

# Hoffmann® LRF smarHEX™

## Strut Controller and Mobile Application User manual



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For smartheX, HexConnect or Hoffmann LRF Hexapod assistance, contact Stryker OR Assist Customer Service at:  
+1 (844) 393-4933

For non-urgent requests, contact the Hoffmann LRF helpdesk via email at: [smartheX@stryker.com](mailto:smartheX@stryker.com)

## Introduction

The Hoffmann LRF smartHEX platform is designed to guide patients through the recovery process following surgical application of an external fixation device by automatically performing the necessary corrections at the appropriate times, as prescribed by a surgeon.

The Hoffmann LRF smartHEX platform consists of an external fixation device, smartHEX struts and strut controllers, and the HexConnect Mobile Application.

The smartHEX strut controllers are attached to the smartHEX struts, and the HexConnect mobile application enrolls with the strut controllers. Once enrolled, the strut controllers can adjust the frame according to the prescribed correction plan by using wireless control commands from the HexConnect mobile app.

The prescribing surgeon may access correction data through the Hoffmann LRF smartHEX Web Application (for healthcare providers only).

## Indications for use

The Stryker Hoffmann LRF System is indicated in pediatric (2 through 21 years of age) and adult patients for the treatment and fixation of:

- Open and closed fractures
- Post-traumatic joint contracture which has resulted in loss of range of motion
- Fractures and disease which generally may result in joint contractures or loss of range of motion and fractures requiring distraction
- Pseudoarthrosis or non-union of long bones
- Limb lengthening by epiphyseal, diaphyseal, or metaphyseal distraction
- Correction of bony or soft tissue deformity
- Correction of segmental bony or soft tissue defects
- Joint arthrodesis
- Management of comminuted intra-articular fractures of the distal radius
- Bone transport

The Hoffmann LRF System is indicated in adults for:

- Osteotomy
- Revision procedure where other treatments or devices have been unsuccessful
- Bone reconstruction procedures
- Fusions and replantations of the foot
- Charcot foot reconstruction
- Lisfranc dislocations

## Use environment

The Hoffmann LRF smartHEX platform is a prescription device that is intended for use in accordance with the directions of a healthcare provider. The device is intended to be used in a professional or home health-care environment by the patient or homecare provider.

## Contraindications

- Since external fixation devices are often used in emergency situations to treat patients with acute injuries, there are no absolute contraindications for use. The surgeon's education, training and professional judgment must be relied upon to choose the most appropriate device and treatment for each individual patient. Whenever possible, the device chosen should be of a type indicated for the fracture being treated and/or for the procedure being utilized.

Conditions presenting an increased risk of failure include:

- Insufficient quantity or quality of bone which would inhibit appropriate fixation of the device
- Compromised vascularity that would inhibit adequate blood supply to the fracture or operative site
- Previous history of infections
- Any neuromuscular deficit which could interfere with the patient's ability to limit weight bearing
- Any neuromuscular deficit which places an unusually heavy load on the device during the healing period
- Malignancy in the fracture area
- Mental, physical or neurological conditions which may impair the patient's ability to cooperate with the postoperative regimen

# Introduction

## Warnings

- Always use smartHEX strut controllers as directed. The smartHEX strut controllers, in conjunction with the HexConnect mobile application, are intended to be used by adults or under adult supervision. Keep all parts away from pets and children to avoid injury from sharp edges and moving parts, choking on small parts, and avoid damage that may impact device performance.
- Do not submerge strut controllers in water or any other liquid. The strut controllers are IP24 rated and can withstand the water spray of a shower, but they are not designed for full immersion. A user must contact the care team if a frame has been submerged with the strut controllers attached.
- Batteries should only be replaced by qualified healthcare professionals.

## Cautions

- The HexConnect Mobile Application should be set up by the prescribing surgeon or care team. The smartHEX strut controllers must be enrolled by a qualified healthcare professional. Improper enrollment and setup of the smartHEX strut controllers may result in injury and impact the recovery process.
- To minimize the risk of device damage due to falls and to ensure timely care, all medical devices must be handled with care. Users must promptly report any instances of fall or damage of a strut controller to the care team. To prevent delays in patient care caused by device malfunction or breakage, the care team must ensure that replacement devices are readily available.
- Corrections must always be completed at the dates and times indicated by the HexConnect application and as instructed by the care team. Failure to do so could result in pain or injury or have an impact on the recovery process.
- Only allow trusted members of the care team to access the HexConnect application via the patient's mobile device. Use of the HexConnect application requires the care team to use the patient's mobile device to enroll or replace strut controllers and monitor the patient's recovery. If someone other than a trusted healthcare provider accesses the mobile device, the patient's personal data may be at risk.
- If strut controllers are removed for any reason (e.g., swimming, bathing), replace the numbered strut controllers on the corresponding numbered struts (i.e., Strut 1 to Controller 1, Strut 2 to Controller 2). A strut

controller mismatch could result in pain, injury, or have an impact on the patient's recovery process.

- When executing a correction, patients should be in a seated or lying position while keeping the frame clear from loose clothing, bedding, and bandages. This allows the strut controllers to work more efficiently.
- If a correction plan is suspended (due to too many missed corrections) or stopped (by the user pressing the stop button), the user must contact the care team for a re-evaluation of progress and to receive a new correction plan.
- The HexConnect application is designed to be used with system notifications that provide users with a reminder when a correction is due. Users must use caution when disabling notifications in application settings and always allow notifications for the HexConnect application.
- Some smart devices will change notification behavior when in battery saver mode, typically by delaying or limiting less important notifications in order to conserve battery life. Users should minimize the time spent in battery saver mode to ensure correction notifications are received in a timely manner.
- Date and time settings should be set to **"Set Automatically"** to ensure the smart device is always set to the user's current date and time.
- The mobile device must remain within 5 meters (approximately 16 feet) of the strut controllers during corrections and firmware updates. The mobile device must remain on with Bluetooth® enabled during these operations.

# Introduction

## Safety information

**Explanation of symbols on labels.** Table 1 describes the symbols used with the smartHEX Strut Controller.

**Table 1 — Symbol glossary**

| Symbol      | Title                                                                                                                                                | Description                                                                                                                              | Reference   | Section |
|-------------|------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------|-------------|---------|
|             | Manufacturer                                                                                                                                         | Indicates the medical device manufacturer                                                                                                | ISO 15223-1 | 5.1.1   |
|             | Catalog number                                                                                                                                       | Indicates the manufacturer's catalog number so that the medical device can be identified                                                 | ISO 15223-1 | 5.1.6   |
|             | Serial number                                                                                                                                        | Indicates the manufacturer's serial number so that a specific medical device can be identified                                           | ISO 15223-1 | 5.1.7   |
|             | Batch code                                                                                                                                           | Indicates the manufacturer's batch code so that the batch or lot can be identified                                                       | ISO 15223-1 | 5.1.5   |
|             | Type BF applied part                                                                                                                                 | To identify a type BF applied part complying with IEC 60601-1                                                                            | IEC 60601-1 | 5333    |
|             | Electronic waste should be collected separately for recycling per the European Community Waste Electrical and Electronic Equipment (WEEE) Directive. | To indicate that separate collection for waste electric and electronic equipment is required per European Community Directive 2012/19/EU | IEC 60417   | 6414    |
| <b>IP24</b> | Ingress Protection                                                                                                                                   | 2: Protected against solid foreign objects of 12,5mm Ø and greater<br>4: Protected against splashing water                               | IEC 60529   | 4       |
|             | Direct Current                                                                                                                                       | Operating Voltage = 3VDC                                                                                                                 | IEC 60417   | 5031    |
|             | Refer to the instruction manual/booklet.                                                                                                             | To signify that the instruction manual/booklet must be read                                                                              |             |         |
|             | Bluetooth logo                                                                                                                                       | To indicate this device uses Bluetooth wireless or enabled technology                                                                    | ISO 7010    | M002    |

| Symbol                                                                              | Title                                                                                     | Description                                                                                                                                                                                                                                                                                                                                                                 | Reference                              | Section |
|-------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------|---------|
|    | CSA Certification for Canada and the US                                                   | To identify Canadian Standards Association as the IEC 60601 certification authority                                                                                                                                                                                                                                                                                         | Bluetooth Special Interest Group (SIG) | N/A     |
|    | Temperature limit                                                                         | Indicates the temperature limits to which the medical device can be safely exposed                                                                                                                                                                                                                                                                                          | ISO 15223-1                            | 5.3.7   |
|    | Humidity limitation                                                                       | Indicates the range of humidity to which the medical device can be safely exposed                                                                                                                                                                                                                                                                                           | ISO 15223-1                            | 5.3.8   |
|    | Atmospheric pressure limitation                                                           | Indicates the range of atmospheric pressure to which the medical device can be safely exposed                                                                                                                                                                                                                                                                               | ISO 15223-1                            | 5.3.9   |
| <b>Rx Only</b>                                                                      | Rx only                                                                                   | Caution: Federal law restricts this device to sale by or on the order of a physician                                                                                                                                                                                                                                                                                        | FDA Guidance                           | N/A     |
|    | Do not re-use                                                                             | Indicates a medical device that is intended for one single use only.                                                                                                                                                                                                                                                                                                        | ISO 15223-1                            | 5.4.3   |
|  | Do not use if package is damaged and consult instructions for use                         | Indicates that a medical device that should not be used if the package has been damaged or opened and that the user should consult the instructions for use for additional information                                                                                                                                                                                      | ISO 15223-1                            | 5.2.8   |
|  | Keep dry                                                                                  | Indicates a medical device that needs to be protected from moisture                                                                                                                                                                                                                                                                                                         | ISO 15223-1                            | 5.3.4   |
|  | Consult instructions for use                                                              | Indicates the need for the user to consult the instructions for use                                                                                                                                                                                                                                                                                                         | ISO 15223-1                            | 5.4.3   |
|  | Non-sterile                                                                               | Indicates a medical device that has not been subjected to a sterilization process                                                                                                                                                                                                                                                                                           | ISO 15223-1                            | 5.2.7   |
|  | MR unsafe                                                                                 | Indicates an item which poses unacceptable risks to the patient, medical staff or other persons within the MR environment.                                                                                                                                                                                                                                                  | F2503                                  | N/A     |
|  | Australian/New Zealand Regulatory Compliance Mark for electrical and electronic equipment | The RCM shows the equipment complies with the requirements imposed upon or covered by regulations in Australia and New Zealand                                                                                                                                                                                                                                              | AS/NZS 4417.1                          | Part 1  |
|  | FCC declaration of conformity                                                             | United States wireless compliance labeling content: This device complies with Part 15 of the Federal Communications Commission (FCC) Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation. |                                        |         |

## Product overview

The smartHEX struts, strut controllers, and HexConnect mobile application are part of the overall smartHEX platform. This platform was designed with ease of use in mind to guide patients through recovery following external fixation surgery by automatically adjusting the external fixation frame per a prescribed correction plan.

### HexConnect Mobile Application

The HexConnect App is installed on the patient's mobile device from the Apple App Store or Google Play Store.

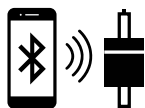


The HexConnect app is intended for use for the following smartHEX user types as determined by the prescribing surgeon when generating a correction plan in the smartHEX Web Application:



Mobile app user

**Mobile app user:** struts are adjusted manually by the patient or caregiver in accordance with the correction plan generated by the web application. The correction plan is accessed through the patient's HexConnect Mobile Application, which also provides alerts, reminders, and instructions.



Smart strut user

**Smart strut user:** struts adjust using smartHEX controller assistance in accordance with the correction plan generated by the web application. The correction plan is accessed through the patient's HexConnect Mobile Application, which also provides alerts, reminders, and instructions.

After the prescribing surgeon generates the patient's correction plan in the smartHEX web application, the correction plan is sent to the patient and uploaded to the HexConnect mobile application on the patient's mobile device. For "Smart Strut Users": following enrollment of the smartHEX strut controllers (at a healthcare facility), the HexConnect application sends periodic wireless signals to the smartHEX strut controllers to perform scheduled corrections. For "manual strut users": the patient uses the HexConnect mobile application as a guide and schedule for completing manual smartHEX strut adjustments. For instructions specific to "mobile app users", make sure to review the Instructions for Mobile App Users section of the manual.

At a scheduled time, the patient will receive an alert on their mobile device. Tapping on the alert will open the HexConnect mobile application to the correction page. When the current correction is selected, the app displays what will be done and requests the user's permission to continue. Once permission is granted, the smartHEX strut controllers will execute the correction step.

## Product overview

Once a correction step is completed, the system awaits the next correction time to repeat the process over the course of the correction plan.



The HexConnect App requires a connection to a network (WiFi or cellular). The network connection is only required when downloading the correction plan and after executing corrections (to update status)."

### Hoffmann LRF smartHEX Strut Controllers (REF 4938-0-500)

The strut controllers are battery-operated, motorized devices that adjust the smartHEX struts in response to wireless command signals from the HexConnect Mobile Application. A strut controller is attached to each of the six smartHEX struts. The struts and controllers are numbered 1 through 6.

The strut controllers are packaged as a set of six. They are also offered individually (4938-0-500) as a replacement for a lost or damaged controller.

