



MYANT

Instructions For Use

Myant Health Digital System (MHDS) (Canada)

IFU-157488-MHDS

Revision:	1.1
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1. Introduction

This document provides instructions for the safe and effective use of the Myant Health Digital System (MHDS) within Canada. The MHDS is a software suite comprising a mobile application for patients and a web portal for healthcare professionals, designed to work with Skiin Connected Clothing and Electronics.

Note: For detailed instructions on navigating the SCLA-A and MVCP software, please refer to their respective User Guides. For detailed information on the Skiin Pod and Skiin Garment, including their physical specifications, handling, charging, cleaning, and maintenance, please refer to the Operations and Safety Manual (OSM).

2. Device Identification

Device Name: Myant Health Digital System (MHDS)

Device Model Number: Ver. 2.5

Device Components:

Device Name	Model	Description
SCLA-A: Skiin Connected Life Heartbeat	Ver. 2.5	Mobile app for ECG data acquisition and visualization.
MVCP: Myant Virtual Clinic Portal	Ver. 2.5	Clinical portal for ECG review and patient monitoring.
MBE: Myant Back End	Ver. 2.5	Backend infrastructure for secure data storage and management.

Manufacturer:

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Mississauga, ON, Canada, L5K 2L1
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3. Device Overview

3.1. Device Description

The Myant Health Digital System (MHDS) is a Software as a Medical Device (SaMD) intended to support remote cardiac monitoring by securely receiving, storing, displaying, and managing physiological data from compatible devices.

The MHDS consists of three integrated software components, SCLA-A, MVCP, and MBE, that collectively enable:

- Secure data reception from compatible, connected devices.
- Storage and archiving of ECG data.
- Visualization of ECG waveforms and other physiological data.
- Management and export of patient data for further review.
- Download of ECG recordings for analysis using compatible third-party Holter analysis software, supporting integration into external diagnostic workflows.

Specifically, the types of data and sources are as follows:

Electrocardiogram (ECG) signals: Acquired from patients wearing the Skiin Garment and Skiin Pod.

Blood Pressure (BP) readings: Acquired from compatible home BP devices.

Weight measurements: Acquired from compatible home weight scale devices.

In addition to its medical functions, the MHDS also collects and displays non-medical wellness metrics, including steps, posture, and estimated body temperature, to provide users with a holistic view of their health and activity. These wellness features are provided for general lifestyle purposes only and are not intended for diagnosis, treatment, monitoring, or prevention of any disease or medical condition.

3.2. MHDS components

The system consists of two primary software interfaces:

Skiin Connected Life Heartbeat (SCLA-A): A mobile application intended for use by patients/wearers and their personal caregivers (Care Circle) to view data, log symptoms, and manage device connectivity.

Myant Virtual Clinic Portal (MVCP): A web-based portal intended for use by healthcare professionals (HCPs) to prescribe monitoring, review patient data, and manage patient cohorts.

3.3. Connected Hardware

The MHDS is designed to interface with the Skiin Pod and Skiin Garment.



The Skiin Pod captures ECG signals from the Skiin Garment and transmits these signals to the SCLA-A app. The collected data is then uploaded to the MBE, enabling clinicians to visualize and analyze the data via the MVCP.

The hardware is supplied in Kits. A standard kit includes:

- 1 Skiin Pod
- Moisturizer (optional)
- Skiin Garments - up to three per box
- 1 Washbag
- Charger Accessories: USB Charging Dock, Micro-USB Cable, Wall Plug

3.4. Third-Party Bluetooth Devices

The MHDS supports the integration of third-party physiological measurement devices for the collection of Blood Pressure and Weight data. The following device models have been validated for compatibility:

- Blood Pressure Monitor
 - A&D Medical UA-651BLE
 - A&D Medical UA-651BLE-V
 - Omron BP7450
- Digital Weight Scale
 - A&D Medical UC-352BLE
 - A&D Medical UC-352BLE-V

4. Intended Use and Indications

4.1. Intended Use / Indications for Use

The Myant Digital Health System (MHDS) is a Software (SaMD) intended for signal processing, analysis of adult ambulatory ECGs, and providing display, reports, and notifications to patients and clinicians through connections to other compatible and licensed 3rd party medical system software. The MHDS is intended to be used by Medical Professionals as an aid for non-urgent clinical decision-making. The MHDS is intended for use at a healthcare facility, medical research organization, or a Clinic under the direction of a licensed medical professional.

