

Risk Management Report

Write the ISO 14971:2019 risk management report: each hazardous situation scored before and after control against your acceptability policy, with control priority, verification, benefit-risk and the overall residual risk checked.

WRITES

RMF ISO 14971

PRODUCT TYPE

Medical devices

**GUIDANCE IT
FOLLOWS**

ISO 14971:2019;
ISO/TR
24971:2020; FDA
recognised
consensus
standard (ISO
14971:2019); 21 CFR
820 (QMSR); EU
MDR 2017/745
Annex I (GSPR 1–9)
and Annex II; IEC
62366-1 (usability);
IEC 62304
(software)

TIME TO LEARN

About 20 minutes
with the example

Open the tool at <https://app.cmcfy.com/app/risk-management-report.html>. This guide is also online at <https://cmcfy.com/guides/risk-management-report.html>

1. What this module does

You set the acceptability threshold and list each hazardous situation with its severity, probability, risk control, control type, verification and residual probability.

The tool scores the risk before and after control, flags situations not acceptable without a control, unverified controls, information for safety used alone for serious harms, residual risks needing a benefit-risk analysis, and a missing overall evaluation, review or post-production plan.

What you get

- A Word or PDF file: risk management report.

2. Before you start

Have these ready. You can still start with the example data and replace it piece by piece.

- The risk management plan with the acceptability policy.
- The hazard analysis.
- Verification evidence for each risk control.

Your data stays on your computer. The bar under the title counts every network request the page makes; it stays at 0 because your data never leaves your computer. [Download offline](#) [copy](#) saves a single file that opens from your own computer with all network access blocked, for air-gapped PCs.

3. Step by step with the example

Open the tool at app.cmcfy.com/app/risk-management-report.html. The example is loaded when the page opens, so every panel already has realistic data. Follow the steps to see how it works, then replace the example with your own data.

1 Set the policy

Give the acceptability threshold (severity × probability) and tick the overall residual risk evaluation and the review.

CMCfy Risk Management Report (ISO 14971) Projects All modules Training Security Runs entirely on this device [Training guide](#)

PROJECTS Keep this work in a project, with version history and your company logo on every report. [Choose projects folder](#) [Keep in this browser](#)

- Network requests since load: 0**
Counted live by your browser. Your data never leaves this device.
- Works offline**
Everything the tool needs is inside this page.
- Locked offline copy**
Save a single file that opens from your own computer with all network access blocked.

[RMF](#) [ISO 14971](#) [Save project](#) [Open project](#) [Start blank](#) [Load example](#)

Write the risk management report for a medical device to ISO 14971:2019. The tool scores each hazardous situation before and after control against your acceptability policy, checks the priority of the risk controls and their verification, needs a benefit-risk analysis for any residual risk that is not acceptable, and checks the overall residual risk evaluation and post-production plan.

Guidance: ISO 14971:2019; ISO/TR 24971:2020; FDA recognised consensus standard (ISO 14971:2019); 21 CFR 820 (QMSR); EU MDR 2017/745 Annex I (GSPR 1-9) and Annex II; IEC 62366-1 (usability); IEC 62304 (software)

1 - DEVICE AND POLICY

Device

CMX FlowSense infusion monitor

Risk management file

RMF-0042 rev B

Acceptable when severity x probability is at or below

6

☒ Overall residual risk evaluated against the benefits

☒ Risk management review before release (clause 9)

Production and post-production information plan (clause 10)

Complaint trending, MDR/vigilance reports, field service data

Benefit-risk analysis for residual risks that are not acceptable

RESULT

1 critical issue in the risk management report

5 hazardous situations; 5 not acceptable before control, 0 after. Acceptability threshold: severity x probability ≤ 6.

SITUATIONS	UNACCEPTABLE BEFORE	UNACCEPTABLE AFTER
5	5	0
UNVERIFIED CONTROLS		
1		

RISK BEFORE AND AFTER CONTROL

ID	HAZARDOUS SITUATION	S	P	RISK	CONTROL	TYPE
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2 Enter the hazard analysis

One row per hazardous situation. Control type is design, protective or information.

3 Read the result

The headline gives the outcome, for example "1 critical issue in the risk management report".

RISK BEFORE AND AFTER CONTROL						
ID	HAZARDOUS SITUATION	S	P	RISK	CONTROL	TYPE
HZ-01	Clinician relies on a falsely normal reading	4	3	12	Dual-path sensing with cross-check; fault alarm	design
HZ-03	Infusion stops without alarm	4	3	12	Occlusion detection algorithm with 30 s alarm	protective
HZ-05	Alarm in a noisy ward	4	2	8	Alarm volume range and visual alarm; IFU warning on volume	protective
HZ-07	Altered readings sent to the EHR	4	2	8	TLS 1.3 encryption and device authentication	design
HZ-09	Monitor on wrong line	3	3	9	IFU instructions and line label	info

Risk before and after control.

4

Resolve alerts and download

Unverified controls, unacceptable risks without a control or without a benefit-risk analysis, and no overall evaluation are critical. Then preview and download.

Preview and review before download Close

Review

Checked on this device: gaps in the data, gaps in the report against ICH and regional expectations, and differences from the protocol.

1 critical 1 recommended

MISSING INFORMATION (1)

"Benefit-risk analysis for residual risks that are not acceptable" is empty.

Enter it in the tool, or confirm it does not apply. Empty inputs show as placeholders or gaps in the report.

recommended · Device and policy Ignore

DATA AND INPUTS (1)

HZ-07: the risk control is not verified.

Verify the control is implemented and effective; record the evidence.

critical · Verification · ISO 14971:2019 7.2 Ignore

Compare with the protocol

Load or paste the approved protocol. Every requirement and acceptance criterion in it is looked for in the report.