#### smartHEX Strut Controller Kit (REF 4938-0-510)

##### Contents

- 6× smartHEX strut controllers
- 6× numbered and color-coded ID caps
- 1× 2.5mm hex key
- 1× ID color label sheet (for use in lieu of the ID caps)





# Product overview

The inside lid of the kit contains a Quick Start Guide with brief instructions on setting up the device.

| Strut controller kit |            |
|----------------------|------------|
| Quanity              | 6-pack     |
| Item #               | 4938-0-510 |

| 2.5mm Hex key |              |
|---------------|--------------|
| Quanity       | 1            |
| Item #        | 700002844983 |



| ID Caps |                 |
|---------|-----------------|
| Quanity | 1 of each color |
| Item #  | 4938-1-051-1    |
|         | 4938-1-051-2    |
|         | 4938-1-051-3    |
|         | 4938-1-051-4    |
|         | 4938-1-051-5    |
|         | 4938-1-051-6    |

| Strut controller |               |
|------------------|---------------|
| Quanity          | 6             |
| Item #           | 4938-0-500-TE |

| Label ID sticker |              |
|------------------|--------------|
| Quanity          | 1            |
| Item #           | 700002844983 |

Figure 1



Figure 2

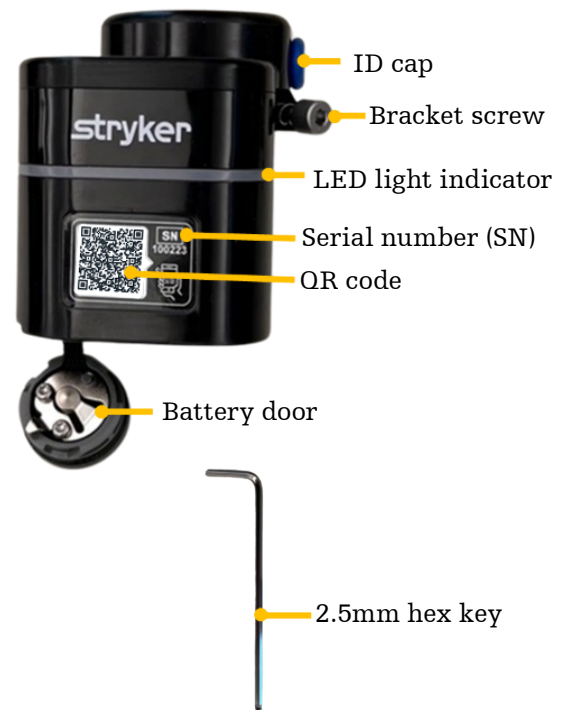
An ID Cap Kit (REF 4938-1-051) is offered separately from the Strut Controller Kit in case additional ID components are needed.

Batteries for the strut controllers are only offered in a pack of 6 and must be ordered separately: Strut Controller Batteries Multipack (REF 4938-3-203)

## Product overview

### Strut controller features

- **Mounting bracket:** Mounts the controller to the strut. Allows for secure placement in one of four positions to minimize interference with the patient.
- **Bracket screw:** once mounted, the bracket screw secures the controller in place; use the 2.5mm hex key (supplied).
- **LED light indicator:** translucent ring that illuminates in colors to indicate the strut controller status
- **QR code front label:** consisting of a QR code and serial number that identifies the strut controller within the mobile application
- **Battery door:** the battery door provides access to the strut controller battery (shown open)
- **ID caps:** identifies the strut controller by number corresponding to the strut.
- **ID color labels:** stickers used to label each strut controller with the color and number corresponding to the strut (may be used in lieu of ID caps)
- **2.5mm hex key:** used to tighten the strut controller to the strut



**Figure 3**



# User instructions

## Setting up the strut controllers

### Battery insertion

NOTICE

Battery replacement should be performed by a healthcare professional to ensure proper handling and safety; however, in an emergency situation where professional assistance is not immediately available, a patient or caregiver may perform the replacement, provided the specified guidelines are followed.

The strut controller automatically turns on when the battery is inserted, and the door is closed. For best performance, use the Stryker-provided CR2 lithium batteries.

Open the battery door by rotating it counterclockwise. A coin or finger may be used to rotate the tab. The door is tethered, so it will not fall away. Once the door is opened, insert the fresh CR2 battery with the positive terminal facing outward. **(Figure 4)** A battery polarity label will also show this on the inside of the battery compartment. When the battery is inserted, close and lock the battery door by reinserting the door and rotating it clockwise until it stops.

### Strut controller activation

Once batteries are installed, the controller will turn on and activate the LED light indicator with a flashing blue light for approximately 40 seconds. After 40 seconds, the strut controller will enter sleep mode to conserve power.

### Strut controller battery status

Check an enrolled strut controller's battery status at any time from within the mobile application by selecting the strut's battery power icon on the main page. **(Figure 5)** The battery icon for each strut controller will show the battery status and percentage of battery remaining. **(Figure 6)**

**Table 2** details the battery status color indicators, percentage remaining and implications for completing corrections.

Table 2: Strut controller battery status

| Battery status | Color  | Percent range remaining | Able to complete correction? |
|----------------|--------|-------------------------|------------------------------|
| High           | Green  | 61-100%                 | Yes                          |
| Medium         | Yellow | 41-60%                  | Yes                          |
| Low            | Orange | 21-40%                  | Yes                          |
| Critical       | Red    | 0-20%                   | No                           |



Figure 4

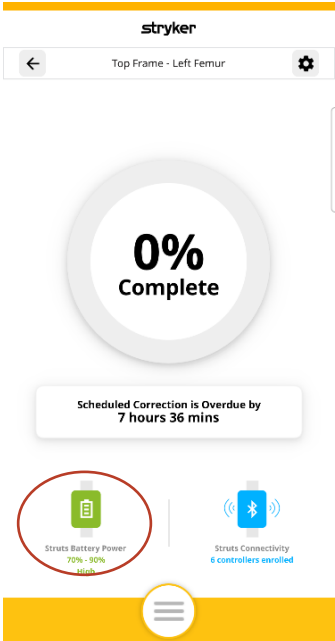


Figure 5



Figure 6

## User instructions

### NOTICE

If a battery icon displays as the color red, indicating a critical status, corrections cannot be completed.

From this screen, controller connectivity may also be checked by tapping the strut number icons. **(Figures 7-8)**

### Battery removal and replacement

If a battery needs to be replaced for any reason, remove the existing battery and follow the same installation instructions with a new battery. When the battery is successfully replaced, the controller will light up green for approximately 40 seconds.



Figure 7

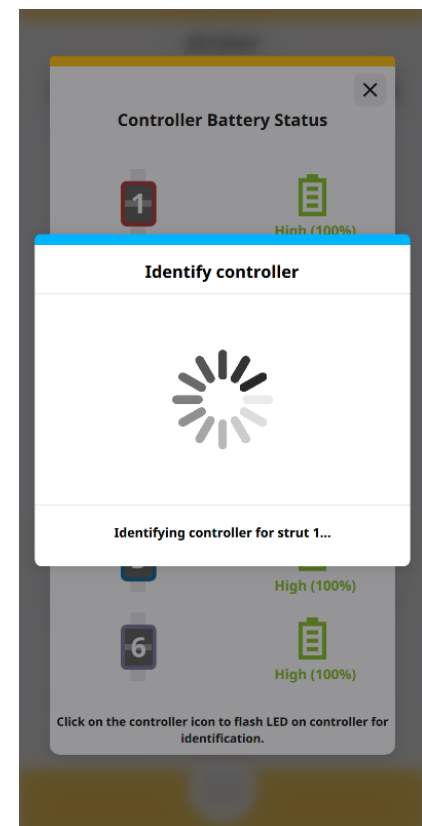


Figure 8

## User instructions

### Mounting the strut controllers

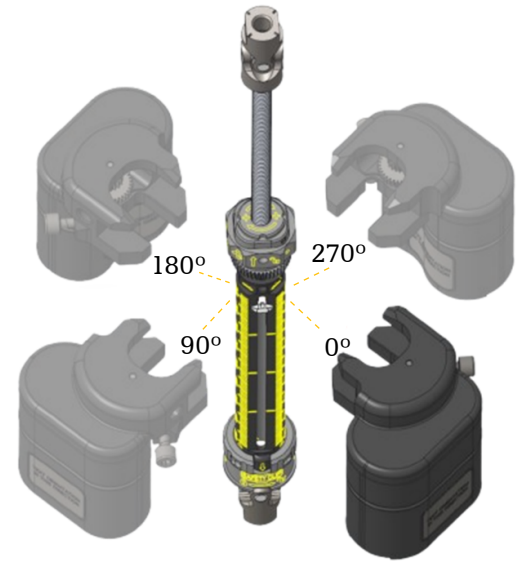
The six strut controllers are mounted to each of the six struts. To mount the strut controller, orient the controller in a way that does not interfere with the patient or obscure radiographic visibility. The controller can be mounted in any one of four positions on the strut: 0°, 90°, 180°, or 270°. **(Figure 9)**

Align the flats on the controller with the square feature on the strut and push it on while lifting the thumb knob. **(Figure 10)**. The strut thumb knob should not turn freely when the strut controller is fully seated against the strut. Once confirmed, secure it to the strut by gently pushing in and tightening the spring-loaded bracket screw in the clockwise direction using the 2.5 mm hex key. Finish by firmly tightening the bracket screw. **(Figure 11)** Repeat for the rest of the strut controllers.

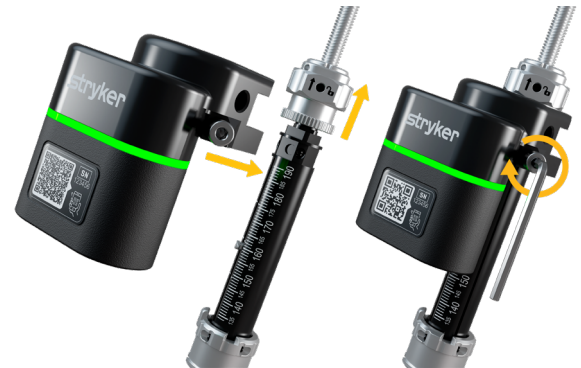
### Attaching ID caps

Once installed on individual struts, Color coded ID caps matching the strut number may be inserted in the provided holes on strut controllers by firmly pressing them into place. **(Figure 12)**

In lieu of using the ID Caps, the ID color labels may be placed on a flat, visible surface of the controller. Avoid placing stickers over the QR code or serial number.

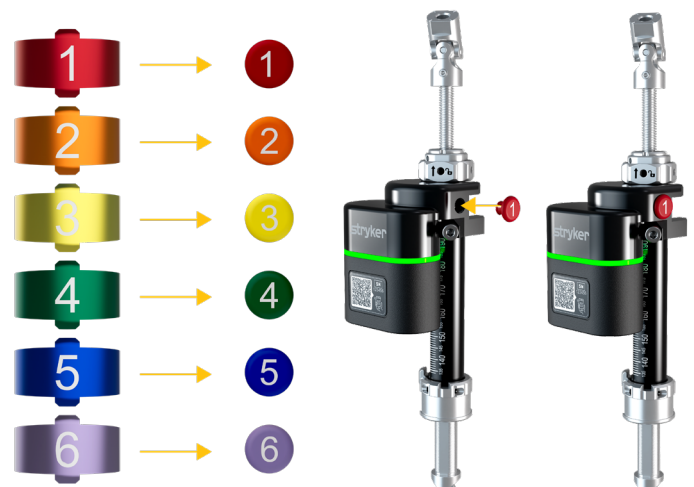


**Figure 9**



**Figure 10**

**Figure 11**



**Figure 12**

## User instructions

### Using the HexConnect Mobile Application

#### Setting up the app

##### Welcome message receipt

After creating a correction plan in the Hoffmann LRF smartHEX Web Application, the prescribing surgeon will generate the patient's account and send the patient a welcome email.

The welcome email will contain:

- Notes from the surgeon
- A link to the patient's correction plan
- Links to the Apple Store and Google Play Store

Upon receipt of the welcome email, the patient can download and open their correction plan in the HexConnect application on their mobile device.

##### NOTICE

If a patient unexpectedly loses access to their mobile device during a correction period, the PDF version of the correction plan may be provided to the patient to guide manual adjustments. Removal of all strut controllers is required to initiate manual adjustments.

#### Downloading the HexConnect Mobile Application

From the patient's mobile device, open the welcome email and select the appropriate link based on the patient's mobile device type: either the Apple Store for iOS/iPhone or the Google Play Store for Android. **(Figure 13)** The mobile application is supported on devices running iOS 17 or later and Android OS 14 or later.

The HexConnect application may also be downloaded by searching for the application name directly in the app store on the patient's mobile device.

Upon downloading and opening the application, a message will display **"No Correction Plan Available Yet"**. **(Figure 14)**

#### Linking the correction plan

With the application downloaded, the patient can now select the Correction Plan Link in the welcome email **(Figure 13)**, which will open the HexConnect app.

##### NOTICE

The prescribing surgeon must ensure that the appropriate correction plan is shared with and received by the patient.

