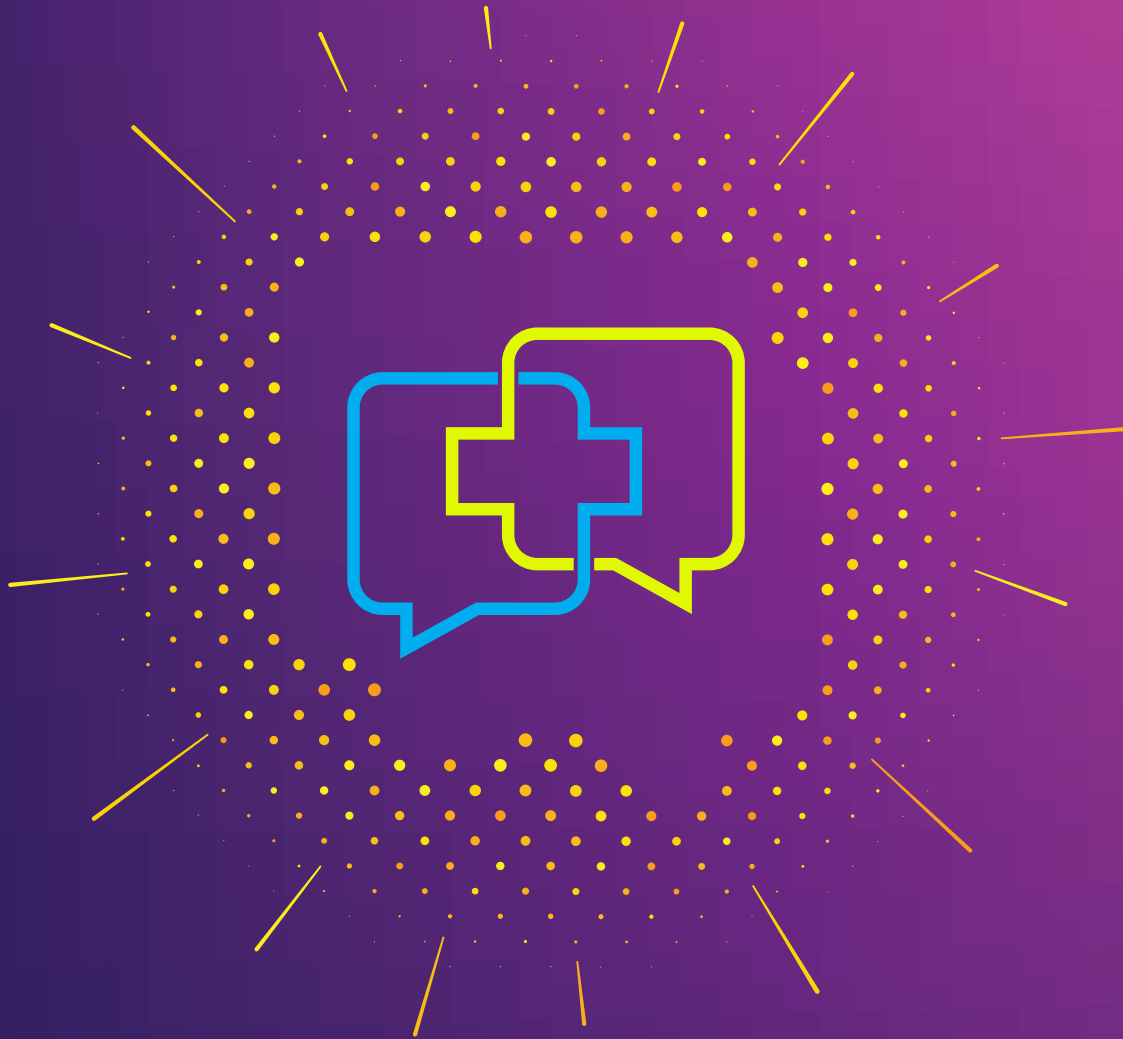




Medical Device Localization: When Every Word Affects Patient Safety

A unique challenge in medical device localization is that translators are no longer working only with documentation; increasingly, they're translating part of the product itself.

By Emi Lecret

A nurse is preparing an infusion pump for a patient. The instructions for use (IFU) tell her to select *Treatment Mode* before confirming the settings. She turns to the touchscreen, scans the menu, and pauses. There is no *Treatment Mode*. Instead, the software displays *Therapy Settings*.

Both translations are linguistically correct. Neither would raise concerns during a terminology review. Yet the discrepancy forces the nurse to stop and decide whether she's looking at the wrong screen, using a different software version, or misunderstanding the instructions.

Those few seconds illustrate a challenge that's unique to medical device localization. Translators are no longer working only with documentation. Increasingly, they're translating part of the product itself.