The MHDS is indicated for use as a remote cardiac monitoring system intended for use for adult patients who require cardiac monitoring and on a continuing basis. The MHDS is not suitable for use as a real-time arrhythmia event monitor.

4.2. Components of MHDS

Skiin Connected Life App - Heartbeat (SCLA-A):

The SCLA-A is intended to display health data without interpretation, to provide patients with access to their own data for tracking purposes only (not for diagnostic use).

The SCLA-A does not diagnose, treat, or prevent a disease. It promotes a healthy lifestyle and does not provide medical advice.

The SCLA-A facilitates the logging and tracking of:

- **Symptoms:** Patient-reported cardiac-related events (e.g., palpitations, chest pain) for clinical correlation with ECG data.
- **Moments:** Manual logging of daily routine tasks and activities to provide lifestyle context.
- **Wellness & Biometric Metrics:** Manual or automated capture of Blood Pressure (BP), Weight, estimated Body Temperature, and Activity data (Steps and Posture).

The SCLA-A facilitates transmission of ECG, accelerometer and wellness data from the Skiin Pod to MBE via the Internet connection of the patient's mobile device.

Myant Virtual Clinic Portal (MVCP):

The MVCP is a webviewer of data stored in MBE. The MVCP is intended to display ECG, patient-logged symptom events, and wellness data of a patient to the licensed healthcare professionals, who can independently review the provided data as an aid in patient management and diagnosis.

The MVCP does not include any diagnostic or therapeutic functions and does not analyze medical device data in a way that replaces the judgment of a healthcare professional. The MVCP is intended for the purpose of enabling healthcare professionals to independently make clinical decisions.

Myant Backend Environment (MBE):

The secure cloud infrastructure that acts as the central repository for all patient data. It receives encrypted data from the SCLA-A, performs secure storage and transformation, and serves the data to the MVCP for clinical review. The MBE ensures data integrity and security in compliance with applicable regulations.

4.3. Target Patient Group

The MHDS is intended for use with adults (18+ years) requiring cardiac monitoring. There are no specific restrictions regarding gender, ethnicity, or skin type, as the software does not involve direct patient contact. The patient population reflects that of the connected devices (Skiin Pod and Skiin Garment), including:

- Adult patients with indications for ambulatory ECG monitoring.
- Patients who can wear the Skiin Garment and have no contraindications to its use.

4.4. Intended Users

The MHDS is composed of three modules, each with distinct intended user groups:

MVCP: Intended for use by healthcare professionals who are qualified in ECG monitoring procedures. These users manage patient monitoring sessions, review ECG data, and oversee clinical workflows. In addition to



clinical users, the MVCP is also intended to be used by authorized administrative staff for non-medical administrative tasks, such as account management, user provisioning, or report handling. Intended for prescription use only.

SCLA-A: Intended for patients who are prescribed ambulatory ECG monitoring. Patients use the app to pair their Skiin Pod, view session status, and receive notifications related to their monitoring.

MBE: The cloud infrastructure that securely processes, stores, and routes data between the MVCP and SCLA-A. The MBE is not intended for direct interface with human users; it operates in the background to ensure data integrity and system functionality.

5. Contraindications

There are no direct patient contraindications specific to the MHDS (software) beyond those applicable to its associated devices (Skiin Pod and Skiin Garment).

- The Myant Health Digital System should not be used with pediatric patients under 18 years old.
- The Myant Health Digital System does not deliver any therapy, administer any drugs, detect or diagnose medical conditions.
- The Myant Health Digital System does not produce alarms and is not intended for active patient monitoring (real-time) and is not indicated for use as life-supporting equipment on high-risk patients such as critical care patients.
- The device is not intended for use in the hospital environment, in patients with active implantable medical devices such as pacemakers or implanted cardioverter defibrillator (ICD), and in magnetic resonance (MR) environments.
- The Myant Health Digital System analysis results are not intended to be the sole means of diagnosis. It is offered to physicians and clinicians on an advisory basis only in conjunction with the physician's knowledge of ECG patterns, patient background, clinical history, symptoms, and other diagnostic information.