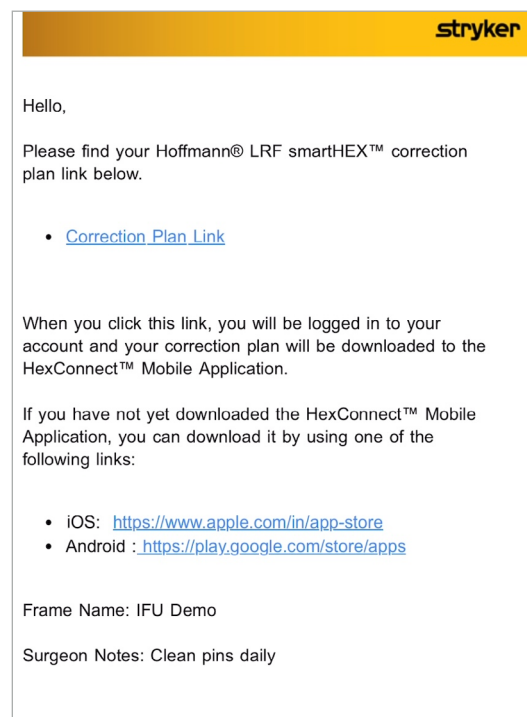


Figure 13

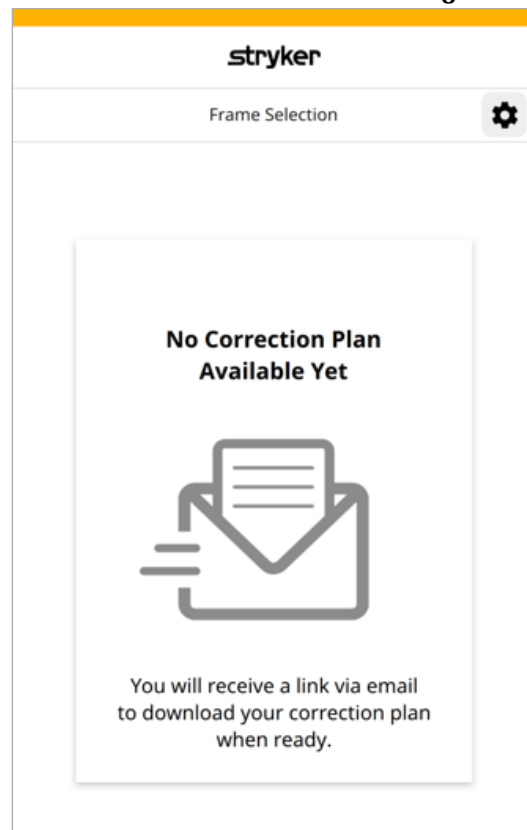


Figure 14



# User instructions

## When the application opens

### End User License Agreement

There will be a prompt to review the End User License Agreement (EULA). **(Figure 15)**  
To accept the agreement, users can check the box at the end of the agreement and select **“I Agree”**.

### Enable Notifications

A dialogue box will request permission to send notifications. **(Figure 16)** Users can select **“Allow”** to enable notifications. Enabling notifications is important for receiving important reminders about corrections.

The correction plan will begin downloading. **(Figure 17)** This may take several minutes.

NOTICE

If the correction plan fails to download, contact your surgeon.

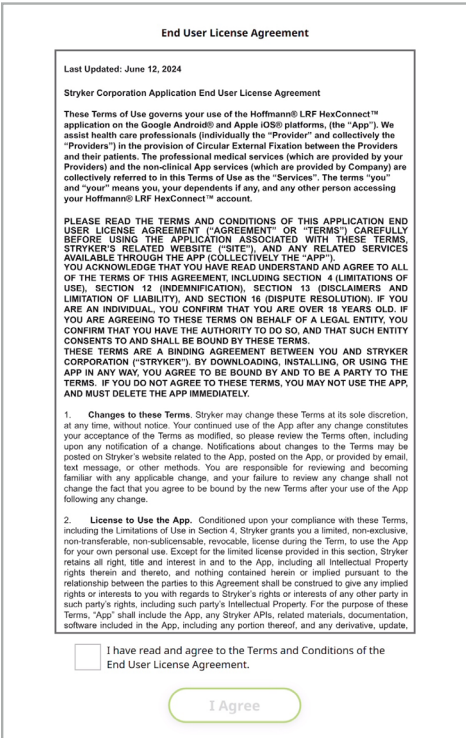


Figure 15

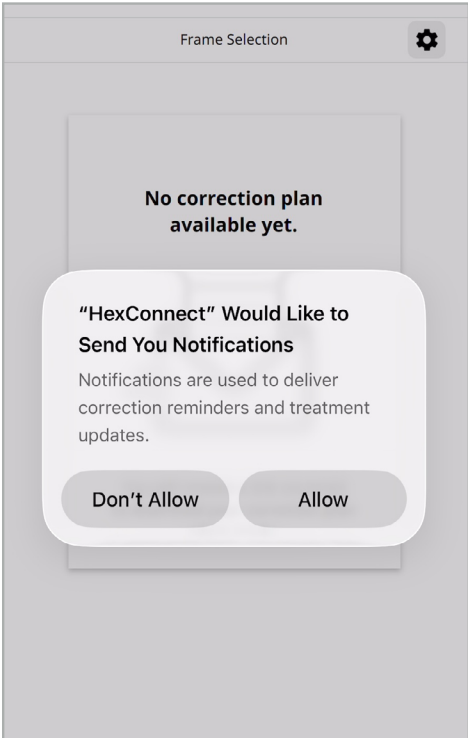


Figure 16

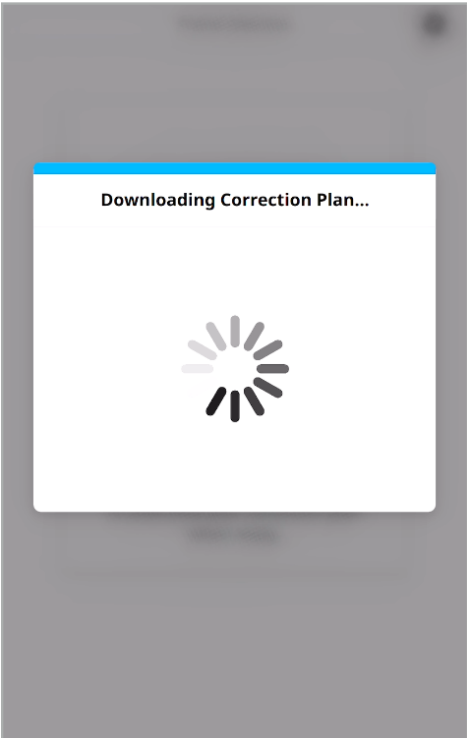


Figure 17

### Enable Bluetooth

A dialogue box will prompt the user to enable Bluetooth. **(Figure 18)**  
Select **“Allow”** to allow the app to utilize Bluetooth Technology. Enabling Bluetooth is necessary to enroll the smartHEX strut controllers with the HexConnect mobile application and the smartHEX web application.

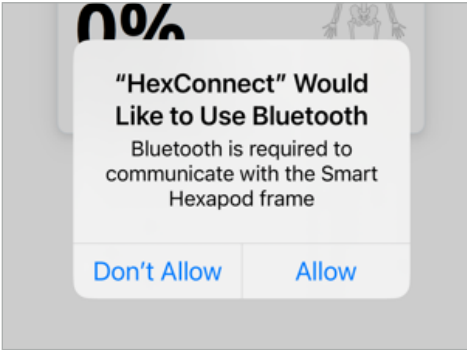


Figure 18

## User instructions

### Open the correction plan

The app's start page displays the patient's case details, which include the case name, case ID, frame name, deformity location and percent completion. **(Figure 19)**

#### ⚠ CAUTION

If the displayed case information is incorrect in that it does not match the patient's actual case, the user must contact the patient's care team for assistance.

Click on the case to open it. Once opened, the home page for that case is displayed. **(Figure 20)** The back arrow button may be used to navigate back to the start page.

If the patient has a second prescribed case, it will also appear on the start page and may be accessed in the same way.

If you are a "mobile app user", meaning you are not utilizing the smartHEX strut controllers and will be performing manual strut adjustments, skip to the section [Instructions for mobile app users](#).

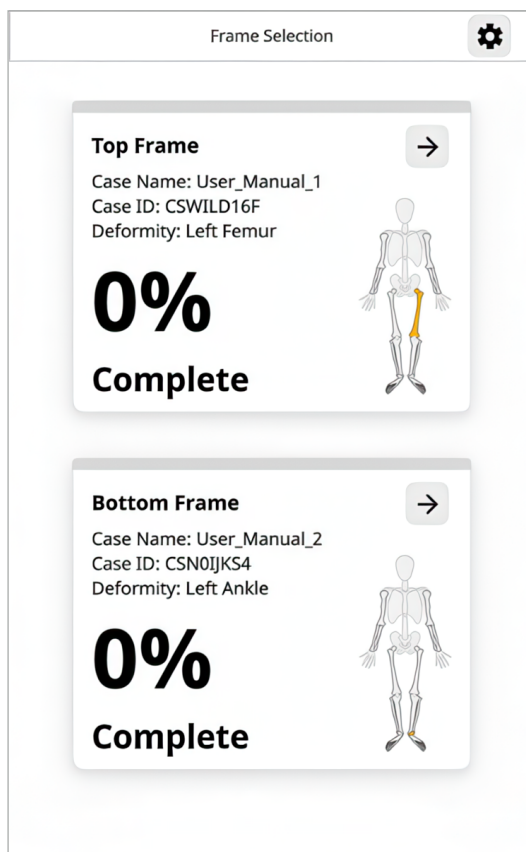


Figure 19

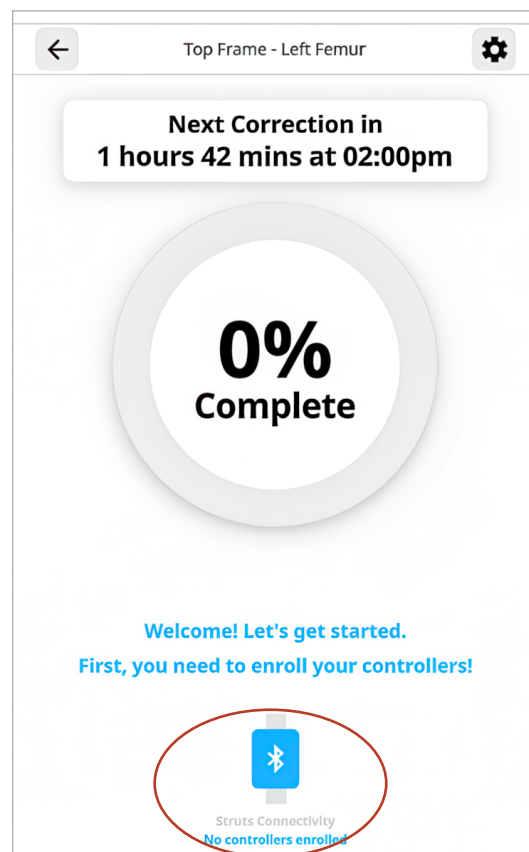


Figure 20



# User instructions

## Enrolling the strut controllers

Once the HexConnect mobile application has been successfully linked to a correction plan, the smartHEX strut controllers may be enrolled.

From the home page of the selected case, navigate to the Controller Connectivity page by tapping the strut controller icon.

(Figures 20-21) The controller connectivity page shows the enrollment status of all six controllers. (Figure 22)

The enrollment process links the patient’s correction plan to each of the strut controllers. The enrollment process is necessary to ensure that the strut controllers operate effectively.

The controller connectivity screen displays all six controllers with the enrollment status. Controllers may be enrolled in any order, as long as each enrolled controller is mounted on the corresponding strut.

## Enrollment steps

1. From the Controller Connectivity page, tap the Enroll button for Strut 1.
2. If a controller’s firmware update is necessary, it will be performed automatically at this time. (Figure 23) Upon completion, the enrollment process will continue.
- 3.Strut controllers may be enrolled through an automatic or manual process. From the Controller Enrollment Options screen, the user may choose the enrollment pathway. (Figure 24)

NOTICE

Ensure that the mobile device is within 5 meters of the strut controllers while performing the enrollments.



