



VISIBLE PATIENT PLANNING iOS

Release version 2.3.9

May 2022

New major features

- None.

New minor features

- Update authentication mechanism and allow account creation from the application.
- Update the Account Management view to visualize and edit active account information.
- Enable app files and databases encryption.
- Improve image storage efficiency.
- Update regulatory information according to USA, Australia and New-Zealand regulations.
- Add translations for Czech, Danish, Finnish, Norwegian (Bokmål), Polish, Slovenian and Swedish.

Removed features

- None.

Fixed bugs

- Fix inability to retrieve missing old cases when newer cases have already been retrieved.

Remaining bugs

- None known.

User manual

- Add clarification regarding pediatric usage in intended use.
- Add intended patient population, intended users and intended performances and claims.
- Update instructions for use regarding account management.
- Update system requirements (set minimal iOS version to 12).
- Add US Agent, Australian sponsor and New-Zealand sponsor.
- Add US caution regarding device sale: *"Federal law restricts this device to sale by or on the order of a physician"*.
- Update general warning to state that "any serious incident in relation to the device should be reported to Visible Patient and the local Competent Authority".
- Add mammography contraindication: *"This product is not intended for use with or for the primary diagnosis interpretation of Mammography images (MG)."*
- Update date, version number, UDI and links.
- Update all figures to use iPad captures.
- Add *"First date of CE marking: 2020"* in authorizations.
- Add security policy.