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Urgent Field Safety Notice

SynchroMed™ A810 Clinician Programmer Software Application v2.x.

Notification

November 2024

Medtronic Reference: FA1440
EU Manufacturer Single Registration Number (SRN): US-MF-000019977

Dear Healthcare Professional,

Medtronic has identified four software issues in the SynchroMed™ A810 Clinician Programmer (CP) Software application (app) version 2.x, used for the Model 8637 SynchroMed II and Model 8667 SynchroMed III Infusion pumps. This letter is to inform you about these issues, their potential impact on patients, and recommendations until a permanent solution can be implemented.

Issues and Recommendations

The following items provide a high-level summary of the four software issues. Additional details, along with instructions on how to identify the software version number, can be found in Attachment A.

1. **The audible Low or Empty Reservoir Alarm may continue to sound after a pump refill procedure**
   - **Affected Product:** Model 8637 SynchroMed II pump
   - **Description:** A low or empty reservoir alarm may continue to alarm, or may recur, after a pump refill procedure. In this situation, the pump will continue to deliver therapy as programmed.
   - **Patient Impact:** Since December 2023, there have been 154 complaints; 2 resulted in (unnecessary) pump replacements.
   - **Recommendation:** Silence the alarm using the A810 CP app. This will stop the current alarm however any future alarm events will still produce an audible alert.
2. **Potential for incorrect ERI/EOS Dates**
   - **Affected Product:** Model 8637 SynchroMed II pump
   - **Description:** During the first programming session after the pump has reached the elective replacement indicator (ERI), the A810 CP app will display a recommended pump replacement date

(end of service (EOS) date). However, in subsequent programming sessions, the recommended pump replacement date may be incorrectly updated to indicate a date further out in the future than the actual EOS date.

- **Patient Impact:** Since December 2023, there have been 2 complaints; one resulting in hospitalization for withdrawal symptoms due to the pump stopping at the actual EOS date, not the incorrect later date displayed on the A810 CP app.
- **Recommendation:** Record ERI and EOS dates in the medical records and review session logs. Patients that have their pump replaced prior to ERI will not encounter this issue.

3. **Forced Restart of the A810 CP app**
    - **Affected Products:** Model 8637 SynchroMed II and Model 8667 SynchroMed III pumps
    - **Description:** The A810 CP app may need to be restarted if the previous session was not properly closed. This results in the A810 CP app displaying a "Connection Interrupted" alert.
    - **Patient Impact:** Since December 2023, there have been 20 complaints. A required restart of the A810 CP app may cause procedural delays as pending settings may be lost.
    - **Recommendation:** Close the A810 CP app by using the "end session" option or restart the clinician tablet before initiating a new session.
4. **Flex Infusion Mode Programming Error**
    - **Affected Products:** Model 8637 SynchroMed II and Model 8667 SynchroMed III pumps
    - **Description:** Out-of-range programming durations (in the minutes drop-down menu) may be selectable in Flex Infusion Mode with the 24-hour lock "ON." If out-of-range values are selected,
        - The A810 CP app may fail, requiring a restart; pump continues to deliver therapy as previously programmed.
        - The A810 CP app may fail to enforce the locked total daily dose, allowing out of range infusion steps to be programmed in a 24-hour period.
    - **Patient Impact:** Since December 2023, there have been 2 complaints where procedural delays were encountered as the A810 CP app was required to be restarted. Programming a pump with out-of-range infusion durations may lead to withdrawal or overdose if the displayed cautions and warnings are ignored. Medtronic has not received any reports of programming errors due to out-of-range durations, leading to withdrawal or overdose.
    - **Recommendation:** To increase the 24-hour dose, unlock the 24-hour dose and configure the flex programming changes. To continue with the current 24-hour dose, select the programming values that are in range. Review displayed cautions and warning prior to programming the settings into the pump.

Customer Actions:

- Share this notice with all those who need to be aware of this issue within your organization and maintain a copy of this notice in your records.
- Please complete and return the Customer Acknowledgement Form enclosed with this letter, acknowledging that you have received this information.