Figure 21

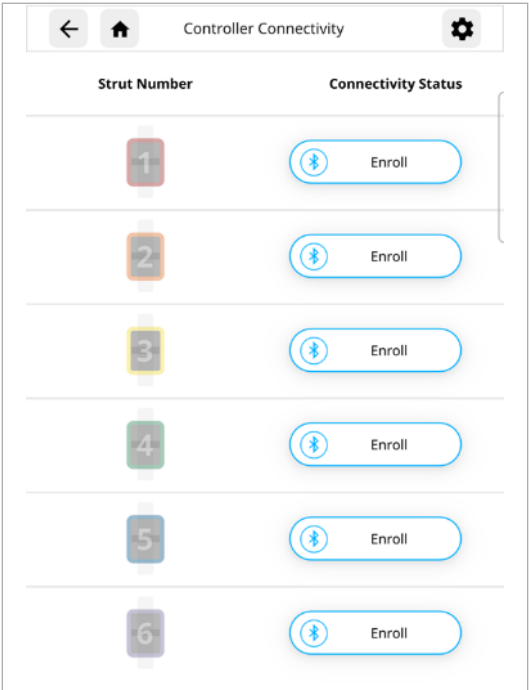


Figure 22

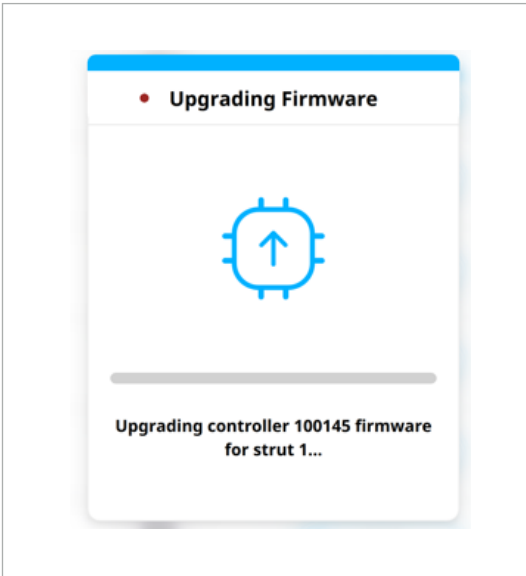


Figure 23

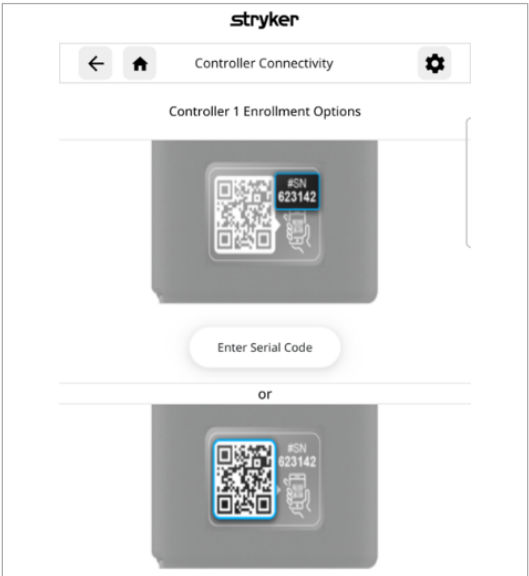


Figure 24

## User instructions

### Automatic

- From the Enrollment Options screen, select the second option: **“Scan QR Code”**.
- A dialogue box will request permission to access the mobile device’s camera
- Select **“Allow”** to enable camera access. If the camera cannot be accessed, proceed with manual enrollment.
- Aim the camera at the QR code on the front of the strut controller. **(Figure 25)**  
Take care to avoid accidentally scanning the QR code of a nearby controller.
- When the QR code is successfully captured, the screen will display the enrollment progress. **(Figure 26)**  
Upon successful enrollment, the app will display a verification message **(Figure 27)** and play a tone.

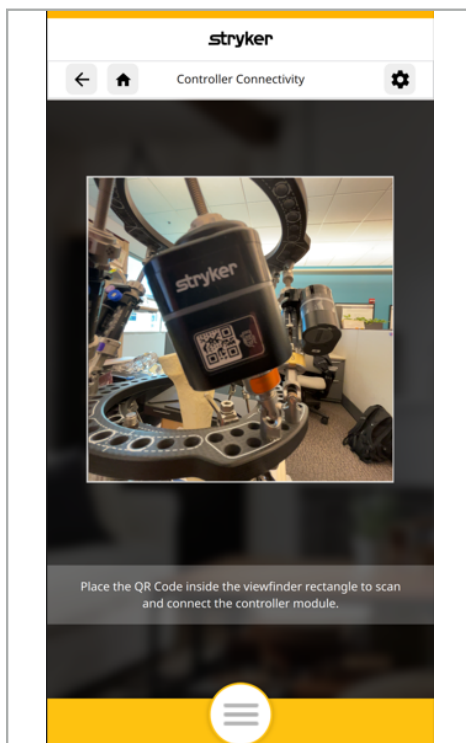


Figure 25

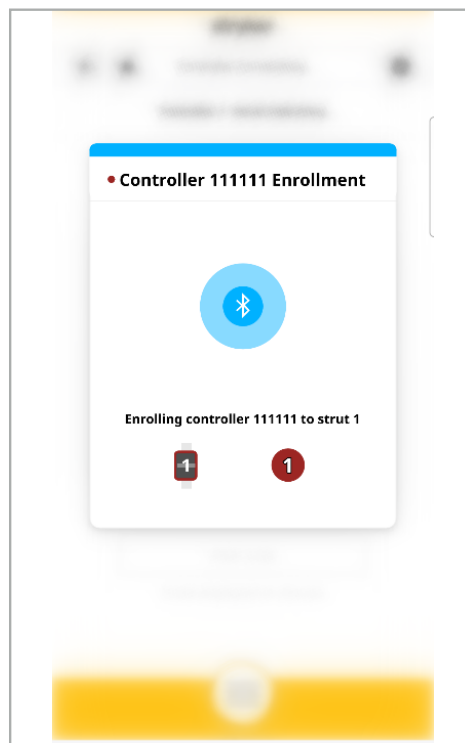


Figure 26

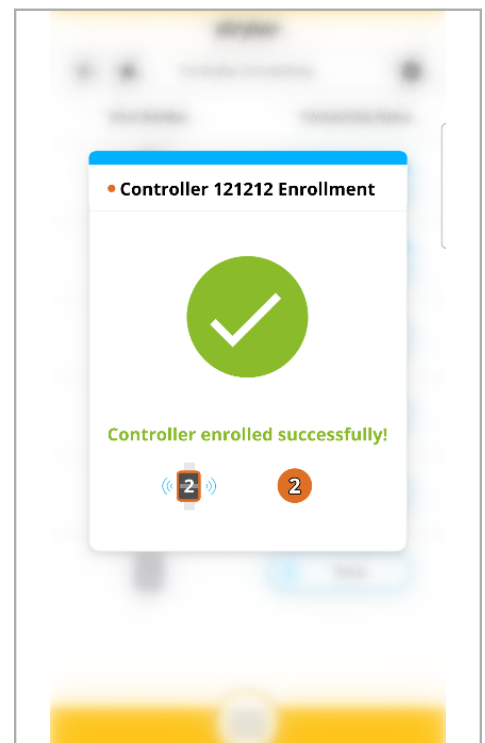


Figure 27

## User instructions

### Manual

- From the Enrollment Options screen, select the first option: **“Enter Serial Code”**.
- Locate the strut controller’s unique serial code, which can be found on the front of the strut controller, printed to the right of the QR code. **(Figure 28)** Enter the serial number into the text field and tap Continue.
- If the serial code is successfully captured, the screen will display the enrollment progress. Upon successful enrollment, the app will display a verification message and play a tone.

#### NOTICE

An automatic operational efficiency check will occur upon successful enrollment of a strut controller. The strut controller will automatically adjust slightly in the clockwise and counterclockwise direction and then return to the starting position. The purpose of this adjustment is to ensure that there is adequate engagement of the strut controller with the strut so that the device can operate effectively. After the automatic operational check is complete for all controllers, the bracket screws on each strut controller must be re-tightened using the 2.5 mm hex key.



Figure 28

## User instructions

### Enroll the remaining strut controllers

Return to the Controller Connectivity screen and repeat the same enrollment steps to enroll the remaining controllers. **(Figure 29)**

#### NOTICE

When all strut controllers are enrolled, confirm the app-to-controller enrollings are correct by tapping each strut number icon from the Controller Connectivity screen. If one or more strut controllers are mis-enrolled, proceed with the “Replace Enrollment” process. For example: Tapping icon #1 causes Strut Controller 1 to light up. No action is required. Tapping icon #2 causes Strut Controller 3 to light up. There is a enrolling mismatch, so “Replace Enrollment” is required.

### Replace enrollment

In some circumstances, a strut controller’s enrollment may need to be revised, either due to accidental enrollment during scanning or because of a device malfunction. The Replace Enrollment feature can be utilized to re-enroll individual controllers.

- Tap the Replace Enrollment button for the strut number to be replaced **(Figure 30)**
- Select “Yes” to proceed with Enroll Replacement **(Figure 31)**

If enrollment has already been locked, the surgeon must unlock the controllers via the smartHEX Web Application. Once unlocked, the replace enrollment steps may be completed.

### Exchanging a strut controller

In some circumstances, a strut controller may need to be replaced with a new one because of damage or issues with functionality. To replace a controller:

- Remove the controller by reversing the steps described in the [Mounting the strut controllers section](#)
- Insert a new battery into the new controller
- Mount the new controller
- Follow the “Replace enrollment” process

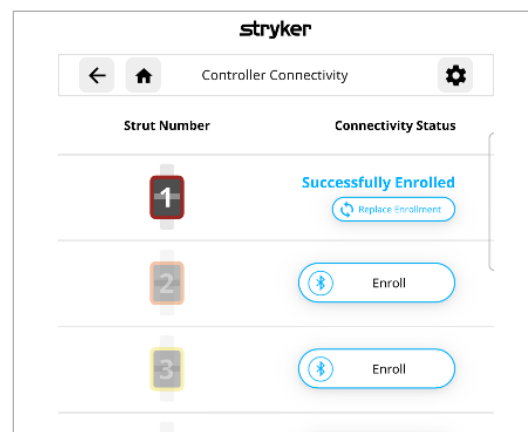


Figure 29

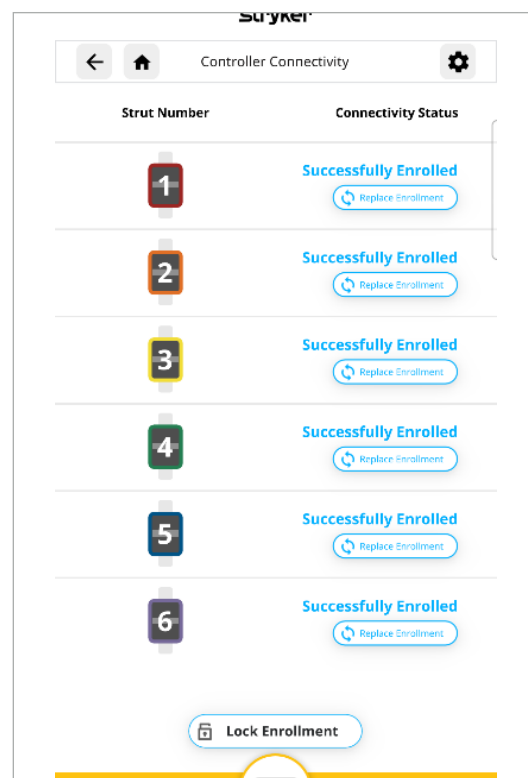


Figure 30

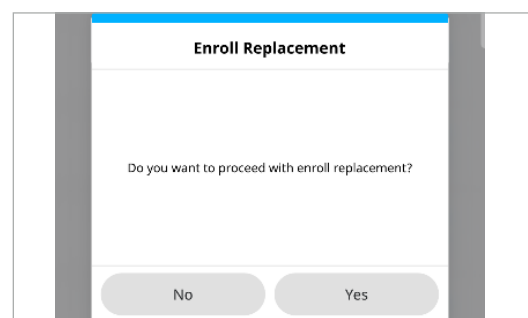


Figure 31



# User instructions

## Lock enrollment

Once all the controllers have been successfully enrolled and there is no foreseeable need for replacement, the enrollment should be locked. Locking the enrollment prevents misuse caused by the incidental exchange of strut controllers and ensures that the correction plan executes according to plan. To lock enrollment, tap the Lock Enrollment button. **(Figure 32)** and select "OK". **(Figures 33-34)** If not manually locked shortly after enrollment, the app will automatically lock enrollment after two hours. Once enrollment is locked, it must be unlocked by the prescribing surgeon using the Hoffmann LRF smartHEX Web Application.

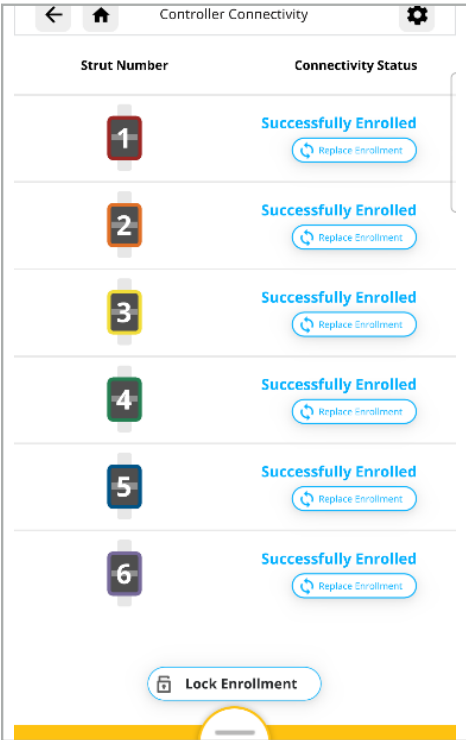


Figure 32

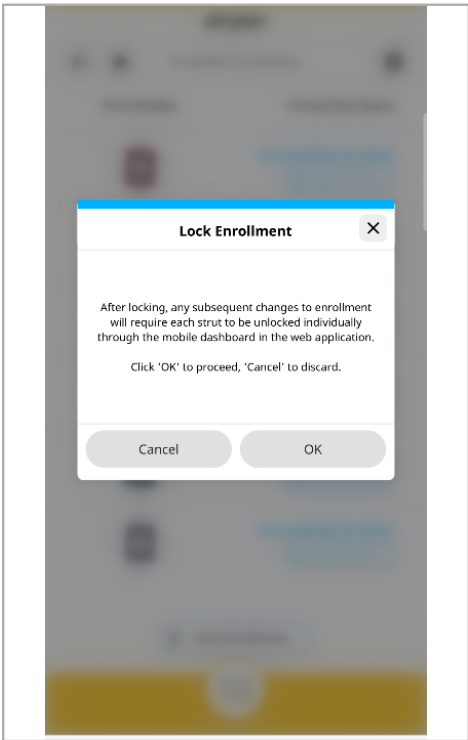


Figure 33



Figure 34

## User instructions

### Executing the correction plan

#### Access the scheduled correction

- Open the HexConnect mobile application.
- Open the correct case. If there is more than one case prescribed, ensure that the relevant one is selected.
- Navigate to the correction plan using the pop-up menu located near the bottom of the screen and choosing Correction Plan.
- You can also access the plan by tapping the “Next Correct In...” button on the home screen.
- The upcoming correction will be highlighted with a gold box. (Figure 35)

#### Strut correction reminders

When a correction is due, a reminder notification is sent. Tap the banner notification to be directed to the correction plan.