6. Claims

The following claims are made for the MHDS, which operates as a software platform to receive, display, and manage ECG data collected from the Skiin Pod and Skiin Garment. These claims are based on verification, validation, and clinical data associated with the integrated device system.

6.1. Clinical Claims

The MHDS enables the secure reception, storage, and visualization of three-lead ECG data transmitted from the Skiin Pod, which collects cardiac electrical activity through the Skiin Garment.

The MHDS supports healthcare professionals in the remote management and review of patient cardiac monitoring sessions, ensuring data is available for clinical interpretation.

The system facilitates longitudinal cardiac monitoring of up to 30 consecutive days by managing and displaying session data in compliance with medical device data security and privacy requirements.



Patient-benefits

By enabling remote, continuous monitoring, the MHDS helps reduce the need for repeated in-person clinic visits for routine cardiac data collection.

Patients gain visibility into their session status (via SCLA-A), fostering improved compliance and engagement in cardiac monitoring regimens.

6.2. Non-Clinical Claims

The MVCP offers a web-based portal with intuitive dashboards, improving usability for healthcare professionals managing multiple patient monitoring sessions simultaneously.

The SCLA-A app provides session status notifications and reminders to patients to maintain engagement and proper device usage.

Disclaimers

The MHDS is not intended to provide automated diagnosis, clinical decision-making, or therapeutic recommendations. It serves solely as a data collection and visualization tool for qualified healthcare professionals.

The MHDS does not perform real-time cardiac monitoring or alarm for acute cardiac events; it is intended for retrospective review of recorded data.

The MBE (Myant Back End) operates as a background cloud infrastructure and is not intended for direct use or interaction by patients or healthcare professionals.

7. Warnings and Precautions

This section contains critical safety information that you must read and understand before using the MHDS. Failure to follow these instructions could result in inaccurate data, system malfunction, or compromise of data integrity. For safety information specific to the Skiin Pod and Skiin Garment, refer to their respective Operations and Safety Manuals (OSM).

7.1. Warnings

WARNING: Not for Diagnostic or Real-time Monitoring Use

- **Description of Risk:** The MHDS is designed to support clinical assessment by organizing and presenting ECG data but is not intended to provide diagnostic conclusions or replace physician judgment. It does not perform real-time cardiac monitoring or alarm for acute cardiac events; it is intended for retrospective review of recorded data.
- **Potential Harm:** Misinterpretation of physiological data, leading to incorrect assumptions about the user's health status or delayed/inappropriate medical intervention if relied upon for diagnosis or acute event detection.
- **Measures to Take:**
 - **ALWAYS** consult a qualified healthcare professional for medical diagnoses, treatment decisions, or any health concerns.
 - **DO NOT** use the MHDS as a substitute for professional medical advice, diagnosis, or treatment.

- **DO NOT** rely solely on MHDS data for critical health decisions or for real-time monitoring of acute cardiac events.

WARNING: Risk of Erroneous or Misleading Clinical Information

- **Description of Risk:** The algorithms and data processing within the MHDS software may be affected by various factors, including interference from other devices, ambient noise, or limitations in detecting specific ECG patterns (e.g., wide QRS complexes). This can lead to inaccurate outputs, missing events, or unreliable biometric information being presented.
- **Potential Harm:** Clinicians or users relying on the interfaced medical device and/or software may receive erroneous patient data, causing misinformation about a patient's event as an adjunct to diagnosis, potentially impacting patient management.
- **Measures to Take:**
 - The MHDS data is intended as an adjunct to, not a replacement for, clinical assessment and physician judgment.
 - Be aware that environmental electromagnetic interference can affect the quality of data collected and processed.
 - Clinicians can visually assess signal quality on any available ECG strips (e.g., in the MVCP) to infer heart rate accuracy and use discretion when interpreting presented data.
 - If patients notice inaccurate readings or inconsistencies, they shall ensure the software is updated and consult a healthcare professional.

WARNING: Cybersecurity Vulnerabilities and Data Compromise

- **Description of Risk:** Like all digital systems, the MHDS is susceptible to cybersecurity threats such as unauthorized access, data breaches, or malicious attacks if proper security measures are not maintained.
- **Potential Harm:** Compromise of patient privacy, unauthorized access to sensitive health information, data manipulation, or system malfunction.
- **Measures to Take:**
 - Refer to the "Cybersecurity" section of this IFU for detailed information and responsibilities.
 - Maintain strong, unique passwords for all MHDS accounts and change them regularly.
 - Implement multi-factor authentication (MFA) where possible.
 - Immediately deactivate accounts if unauthorized access is suspected or if a user leaves the institution.
 - Keep the MHDS software and associated applications updated by promptly installing patches and new versions.
 - Access sensitive patient data only within a secure network environment and avoid unsecured public Wi-Fi.

