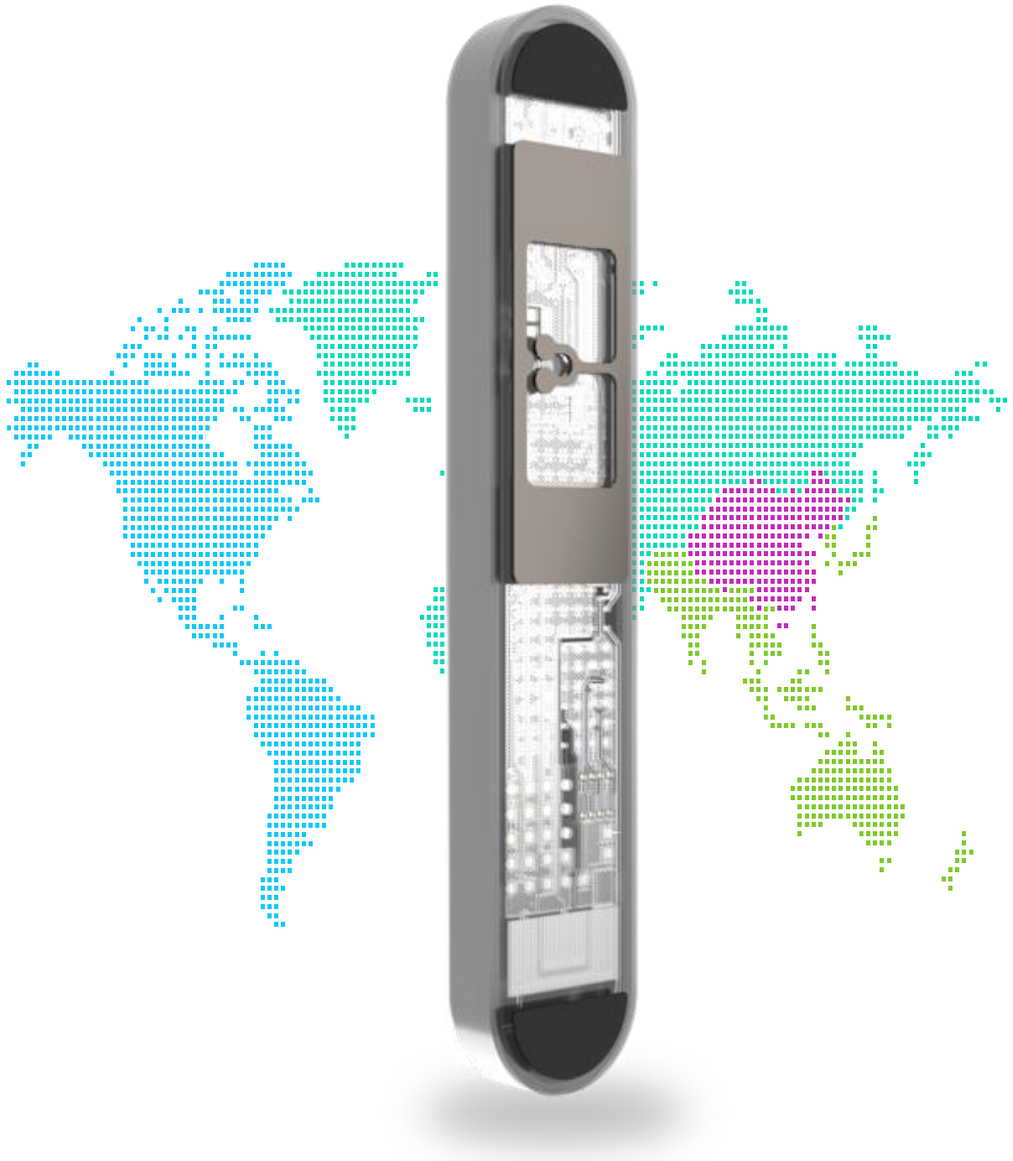
Quality & Regulatory contracts requirements

Basic concepts

Good Distribution Practices Guidelines

- DISTRIBUTOR shall comply with Applicable Law and recognized guidelines in the Territory regarding the proper warehousing and distribution of the Products. This requirement includes, where applicable, the Eucomed 2010 Good Distribution Practice Guidelines, or other guidelines as Medtronic may provide to DISTRIBUTOR from time to time.

- Upon request, DISTRIBUTOR shall provide to Medtronic certificates or other documentation showing conformance to such guidelines and requirements.



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Quality & Regulatory contracts requirements

Basic concepts

Prohibition to distribution

- The DISTRIBUTOR must not distribute the products if:
  - DISTRIBUTOR has reason to believe that the Product is potentially a Non-Conforming Product (for example damaged or will not perform as intended);
  - The packaging has been damaged, opened or incomplete, the seal has been broken, or the labeling is compromised
  - Its use by date is passed; or
  - It is part of a product recall.

Product Returns

- Medtronic's Product Return Policy is described in Annex C of the Contract
- DISTRIBUTOR shall not return any Product to Medtronic without fully complying with the Product Return Policy, unless DISTRIBUTOR has received prior written instructions from Medtronic superseding expressly such procedure, exceptionally or for the remainder of the term of this Agreement

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Quality & Regulatory contracts requirements

Basic concepts

Document retention and inspection rights

- DISTRIBUTOR shall, for the longer of the period mandated by Applicable Law, the lifetime of the Product in question plus one year, or twenty (20) years after such records are considered obsolete or superseded, store and make available to Medtronic and inspectors the following information:
    - Traceability records for Products,
    - Original Licenses and documents provided to any Public Authority used to obtain Licenses,
    - All records of training/qualification of employees acting for DISTRIBUTOR under this Agreement (iv) Product Complaints and Field Action execution evidence
- DISTRIBUTOR shall inform Medtronic immediately of any issues identified in any external or internal audits or inspections that may negatively impact Medtronic Product quality or distribution.

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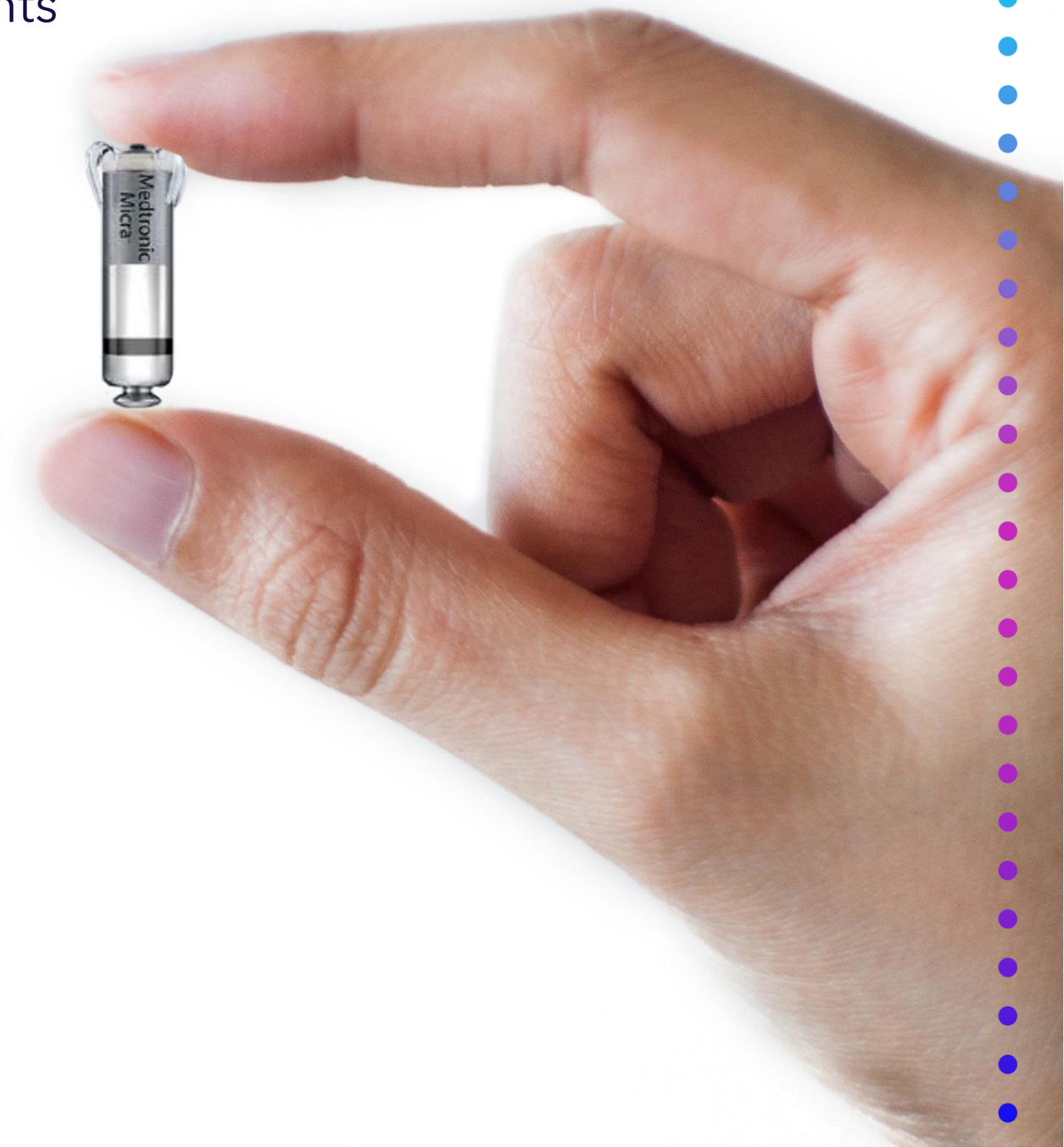
Quality & Regulatory contracts requirements

Basic concepts

Traceability and product tracking

- DISTRIBUTOR shall ensure Product traceability throughout the duration and after the expiry/termination of this Agreement.