If a scheduled correction is missed, the app will send a reminder notification every 30 minutes until the correction is performed. (Figure 36).

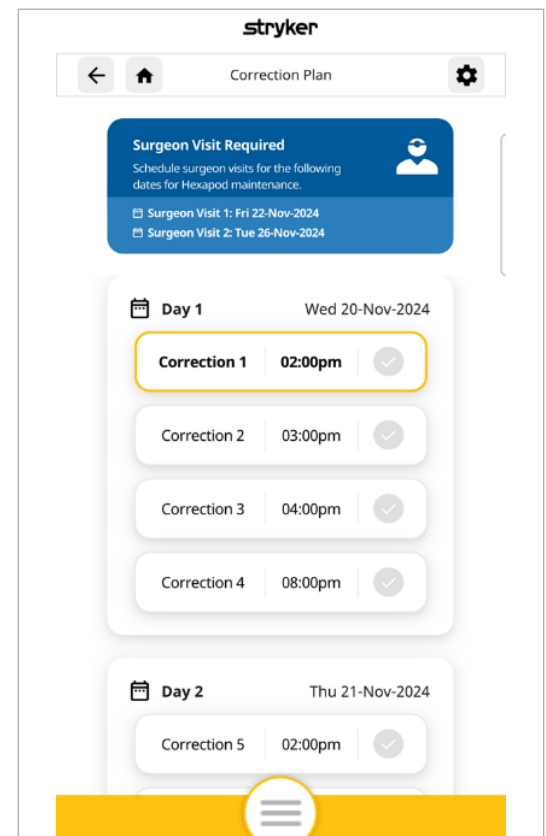


Figure 35

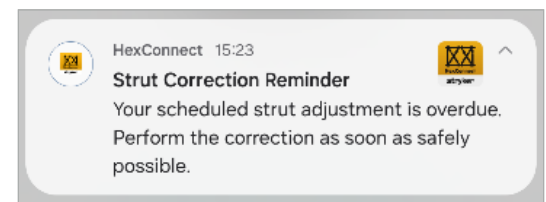


Figure 36



# User instructions

## Navigating the app

### Main menu

The main menu can be accessed from the home page using the menu button toward the bottom center of the home screen. **(Figure 37)**

The main menu contains links to the following pages:

### Controller connectivity

- Correction Plan
- Controller Details
- Deformity Details
- Frame Simulation

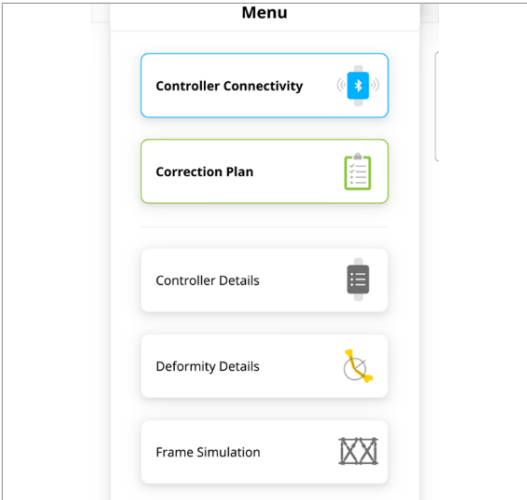


Figure 37

### Controller connectivity

The controller connectivity page displays the enrollment status of the strut controllers. From this page, users can: enroll controllers, replace enrollment, lock enrollment, replace controllers, and perform an identity-check of the controller. **(Figure 38)**

Tapping any of the strut number icons for Struts 1-6 will flash the LED light indicator on the corresponding strut controller to identify the strut. If enrollment is not locked, the strut controller will also adjust slightly as part of an operational check.

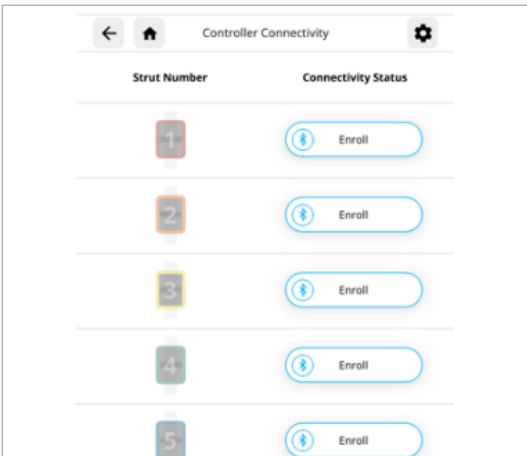


Figure 38

### Correction plan

The Correction Plan page houses the patient’s correction plan. From this page, users can initiate a scheduled adjustment. The page displays the entire correction plan including any required surgeon visits for strut adjustments or change-outs. **(Figure 39)**

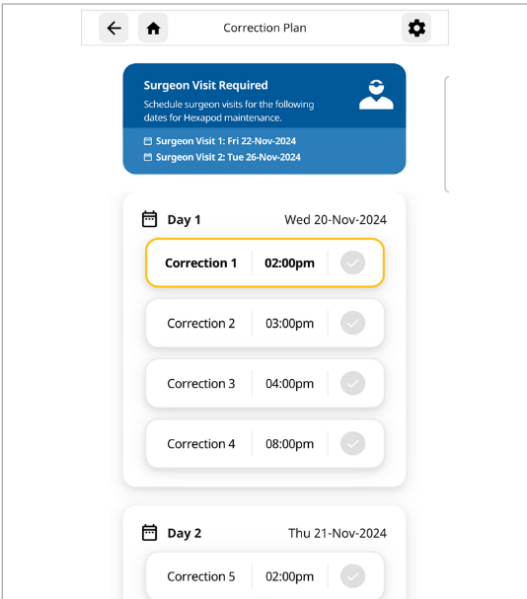


Figure 39



# User instructions

## Controller details

The Controller Details page displays the software version of each strut controller. The prescribing surgeon may ask for this information if an issue arises with the device, or if a firmware update is required. **(Figure 40)**

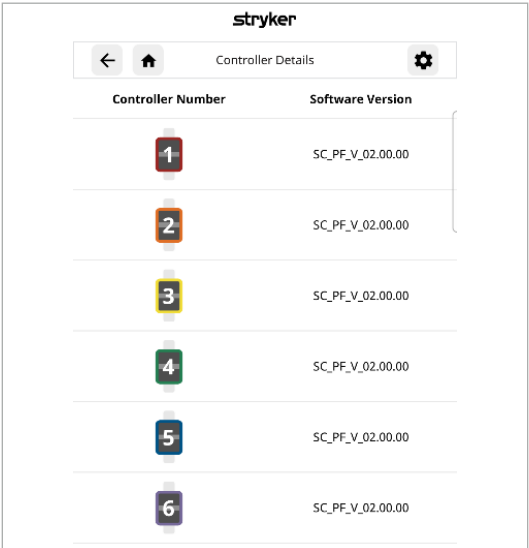


Figure 40

## Deformity details

The Deformity Details page displays a report of the patient’s deformity correction plan, including an image showing the AP, Lateral, Axial, and perspective views of the deformity as input by the prescribing surgeon. **(Figure 41)**

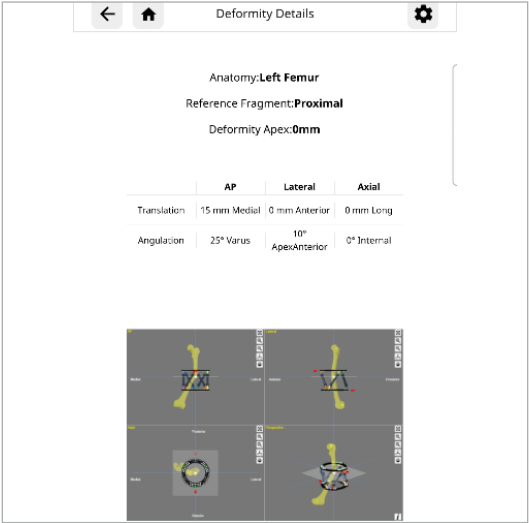


Figure 41

## Frame simulation

The Frame Simulation page displays an animated simulation of the patient’s correction progression over time. The play button activates the animation, and the slider tool can fast-forward to any part of the correction. **(Figure 42)**

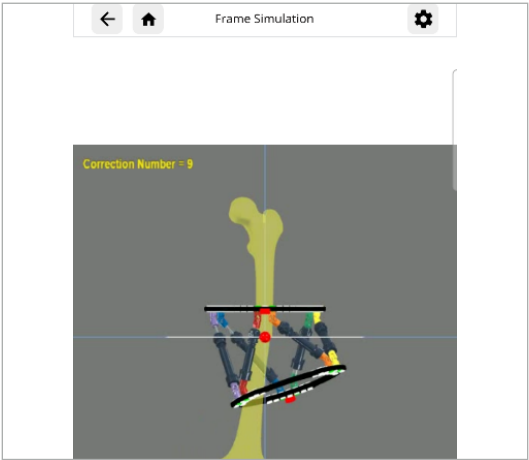


Figure 42

## User instructions

### Settings

The settings menu can be accessed from home page using the gear icon toward the upper right corner of the screen.

The settings menu contains links to:

- Product Information
- Reminder notifications
- Terms and Conditions

### Product information

The Product Information page contains instructional videos for the HexConnect mobile application and smartHEX strut controllers as well as a Frequently Asked Questions (FAQ) section. There is a link to Stryker's Hoffmann LRF Hexapod patient website (external site), which contains additional information for patients and caregivers. **(Figures 43-45)**

### Reminder notifications

The Reminder Notifications page allows users to adjust the timing of reminders before a scheduled correction is due. The notifications can be set between 5 minutes (default) and 60 minutes. **(Figure 46)**

**Repeated reminders:** a checkbox turns on or off repeated reminders to perform a correction. Repeated reminders are sent every 5 minutes (starting from the notification time set) until the time of the scheduled correction.

Reminders for overdue corrections are sent every 30 minutes until the correction is executed.

### Terms and conditions

The Terms and conditions page contains the full list of Terms and Conditions of the mobile application, which can be reviewed at any time.

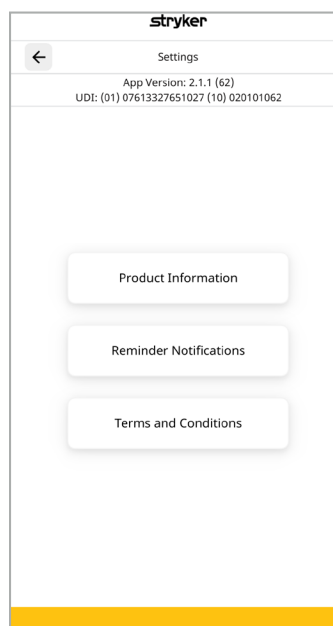


Figure 43

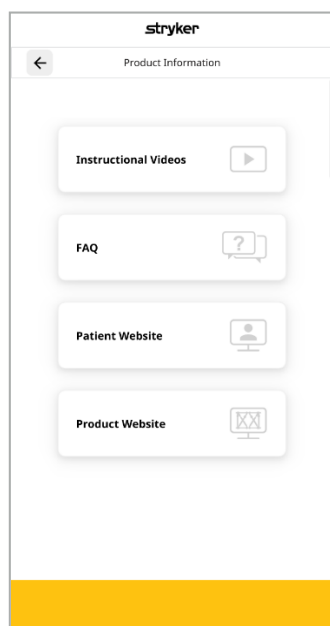


Figure 44

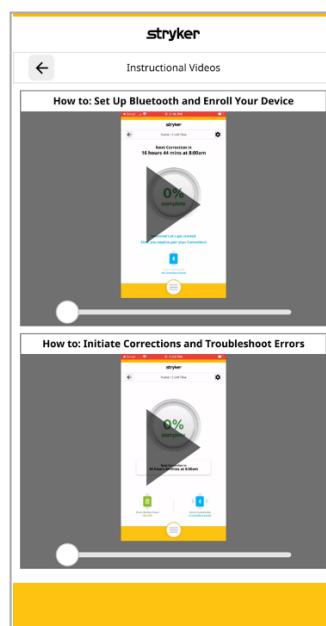


Figure 45

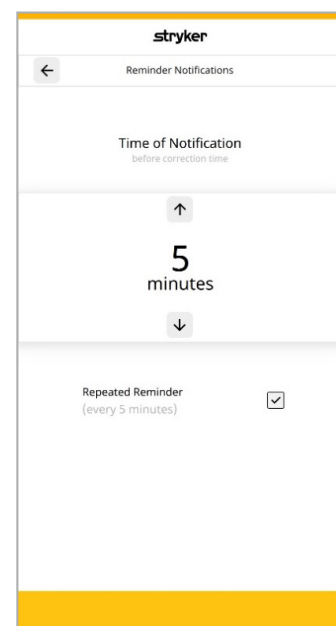


Figure 46

## User instructions

### Performing a correction

The Correction Plan page lists past and upcoming corrections as well as when an in-person visit with the surgeon may be required for strut change-outs or adjustments.