WARNING: Unauthorized Modification

- **Description of Risk:** Any unauthorized modification of the MHDS software or system components.
- **Potential Harm:** May compromise the safe and intended operation of the equipment, lead to inaccurate data, or create unforeseen hazards.
- **Measures to Take:**
 - Unauthorized modification of this equipment is not permitted.

- Only use hardware, including accessories and cables, specified or provided by Myant Health. Use of unauthorized hardware could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

7.2. Precautions

CAUTION: Use in Pregnant Women

Description of Risk: The safety and effectiveness of the Myant Skiin Garment system for cardiac monitoring have not been established in pregnant women. Changes in body morphology, skin impedance, and physiological cardiovascular shifts during pregnancy may affect the signal quality or clinical accuracy of the recorded ECG.

Potential Harm: Inaccurate or unreliable ECG data and heart rate metrics, which may lead to incorrect clinical interpretations or missed cardiac events by the reviewing healthcare professional.

Measures to Take:

- Consult with a licensed healthcare provider before using the Skiin Garment system if you are pregnant or planning to become pregnant.
- Healthcare professionals should exercise clinical judgment when prescribing this device to pregnant patients, considering that the normative data and algorithmic performance have not been validated for this population.
- If used during pregnancy, regularly verify that the Skiin Garment maintains consistent, snug contact with the skin at the designated electrode sites as body measurements change.
- Promptly report any skin irritation or discomfort to your physician, as skin sensitivity may be heightened during pregnancy.

CAUTION: Compatibility Issues with Firmware and Software

- **Description of Risk:** Incompatibility between the Skiin Pod's firmware version and the MHDS mobile application/software release can lead to data not being captured or incorrect device functionality.
- **Potential Harm:** Unavailable or inaccurate data, leading to a missed understanding of health patterns.
- **Measures to Take:**
 - Always ensure that the MHDS mobile application and the Skiin Pod firmware are compatible versions. Refer to Myant Health's official documentation or updates for compatibility requirements.
 - Promptly install recommended software and firmware updates.
 - If you encounter issues after an update, consult Myant Health Customer Support.

CAUTION: Data Loss or Connectivity Interruptions

- **Description of Risk:** Bluetooth Low Energy (BLE) connectivity between the Skiin Pod and the connected mobile application/system may be temporarily interrupted due to environmental interference, exceeding range limits, low battery on the connected device, or software glitches. This can lead to delays in data synchronization, incomplete data sets, or loss of stored data.

- **Potential Harm:** Incomplete or delayed access to physiological data, which may affect the user's ability to monitor trends effectively or prevent accurate algorithmic analysis.
- **Measures to Take:**
 - Ensure the connected mobile device is within the specified Bluetooth range of the Skiin Pod (refer to Skiin Pod OSM for range details).
 - Keep your mobile device adequately charged.
 - Regularly update the Skiin Pod firmware and the MHDS mobile application to the latest versions.
 - If connectivity issues or data loss persist, try restarting the Skiin Pod (refer to OSM) and/or the mobile application.
 - Ensure adequate storage space is available on your mobile device for data synchronization.
 - Minimize interference by keeping the Skiin Pod and your connected device away from other strong electronic devices or sources of electromagnetic radiation during data transmission.

CAUTION: Third-Party Device Integration and Usage

- **Description of Risk:** The MHDS integrates with supported third-party Bluetooth medical devices (Blood Pressure Cuffs, Weight Scales) to collect supplementary biometric data. Improper physical placement, usage, or maintenance of these external devices can result in inaccurate biometric readings being transmitted to the MHDS.
- **Potential Harm:** Display of inaccurate health metrics on the Skiin Connected Life App and Myant Virtual Clinic Portal, potentially leading to user confusion or incorrect clinical interpretations by a healthcare provider.
- **Measures to Take:**
 - When interfacing the MHDS with supported third-party licensed medical devices, you must strictly read and adhere to the respective manufacturer's Instructions for Use (IFU) for proper setup, physical operation, and maintenance of those devices prior to transmitting data to the Skiin Connected Life App.
 - Ensure the third-party device is properly paired with the mobile application, following the on-screen prompts, to prevent data assignment errors.