- The tracking system shall record or allow retrieval of Product information at a LOT/serial no. level and include information on all parties involved in the Product's chain of distribution and its end users, information on such Product performance and safety records and any further information needed to comply with Applicable Law.



Quality & Regulatory contracts requirements

Basic concepts

Product storage requirements

Storage facilities shall be such that they preserve the quality of Products:

Pest Control	Temperature Control	Storage	Transportation	Cleaning
The environment must be pest free and pest control measures must not have adverse effects on the products	The temperature and humidity must be within the ranges established on the labels and the instructions for use of the product The sensors are calibrated regularly and calibration status is indicated on the sensors Excursions shall be investigated, product segregated and dispositioned The records shall be recorded at minimum every 15 minutes and archived unless otherwise specified for the product and in the quality agreement	Products should not be exposed to direct sunlight or stored directly in the ground Products should be stored according to their status and an ERP system should be used that reflects the actual status of the products. In case of Non-Conforming Products (including Products beyond their expiry date or shelf life), such Products shall be immediately segregated and stored in a separate locked area to prevent distribution of such Products to users/customers.	The distributor must ensure that the specific requirements of the products (eg humidity and temperature requirements) are met during transport and shipping	Storage areas should be cleaned at regular intervals. A record of the frequency and methods of cleaning facilities and areas should be kept. You should NOT allow the consumption of tobacco and food or beverages in the areas used for the storage and handling of products.

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PRODUCT HANDLING OVERVIEW

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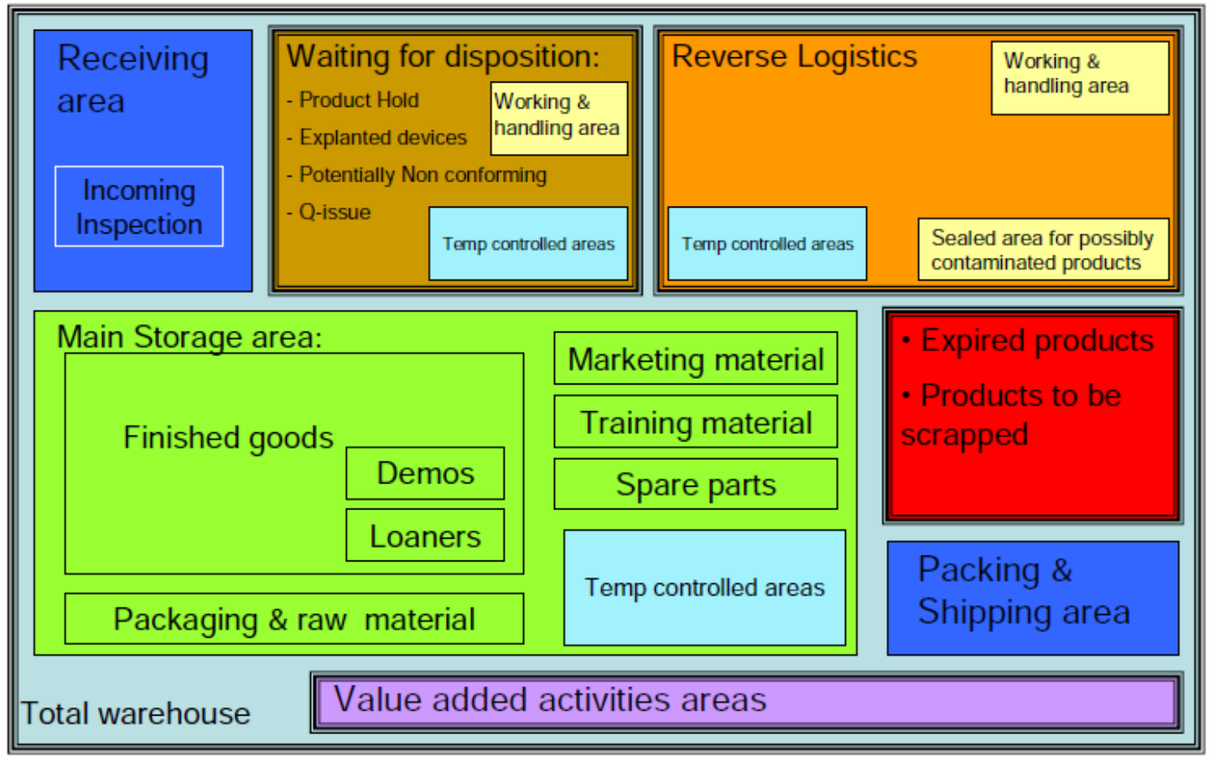
Product Handling

Segregation



= segregated area within the warehouse

This diagram below should provide an idea on the ideal warehouse segregation that Medtronic expects from distributors .

1. Areas must be clearly identified in order to minimize the risk of errors, cross contamination , mixtures and generally any effect which affect the quality of the products.

2. Storage areas should be designed or adapted to ensure good storage conditions (clean within acceptable temperature limits) .

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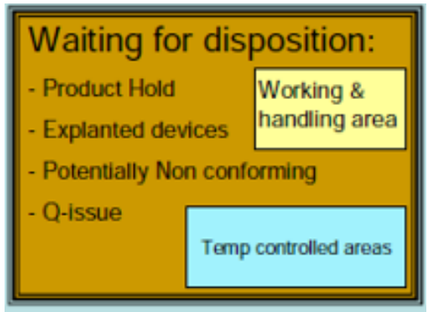
Product Handling

Segregation



Receiving Area

- Each shipment must be checked against the list of contents , quantity and external damage boxes.

Waiting for dispotition

- Items will be identified and segregated as a group according to their status : Quarantine, Returns , Disposal , Demos, Non-conforming , Recalls, Products on Hold (PHO), etc.

Expired Products

- Expired products must be electronic and physically segregated.

Scraps

- In the event that products need be destroyed , this should be done by a qualified technician who is registered with local authorities' provider . The distributor shall deliver a certificate of destruction.

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Product Handling

Segregation

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Product Handling

Segregation

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DESCRIPTION OF THE PROCESS OF CORRECTIVE ACTIONS IN THE FIELD (FIELD ACTION)

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Corrective Action Process in Field

Basic concepts

- A Field Corrective Action or (FCA) is a corrective action that a manufacturer (Medtronic) takes in order to prevent the risk associated with the use of a medical device that is either commercialize or distributed.
- The risk can vary from health deterioration to death of a patient.

FCAs may include the following types of activities:

- ✓ Product Retrieval
- ✓ Communication to customers of actions needed related to product performance issues
- ✓ Educational briefs
- ✓ Advisory notices
- ✓ Health safety alerts

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Quality & Regulatory contracts requirements

Basic concepts

Product Recalls, Field Actions

DISTRIBUTOR shall actively execute any action required by Medtronic to implement such field corrective action with regard to the Products, and in the timeframe specified by Medtronic, including but not limited to notification of customers and patients, implementation of any update, change order, recall or withdrawal of Products.

DISTRIBUTOR shall provide Medtronic with regular updates, when requested, for status on field action closure.

DISTRIBUTOR shall provide Medtronic with all records required as objective evidence of field action completion within the timeframe established in each field action.

DISTRIBUTOR shall not carry out any recall or field corrective action concerning the Products in the Territory except in coordination with, and with the prior written consent of, Medtronic.

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Corrective Action Process in Field

Types of Field Actions

Customer Communication	Retraining/ Software update	Technical Service	Recall
This type of FCA involves sending a communication about the problem; instructions for use or steps to prevent a problem with the device from occurring. All field actions include communication with the customer.	This type of FCA requires to retrain the patient or Health care provider on how to use a device again due to a software update or new way to property use the device. Ex- Teaching a diabetic patient how to property load insulin pump.	This type of FCA involves a field correction that may be a software upgrade or an equipment fix.	This type of FCA involves a product retrieval it can be voluntary by the company or due to problem identified by users, government, etc. The Product can then be: Return to the manufacturer or Scrapped

Corrective Action Process in Field

Field Actions Phases

Field Actions are divided in three phases and Distributor will be directly involved in two phases: Execution of FCA and Closing of FCA.

FCA Communication

Medtronic representative will contact all affected distributors via e-mail, phone call, registered mail.

This notification will come as a package with different section that will detail all the actions the distributor must do.

FCA Execution

The package will contain but not limited:

1.Customer Letter
2.Customer Contact Record (CCR)
3.Field Action Confirmation Sheet (FACS)
4.Return Instructions
5.Other (ex. disposal instructions if applicable)

FCA Closure

The package must be returned to the issuer within the established deadlines.

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Corrective Action Process in Field

Distributor Actions

Field Actions are divided in three phases and Distributor will be directly involved in two phases: Execution of FCA and Closing of FCA.

FCA Communication

Medtronic representative of your region will contact the distributors about the new Field Actions.

Action: PACKAGE SENT TO DISTRIBUTOR

FCA Execution

ACTIONS TO BE CARRIED OUT BY THE DISTRIBUTOR:

1. Read each part of the package. The sections of the Field Actions and the require actions by distributors are described in this training material

2. A timeline will be provided with due dates for each section. Note: These timelines are very important and should be strictly follow by all distributors.

3. Communication with Competent Authorities: Depending on your country's regulations, you must inform the Regulatory Agencies of any new Field Action affecting your region regardless if the FA is regulated or not following the timeline provided.

Depending on your country's regulations, you must inform the Regulatory Agencies of any new Field Action affecting your region regardless if the FA is regulated or not following the timeline provided.

Note: If you hold the Distribution License is may be your responsibility (based on country / region regulation) to inform the authorities, of the opening and closing of the FA. Please communicate with your Quality Specialist/Regulatory Agency if you have any inquiries.

1. 4. Start communication with Patients/Doctors/Hospitals only use the letters provided in the package and make sure to document all communication using the Customer Contact Record (CCR forms). Execute and document at least (3) attempts for customers not responding.