- Tap to open the next scheduled correction (highlighted in a gold box).
- Review and accept the Adjustment Cautions notification by selecting the “X” in the upper right corner, which will close the dialogue box. **(Figure 47)** This notification reminds the patient to be positioned comfortably and non-weight-bearing before initiating a correction.
- When the patient is seated or lying comfortably and ready, tap the Start Strut Adjustment button toward the bottom of the screen to begin the correction. **(Figure 48)**

Within a few moments, the strut controllers will begin to light up green. This indicates that the strut controllers are communicating with the mobile device and that battery checks are in progress. The application checks the status of each strut controller **(Figure 49)** before starting a correction to ensure they are functioning properly and that there is enough battery power to complete the correction.

- When all battery checks are completed, the strut controllers will automatically adjust the strut to execute the correction.
- The strut controllers will continue to adjust until all struts have been corrected according to the plan. Upon successful completion of the corrections, the message “Successful adjustment complete!” will display **(Figure 50)**, and the app will play a tone.
- The patient then waits until the next scheduled correction to repeat this adjustment process until the correction plan is complete. **(Figure 51)**

#### ⚠ CAUTION

Use of smartHEX strut controllers in an aircraft is not recommended. If air travel is necessary while being treated with a smartHEX device, the corrections schedule should be adjusted at the care team’s discretion.

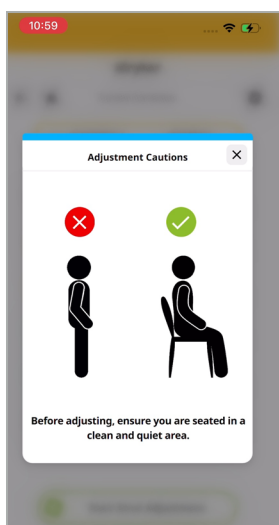


Figure 47

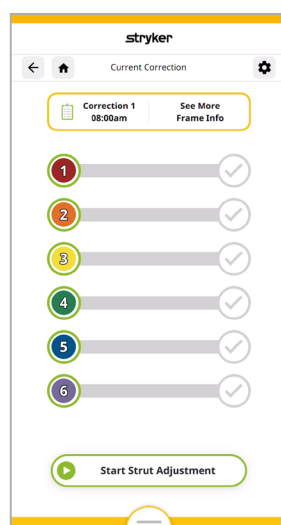


Figure 48

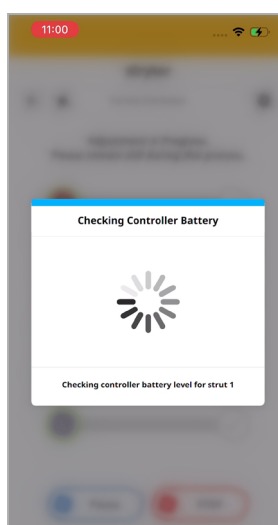


Figure 49

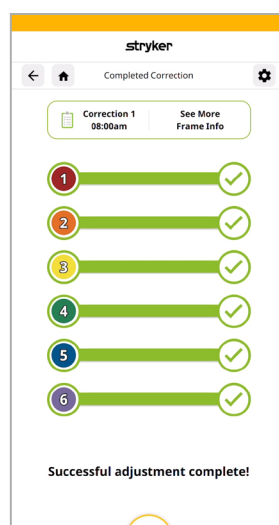


Figure 50

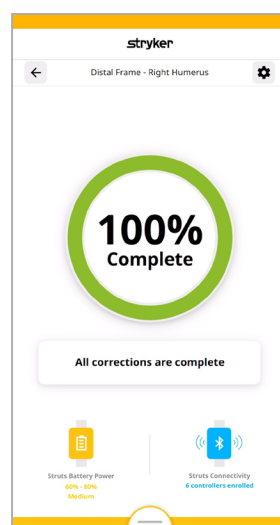


Figure 51

## User instructions

### Pausing or stopping a correction plan

If a correction needs to be suspended for any reason, a pause and stop button are located toward the bottom of the correction screen. **(Figure 52)**

#### Pause function

Allows for temporarily pausing a correction. Corrections that have been paused may be resumed. Reasons for pausing a correction may include convenience, encountering a disturbance, or discomfort experienced while performing the correction. **(Figure 53)**

To pause a correction:

- Tap the Pause button. After a moment, the strut controllers will pause movements one by one.

#### NOTICE

Allow up to 15 seconds for all strut controllers to stop moving.

- When ready to resume the correction, tap the Resume button. After a moment, the strut controllers will start moving again and the correction will resume where it left off.

#### Stop function

The stop feature is intended for emergency use and will completely halt the correction plan. Due to the definitive nature of this function, a “Stop Action” disclaimer will request the user to confirm the decision to stop. **(Figure 54)** Once a correction plan is stopped, the prescribing surgeon must reissue the correction plan.

To stop the correction:

- Tap the STOP button. After a moment, the strut controllers will pause movements one by one.

#### NOTICE

Allow up to 15 seconds for all strut controllers to stop moving.

- When the “Stop Action” disclaimer appears, select “Yes, STOP”. This will suspend the plan. **(Figure 54)**
- A confirmation message will display at the top of the screen: “Correction has been STOPPED. You must contact your surgeon to send an updated correction plan.” **(Figure 55)**
- Once the correction plan has been reissued by the prescribing surgeon, a new email containing an updated correction plan link will be sent to the patient.

#### NOTICE

If the STOP button was pressed in error, select “No, go back” to resume the correction plan.



Figure 52

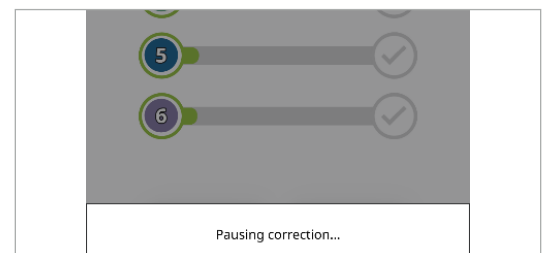


Figure 53

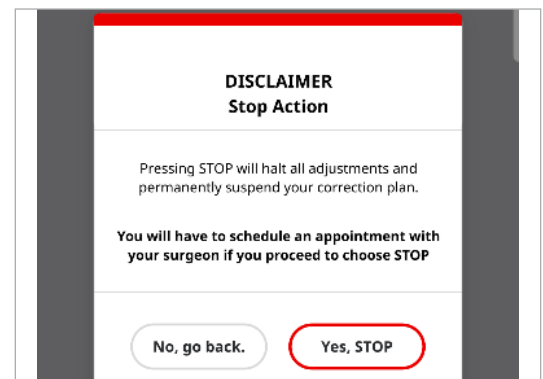


Figure 54

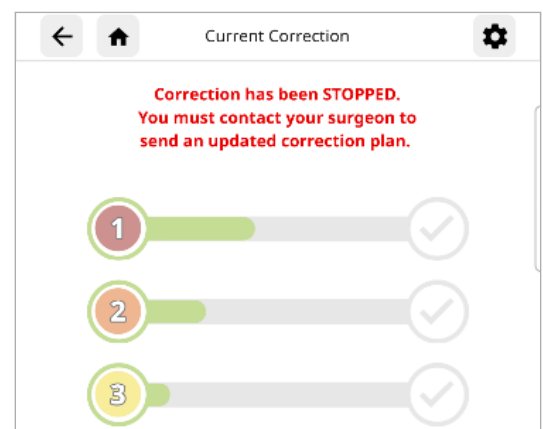


Figure 55



# User instructions

## Managing missed corrections

In the event that a scheduled correction is missed, it can be executed later in same calendar day, up until midnight, without any effect on the correction plan.

If one or more missed corrections is not executed within the same calendar day, the correction will be highlighted with a red border and marked as “Missed”, and the correction schedule will adjust accordingly.

The missed correction(s) will be postponed to the following calendar day, and the remainder of the correction plan will be rescheduled accordingly.

### Example 1:

Correction 8 was due at 2:00 pm on Day 2, Tuesday (**Figure 56**) but was not executed during that calendar day and was marked as missed. (**Figure 57**) Correction 8 has moved to Day 3, Wednesday, and the remainder of the corrections have adjusted back one day accordingly. (**Figure 58**)

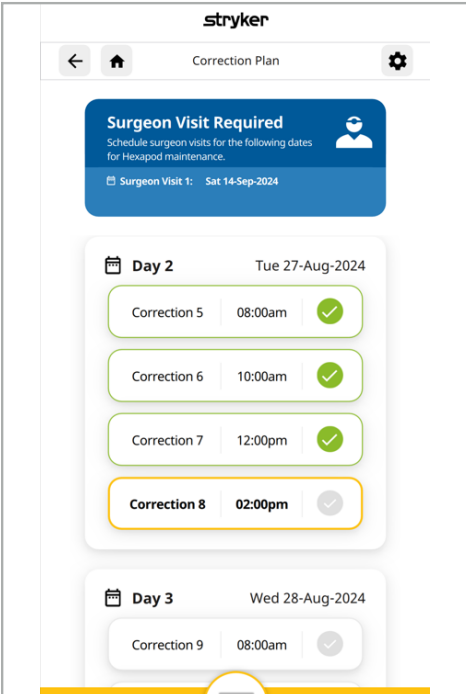


Figure 56

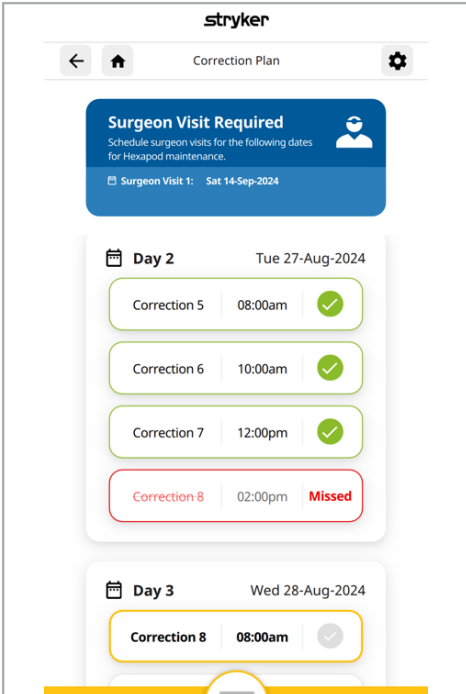


Figure 57

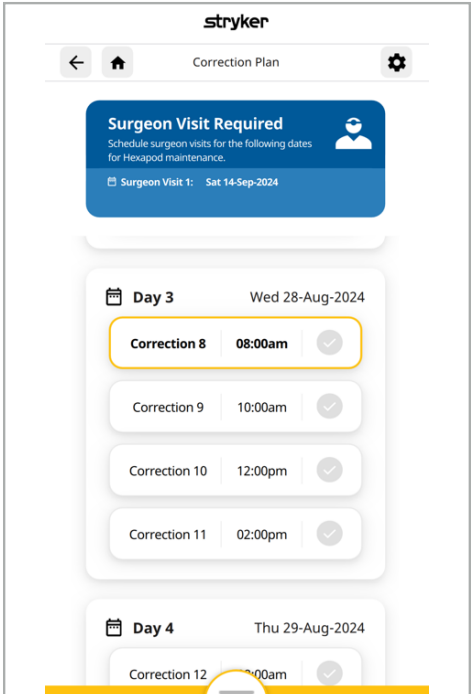


Figure 58



# User instructions

## Example 2:

Correction 8 was scheduled for 8:00pm on Day 2, Friday but was not executed during that calendar day. It was postponed to Day 3, Saturday, and the remainder of the corrections were shifted back accordingly. On Day 3, all four scheduled corrections (Corrections 8-11) were not executed. They are now postponed to Day 4, Sunday, starting with Correction 8. **(Figure 59)**

## Missing consecutive days

If more than two days of consecutive corrections are missed, the correction plan will be automatically suspended, preventing any further corrections. A suspended plan is indicated by a correction with a gold border that is marked “Suspended”. **(Figures 60-62)**



The prescribing surgeon must be contacted immediately if a correction plan is suspended. This will allow the surgeon to check on patient progress and reissue a new correction plan as appropriate.

