What happens when your user cannot read your device interface?

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. Idem recommends that your team consider the following in your risk analysis as you decide whether you will translate the user interface together with the labelling:

*   Can a user who does not speak English safely interact with an English user interface that they cannot understand?
*   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.

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.

(See paragraph 12.9 in Annex I of MDD, Directive 93/42/EEC, for identical requirement.)

In this regard, compliance hinges on the word "understandable." This dovetails with Annex C of ISO 14971:2012, which includes the questions:

*   Is successful application of the medical device critically dependent on human factors such as the user interface?
*   Can the user interface design features contribute to use error?

Drafting the English Instructions

Regardless of whether the interface will be translated, it is a good idea to clearly and consistently indicate the on-screen elements within the instructions themselves. 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:

<div align="center">

bold italics for buttons and other on-screen labels

"text in quotation marks" for system messages

</div>

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.

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 easily provided within the instructions themselves as part of the flow of text. See the French example below, where the translation for on-screen elements is indicated in parentheses.
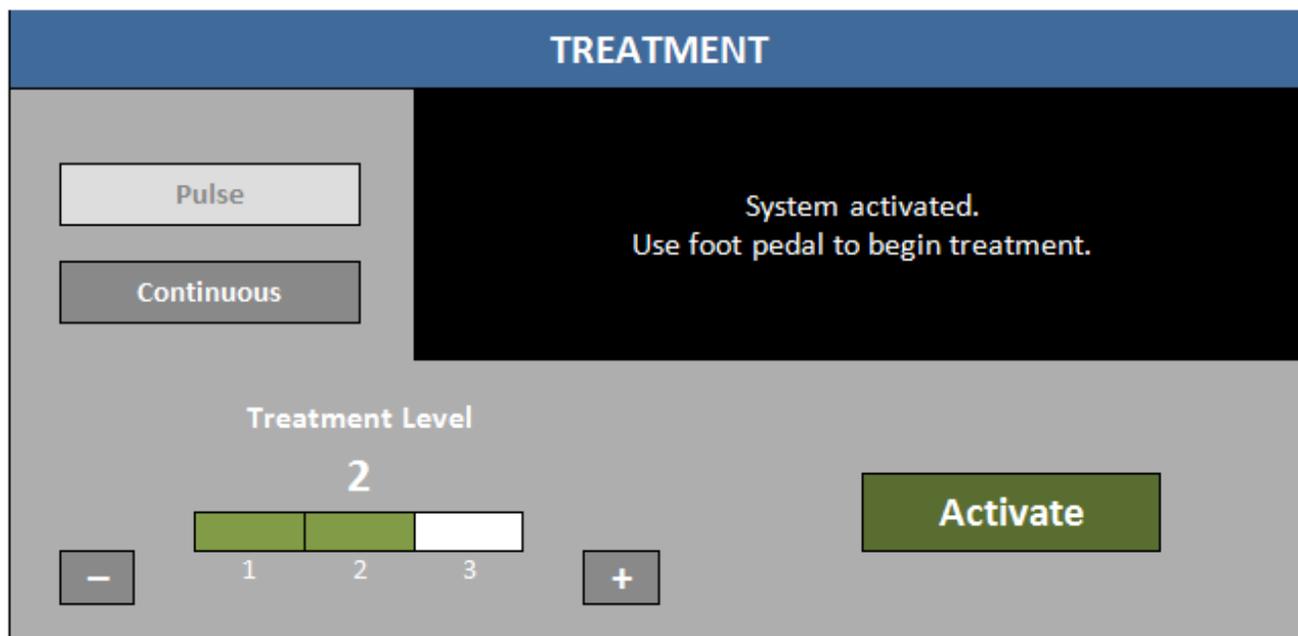
English	Select the *Pulse* button and click *Activate*. The screen will indicate: "System activated. Use foot pedal to begin treatment."
French	Sélectionnez le bouton *Pulse* (Pulsation) et cliquez sur *Activate* (Activer). La fenêtre contextuelle indique : "System activated. Use foot pedal to begin 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 then 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.)"