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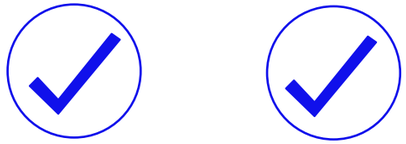
Corrective Action Process in Field

Distributor Actions

FCA Communication → FCA Execution → FCA Closure



DISTRIBUTORS TO DO LIST:

1. Following the timelines after all customer communication has been completed. Make sure to fill out the Customer Contact Records (CCR forms), as well as provide feedback if some costumers were not found.
2. Provide proof of return items
   Note: Tracking numbers are very important
3. If a distributor holds the Distribution License for the product affected in the FCA, it is their responsibility to also inform the Regulatory Agency of your country of the closure of FCA.
4. Please send copy of all these documents to your Medtronic Representative.
5. Once you have provided all information the Medtronic Representative will fill out the Field Action Confirmation Sheet (FACS sheet)and officially close the Field Corrective Action.
6. A timeline will be provided to you with due dates for each part.

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DESCRIPTION OF THE PRODUCT COMPLAINTS MANAGEMENT PROCESS

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Product complaint handling

General concepts

What is a Product Complaint?

Identity
- The serial number does not match the label.
- Product size does not match the label.

Quality
- Broken safety seal.

Durability
- Premature battery depletion
- Corrosion of equipment after decontamination

Safety
– Blockage of Insulin Pump

Reliability
- An alarm of a device turns on occasionally
Safety
– Blockage of Insulin Pump

Effectiveness
- The symptoms do not improve in spite of having the device.

Complaints are not considered:

- Design Tips
- Complaints relating to cost or revenues
- Complaints about service or shipping
- Requests for replacement product without express dissatisfaction or device failure

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Product complaint handling

General concepts

Sources:

Product complaints can present themselves through any of the following sources:

- Customers (Patients, Physicians, Medical Professionals, Medical Institutions, Insurance Companies)
- Regulatory Authorities
- Medical or scientific literature (published or unpublished)
- Own research, testing, evaluation, servicing or maintenance of Medtronic devices
- Adverse events collected in clinical studies

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Product complaint handling

General concepts

Information for the report

DISTRIBUTOR shall notify Product Complaints to Medtronic immediately, but in any event within a maximum of 48 hours after learning of the event. The following information, if available and Permitted by law, shall be collected by DISTRIBUTOR and shall be reported with the Product Complaint:

Customer information	• Name and telephone number of the client • Name and address of hospital / facilities
Product Information	• Model number and lot / series number • Product information: Implant, explant and procedure date (if applicable) • Product return status (e.g. device will be returned, discarded etc.)
Event information	• Event date (when the experience / difficulty with the product occurred) • Notification / knowledge date (date on which the Medtronic employee first heard about the event) • Event description (present as many facts as possible for an appropriate understanding of the event) • Additional evidence / documents (eg x-rays, photographs, prints, STD files)
Patient / User Information	• Patient Reference Number • What happened to the patient / user? (Details of patient injury) • Action (s) taken (eg medical intervention, hospitalization) • Patient status after the actions taken • Patient's age (FDA requirement for pediatric cases)
Information of the person making the report	• Contact details of the Medtronic employee who reports the complaint

Importance of Reporting

Reporting within 48 hours ensures:

- Information reaches the right people and is not lost.
- The regulatory requirements are met.
- The issue will be investigated on a timely manner. If necessary, Field Corrective Actions are initiated, changes in design, manufacturing, as applicable are implemented.

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MPXR MOBILE PRODUCT EXPERIENCE REPORTING GUIDE

Medtronic

Mobile Product Experience Report

Basic concepts

What is mpxr?

- ✓ Mobile Product Experience Reporting.
- ✓ Unified tool for complaints management
- ✓ Ease of handling the complaint only with internet connection.
- ✓ Interactive form that offers a range of questions depending on the previous answers

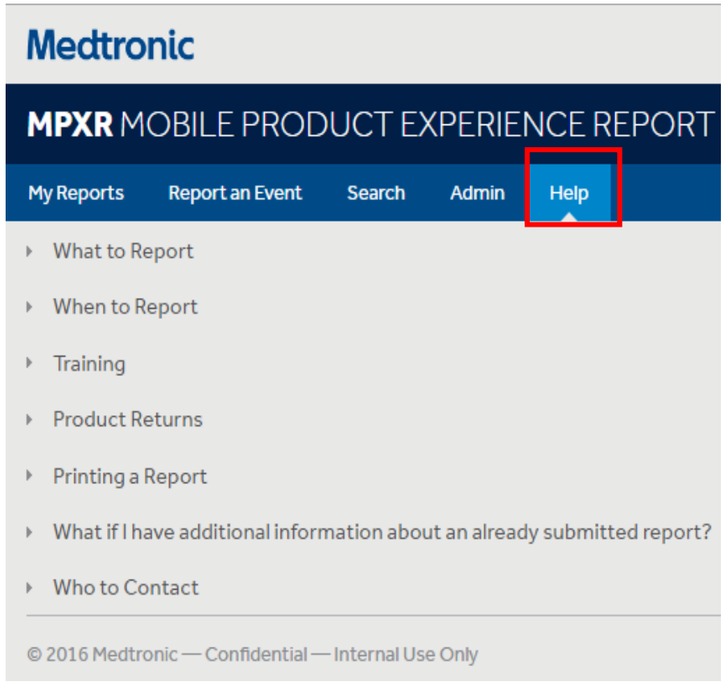

iPhone


Laptop


iPad


Android Phone

No need to be on the Medtronic network to submit a report!



Additional training available!

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Mobile Product Experience Report

Basic concepts

Why use mpxr?

✓Reduce effort in the field by replacing manual PIR/PER forms

✓Eliminate or reduce follow-up on submitted reports

✓Improve accuracy, completeness and delayed reporting of product events to regulatory bodies

✓One Medtronic solution that can be globally deployed across multiple businesses

Key features to reduce effort and follow-up

✓The report can be started on one device (iPad, laptop or phone) and finished on another device.

✓Multiple attachments can be sent with the report.

✓mPXR will identify any missing information prior to submitting report.

✓Product experience reports are sent directly to complaint handling groups

Mobile Product Experience Report

From a computer

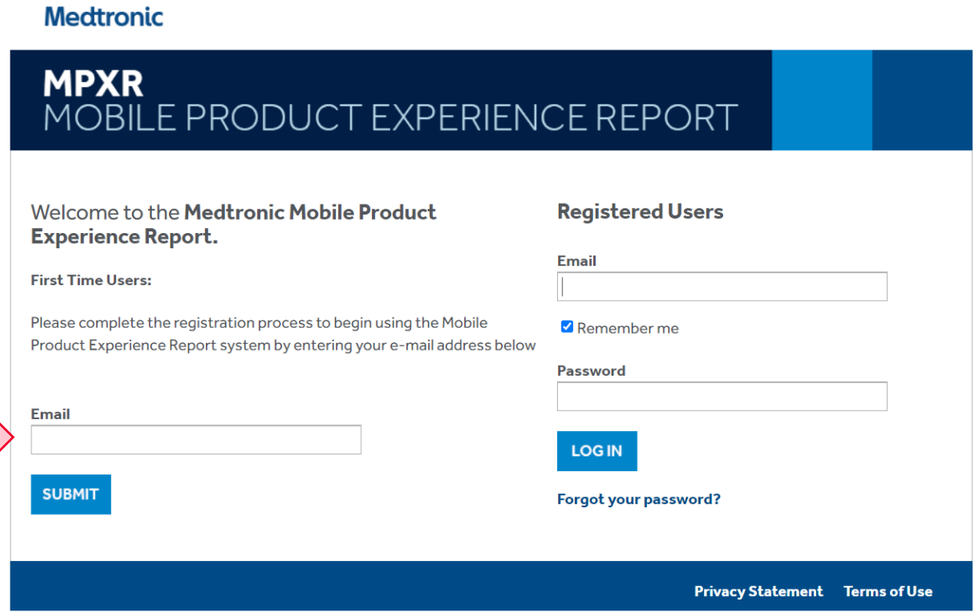
Registration and access to a user ID

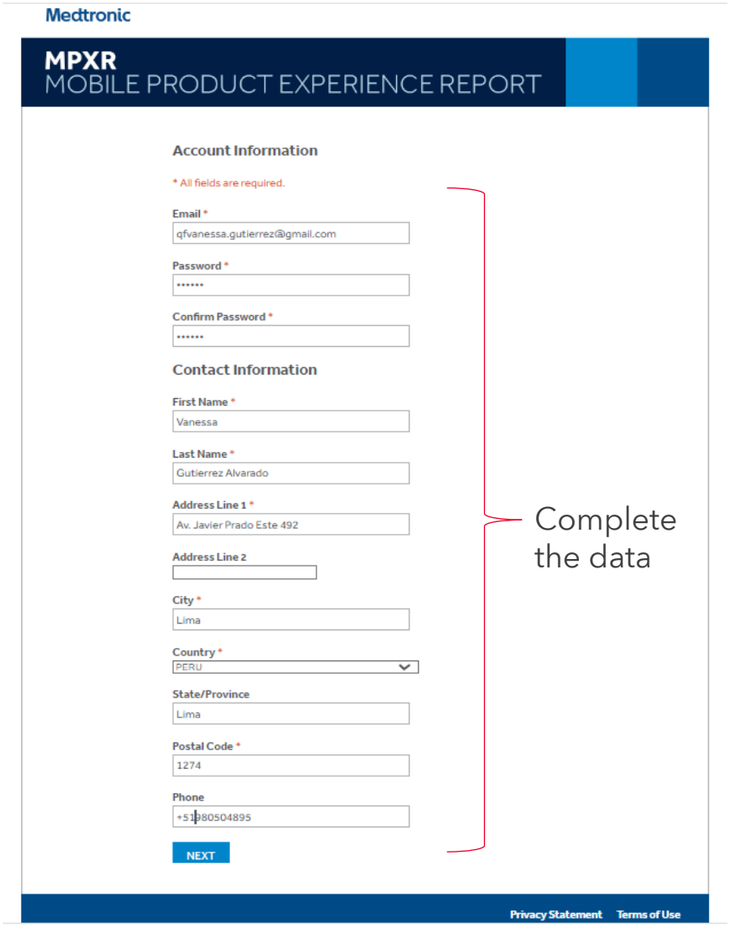
If you have not registered for access to Medtronic´s Mobile Product Experience Reporting (mPXR) on-line tool, please complete the following steps:

1. Open an internet browser.

   a. Copy and paste the following address into the address field of the browser: https://wwwp.medtronic.com/extregistration/login/showLogin?appName=MPXR

Enter your email





Complete the data

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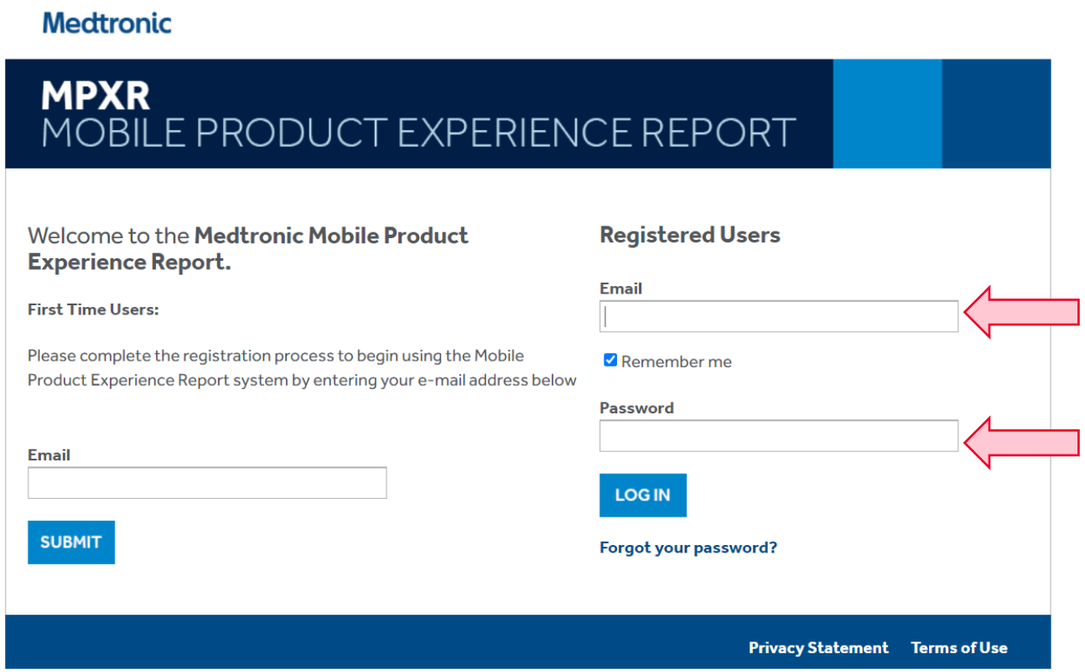
Mobile Product Experience Report

From a computer

Access to mpxr

1. Open an internet browser
2. Copy and paste the following address into the address field of the browser: https://wwwp.medtronic.com/extregistration/login/showLogin?appName=MPXR
3. This screen will appear.



4. Enter your email Enter your username.
5. Enter the password you set when you created your account
6. Choose ENTER

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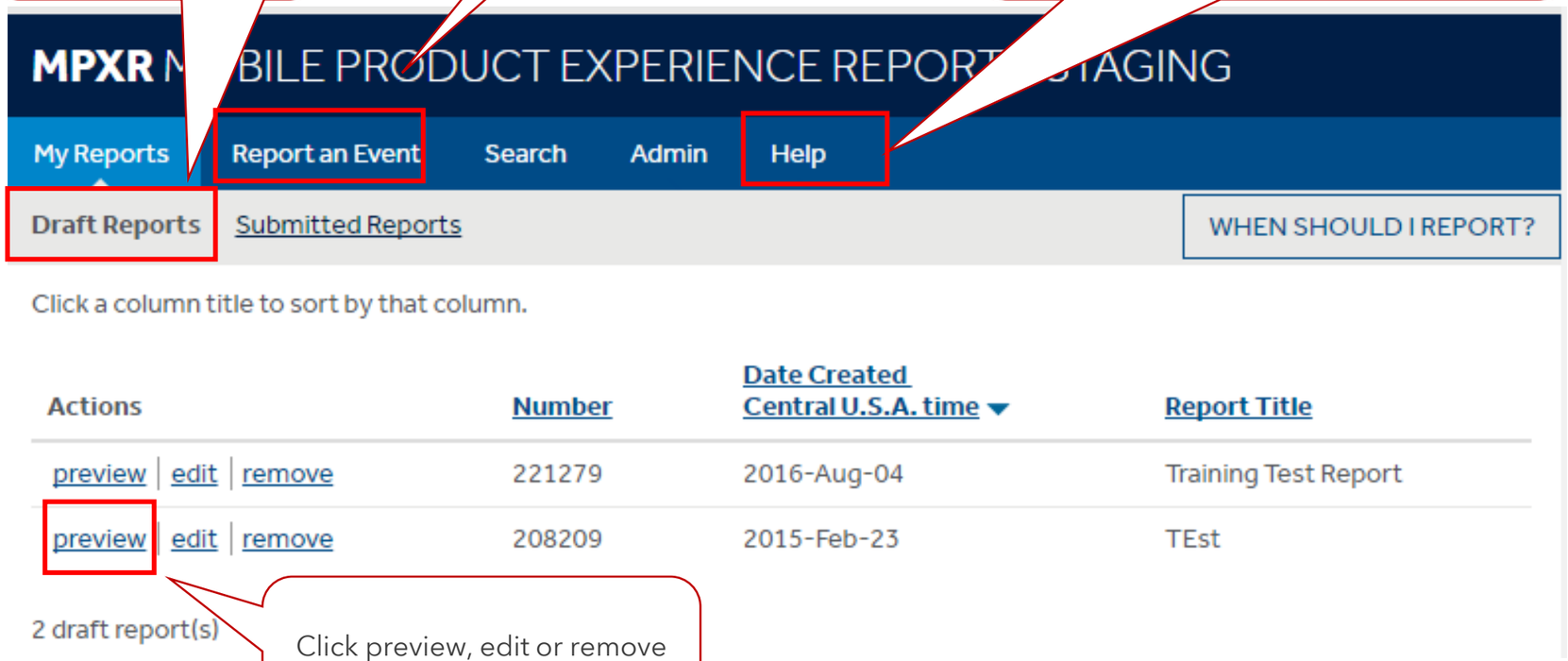
Mobile Product Experience Report

mPXR Home Page

Press **Draft Reports** or **Submitted Reports** to view the projects or reports.

Click Report an Event link to submit a report .

Click Help to learn:
- When to submit a report
- Product returns
- Returned product analysis
- Rush requests
- Who to contact



Click preview, edit or remove link to preview, edit or remove a report that has been started.

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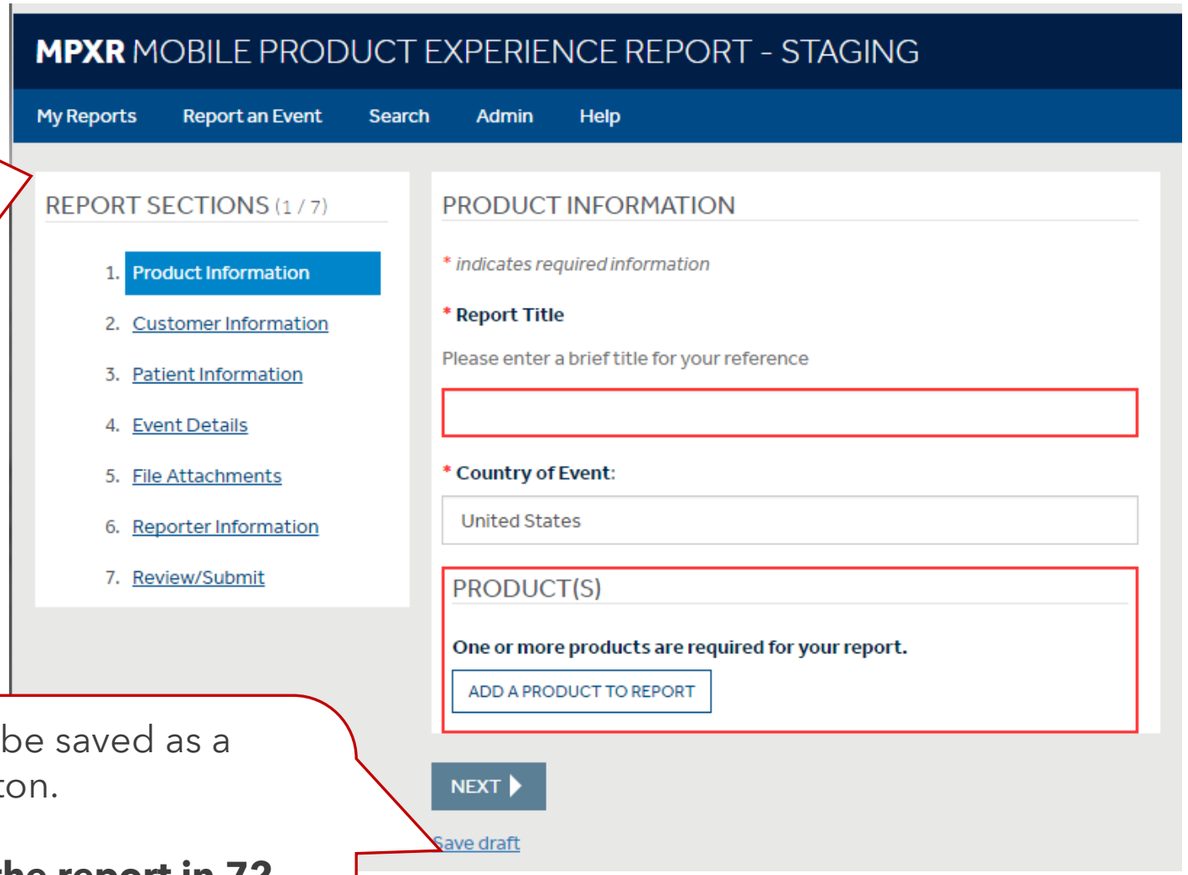
Mobile Product Experience Report

mPXR Functionality

You are able to move around using the **Report Sections.**

Click on the section you would like to go to.

