Below is the label for Methinks Stroke Suite 2.2.0:

Methinks Stroke Suite

Número de versión: 2.2.0

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(CO-898) Instructions For Use and Label | Methinks Stroke Suite 2.2.0

Description

The labels in English, Catalan, Spanish, Romanian, and Serbian have been updated to include the latest version of Methinks Stroke Suite (2.2.0) and the lot number. The following changes have been applied to the IFUs in Serbian: Join has been removed as a notification tool, and Figure 1 (label) has been updated. Figures 3, 6, 8, and 9 have been revised to reflect the new notification layout, while the Join notification example has been removed from Figure 7. An example notification displaying PHI has been added to Figure 6. In the Image Pre-Processing Module section, de-identification/pseudonymization has been marked as optional, as it will depend on the configuration selected by the hospital. The following changes have been applied to the IFUs in Romanian and English: Figure 1 (label) has been updated, and Figures 3, 6, 8, and 9 have been revised to reflect the new notification layout. Furthermore, the IFUs in Spanish and Catalan have been updated and directly translated from the English version.

Justification

Due to the update of Methinks Stroke Suite 2.2.0, the labels and IFUs in English, Catalan, Spanish, Romanian, and Serbian have been updated.

Assigned To:	Initiated By:	Priority:	Impact:
Adrián Alvarez	Adrián Alvarez	Low	Major

Version History:

Author	Effective Date	CO#	Ver.	Status
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