Additional Information:

Medtronic is actively working on a permanent solution and will inform you as soon as it becomes available

Medtronic has notified the Competent Authority of your country of this action.

We regret any inconvenience this may cause. We are committed to patient safety and appreciate your prompt attention to this matter. If you have questions related to this issue, please contact your local Medtronic representative at 01 511 1400.

Sincerely,

Bethany Moxon

Associate Regulatory Affairs Specialist – UK and Ireland

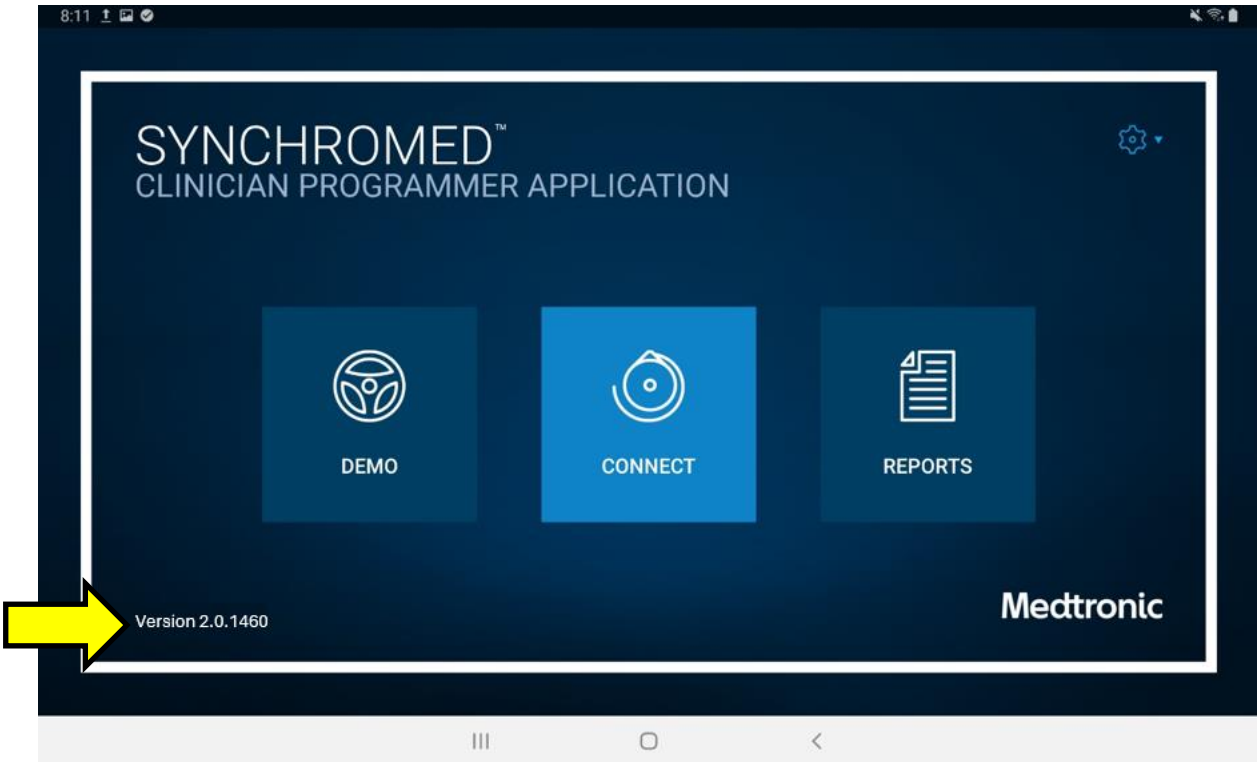
Enclosures:

- Appendix A – Identifying the A810 CP app version
- Customer Acknowledgement Form

Appendix A

Identifying the A810 CP app version

The version of the A810 CP app software can be found in the lower left corner of the of the Main Menu screen, an example is shown below.