Also, you will want to take into account how much your instructions repeat themselves. Does every instance of an on-screen element need to be followed by its translation? Or should the translation only be provided at the first occurrence in the manual/section/chapter?

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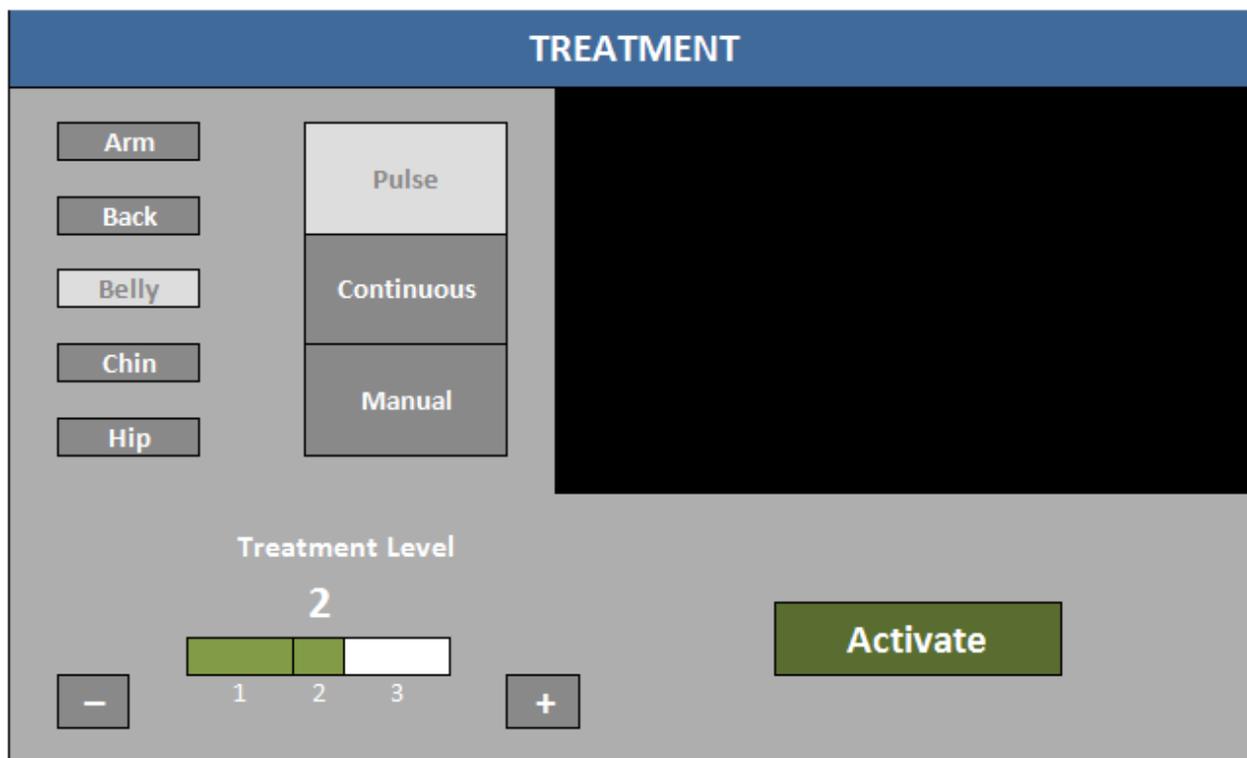
English	French
TREATMENT	TRAITEMENT
Arm	Bras
Back	Dos
Belly	Ventre
Chin	Menton
Hip	Hanche

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 and how frequently you want them to appear in the instructions.

Step 5: Determine if you need to add translation tables for each screenshot to ensure the user can understand all on-screen elements during use of the device.

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 (CROs), healthcare research centers, and institutional review boards (IRBs). The company is a WBENC-certified woman-owned business and holds certifications to ISO 9001:2008, ISO 13485:2003, and ISO 17100:2015.

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