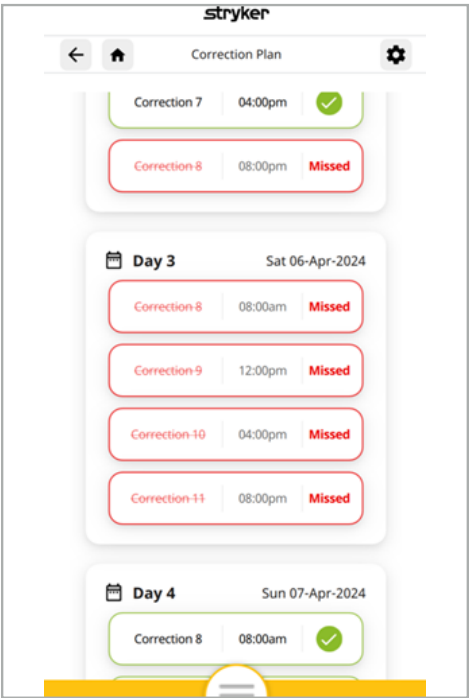


Figure 59

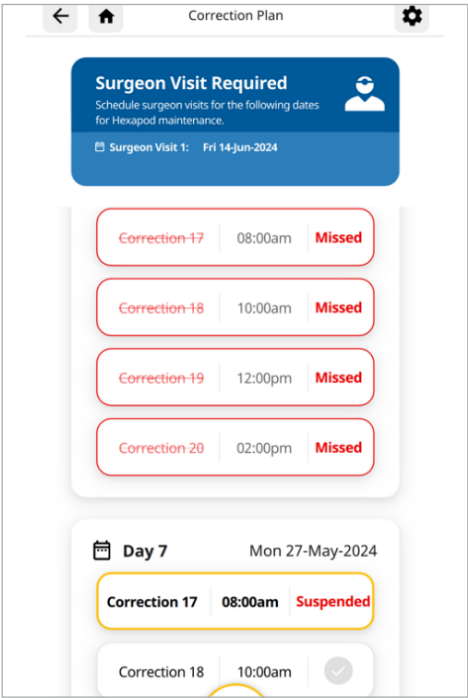


Figure 60

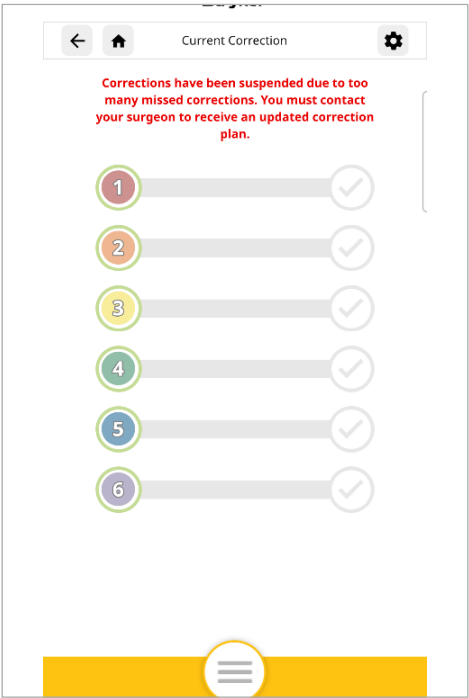


Figure 61

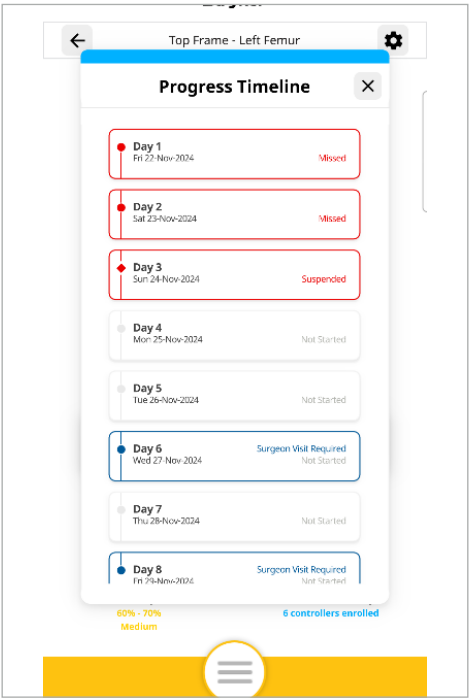


Figure 62

## Indications and errors

The LED light indicator on the strut controller is designed to alert users to the various normal indications and errors that can arise while using the device. It's important to understand how to identify each error so that efficient troubleshooting can occur.

The LED light indicator illuminates for approximately 40 seconds for each indication. After that, the controller re-enters sleep mode to conserve battery power. More information on the individual indications may be found in the mobile application. **Table 3** outlines the indications and errors.

**Table 3: Indications and Errors**

| LED status                          | Presentation                                                                        | Bluetooth status            | Correction status                                           | Enrolled status           | Errors           | Patient action                                                                                                                              |
|-------------------------------------|-------------------------------------------------------------------------------------|-----------------------------|-------------------------------------------------------------|---------------------------|------------------|---------------------------------------------------------------------------------------------------------------------------------------------|
| Flashing green<br>(2 blinks/second) |    | Connected/<br>Not connected | Correction in progress (struts moving)                      | Enrolled                  | No errors        | No action required                                                                                                                          |
| Solid green                         |   | Connected/<br>Not connected | Correction in progress (communication, battery check, etc.) | Enrolled                  | No errors        | No action required                                                                                                                          |
| Flashing blue<br>(2 blinks/second)  |  | Not connected               | Correction not in progress                                  | Not enrolled              | No errors        | No action required; awaiting enrollment                                                                                                     |
| Solid blue                          |  | Connected                   | Correction not in progress                                  | Not enrolled              | No errors        | No action required; awaiting enrollment                                                                                                     |
| Solid red                           |  | Connected/<br>Not connected | Correction not in progress                                  | Enrolled/<br>Not enrolled | Controller error | Low battery, motor over current, or out of Bluetooth range; follow instructions in Mobile Application (or in troubleshooting section below) |

## Indications and errors

### Troubleshooting

Errors with the strut controller device may represent hard faults or soft faults. These faults are indicated by a solid red LED light ring. Soft faults may be resolved on their own after updating the error status to connected HexConnect Mobile App or with a device reset by turning the strut controller off and back on by opening and closing the battery door. Hard faults require replacement of the strut controller.

The HexConnect mobile application is equipped with numerous error messages to help describe issues with device connectivity or battery levels. These error messages and recommended troubleshooting actions for the strut controllers and mobile application are outlined in **Table 4**.

In the event of a severe mechanical shock or drop of the strut controller, an operational check of the strut controller may be performed to verify proper operation per the Controller Connectivity section,

For additional troubleshooting support, contact the customer support team at +1 (844) 393 4933. For non-urgent requests, contact the helpdesk at [smartheXqa@stryker.com](mailto:smartheXqa@stryker.com).

**Table 4: Error messages and recommended actions**

| Strut controller         |                                                                                      |              |                                                                                                                                                                                                                                                                                |
|--------------------------|--------------------------------------------------------------------------------------|--------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Indication               | Error message                                                                        | Fault status | Recommended action                                                                                                                                                                                                                                                             |
| Solid Red LED Light Ring | Controller has failed, Software issue, error code (0x0001) – over current error      | Soft Fault   | Check for excessive debris on the strut or that the strut is not jammed.<br>Press Resume to try again.<br>If pain is present or the strut is physically jammed, do not resume, contact your healthcare professional.                                                           |
|                          | Controller has failed, Software issue, error code (0x0002) – motor failure           | Hard Fault   | Contact your healthcare professional for controller replacement.<br>In the event of a hard fault, device operation is stopped. Operation of the controller may also be terminated by removing the battery as described in the Battery removal and replacement section above.   |
|                          | Controller has failed, Software issue, error code (0x0004) – encoder failure         | Hard Fault   | Contact your healthcare professional for controller replacement.<br>In the event of a hard fault, device operation is stopped. Operation of the controller may also be terminated by removing the battery as described in the Battery removal and replacement section above.   |
|                          | Controller has failed, Software issue, error code (0x0008) – heartbeat error         | Soft Fault   | Communication with your device was lost during the correction. This could be caused by a broken device, the device turned off, or dead battery.<br>Repair, recharge, or turn the device back on, navigate to the last correction, and press Resume to continue the correction. |
|                          | Controller has failed, Software issue, error code (0x0010) – five-volt error failure | Hard Fault   | Contact your healthcare professional for controller replacement.<br>In the event of a hard fault, device operation is stopped. Operation of the controller may also be terminated by removing the battery as described in the Battery removal and replacement section above.   |

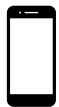
## Indications and errors

| Strut controller         |                                                                 |              |                                                                                                               |
|--------------------------|-----------------------------------------------------------------|--------------|---------------------------------------------------------------------------------------------------------------|
| Indication               | Error message                                                   | Fault status | Recommended action                                                                                            |
| Solid Red LED Light Ring | Controller has failed, Bluetooth connectivity issue             | Soft Fault   | Move your mobile device closer to your frame and press resume.                                                |
|                          | Controller has failed, turn on Bluetooth to perform corrections | Soft Fault   | Check your devices settings and ensure Bluetooth is turned on.<br>When Bluetooth turned back on press Resume. |
|                          | Insufficient controller battery level to execute correction     | Soft Fault   | Contact your healthcare professional for battery replacement.                                                 |

| Mobile application             |                                                                                                |                                   |                                                                                                                                                         |
|--------------------------------|------------------------------------------------------------------------------------------------|-----------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------|
| Problem                        | Error message                                                                                  | Fault status                      | Recommended action                                                                                                                                      |
| Unable to Enroll               | Enrollment – Failed to register controller X (1–6) with strut                                  | None                              | Check your internet connection and try again.<br>You must be connected to the internet to enroll a strut and link it to the correction plan.            |
| Unable to perform a correction | A surgeon visit is required for this correction.                                               | None                              | Contact your surgeon for required strut change or adjustment.<br>The surgeon must mark the visit as complete in the web portal before you can continue. |
| Unable to perform a correction | Checking controller battery – Failed to read battery level of one or more controllers          | None                              | Move your mobile device closer to your frame and try again.                                                                                             |
| Unable to perform a correction | Insufficient phone battery to execute correction- less than 20%                                | None                              | Recharge device to greater than 20%.                                                                                                                    |
| Unable to perform a correction | Correction has been STOPPED. You must contact your surgeon to send an updated correction plan. | None                              | After pressing the STOP button, you must contact your surgeon to verify everything is ok and get a new correction plan.                                 |
| Unable to perform a correction | Checking controller battery error                                                              | None                              | Press OK and try again.<br>If the issue persists, call support.                                                                                         |
| Unsuccessful Strut Adjustment  | Controller has failed – Unable to connect with the controller                                  | Solid Red LED Light Ring (30 sec) | Ensure Bluetooth functionality of your mobile device.<br>Move your mobile device closer to your frame and press resume.                                 |
| None - Informational message   | The battery level for one or more controllers is running low                                   | None                              | Contact your healthcare professional for a battery replacement.                                                                                         |



## Instructions for mobile app users (manual adjustments)



Mobile app user

**Mobile app user:** struts are adjusted manually by the patient or caregiver in accordance with the correction plan generated by the web application. The correction plan is accessed through the patient's HexConnect Mobile Application, which also provides alerts, reminders, and instructions.

After downloading and opening up the prescribed correction plan in the HexConnect application, users can access the correction schedule that will guide the manual adjustment of the smartHEX struts. **(Figure 63)**

When a correction is selected, each strut is listed with the number and direction of clicks as well as the adjustment length. Each adjustment can be marked as complete as corrections are executed.

**For example:** Strut 1 should be adjusted 2 clicks in the clockwise (+) direction. When the adjustment is complete, the scale on the side of the strut should read 135.5. **(Figure 64)**

| Strut | Clicks         | Length | Status        |
|-------|----------------|--------|---------------|
| 1     | 2 <sup>+</sup> | 135.5  | Mark Complete |

A full correction is considered complete when all struts are adjusted and the status is changed for each, indicated by six green check marks. **(Figure 65)**