Paste the protocol text here, or load the file.

Load protocol file Compare

RMF Risk management report (ISO 14971:2019)

CMX FlowSense infusion monitor · CMX FlowSense infusion monitor · RMF-0042 rev B

Device	CMX FlowSense infusion monitor
Risk management file	RMF-0042 rev B
Acceptability policy	Severity × probability ≤ 6

Hazard analysis and risk control

ID	Hazardous situation	Harm	S × P	Risk control	Residual
HZ-01	Clinician relies on a falsely normal reading	Under- or overdose	4 × 3 = 12	Dual-path sensing with cross-check; fault alarm (design); verified	4 acceptable
HZ-03	Infusion stops without alarm	Delayed therapy	4 × 3 = 12	Occlusion detection algorithm with 30 s alarm (protective); verified	4 acceptable
HZ-05	Alarm in a noisy ward	Delayed therapy	4 × 2 = 8	Alarm volume range and visual alarm; IFU warning on volume (protective); verified	4 acceptable
HZ-07	Altered readings sent to the EHR	Wrong treatment decision	4 × 2 = 8	TLS 1.3 encryption and device authentication (design)	4 acceptable
HZ-09	Monitor on wrong line	Wrong reading	3 × 3 = 9	IFU instructions and line label (info); verified	6 acceptable

Risk management review

The risk management plan has been carried out, the overall residual risk is acceptable and methods are in place to collect and review production and post-production information.

Fix or justify the 1 blocking alert before downloading. Or choose "Download anyway".

Download anyway Download Word (.docx) Download PDF

Document text

4. Field reference

Every input in the tool, panel by panel. Tables accept rows pasted straight from Excel, comma-separated text, or a loaded file; check the columns after loading a file. Fields marked “when it applies” appear only for the choices that need them.

1 · Device and policy

FIELD	WHAT TO ENTER
Device	Type it in.
Risk management file	Type it in.
Acceptable when severity × probability is at or below	Type a number.
Overall residual risk evaluated against the benefits	Tick the box if it applies.
Risk management review before release (clause 9)	Tick the box if it applies.

FIELD	WHAT TO ENTER
Production and post-production information plan (clause 10)	Type it in.
Benefit-risk analysis for residual risks that are not acceptable	Type or paste text.

2 · Hazard analysis

One row per hazardous situation. Control type: design, protective or information. Verified: yes when implementation and effectiveness are verified.

FIELD	WHAT TO ENTER
Hazardous situations	Severity and probability on 1 to 5 scales. A table. Columns: ID Hazard Hazardous situation Harm Severity Probability before Risk control Control type Verified (yes/no) Probability after New hazards from the control (yes/no). Paste rows from Excel, type comma-separated rows, or press Load file (Excel, CSV, Word, PDF or a scan).

5. Checks and alerts

Calculations and pass/fail outcomes always come from fixed rules, never from AI. The tool checks:

- Risk before and after control.
- Control priority and verification.
- Benefit-risk, overall residual risk and post-production.

How to resolve alerts

- **Critical** alerts block the download and must be fixed in the data. A failing result can instead be linked to an investigation: type the investigation reference and outcome and press [Record](#).
- **Major** alerts block the download until you fix them or type a justification and press [Accept justification](#).
- **Minor** alerts do not block anything. They are listed in the documents so the reviewer sees them.
- Some alerts have an [Apply fix](#) button that makes the change for you. [Reopen](#) undoes a justification.

Narratives

This module writes: Conclusion. Each narrative is written by fixed rules from your data. You can edit it in the box. **Rewrite with AI** (where your plan includes AI) rewrites it in regulatory style; every number in the text is checked against your data, and a number that does not match is flagged under the box and blocks the download until you correct it. **Reset to rule-based text** brings back the original.

6. Preview, gap review and download

1. Press **Preview** next to a section, or **Preview and download all**. The document opens in a preview window, exactly as the Word file will read.
2. The left side lists the review, run on your device: **gaps in the data** (missing values, open alerts), **gaps in the report** (missing content the guidance expects, placeholders such as [site] or TBD left in the text) and, if you load the approved protocol under **Compare with the protocol**, **differences from the protocol** (requirements, criteria, batches or time points it plans that the report does not show).
3. Click a finding to jump to the place in the preview. Fix it in the tool, then preview again.
4. Optional **AI review**: a second read for contradictions, claims without data and vague wording. The report text is sent to Claude only when you press it, and only where your plan includes AI. Check every AI finding; AI can be wrong.
5. Press **Download Word (.docx)** or **Download PDF**. With several documents open, **All as Word (.zip)** and **All as PDF (.zip)** download the set. The download buttons stay disabled while a blocking alert is open; the preview still works.

Documents this module produces

SECTION	DOCUMENT
RMF	Risk management report (ISO 14971:2019)

Use **Save project** to keep your work as a file on your computer, and **Open project** to continue later. **Start blank** clears every field; **Load example** brings the example back. Nothing is stored on CMCfy servers.

7. US and EU submissions

ISO 14971:2019 is recognised by FDA and harmonised under the EU MDR; the EU also needs risks reduced as far as possible (Annex I).

8. Working with other modules

- Risk controls are traced in the Design History File.

9. Common pitfalls

- Relying on a warning in the IFU for a serious harm.
- Releasing with unverified risk controls.

10. Practice exercises

Each exercise starts from the example (press [Load example](#) to reset). We run these on every update of this guide, so the result you see should match.

1. **Verify the network control**

Mark the HZ-07 control as verified.

EXPECTED RESULT

All residual risks are acceptable.

Guide updated 28 October 2026 for the current version of the tool. CMCfy drafts are for review by a qualified person before use in a submission.