CAUTION: General Operational Integrity and Maintenance

- **Description of Risk:** Failure to adhere to operational best practices for the MHDS software can introduce security vulnerabilities or operational inefficiencies.
- **Potential Harm:** Compromise of patient data, system instability, or inefficient workflow.
- **Measures to Take:**
 - Clinical staff should always review the latest patient data within a secure network environment and avoid using unsecured public Wi-Fi when accessing sensitive data.
 - Follow all disposal policies set out by your local governing authority for the Skiin Pod and Skiin Garment (refer to their respective OSMs for specific instructions).

8. Risk Management Information

The MHDS has undergone a comprehensive risk management process consistent with ISO 14971 to identify, evaluate, and control risks associated with its use.

- **Undesirable Side Effects:** No undesirable side effects are known to be associated with MHDS software use. Physical side effects may result from the use of the Skiin Garment and are reviewed in the device's OSM.

9. Summary of Safety and Clinical Performance

9.1. Residual Risks

The MHDS is designed and manufactured to minimize risks as far as possible. All identified residual risks that remain after the implementation of risk control measures related to the MHDS system, software, and data interpretation are explicitly addressed in the “7.1. Warnings” and “7.2. Precautions” sections of this Instructions for Use.

For residual risks pertaining specifically to the physical hardware of the Skiin Pod (e.g., battery safety, electrical shock from physical damage, water ingress, material degradation) and the Skiin Garment (e.g., skin irritation from materials, physical fit, washing), please refer to their respective OSM. Users are encouraged to carefully review all relevant manuals to understand potential risks and the measures they can take to ensure safe and effective use of the entire system.

9.2. Clinical Performance

The MHDS reliably receives, stores, and displays three-lead ECG data collected via the Skiin Pod and Garment. It allows healthcare professionals to review cardiac data remotely and export recordings for diagnostic analysis. Clinical claims have been verified through performance validation, usability testing, and equivalence to existing systems used in ambulatory ECG monitoring. The system does not generate automated diagnoses. Final data interpretation remains the responsibility of qualified clinicians.

9.3. Expected Clinical Benefits

Enables early identification of ECG abnormalities through extended monitoring. Improves patient engagement and compliance via app-based feedback. Supports data-driven decisions by healthcare professionals. Reduces in-person visits for routine cardiac data collection.

10. Setup and Installation

10.1. Preparation of Connected Hardware

To ensure effective and secure operation of the MHDS, the following general steps are required for preparing the Connected Hardware. For detailed instructions on the physical handling, charging, and preparation of the Skiin Pod and Skiin Garment, refer to the respective OSM.



- Ensure the Skiin Garment is correctly sized for the patient and prepared as per its OSM. For optimal readings, apply a quarter-size amount of moisturizer on each sensor area, up to 3 times daily.
- Ensure the Skiin Pod is fully charged and activated as per its OSM. A full charge takes about 1.5 hours. For daily maintenance, charge for 20 minutes to prevent the battery from running down and ensure continuous monitoring.
- Refer to the table below for meanings of different LED colors.

Light Color	Meaning
Purple (Solid)	Charging in progress from a dead battery (will not turn Green when fully charged) / firmware update initiated by Skiin Connected Life Heartbeat App.
Green (Solid)	Fully charged in charging dock.
Red (Solid)	Pod is in error state. Contact customer support.
Red (Blinking)	Pod battery is very low and needs to be charged for 1.5 hours.
Blue (Blinking)	Pod is connected to Skiin Connected Life Heartbeat app.
Yellow (Blinking)	Pod is not connected and ready to be paired/connected.

10.2. SCLA-A Mobile Application Setup (Patient User)

SCLA-A: Download and install the latest version from a trusted source (App Store or Google Play). Ensure your mobile device meets the minimum OS requirement (iOS 15+, Android 13+). Grant required permissions (Bluetooth, notifications, storage access). Ensure BLE (Bluetooth Low Energy) is enabled on the device. Launch the app and follow on-screen instructions to pair the Pod via Bluetooth. Confirm successful pairing using the visual indicator on the app dashboard. Verify Internet Access: Ensure Wi-Fi or cellular data is active to enable secure cloud synchronization. Check Signal Quality: Use the app’s signal quality indicator before starting a recording session. Adjust the Skiin Garment if signal is not detected.