Modern medical devices combine embedded software, touchscreen interfaces, mobile applications, warning messages, packaging, quick reference guides, and IFUs into a single user experience. From the manufacturer's perspective, these components may be created by different teams and translated at different times. From the user's perspective, however, they are one product. If they don't "speak" the same language, confidence—and sometimes safety—can suffer.

For translators, this changes the job in subtle but important ways. Medical terminology is still essential, but success in MedTech localization also depends on understanding software, usability, and the regulatory environment in which every word will ultimately be used.

You're Not Translating Documentation, You're Localizing a Regulated Product

Most technical translations are intended to inform. Medical device localization must also support action.

Users don't simply read the text; they interact with it while setting alarms, entering patient data, calibrating equipment, or responding to alerts. The localized interface becomes part of the workflow itself.

This distinction matters because regulations governing medical devices consistently require manufacturers to provide information that enables devices to be used safely and effectively by their intended users.¹ Although

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regulations don't prescribe individual word choices, they place significant emphasis on clarity, consistency, and usability. For translators, this means that a seemingly minor linguistic decision can have consequences beyond readability.

A warning message that's technically accurate but unnecessarily complex may slow comprehension. A button label that differs from the terminology used in the IFU may increase hesitation. A translation that ignores space limitations may require software redesign late in development. In other words, language becomes one component of the device's risk-control strategy.

Challenge 1: Software Strings Rarely Come with Enough Context

Ask experienced software localizers about their biggest frustration and many will give the same answer: lack of context.

Medical device projects often arrive as hundreds (or thousands) of isolated strings exported from the software. For example:

- Prime
- Lead
- Home
- Resume
- Stop

Without screenshots or developer comments, each string may have multiple valid interpretations.

Does *Prime* mean preparing an infusion line before treatment? Is *Lead* an electrocardiogram (ECG) cable or a verb? Does *Resume* restart a paused therapy or simply return to the previous screen?

Outside the MedTech industry, these ambiguities may result in awkward wording. Within a regulated medical device, such ambiguities can spread much further. A mistranslated interface string may later appear in screenshots, training materials, validation reports, and future software versions through translation memory (TM).

I've found that one of the most valuable skills in MedTech localization isn't finding the perfect translation; it's recognizing when there isn't enough information to translate confidently.

Good translators don't guess. They ask whether a message appears before or after treatment begins. They ask whether the intended users are clinicians, biomedical engineers, or patients. They ask for screenshots. They ask whether a button opens a menu or immediately performs an action.

Some project managers worry that questions slow projects down. In reality, unanswered questions often create far more work later, when inconsistencies have already spread across software builds,

Beyond Translation: Preparing for Medical Device Localization

- Translators interested in medical device localization benefit from looking beyond terminology, standards, and regulatory texts. These are essential, but they do not replace direct exposure to the MedTech industry itself.
- Attending medical device conferences, webinars, trade events, and professional meetings can help translators understand how manufacturers, software developers, regulatory teams, clinicians, patients, and other stakeholders actually interact with medical technologies. It also provides insight into the operational challenges companies face, the constraints affecting product development, and the concerns that matter most to intended users. This real-world understanding is difficult to acquire from reference materials alone.
- The resources available to translators already working in this field vary by region and by type of device. There is no single universal framework. Translators should therefore become familiar with the regulatory texts and professional guidance relevant to the markets they serve. In the European Union, this includes [Regulation \(EU\) 2017/745](#) on medical devices, together with applicable standards and guidance on information supplied by the manufacturer and usability engineering. Other jurisdictions have their own regulatory requirements and human factors guidance.
- When translators identify an inconsistency or potentially problematic wording, they should avoid presenting the issue as a matter of linguistic preference alone. Clients are more likely to understand its importance when the translator explains its possible effect on the product and its use, as well as the potential financial implications and impact on time to market. For example, explaining that a terminology mismatch may prevent users from following the instructions exactly. An ambiguous command may increase hesitation during a critical task. Inconsistent wording across the software and documentation may affect usability testing, training, validation, or ultimately patient safety. The translator should also flag that these issues could have direct financial consequences if they require late-stage corrections, software updates, repeated validation, or changes to documentation shortly before launch.
- Effective collaboration depends on connecting language decisions to concrete product risks. Translators, developers, technical writers, and product teams achieve better results when linguistic issues are discussed in terms of user behavior, workflow, usability, and safe use rather than style alone.

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documentation, and validation activities.

Challenge 2: The Interface and the IFU Can Drift Apart

One of the most common localization problems isn't incorrect translation. It's inconsistency between the software and documentation.

