Matrix eIFU

eIFU Ready

The Complete Guide to implementing electronic Instructions for Use under MDR

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>88%

of HCPs prefer eIFU over paper

27+

EU Member States with distinct language rules

20

IFU writing best practices to reduce use errors

BY MATRIX eFIU — MATRIX ONE

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How to write your IFU clearly ?

The user needs to know what to do, how to do it, and when to do it.

Don't bury this important information in a lot of text

Good to know

- Focus on **how to operate** the device.
- Assume that your user **does not have a device** or **medical knowledge** or ability.
- Provide **logically ordered steps** for the task.
- State the **purpose** and the **expected outcome** of each task.
- **Be clear** the first time they are read. Many people will not re-read something they do not understand.

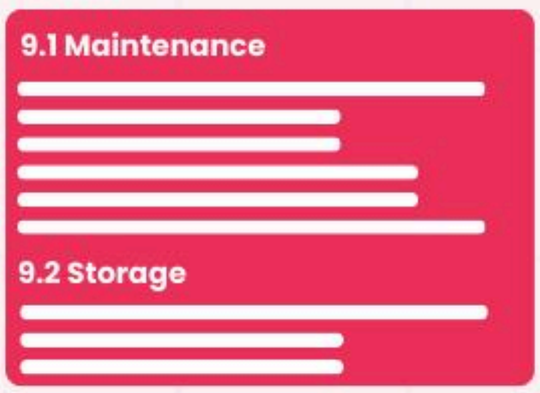
20-writing tips & best practices to apply in your IFU

1. Write procedures in **short, identifiable steps**. Put the **steps in the order** that they should be performed.
2. Before each set of steps, **tell the reader how many steps are in the procedure**. This helps the reader avoid missing, steps.
3. Limit each step to no more than **three logically connected actions**.
4. Make the **instructions** for each action **clear** and **definite** to prevent **misunderstandings**.
5. Tell the user what to **expect from an action**.
6. Discuss common **use errors**. Provide **information** to prevent and **correct use errors**.
7. **Each step** should be contained on **one page**.
8. **Avoid** referring the user to another place in the IFU for other information with vague information (unclear **cross-referencing**)
9. Use as **few words as possible** to present an idea or describe an action
10. Use **no more than one clause** in a sentence.
11. Write the way you talk. **Avoid formal language**.
12. Express **ideas** of **similar** content in similar **form**.
13. Users should be able to **read the instructions aloud**. Do **not use parentheses** for information that should be read.
14. Use the **same term** to identify the **device** and its parts throughout the manual. **Avoid synonyms** or alternate phrases.
15. Use **specific terms**. Vague terms may be misinterpreted.
16. Use **active** rather than passive **verbs**.
17. Use **action verbs**, not nouns created from verbs.
18. Avoid **abbreviations or acronyms**. If you feel it's necessary, define them the first time you use them. Use them consistently
19. Use **lay language** rather than uncommon jargon or technical terms, especially for MD intended to be used by **lay persons**.
20. **Terms** should be **defined** the first time that they occur in the text. Keep **definitions simple** and **concise**.

IFU elements as "Risk Control Measures" may require validation through summative usability testing.

4 main formats to use in your IFU ↓

1. Text



Pros:

- Familiar
- Easy to develop, update and handle
- It can be constructed to tell the user that other steps are necessary

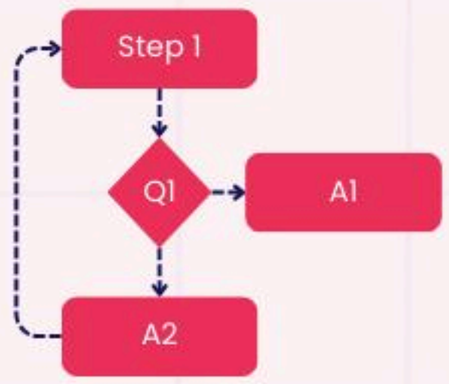
2. Text + Photos



Pros:

- Complementary to text
- Quick identification
- Guide the user with a visual aid
- Avoid use error on complex interfaces (software / hardware)

3. Flowchart



Pros:

- It uses symbols in a logical order
- It guides users through a series of sequential, simple decisions
- It simplifies conditional actions