10.3. Connecting Third-Party Devices

For step-by-step guidance on how to pair a Bluetooth-enabled weight scale or blood pressure cuff with the SCLA-A application, please refer to the SCLA-A User Guide.

A comprehensive list of supported third-party hardware models is maintained in Section 3.4 (Third-Party Bluetooth Devices) of this IFU.

10.4. MVCP Web Portal Access (Healthcare Professional)

MVCP: Access the Portal: Go to <http://scwp.skiinserver.com> using a secure browser (Chrome 127+ or Safari 17.5+). Login Credentials: Enter username and password. Complete 2-factor authentication if enabled. User Role Verification: Confirm administrative or clinical access rights for managing patient data and reports. System Readiness Check: Review the clinician dashboard to confirm active sessions, incoming data, and system status.



10.5. Environmental Requirements

Avoid exposure to electromagnetic interference (EMI) from strong sources such as MRI scanners, industrial equipment, or high-voltage transformers. Do not operate the system in conditions outside the device requirements of the smartphone or browser platform. Maintain normal ambient room temperatures and humidity during use; no operation is intended in extreme environments.

11. Operating Instructions

11.1. Use and Operation

For detailed operating instructions for the SCLA-A application, refer to the SCLA-A User Guide.

For detailed operating instructions for the MVCP, refer to the MVCP User Guide.

11.2. Connected Devices

The MHDS is designed to operate in conjunction with the Skiin Pod (collects and transmits 3-lead ECG data to the SCLA-A mobile app via Bluetooth Low Energy (BLE)) and Skiin Garment (integrates textile-based sensors to capture cardiac electrical activity and interface with the Skiin Pod). General-Purpose Equipment Requirements: Mobile devices with BLE 5.0+, computers or tablets with high-speed internet access and secure browser support, and institutional IT infrastructure with data protection measures (e.g., firewalls, antivirus, user authentication). For detailed instructions for the Skiin Pod and the Skiin Garment, refer to the OSM.

12. Maintenance and Care

12.1. Routine Maintenance and Updates

Myant provides regular software updates for all MHDS modules (SCLA-A, MVCP, and MBE) and Skiin Pod Firmware. These updates may include performance improvements, UI enhancements, compatibility adjustments, and regulatory updates. Critical security patches are issued to mitigate identified cybersecurity risks. All updates are version-controlled, and release notes are provided. Clinics are encouraged to keep logs of installed versions. The MBE infrastructure is continuously monitored by Myant's IT team for system uptime, performance, and security. Regular audits of data transmission pathways and storage systems are conducted to validate encryption and security compliance.

12.2. Connected Hardware Maintenance

For instructions on routine cleaning, recharging, visual inspection, and firmware updates for the Skiin Pod and Skiin Garment, refer to their respective OSM. The Skiin Pod is a non-serviceable electronic device and contains no user-replaceable parts. All internal servicing must be conducted by Myant-authorized personnel.

Connected hardware includes the Skiin Garment, which is a reusable wearable item. It should be replaced when visibly worn, frayed, or after reaching the manufacturer-specified reuse limit. The Skiin Pod is rechargeable and reusable; refer to the OSM for its replacement guidelines.

Patients and clinics must clean connected hardware (Skiin Pod and Garment) in accordance with the OSM. Mobile phones used to access MHDS should be routinely disinfected using device-safe alcohol wipes in clinical settings, especially in multi-user environments.

12.3. Storage Conditions

The MHDS is a software-only medical device. It does not require physical storage for the software itself. For storage conditions applicable to the Skiin Pod and Skiin Garment, refer to their respective OSM.

13. Troubleshooting

For technical support related to any MHDS component or connected hardware, contact Myant Customer Support at Email: support@myant.ca or Phone +1-844-722-9977

In the event that an unexpected software error occurs within the SCLA-A application, an error message will be displayed on the App. For detailed navigation and usage of the SCLA-A application, refer to the SCLA-A User Guide.

If the Pod's LED blinks green indicating an error state, contact Customer Support for assistance. For further troubleshooting of the Pod, refer to the Pod OSM.