Additional information for the four A810 CP app Software Anomalies version 2.x

1. **The audible Low or Empty Reservoir Alarm may continue to sound after a pump refill procedure**

   The SynchroMed II pump sounds an audible alarm when it reaches the calculated low and/or empty reservoir volume. Prior to refill, if a pump reaches this state and the pump alarms, the alarm is designed to automatically clear after the pump is refilled and the reservoir volume is updated with the A810 clinician software application. **While the pump will continue to deliver therapy as programmed,** the pump may continue to alarm or encounter a delayed recurrence of the alarm after the refill programming was completed. This is also observed as an "Active Alarm" on the home screen, however there is no alert displayed (on the home screen).

   The pump's audible alarms may be silenced from the Active Alarm option from the "Home" screen by enabling the silence alarm function on the A810 CP app and selecting "update" on the Finish screen. This will stop the current alarm, but any future alarm events will still produce an audible alert.

2. Potential for incorrect ERI/EOS Dates

The SynchroMed II pump calculates the number of service months remaining based on actual usage rates. When a pump reaches end of service (EOS), it is designed to automatically shut off with adequate warning. EOS is calculated 90 days after the Elective Replacement Indicator (ERI) notification has been reached. With the first programming session after ERI has been reached, the A810 CP app will display the correct EOS date. Record the replacement date in the patient's medical records. However, in subsequent programming sessions, the EOS date may may be incorrectly updated to show a date further out in the future than the actual EOS date.

3. Forced Restart of the A810 CP app

During an active programming session, the clinician may be forced to restart the A810 CP app if the previous session was not properly closed. In this scenario, the A810 CP app will display the "Connection Interrupted" alert (service code 338), which requires the clinician to restart the application. If there were pending settings that were not programmed to the pump, those settings will be lost and will need to be re-entered after restarting the session. Record all pertinent information (e.g., catheter information) into the patient's medical records.

This issue does not have any impact on settings already programmed to the pump and the **pump will continue to deliver therapy as programmed.**

4. Flex Infusion Mode Programming Error

The A810 CP app offers three infusion modes that a clinician can select when programming a SynchroMed Pump: Simple Continuous, Minimum Rate, and Flex Dosing. This software anomaly is related to flex dosing which is a programmed infusion mode that can deliver a sequence of independent steps of varying doses, rates, and durations within a 24-hour period.

When programming in Flex Dosing mode, with the 24-hour lock "ON" selected (default is "OFF"), the A810 CP app allows the clinician to select a step duration that is not valid, or out-of-range, in the minutes drop-down menu.

If the user selects an out-of-range step duration (a value that should not be available or offered for selection) it may result in:

- the A810 CP app may fail, requiring a restart
- the A810 CP app failing to enforce the locked total daily dose, allowing out of range infusion steps to be programmed in a 24-hour period

Medtronic has not received any reports of Flex Infusion Mode programming errors related to this issue. However, if such errors occur and multiple caution, warning, and acknowledgment prompts on the A810 CP app are ignored, it could lead to withdrawal or overdose symptoms due to inadequate or excessive drug delivery. This may require outpatient or inpatient management, and in severe cases, could result in life-threatening or fatal withdrawal or overdose symptoms.

FA1440 Customer Acknowledgement Form - Response is required
A810 SynchroMed Clinician Programmer App v2.x

Please complete this Form in its entirety.

Date: _____

Name of Person Completing this Form: _____

Title:_____

Direct Phone #:_____

Email:_____

Account Name:_____

Account Number:_____

Account Address:_____

City: _____Zip Code:_____

Country:_____

I have read and understand the instructions provided and acknowledge receipt of the notification regarding the use of the A810 SynchroMed Clinician Programmer App v2.x by signing below. I also agree to further distribute and communicate this important information within my facility and to anyone whom I have further distributed A810 SynchroMed Clinician Programmer App v2.x as required.

_____ _____ _____

Name: (print) Signature: Date:

If you have any questions regarding this notification, please contact your Medtronic sales representative.

PLEASE EMAIL THIS ACKNOWLEDGEMENT TO: rs.regulatoryuk-ire@medtronic.com