



Translating a User Manual: Handling an English-only User Interface

When medical devices contain a user interface, this interface must work together with the user instructions to ensure safe and proper use of the device. The typical translation workflow has four stages:

1. generate English screenshots for the user manual
2. translate the software
3. generate and validate the localized screenshots
4. translate the user manual and insert the localized screenshots

A common question is whether the user interface requires translation or whether it can remain in English for international users. As your team decides whether you will translate the user interface together with the labelling, we recommend that you consider the following in your risk analysis:

- Can a non-English-speaking user safely interact with an English-language user interface that they cannot read?
- Are there any risks to the patient or operator if they misunderstand an on-screen message or button?
- How much English text appears on each screen? That is, how much unreadable “noise” is there for a non-English-speaking user to sift through when using the device?

There is no doubt that a translated interface increases understandability for non-English-speaking users and reduces the risks associated with linguistic use error. However, based on your regulatory timeline and the flexibility of your European regulators, you may need to translate your labelling before the device software. This workflow creates new obstacles for translation that you will want to consider.

Drafting the English Instructions

Regardless of whether the user interface will be translated, it is a good idea to clearly and consistently indicate on-screen elements within the instructions for use/user manual. This helps all users quickly and effectively identify interactive elements, such as menu items, buttons, and messages. The easiest way to achieve this is by using special formatting to indicate elements of the interface within the instructions. For example:

bold italics for buttons and other on-screen labels

“text in quotation marks” for system messages

A key benefit to formatting on-screen elements in your English instructions is the opportunity it provides to verify that the words used on the interface are identical to those used in the instructions. Word-for-word consistency is particularly important when the user cannot read the interface and must reconcile the instructions with the interactive screen in order to properly use the device.

European regulations clearly require that labelling be provided in local language, but some ambiguity remains around the requirements for user interfaces in medical devices. According to paragraph 21.3 in Annex I, General safety and performance requirements, of the MDR (2017/745):

“The function of the controls and indicators must be clearly specified on the devices. Where a device bears instructions required for its operation or indicates operating or adjustment parameters by means of a visual system, such information must be understandable to the user and, as appropriate, the patient.”

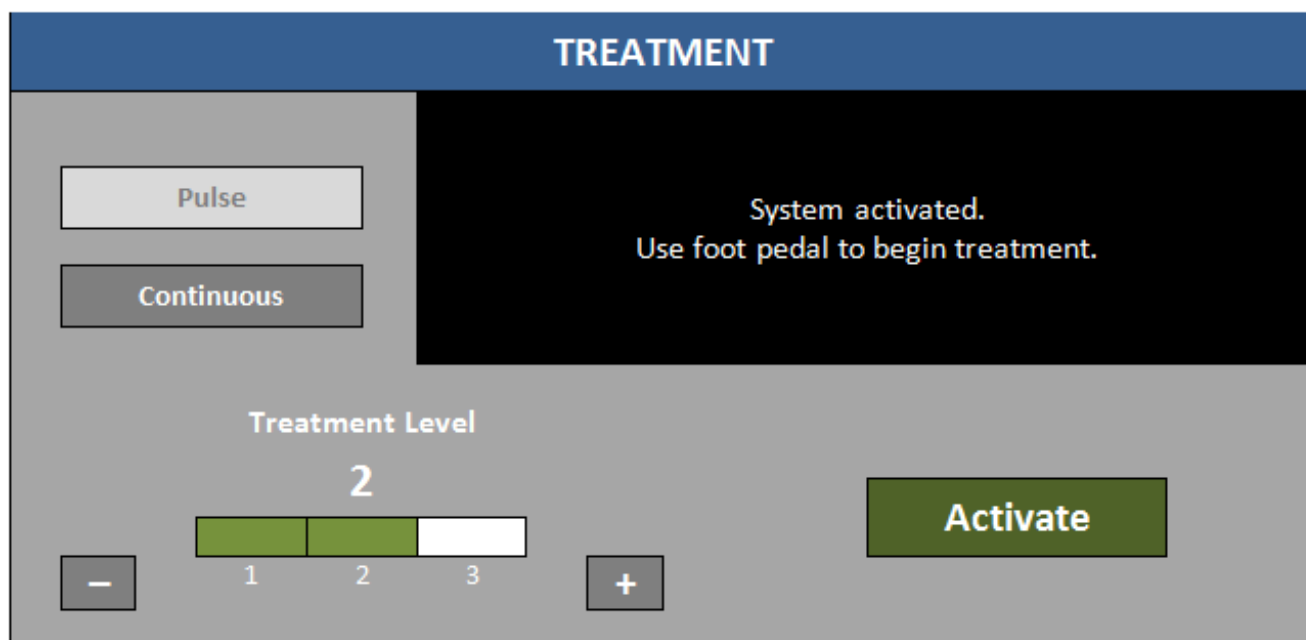
In this regard, compliance hinges on the word “understandable.” This dovetails with Annex A.2 of ISO/TR 24971:2020, guidance for the application of 14971:2019, which requires manufacturers to think critically about the role of the user interface in supporting proper use of the device:

- Is successful application of the medical device dependent on the usability of the user interface? (A.2.31)
- Can the user interface design features contribute to use error? (A.2.31.1)

| Risky: Without Formatting | Better: With Formatting |
|---|---|
| Select the Pulse button and click Activate. The screen will indicate System activated. Use foot pedal to begin treatment. | Select the Pulse button and click Activate . The screen will indicate: "System activated. Use foot pedal to begin treatment." |

Handling On-Screen Elements: Simple Interfaces

For simple interfaces, the operator’s instructions may provide sufficient context to ensure proper use of the device. In such cases, translations of the on-screen text can be provided within the flow of text. See the French example below, where the translation for on-screen elements is indicated in parentheses after the associated English.



| | |
|---------|---|
| English | Select the Pulse button and click Activate . The screen will indicate: "System activated. Use foot pedal to begin treatment." |
| French | Sélectionnez le bouton Pulse (Pulsation) et cliquez sur Activate (Activer). La fenêtre contextuelle indique : "System activated. Use foot pedal to begin treatment. (Système activé. Utilisez la pédale pour commencer le traitement.)" |

In this way, a non-English-speaking user can understand the intention behind each button and message, and can match them up with the appropriate on-screen element during use of the device.

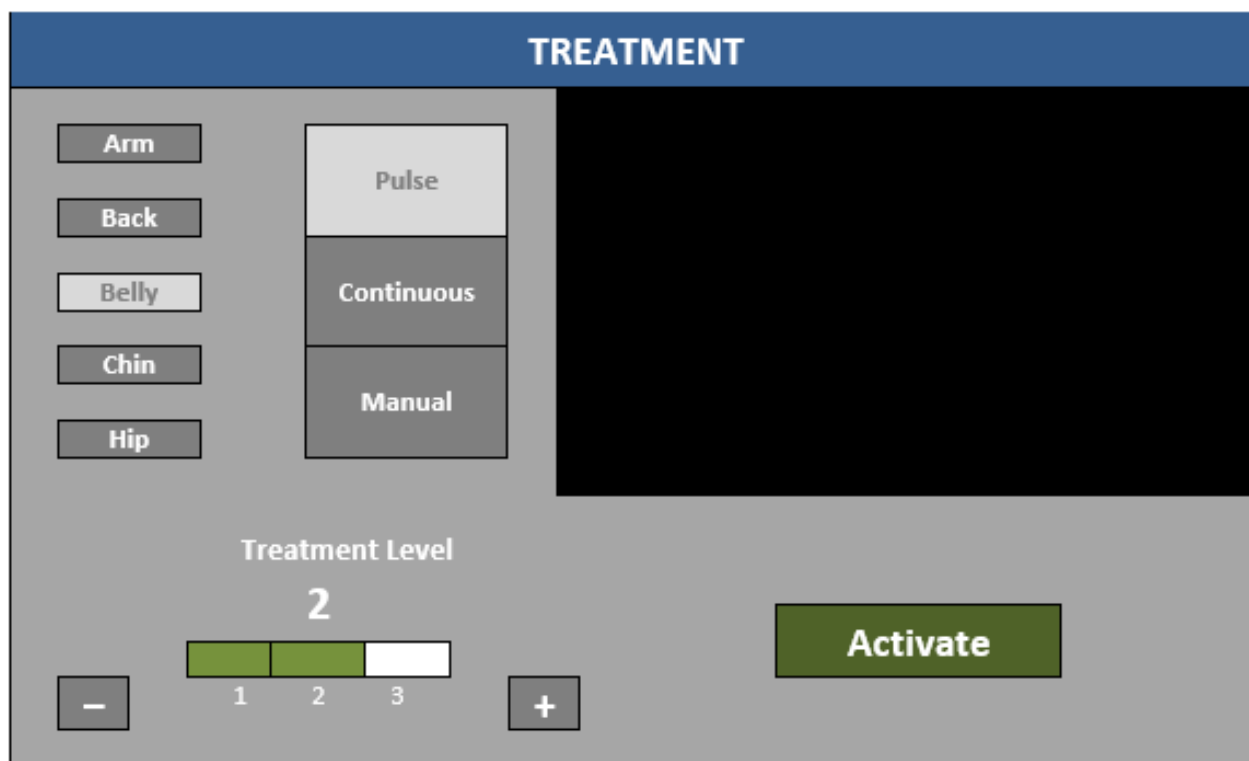
You may also want to consider whether your translation provider should use the same special formatting for the translations of on-screen elements as your team used for the English. If on-screen text is relatively short, consistent formatting will look the most professional. If on-screen elements are long, however, this may make the instructions feel "heavy". For example:

French Sélectionnez le bouton **Pulse (Pulsation)** et cliquez sur **Activate (Activer)**. La fenêtre contextuelle indique : "System activated. Use foot pedal to begin treatment. (Système activé. Utilisez la pédale pour commencer le traitement.)"

Whatever you decide, ensure that the instructions are formatted consistently throughout. This lends a professional appearance to the document while supporting safe use for English-speaking and non-English-speaking users alike.

Handling On-Screen Elements: Complex Interfaces

For more complex interfaces, the instructions may not provide the user with enough information to understand each screen and you will need to provide a non-English-speaking user with additional translations. In such cases, a table may be placed beneath each screenshot to translate all the on-screen options.



| English | French |
|-----------|------------|
| TREATMENT | TRAITEMENT |
| Arm | Bras |
| Back | Dos |
| Belly | Ventre |
| Chin | Menton |
| Hip | Hanche |

| English | French |
|-----------------|----------------------|
| Pulse | Pulsation |
| Continuous | Continu |
| Manual | Manuel |
| Treatment Level | Niveau de traitement |
| Activate | Activer |

How to Prepare for Success

Although translated interfaces are always best for the user, it is often possible to reduce the risks associated with an untranslated interface via careful handling of the user manual translation. Here is how to plan for a successful translation project:

- Step 1:** Perform a thorough risk analysis to confirm that it will be safe for non-English-speaking users to interact with English-only software.
 - Step 2:** Triple check that the user manual instructions are extremely clear. If the interface is not translated, your instructions need to do all the work for non-English-speaking users.
 - Step 3:** Use special formatting to tell the reader which text appears on-screen. Verify a perfect match between the actual software strings and the software references in the user manual.
 - Step 4:** Decide how you want to format the translations for the most professional appearance.
 - Step 5:** Determine if you need to add translation tables for each screenshot to ensure that non-English-speaking users can understand all on-screen elements during use of the device.
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About Idem Translations

Founded in 1983, Idem Translations, Inc. is a full-service provider of translation and localization services. Idem specializes in certified translations for medical device, biomedical, and pharmaceutical companies, as well as other organizations and entities working in the life sciences sector, such as contract research organizations, healthcare research centers, and institutional review boards. The company is a WBENC-certified woman-owned business and holds certifications to ISO 9001:2015, ISO 13485:2016, and ISO 17100:2015.

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