If the garment does not fit, visit the [Return Policy](#) for instructions on how to return or exchange for the correct size. For comprehensive information on the Garment, refer to the Garment OSM.

If the Pod fails to charge, maintain connection, or powers off unexpectedly, the device must be returned to Myant for assessment. For detailed information on Pod charging and connection, refer to the Pod OSM.

14. Cybersecurity and Data Management

14.1. Cybersecurity Overview

The MHDS implements a secure-by-design architecture to provide reasonable assurance of cybersecurity for its patient data and system functionality.

Risk Management: The MHDS incorporates a comprehensive cybersecurity risk management that includes threat modeling, attack surface reduction, and secure development lifecycles aligned with NIST and AAMI SW96.

Encryption Standards: The system enforces strong encryption for all data in transit and at rest.

- In Transit: All connections utilize a minimum of TLS v1.2.
- At Rest: Data is stored using AES-128 or higher encryption within the Myant Backend Environment (MBE).

Authentication and Access Control: The MBE operates a centralized authentication system for both SCLA-A and MVCP users.



- **Multi-Factor Authentication (MFA):** Clinicians accessing the MVCP are encouraged to utilize MFA to protect unique clinical identifiers.
- **Integrity Checks:** To maintain a secure operating environment, the SCLA-A software includes checks to prevent launching on compromised (jailbroken) mobile devices.

Post-Market Management: Myant maintains a **Coordinated Vulnerability Disclosure (CVD)** plan and established processes for providing regular security patches and updates throughout the device's service life.

14.2. Data Privacy & Regulatory Compliance

The MHDS is designed to satisfy global data protection standards, ensuring that patient privacy is maintained across all operational regions.

- **PIPEDA and PHIPA Alignment:** The system is built to adhere to security and privacy best practices as aligned with the **Personal Information Protection and Electronic Documents Act (PIPEDA)** and the **Personal Health Information Protection Act (PHIPA)**, as well as other provincial health privacy laws in Canada.
- **Regional Data Sovereignty:** The MBE is a cloud-hosted infrastructure that enforces regional data residency. Canadian patient data is managed and stored in accordance with Canadian regulatory requirements.
- **Data Erasure and Retention:** Myant provides a process for users to request account deletion. However, data collected through the MHDS is retained according to the organization's data retention policy to comply with legal and regulatory requirements (such as local regulations for clinical data) before final erasure.
- **Informed Consent:** The SCLA-A app facilitates the presentation and documentation of Electronic Informed Consent, requiring users to review and agree to the Privacy Policy and Terms and Conditions directly on their mobile device before proceeding.

14.3. Secure Use Instructions

To ensure the safe and compliant operation of the MHDS, the following precautions must be observed:

- **Secure Networking:** Clinical staff must access the MVCP only through secure, authenticated networks. The use of unsecured public Wi-Fi is prohibited. All Canadian patient data is stored within secured servers located in Canada.
- **Account Deactivation:** Clinics are responsible for the immediate deactivation of staff accounts upon a change in employment status or suspected unauthorized access.
- **Software Maintenance:** Users are required to keep the SCLA-A and MVCP updated to the latest versions to receive critical security patches and maintain the integrity of the cyber device.

14.4. Vulnerability Reporting

In the event of suspected cybersecurity vulnerabilities or incidents, users must report the incident to:

- Email: support@myant.ca
- Phone: +1-844-722-9977

14.5. Post-Market Security Alerts

Users will receive cybersecurity-related notifications or updates from the manufacturer via direct email communications or in-app notifications within the SCLA-A and MVCP applications. Users are advised to enable notifications and regularly check their email associated with their MHDS account to receive timely alerts.

15. Disposal and End-of-Life Information

The MHDS does not require physical disposal. It is a digital system installed on user-managed hardware (e.g., smartphones, computers). To ensure safe discontinuation: Uninstall the SCLA-A app when no longer in use. Remove patient data in accordance with local data protection policies. Follow institutional procedures for secure device wipe or data deletion if returning or repurposing hardware. Physical disposal information for the hardware is covered in the OSM.

16. Adverse Event Reporting

In the event of an incident involving this device, the use of the product must be immediately paused until the matter is clarified. Users or patients must report the incident to either Customer Support:

- MYANT MEDICAL CORP
2660 Speakman Drive
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