

OFA Considerations for IT Configuration Changes

Konan Medical's new ObjectiveField Analyzer (OFA) follows the latest cybersecurity considerations for medical devices. A comprehensive risk management system has been implemented for every stage of the OFA's product life cycle, from early development to end of life, through an extensive Quality System audited by relevant regulatory bodies and following ISO 13485:2016, IEC 62443, IEC 81001-5-1, AAMI TIR51:206, ISO 29001:2017, ANSI/AAMI SW96:2023, and MDCG 2019-16 guidelines and requirements.

The success and stability of the OFA is dependent upon a complex framework of settings and configurations within the embedded Windows operating system. The standard OFA user account is managed via group policies and permissions designed to prevent issues with hardware, as well as to prevent the software and HIPAA protected data from being compromised.

This device is not meant to be domain joined or its Windows user accounts altered in any fundamental way. Changing the OFA software's passwords, adding network mapped drives, printers, or other USB peripherals are the only changes that should be made by end-users.

IT departments, with the intention of supporting this device internally, should reach out to our support team with any questions prior to implementation. Our specially trained team is available to assist with all questions and technical issues that may arise. Support can be reached in several convenient ways:

Konan Medical USA, Inc.

Customer Service and Technical Support:

Phone: +1 (949) 576 2255

Email: support@konanmedical.com

Web: konanmedical.com/helpdesk