Note: A Report Title is required on the first page before moving to a different section



Once a report is initiated, it can be saved as a draft by clicking **Save Draft** button.

Note: If you do not complete the report in 72 hours, mPXR will automatically submit in order to meet reporting timelines. This will most likely result in a follow-up call to you.

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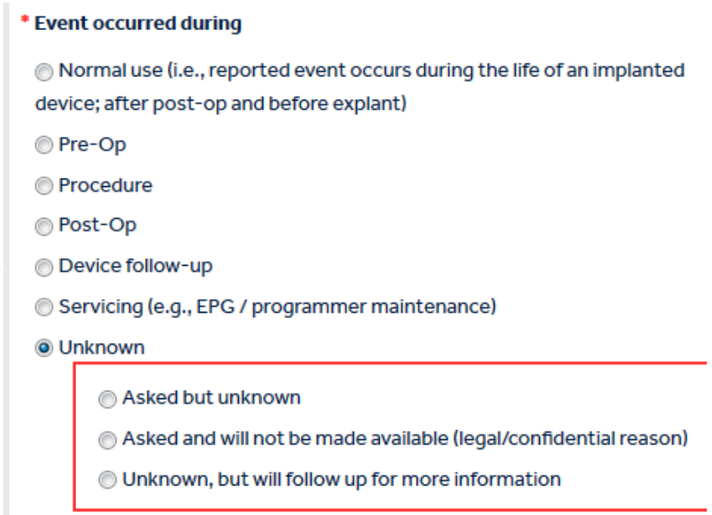
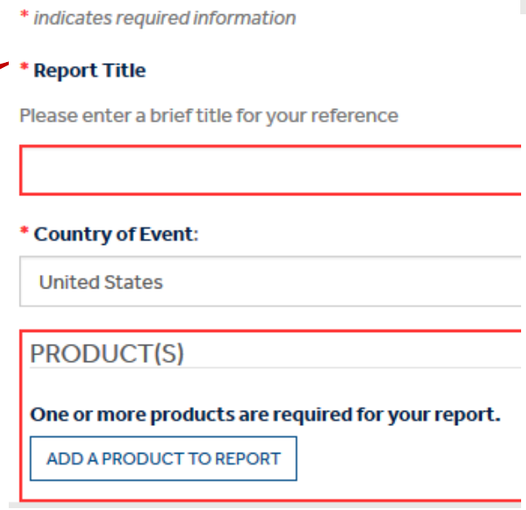
Mobile Product Experience Report

mPXR Functionality

Note: ***Unable*** *to obtain or* ***unknown*** *are options if you do not know or cannot obtain the information.*



Required Spaces
They are marked with an asterisk



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Mobile Product Experience Report

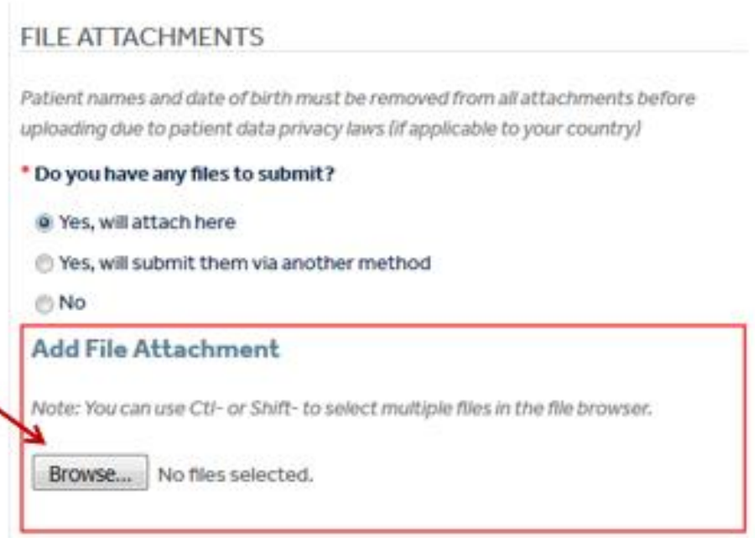
mPXR Functionality

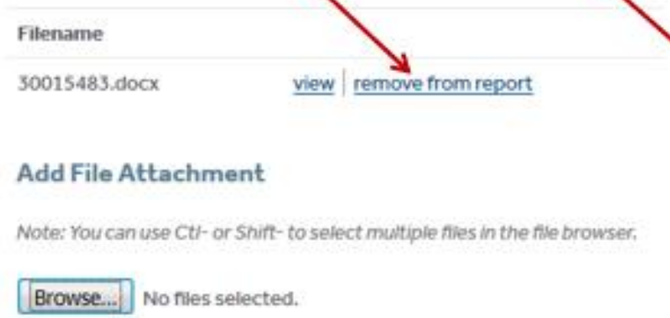
Document-type attachments can only be added via your laptop. Photos can be added via all devices.

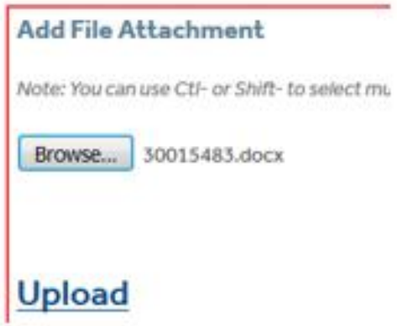
Click **Browse** button to select the file to be attached (multiple files can be attached at once).

Click **Upload** button.

View or **Remove** the attachment or Browse to add more attachments.







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Mobile Product Experience Report

mPXR Functionality

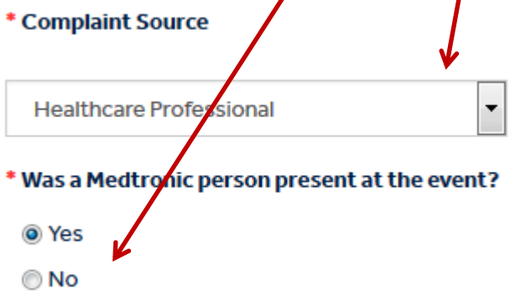
Throughout the app,

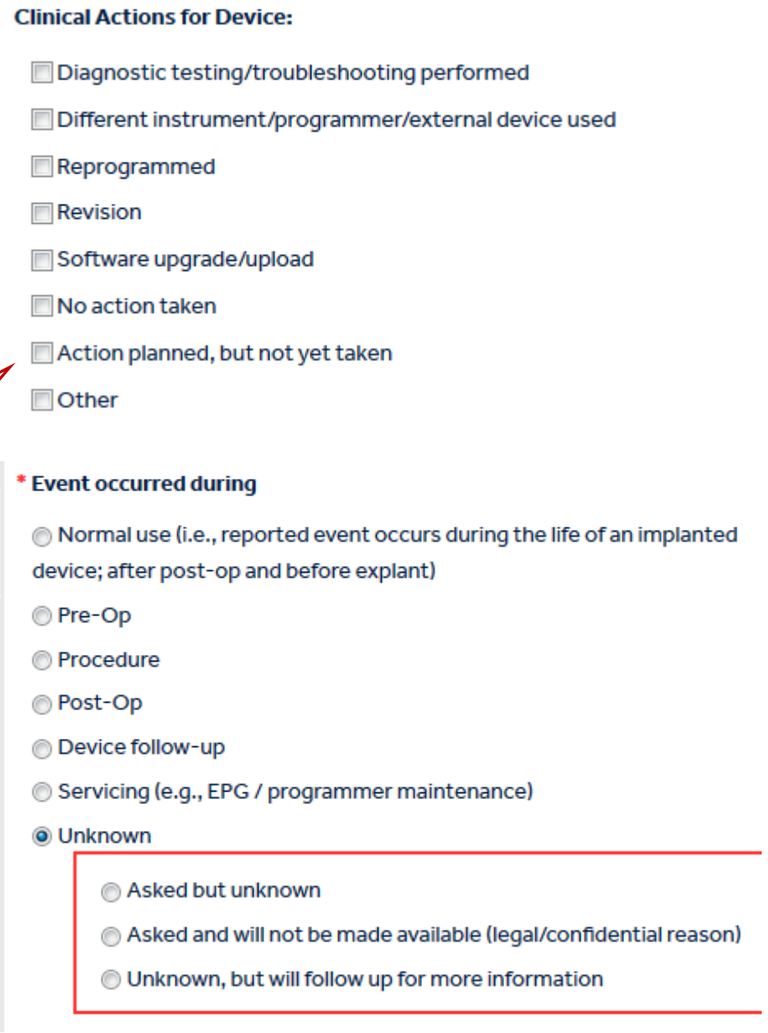
Check Boxes,

Radio Buttons,

and Drop Downs

are used for data entry.





For check boxes click **all that apply.**

Note: Use **'Unknown'** options if you don't know or aren't able to get information.