4. List

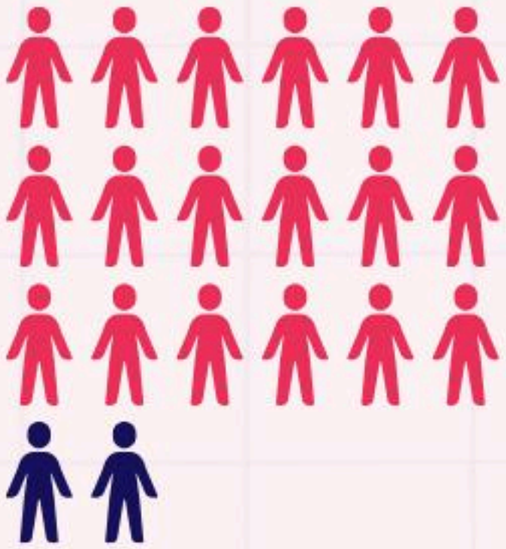


Pros:

- A list may also be a checklist
- It is useful for lengthy tasks
- It is helpful when learning to use an unfamiliar device

Switch from paper to electronic Instructions for Use with Matrix eIFU

9 Reasons to adopt eIFU for your medical devices



>88% HCPs prefer eIFU

>88% of healthcare professionals would prefer to have eIFU, if available.

90 %

Hospital admin staff prefers eIFU

>90% of the hospital administrative staff/hospital pharmacists would prefer to have eIFU for medical devices.

>99%

confirms widespread internet access

The overwhelming majority of HCP have internet access in their workplace, to download your eIFU.

Ref : MedTech Europe position paper "Electronic Instruction for Use for all professional use Medical Devices"; based on 882 responses (750 HCPs/ 132 Admin staff)

eIFU as effective risk control measures



Manufacturers are responsible for informing end-user of hazardous situation that could occur when they interact with the device. eIFU remains the last layer for conveying information.

Real-time updates

Unlike paper, eIFU ensures that the user always has access to the most recent version of the instructions, including the latest safety information.

Improved usability

The electronic format makes the content searchable (keyword search), reducing the time needed to find specific information.

Waste reduction

Eliminating paper significantly cuts waste and resource use. Companies can save around 500 tons of paper per year.

Cost reduction

Printing, storage, and logistics costs associated with paper instructions are eliminated. Updates no longer require scrapping existing stock.

Inclusivity

The eIFU improves accessibility for people with visual or cognitive impairments thanks to adjustable formats (zoom, contrast).

Switch from paper to electronic Instructions for Use with

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Matrix eIFU

Guarantee real-time access to the latest documentation for healthcare professionals and patients, with full audit readiness.

MDR – Language requirements Label/IFU for Professional user

- A Cheat Sheet to implement electronic Instruction For Use (eIFU) -

Matrix eIFU

Guarantee real-time access to the latest documentation for healthcare professionals and patients, with full audit readiness.



Legend

- **English not permitted** (official language of the country)
- **Special case** (upon specific request, possible under certain conditions)
- **English permitted** (and/or specifications)
- **No Data***

Best practice

- Use mandatory **simulated-use studies** to assess IFU **logic**, **structure**, and step-by-step **usability** during first-time use.
- Evaluate **structure**, **word choice**, and i**nformation findability** through location and **comprehension studies**.
- Use optional **simulated-use studies** to assess real-world engagement and identify **design elements** that **influence use**.
- Improve **engagement** by **exceeding minimum** font size recommendations and including **images** for all **critical steps**.

**Source : MDR - Language requirements for manufacturers - Rev. 3 (August 2025) Label/IFU (Art. 10 (11), Annex I, section 23, MDR) for Professional user*

About eIFU implementation ↘

- The **device label** must clearly indicate that instructions are provided in **electronic form instead of paper**.
- Information on how to **access the eIFU** must be provided on the **packaging** or in a **paper document**.
- This access information must include the **Basic UDI-DI or UDI-DI** and **manufacturer contact** details.
- Manufacturers must have a **system** to provide **paper instructions** at **no additional cost** within **7-calendar days** of a request.
- Information on **foreseeable medical emergencies** must be provided on the device or a leaflet.