Medical device software evolves continuously during development. Menu names change. Warning messages are rewritten. Functions move from one screen to another. Meanwhile, technical writers are updating the IFU, regulatory teams are reviewing safety information, and localization teams may already be translating previous versions. Because these activities rarely occur simultaneously, software and documentation can gradually drift apart.

Imagine that engineers rename a menu from *Patient Setup* to *Create Profile* shortly before release. If the localized IFU still instructs users to select *Patient Setup*, both translations may be accurate. The problem is that users can no longer follow the instructions exactly as written.

During usability testing, even a brief hesitation matters. Human factors specialists study how users interact with medical devices

because uncertainty can increase cognitive load and contribute to errors under stressful conditions.² Translators don't conduct those studies, but they influence one of the variables being evaluated: the language users rely on to complete critical tasks.

This is why reviewing software strings in isolation is rarely enough. Whenever possible, translators should also compare interface terminology with the IFU, quick reference guides, and other user-facing materials. From a linguistic perspective, these may be separate files. From the user's perspective, they are all parts of the same conversation.

Challenge 3: Consistency Is a Usability Feature

Most translators value consistency because it improves readability. In MedTech localization, consistency serves another purpose: it reduces the effort required to use the device correctly.

General writing often encourages variation to avoid repetition. Medical devices reward the opposite approach. If the software tells users to *Insert the cartridge*, the IFU shouldn't later instruct them to *Load the cartridge*, and a troubleshooting guide

shouldn't refer to *placing the cartridge* unless those actions are genuinely different. Likewise, alternating between *patient cable*, *ECG lead*, and *patient lead* may seem stylistically acceptable, but users may reasonably wonder whether they're looking at different components.

Translation memory helps maintain consistency across projects, but it shouldn't replace critical thinking. A translation approved five years ago for a hospital-based device may no longer be appropriate for a home-use product. Likewise, a software string translated for a desktop interface may become too long when reused in a handheld device with a smaller screen.

Experienced MedTech translators know that a 100% match is not automatically the right solution. Every segment still needs to be evaluated within the current product, the current interface, and the current user context.

Ultimately, consistency is not about making the translator's work look tidy. It's about allowing users to move through a procedure without stopping to interpret language.

What Sets MedTech Localization Apart

Medical translators are accustomed to working with specialized terminology and highly regulated content. Medical device localization builds on those skills but requires a broader perspective.

The translator is no longer working exclusively with medical language. Software design, interface constraints,

usability engineering³, and documentation all become part of the translation process.

This often means accepting that the best translation isn't always the most elegant one. A shorter button label may be preferable because it fits the interface. Repeating the same term throughout the product may be better than introducing stylistic variation. Requesting clarification from the client may be more valuable than delivering a translation quickly.

In my experience, the strongest MedTech translators share one characteristic: they consistently think like end users. Will a nurse immediately recognize this command during a busy shift? Will a patient using the device at home understand this warning without referring to the manual? Does the wording in the IFU match exactly what appears on the screen? Those questions go beyond language. They reflect an understanding of how localized content contributes to the safe use of the device.

Looking Ahead

Medical devices continue to become more software-driven. Connected platforms, companion mobile applications, remote monitoring systems, and AI are increasing the amount of user-facing content that requires localization. At the same time, manufacturers face growing expectations to demonstrate that their products can be used safely by intended users in different markets.⁴

For translators, this evolution creates an opportunity to contribute beyond terminology alone.

Identifying an ambiguous source string, spotting a mismatch between the software and the IFU, or questioning inconsistent terminology may seem like small interventions. Yet these observations can prevent costly revisions, improve usability, and support the overall quality of a regulated product.

Returning to the nurse standing in front of the infusion pump, the issue was never whether *Treatment Mode* or *Therapy Settings*

was the better translation. The real problem was that the interface and the documentation no longer matched.

Medical device localization is full of similar decisions. Individually, they appear minor. Collectively, they shape how clinicians and patients interact with products designed to diagnose, monitor, and treat disease.

As medical devices continue to evolve, one thing is becoming increasingly clear: translators are no longer translating around the product. They are translating part of the product itself. 

NOTES

- ¹ [Regulation \(EU\) 2017/745 on Medical Devices \(April 5, 2017\), Annex I, Chapter III \(European Parliament and Council of the European Union\).](#)
- ² [Applying Human Factors and Usability Engineering to Medical Devices \(U.S. Food and Drug Administration, February 3, 2016\).](#)
- ³ [International Electrotechnical Commission. IEC 62366-1:2015+A1:2020—Medical Devices—Part 1: Application of Usability Engineering to Medical Devices \(Geneva: IEC, 2020\).](#)
- ⁴ [International Organization for Standardization. ISO 20417:2026—Medical Devices—Information to Be Supplied by the Manufacturer \(Geneva: ISO, 2026\).](#) Also see Notes 1 and 2 above.



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