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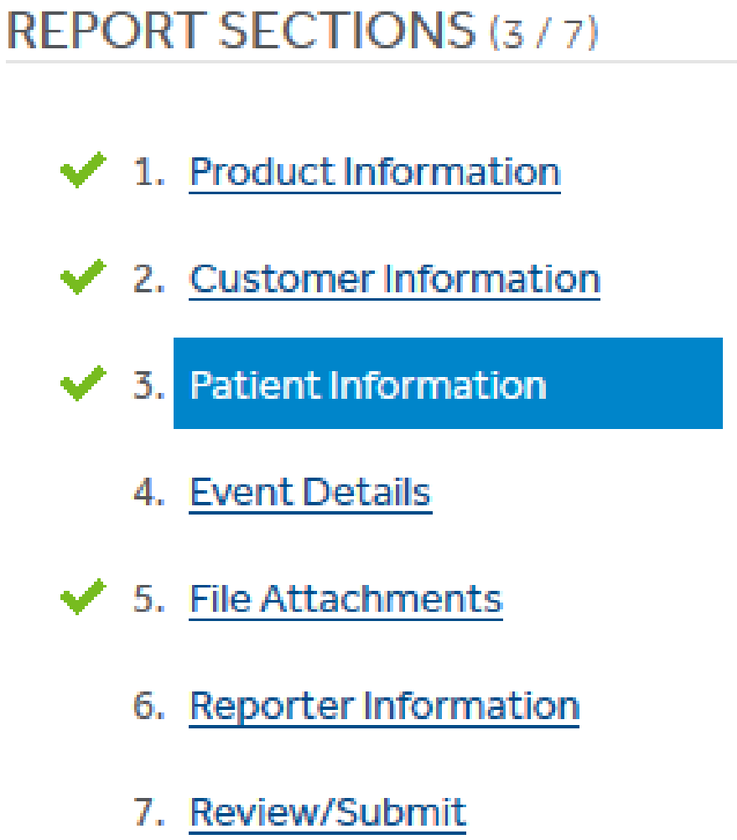
Mobile Product Experience Report

mPXR Functionality

Full sections :

Completed sections are marked by a green check mark in the navigation pane on the left side of the application.



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Mobile Product Experience Report

mPXR Functionality

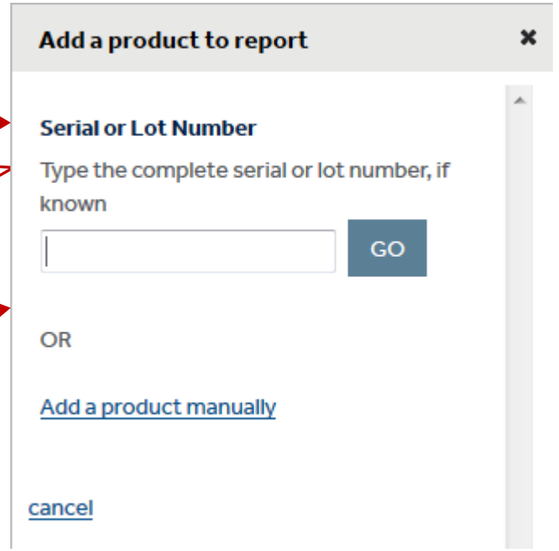
Pre-populate Patient and HCP Information

Information can be pre-populated with a registered **Serial Number**.

Enter **Serial Number**, select **Go** button.

Select the **product(s)** associated with the event.

If the registered serial number is not available, the **Product Information** can be entered manually.



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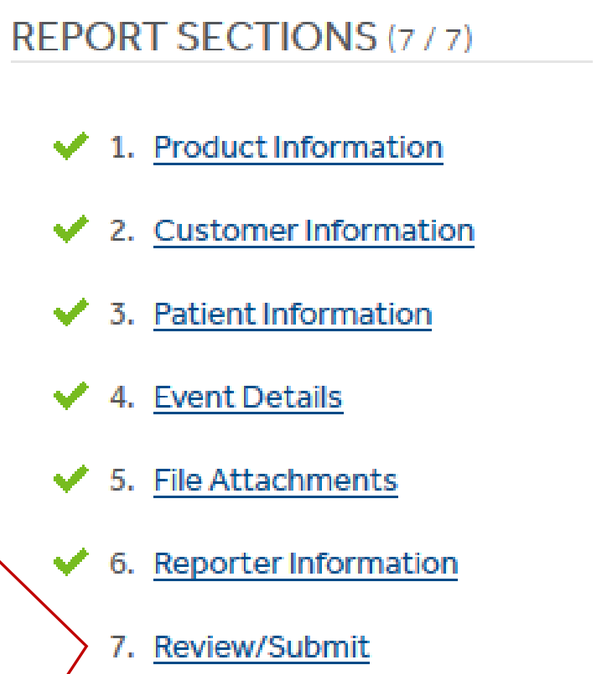
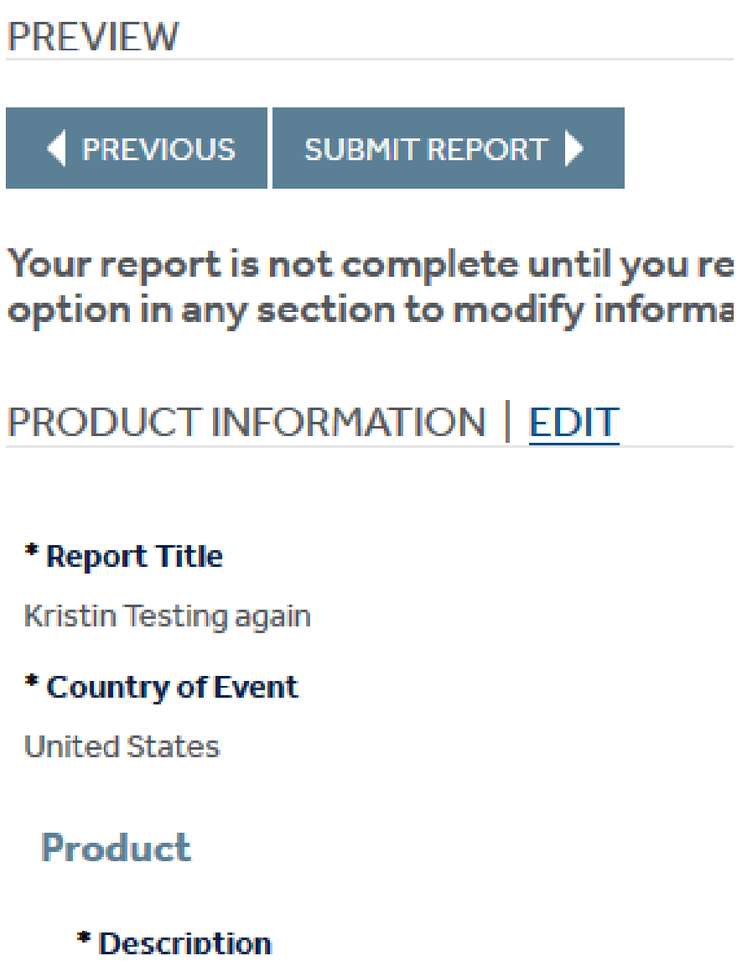
Mobile Product Experience Report

mPXR Functionality

Click **Review / Submit** to review the report and submit it.

Print a copy of the report from your laptop ***or write down the mPXR number if using a tablet/phone on the packing slip*** Include the packing slip with the product in the return mailer kit.





Medtronic

Return Product Complaints

1

Complete mPXR.

2

Fill out the mPXR field

*** What is the return status?**

Will be returned

3

Send an email to your Medtronic contact (Sales Representative, Customer Service / QA) to request the return of the complaint.

Note: Ask for the instructions that apply to you

4

Send the product to the inquiry address and provide the #tracking number.

Once the investigation is finished, they will provide you with the closing letter (applies, if requested)

The product return process is managed locally.

Confirm in the shortest possible time if the product **will be returned**.

Medtronic

CHANGE CONTROL PROCESS

Medtronic

Change Control Process

Importance of generating a Change Control

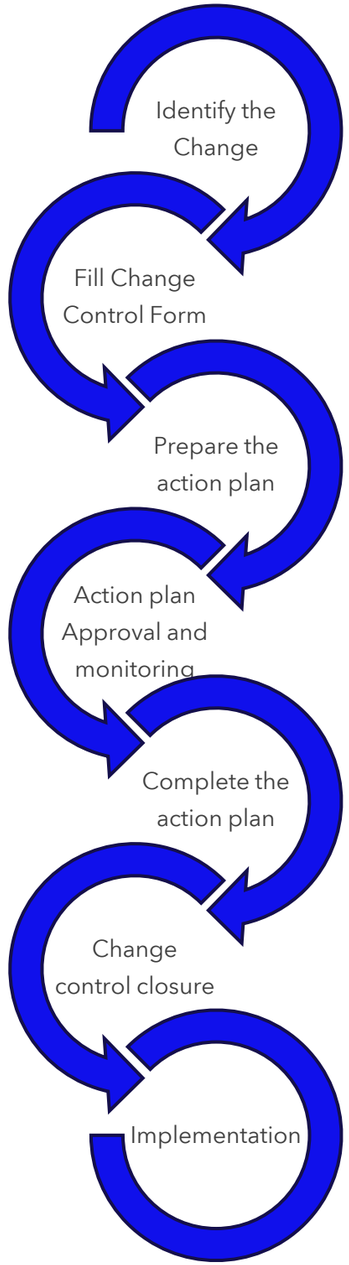
It allows that changes be introduced in the QMS in a controlled and coordinated manner.

It allows that the risk associated with the change before the implementation, being considered, analyzed and defined / implemented with mitigation activities.

- Protect our internal and external customers.
- Meet Regulatory requirements.
- Meet Medtronic Policies and Procedures.

