

# Development of an AI-supported Medical Device

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**Background:** The World Health Organization reports that over 2 million medical devices are categorized into more than 22,000 generic groups. Navigating this extensive range of devices presents significant challenges for healthcare professionals. User errors, often due to inadequate labelling, confusing instructions, poor design, and insufficient training, can lead to operational failures and compromise patient safety. These issues highlight the urgent need for enhanced knowledge management in healthcare settings.

**Aims:** This study aims to develop an AI-driven mobile app to improve the safe use of medical devices by providing real-time, accurate information and reducing user errors.

**Methodologies:** The study utilized the Design Fish Model to develop the product description within the technical documentation. The technical file was structured according to regulatory formats, with certain sections pending completion. A systematic literature review was conducted on June 1, 2024, using the Web of Science database. The review focused on recent, relevant studies to provide insights on the app's features and functionality

**Results:** The proposed app, self-classified as a Class I medical device, will use QR code scanning to provide immediate access to device specifications, usage guidelines, and safety protocols. QR scanning was selected for its efficiency and accuracy. The systematic review identified that the most crucial information for the app includes instructions for use (preferred in video or text format), device descriptions (preferred as brief visual guides), and component images (essential for understanding device parts). These findings, derived from the Spanish survey provide insights on the app's features and functionality.

**Conclusions:** The mobile app, leveraging AI and QR codes, aims to improve medical device usability by offering instant, accurate information. This approach is expected to reduce errors and enhance patient safety. Future development will incorporate user feedback to refine functionality.

**Keywords:** Medical devices, AI, QR code, mobile app, knowledge management, healthcare.