Potential Consequences of Not Implementing a Change Control

- Patient Impact to Health and Safety
- PHO's, FCA's , External Regulatory Findings,
- 483's (FDA).
- Internal Audit Findings, CAPA's, Business Disruptions.



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Change Control Process

The distributor is responsible for communicating (in writing) to Medtronic the proposed process changes before implementation. Changes should not be implemented until written approval is received from Medtronic

The following are examples of common process changes (others may apply as per contract and local regulatory requirements):

Examples

- Change in/of facility locations.
- Name changes (company name).
- Additions to the facilities / modifications to the facilities or major changes to the distribution / layout..
- Changes in environmental conditions (e.g. temperature / humidity parameters).
- Changes in advertising or promotional material.
- Additions or changes of subdistributors.

Medtronic

Approval / Creation of the Change Control Plan

As a minimum, Distributor shall provide the following information (in writing) to Medtronic for evaluation and approval:

- Description of the current situation
- Description of the planned change
- Description of the future situation
- Timing of change
- Reason for change
- Affected procedures/work instructions
- Impact of change / risk / mitigation plan (if applicable)
- Contact person
- Revision history: to record changes to the original version due to changes in plan, time, action, etc.

Medtronic may require additional information related to the change.

Distributor shall have controls in place to avoid implementation prior to Medtronic approval (written approval).

Upon approval or rejection, Medtronic will communicate the change requestor determination in writing.

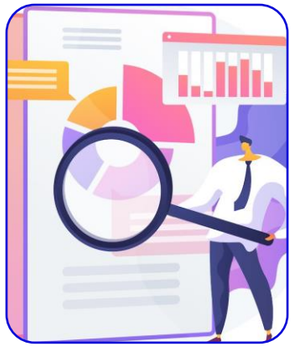
Medtronic

DISTRIBUTORS AUDITs

Medtronic

Audits

Critical risk distributors



Prior to activities initiation and every three (3) years the Critical Risk Distributors should be audit.

Audits should be considered in case of quality/regulatory or compliance issues.

Audit Distributors

Medtronic

Corrective and Preventive Actions

CAPA

A distributor CAPA shall be initiated in case of:

1. Quality/Regulatory issues:
   - Non-conformities found during a distributor audit
   - Gaps identified during performance evaluation

Risk Level	Minimum Review periodicity Performance Evaluation
Critical	Once Per year
Major	Every Two Years

   - Failures to meet pre-established quality and regulatory contract requirements

2. Single event non-conformances with potential impact to the customer/patient safety.

Medtronic

GOOD DOCUMENTATION PRACTICES

Medtronic

Good Documentation Practices (GDP)

Key qualities of regulated documents

Concise

Information easily understandable

- **12/07/2019**

- **12 JUL 2019**

Legible

Calligraphy:

Change the data analysis or produce as a result "Lack of Data"

Accurate

- Review, check and approve correctly.
- The information must be recorded immediately when occur an event and not after the same.

Locatable

- Who recorded the information?
- Which was the information?
- When?
- Why it was documented?

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Good Documentation Practices (GDP)

Records on paper

- Any reviewer must understand the consigned information; additionally, must use N/A when is not applicable.
- Document when an event occur (do not report after it happens)
- Use permanent black or blue ink.
- Identify the pages: Document ID, title, pagination and confidentiality (if applicable)
- Scanned documents must have a good resolution.

Good Documentation Practices (GDP)

Use of forms/formats

Example: (Correct) ~~DHF-BL-005-01,~~ (Incorrect) ~~DHF-BL-005-01~~

CLAVE DE PRODUCTO	U/M	DESCRIPCIÓN DEL ARTÍCULO	NO. LOTE	CANTIDAD	RECIBO DE ALMACEN
18885	PZA	TAPEGUARD EVAC TRACHEAL 8.5	110701143X	9	9 pzas[1]
		N/A Juan Perez 09 JUL 2019			

[1]No. de piezas recibidas 2 pzas: John Rodriguez 27 Ene 2019

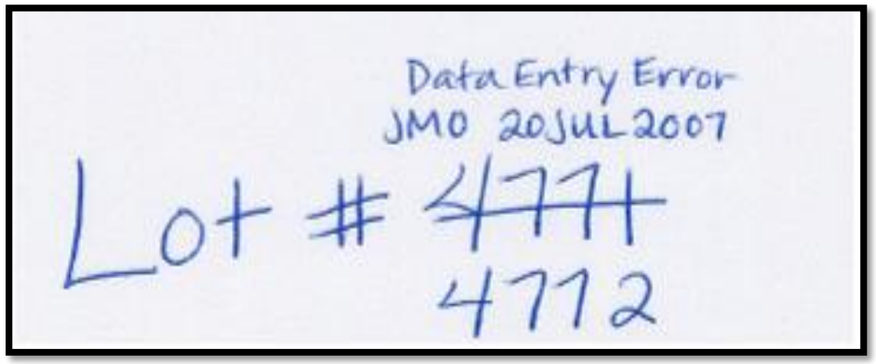
EXAMPLE

DD MMM YYYY

Good Documentation Practices (GDP)

Use of forms/formats

- INITIALS
- STABLISHED FORMAT DATE
- LEGIBLE CORRECTION



EXAMPLE

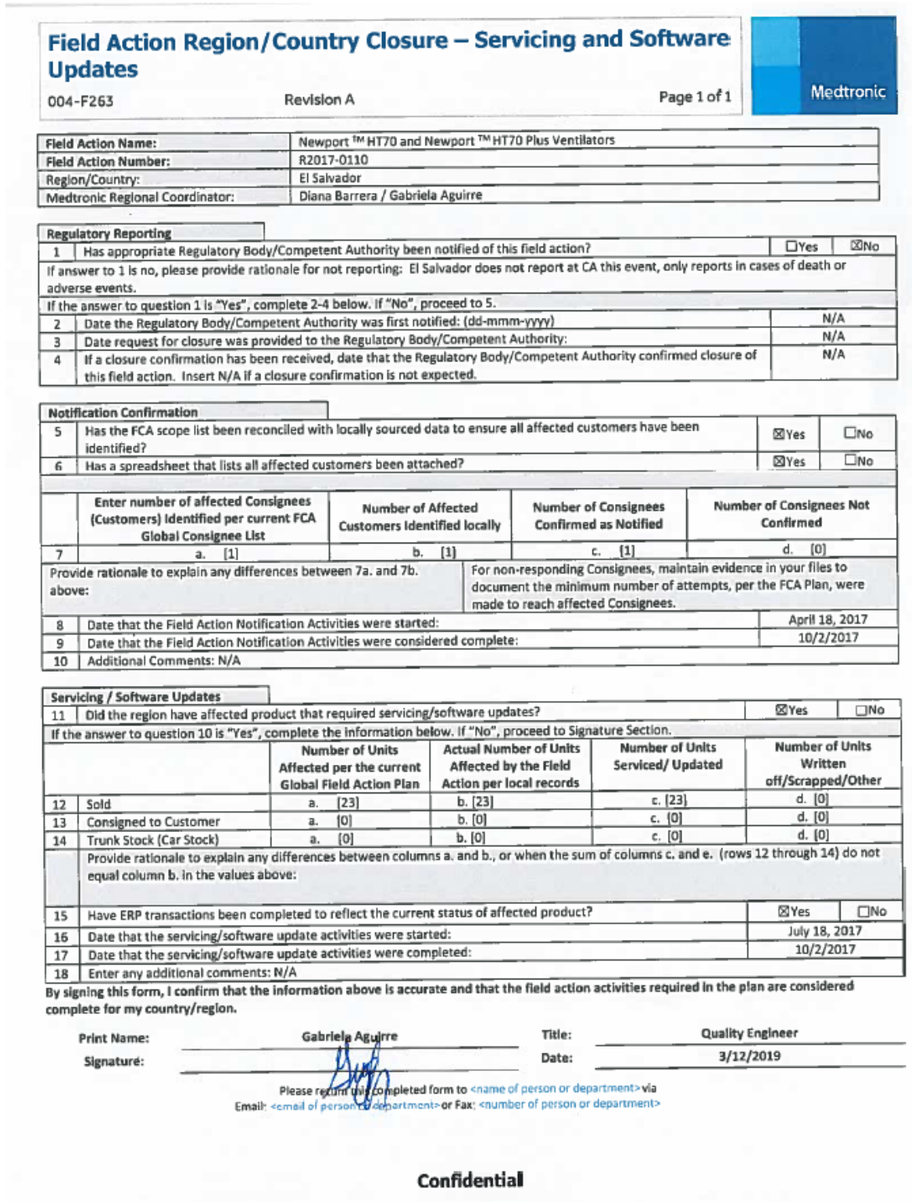
Medtronic

Good Documentation Practices (GDP)

Examples

FACS- Field Corrective Actions

Do not forget to fill out all fields on the records.



Field Action Region/Country Closure – Servicing and Software Updates

004-F263 Revision A Page 1 of 1

Medtronic

Field Action Name:	Newport ™ HT70 and Newport ™ HT70 Plus Ventilators
Field Action Number:	R2017-0110
Region/Country:	El Salvador
Medtronic Regional Coordinator:	Diana Barrera / Gabriela Aguirre

Regulatory Reporting

1	Has appropriate Regulatory Body/Competent Authority been notified of this field action?	☐Yes	☒No
If answer to 1 is no, please provide rationale for not reporting: El Salvador does not report at CA this event, only reports in cases of death or adverse events.			
If the answer to question 1 is "Yes", complete 2-4 below. If "No", proceed to 5.			
2	Date the Regulatory Body/Competent Authority was first notified: (dd-mmm-yyyy)		N/A
3	Date request for closure was provided to the Regulatory Body/Competent Authority:		N/A
4	If a closure confirmation has been received, date that the Regulatory Body/Competent Authority confirmed closure of this field action. Insert N/A if a closure confirmation is not expected.		N/A

Notification Confirmation

5	Has the FCA scope list been reconciled with locally sourced data to ensure all affected customers have been identified?	☒Yes	☐No
6	Has a spreadsheet that lists all affected customers been attached?	☒Yes	☐No

	Enter number of affected Consignees (Customers) identified per current FCA Global Consignee List	Number of Affected Customers identified locally	Number of Consignees Confirmed as Notified	Number of Consignees Not Confirmed
7	a. [1]	b. [1]	c. [1]	d. [0]

Provide rationale to explain any differences between 7a. and 7b. above:	For non-responding Consignees, maintain evidence in your files to document the minimum number of attempts, per the FCA Plan, were made to reach affected Consignees.

8	Date that the Field Action Notification Activities were started:	April 18, 2017
9	Date that the Field Action Notification Activities were considered complete:	10/2/2017
10	Additional Comments: N/A	

Servicing / Software Updates

11	Did the region have affected product that required servicing/software updates?			☒Yes	☐No
If the answer to question 10 is "Yes", complete the information below. If "No", proceed to Signature Section.					
		Number of Units Affected per the current Global Field Action Plan	Actual Number of Units Affected by the Field Action per local records	Number of Units Serviced/ Updated	Number of Units Written off/Scrapped/Other
12	Sold	a. [23]	b. [23]	c. [23]	d. [0]
13	Consigned to Customer	a. [0]	b. [0]	c. [0]	d. [0]
14	Trunk Stock (Car Stock)	a. [0]	b. [0]	c. [0]	d. [0]
	Provide rationale to explain any differences between columns a. and b., or when the sum of columns c. and e. (rows 12 through 14) do not equal column b. in the values above:				
15	Have ERP transactions been completed to reflect the current status of affected product?			☒Yes	☐No
16	Date that the servicing/software update activities were started:			July 18, 2017	
17	Date that the servicing/software update activities were completed:			10/2/2017	
18	Enter any additional comments: N/A				

By signing this form, I confirm that the information above is accurate and that the field action activities required in the plan are considered complete for my country/region.

Print Name: Gabriela Aguirre **Title:** Quality Engineer

Signature: **Date:** 3/12/2019

Please return this completed form to <name of person or department> via Email: <email of person or department> or Fax: <number of person or department>

Confidential

Medtronic

Good Documentation Practices (GDP)

What not to do?

CHECKMARKS

Completely cancelling of the information.
Using of repetition symbols
Fix errors without writing the new entry

Medtronic

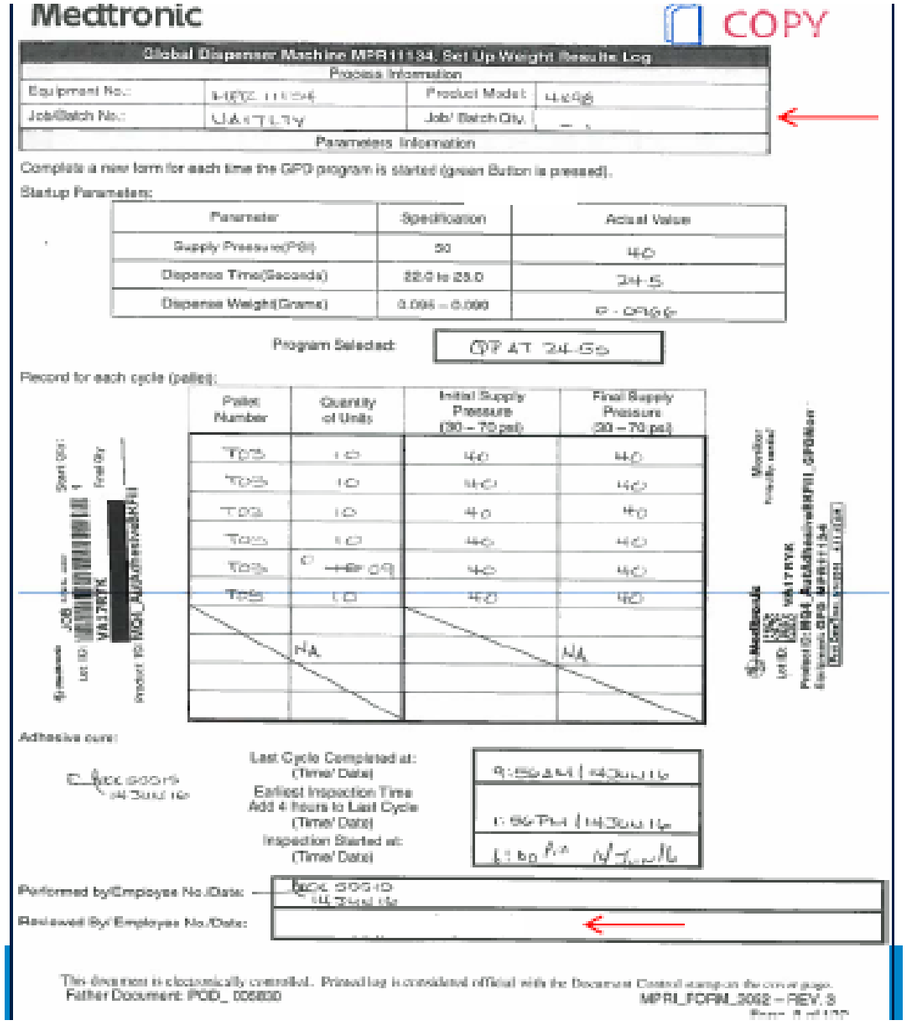
Good Documentation Practices (GDP)

Examples

CHECKMARKS

Populate the forms leaving empty spaces.

In this form the supervisor signature is missing.



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COPY

Global Dispenser Machine MPR11134, Set Up Weight Results Log

Process Information

Equipment No.:	MPR 11134	Product Model:	4408
Job/Batch No.:	4417479	Job/ Batch Qty.	

Parameters Information

Complete a new form for each time the GPD program is started (green Button is pressed).

Startup Parameters:

Parameter	Specification	Actual Value
Supply Pressure(PSI)	50	40
Dispense Time(Seconds)	22.0 to 25.0	24.5
Dispense Weight(Grams)	0.095 – 0.099	0.0956

Program Selected: GP AT 24.5s

Record for each cycle (pallet):

Pallet Number	Quantity of Units	Initial Supply Pressure (30 – 70 psi)	Final Supply Pressure (30 – 70 psi)
105	10	40	40
105	10	40	40
105	10	40	40
105	10	40	40
105	10	40	40
105	10	40	40
	NA		NA

Adhesive cure:

Last Cycle Completed at: (Time/ Date)

Earliest Inspection Time Add 4 hours to Last Cycle (Time/ Date)

Inspection Started at: (Time/ Date)

Performed by/Employee No./Date:

Reviewed By/ Employee No./Date:

This document is electronically controlled. Printed log is considered official with the Document Control stamp on the cover page.

Father Document: POD_ 005800

MPR_FORM_3062 – REV. 3

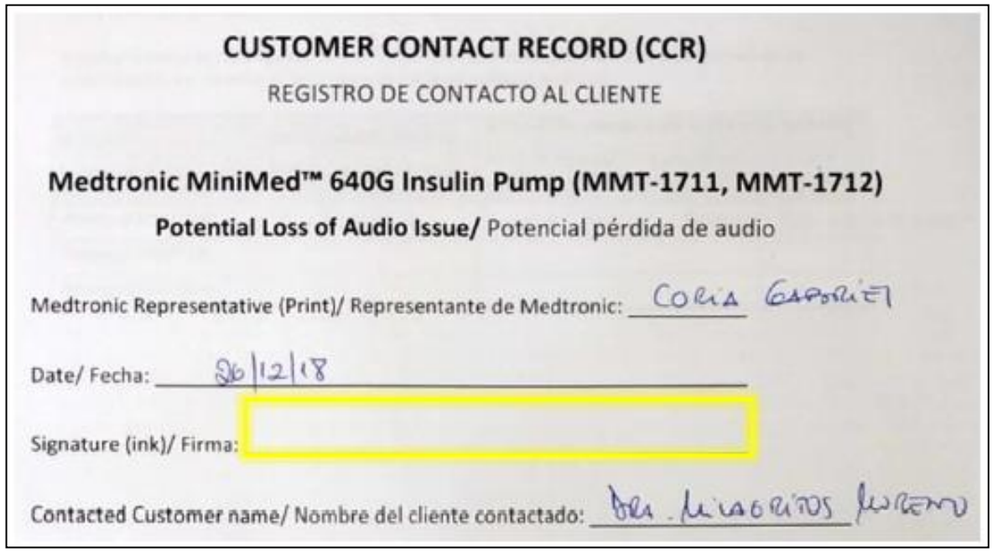
Medtronic

Good Documentation Practices (GDP)

Examples

CHECKMARKS

FCA: The customer must sign the form
FCA: The date on the record must be filled out.



CUSTOMER CONTACT RECORD (CCR)

REGISTRO DE CONTACTO AL CLIENTE

Medtronic MiniMed™ 640G Insulin Pump (MMT-1711, MMT-1712)

Potential Loss of Audio Issue/ Potencial pérdida de audio

Medtronic Representative (Print)/ Representante de Medtronic: CORIA GABRIEL

Date/ Fecha: 26/12/18

Signature (ink)/ Firma:

Contacted Customer name/ Nombre del cliente contactado: [illegible]

CUSTOMER CONTACT RECORD (CCR)

REGISTRO DE CONTACTO AL CLIENTE

Medtronic MiniMed™ 640G Insulin Pump (MMT-1711, MMT-1712)

Potential Loss of Audio Issue/ Potencial pérdida de audio

Medtronic Representative (Print)/ Representante de Medtronic: CORIA GABRIEL

Date/ Fecha:

Signature (ink)/ Firma:

Medtronic