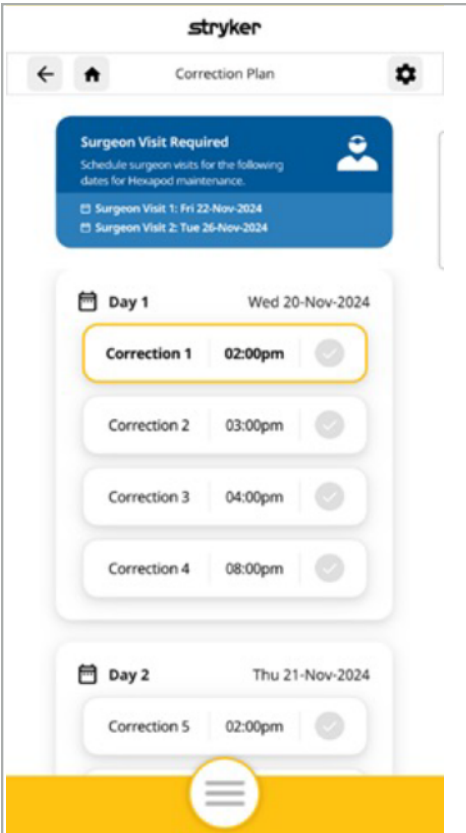


Figure 63

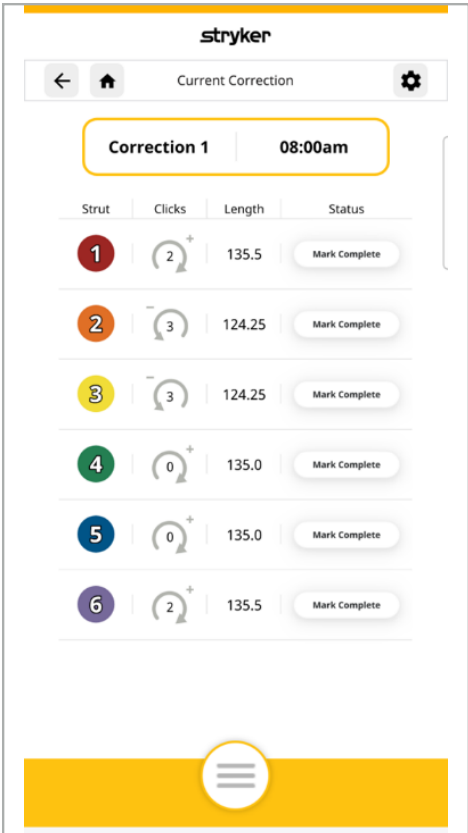


Figure 64

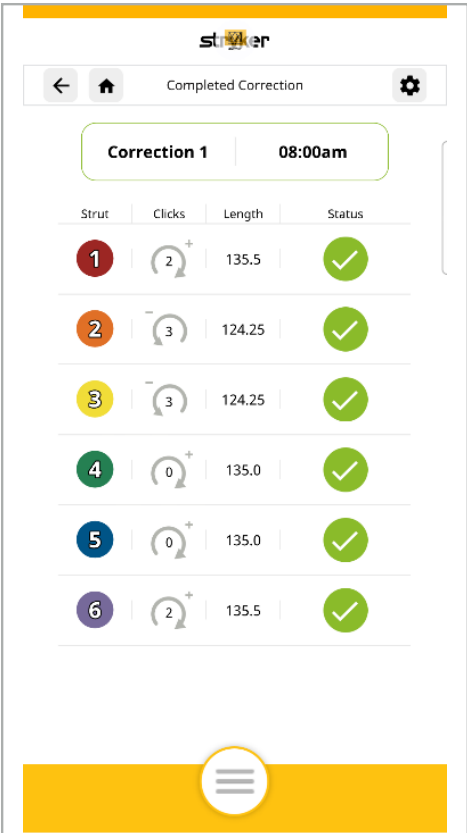


Figure 65

## Cybersecurity

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The communication between the strut controller and the mobile application is a standard Bluetooth Low Energy (BLE) connection. The transmitted data is protected by a proprietary data format and symmetric key encryption.

Symmetric keys are derived using asymmetric (public key) cryptography via ECDH key agreement (Key-Exchange). The integrity of transmitted data is ensured by a cyclic redundancy check (CRC) generated by the sender and verified by the receiver. In addition to the integrity check of the transmitted data using CRC, the integrity of the encrypted payload is achieved using an AEAD Authentication Tag. The enrollment of the strut controller to the mobile app is accomplished during installation of the system with an authenticated login procedure that uses a symmetric key exchange algorithm based on the embedded serial numbers of the controllers. This prevents unauthorized devices from communicating with the strut controller.

Under normal operation, the industry standard BLE protocols allow for many users to be in the same vicinity. As stated earlier, the transmitted data is protected by a proprietary data format and symmetric key encryption. This prevents unauthorized devices from accessing the data even if they are within range and intercept the transmission.

In cases where communication is lost due to being out-of-range or interference, recommunication is only possible with the authenticated mobile application that enrolled the strut controller.



## Connecting the device to a network

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The Strut Controller does not connect directly to a Wi-Fi or cellular network. Instead, it communicates through the HexConnect Mobile Application, which uses the patient's smartphone or tablet's internet connection—whether via Wi-Fi or cellular data—to transfer data securely. While not required for completing corrections, failure of the device to upload data for a period of two days will require you to connect to a network in order to proceed. Therefore, ensure the mobile device has frequent internet access through either a secure private Wi-Fi network or cellular data.

To connect to a Wi-Fi network, follow these steps:

1. Turn on the device and go to the settings or network menu.
2. Select “Wi-Fi Settings” and ensure that Wi-Fi is enabled.
3. Choose the desired Wi-Fi network from the list of available networks.
4. Enter the Wi-Fi password, then confirm to connect. The device will indicate a successful connection.

For reliable operation, connect only to secure, password-protected private networks. Avoid using public or open networks. If needed, consult your router's manual or your internet provider for help managing your home Wi-Fi settings. Always place the device within range of the wireless router to ensure a strong and stable connection. The use of Wi-Fi must not interfere with the safe operation of the device—refer to the section below for details on wireless compatibility and performance.

## FCC compliance statement

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This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

This device has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a residential environment. This equipment generates, uses, and radiates radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference.

However, there is no guarantee that interference will not occur. If this device does cause interference to radio or television reception, which can be determined by turning the device off and on, the user is encouraged to correct the interference by one or more of the following measures:

- Re-orient or re-locate the smartHEX frame and strut controllers.
- Increase the distance between the smartHEX frame and struts controllers and the receiver.
- Contact Stryker OR Assist Customer Service at: +1 (844) 393-4933. For non-urgent requests, contact the Hoffmann LRF helpdesk via email at: [smarthex@stryker.com](mailto:smarthex@stryker.com)

The Intentional Radiator is subject to the FCC Certification procedure, the composite Unintentional Radiator (such as Digital device, Data Interface) is covered by the FCC Suppliers Declaration of Conformity procedure 47 CFR Part 15, Subpart C.

### FCC caution

Changes or modifications not expressly approved by Stryker could void the user's authority to operate the equipment.

# Strut controller specifications

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## Weight and dimensions

- Weight (with battery): 100g
- Dimensions: 57mm (height) × 46mm (depth) × 52mm (width)

## Storage and transport conditions

- Ambient temperature: +2°C to +38°C
- Humidity: 15% to 90%, non-condensing
- Atmospheric pressure: 700hPa to 1060hPa

## Operating conditions

- Ambient temperature: +5°C to + 40°C
- Humidity: 15% to 90%, non-condensing
- Atmospheric pressure: 700 hPa to 1060 hPa

## Duty cycle

- The strut controller operates for less than 1.5 minutes per/day, therefore it's duty cycle is 0.1%

## Accuracy

- +/- 3.24 degrees per 90 degree rotation

## Battery

- Battery type: Panasonic CR2 (Lithium Manganese Dioxide)
- Dimensions: 27mm long × 15.6mm diameter
- Nominal voltage: 3VDC
- Nominal capacity: 850mAh
- Weight: Approx. 11g
- Operating temp: -40°C to 70°C
- Storage temp: 5°C to 35°C

## Device transmitter

- Bluetooth Low Energy (BLE) version: 5.0
- Frequency band: 2.402 GHz to 2.480 GHz
- Transmitted power: -8dBm
- Operating range: 5m indoor
- Antenna type: 2.4 GHz Chip antenna

## Cleaning instructions

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The strut controllers may be cleaned with a soft, lint free cloth dampened with a mild soap and water solution. Gently wipe the surface of the device, avoiding openings. Wipe off any residual soap solution with a clean damp cloth. The strut controllers must not be submerged or cleaned with harsh chemicals.

To remove excessive soil, remove the strut controller from the strut and clean the mounting bracket and gear area with a slightly dampened cotton swab.

The strut controllers have an IP24 rating, which means they are designed to withstand water splashes from any direction. The prescribing surgeon may permit patients to bathe with a light shower during the course of treatment. The strut controllers must not be used for bathing in a bath or swimming pool.

### NOTICE

Strut controllers are not designed to be submerged in water or any liquid and may be subject to irreparable damage if submersion occurs. Patients must contact their care team if a smartHEX device with the strut controllers attached has been submerged in liquid for any time.

### NOTICE

If the care team determines that the patient must submerge the smartHEX device in water for any reason, the strut controllers must be removed prior to submersion.



## Discretionary strut controller removal

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There may be certain instances when removal of strut controllers is required during a treatment period, for instance to improve radiographic imaging, to prepare for water submersion, or to change to manual adjustments. Strut controllers can be safely removed and reapplied to the smartHEX struts using the techniques described in the Mounting the strut controllers section.



## Environmental considerations for safe use

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The strut controllers are intended for use in a home healthcare environment. To ensure proper operation and safety, please observe the following precautions:

- **Dust and lint:** Do not operate the strut controllers in environments with excessive dust or lint (e.g., near open windows, vents, or laundry areas). Accumulation may interfere with device operation.
- **Loose clothing and linens:** Avoid covering the strut controllers with loose clothing, blankets, or bed linens during operation. Obstruction of the gears may result in jamming of the struts, impaired function, or inaccurate readings.
- **Ambient light:** Avoid direct exposure to strong light sources (e.g., sunlight or bright lamps) that may impair LED display function.
- **Pets and pests:** Keep the strut controllers out of reach of pets. Damage from chewing, scratching, or urination can impair safety and performance. Protect the device from insects or rodents that could damage the device and interfere with operation.
- **Children:** This device is not a toy. Do not allow children to play with or operate the smartHEX system unsupervised. Small parts may pose a choking hazard.



## Device disposal

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When disposing of smartHEX strut controllers and lithium batteries, follow local regulations and facility guidelines for the disposal of electronic waste. Do not discard the strut controllers or batteries in household trash or recycling bins. Contact the prescribing healthcare facility for disposal information or check with local waste management authority or recycling center to identify designated e-waste collection points or recycling programs in the area.



## Electromagnetic Compatibility (EMC)

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Hoffmann LRF smartHEX Strut Controller - FCC ID: 2BOED-SMHEX, IC: 33821-SMHEX

- The smartHEX system needs special precautions regarding EMC and needs to be used according to the EMC information provided in this manual.
- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating properly.
- Portable RF communications equipment (including antenna cables and external antennas) should be used no closer than 30 centimeters (12 inches) to any part of the smartHex system. Otherwise, degradation of the performance of this equipment could result.
- Use of accessories and cables other than those specified or provided by Stryker could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- There are no special instructions for maintaining basic safety and essential performance due to EMC for the expected service life of 140 days.



# Guidance and manufacturer’s declaration

## Electromagnetic emissions

The smarHEX strut controllers are intended for use in the electromagnetic environment specified in **Table 5**. The customer or the user of the system should assure that it is used in such an environment.

**Table 5: Guidelines for electromagnetic emissions**

| Emissions test           | Compliance | Electromagnetic environment guidance                                                                                                                                                                                    |
|--------------------------|------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| RF emissions<br>CISPR 11 | Group 1    | The system uses RF energy for short range communication between the strut controller and the companion device, therefore RF emissions are very low and unlikely to cause interference with nearby electronic equipment. |
| RF emissions<br>CISPR 11 | Class B    | The smarHEX system is suitable for use in all environments, including home use environments, hospital environments and healthcare facility environments.                                                                |

## Guidance and manufacturer's declaration

### Electromagnetic immunity

The smartHEX strut controllers are intended for use in the electromagnetic environment specified in **Table 6**. The customer or the user of the system should assure that it is used in such an environment.

**Table 6: Guidelines for electromagnetic immunity**

| Immunity test                                                            | IEC 60601 test level                                         | Compliance level                                             | Electromagnetic environment guidance                                                                                                                                                                                                                         |
|--------------------------------------------------------------------------|--------------------------------------------------------------|--------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Electrostatic discharge (ESD) IEC 61000-4-2                              | $\pm 8$ kV contact<br>$\pm 15$ kV air                        | $\pm 8$ kV contact<br>$\pm 15$ kV air                        | Flooring should be wood, concrete or tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.                                                                                                                      |
| Radiated RF fields IEC 61000-4-3                                         | 3 V/m<br>80 MHz to 2700 MHz                                  | 3 V/m                                                        | Portable RF communications equipment (including antenna cables and external antennas) should be used no closer than 30 centimeters (12 inches) to any part of the smartHex system. Otherwise, degradation of the performance of this equipment could result. |
| Power frequency (50/60 Hz) magnetic field IEC 61000-4-8                  | 30 A/m                                                       | 30 A/m                                                       | Power frequency magnetic fields should be at levels characteristic of those found in a typical domestic, commercial, or hospital environment.                                                                                                                |
| Proximity magnetic fields IEC 61000-4-39                                 | 9 kHz to 150 kHz<br>- 30 kHz – 8 A/m<br>- 134.2 kHz – 65 A/m | 9 kHz to 150 kHz<br>- 30 kHz – 8 A/m<br>- 134.2 kHz – 65 A/m | Proximity magnetic fields should be at levels characteristic of those found in a typical domestic, commercial, or hospital environment.                                                                                                                      |
|                                                                          | 150kHz to 26 MHz<br>- 13.56 MHz – 75 A/m                     | 150kHz to 26 MHz<br>- 13.56 MHz – 75 A/m                     |                                                                                                                                                                                                                                                              |
| Proximity fields from RF wireless communications equipment IEC 61000-4-3 | See table below                                              | Compliance to the tested levels                              | Portable RF communications equipment (including antenna cables and external antennas) should be used no closer than 30 centimeters (12 inches) to any part of the smartHex system. Otherwise, degradation of the performance of this equipment could result. |

## Guidance and manufacturer's declaration

**Table 7** lists the immunity levels at specific test frequencies for testing the effects of some wireless communications equipment. The frequencies listed in the table are representative examples in various locations where the smartHEX strut controllers may be used.

**Table 7: Immunity levels by test frequency**

| Frequency in MHz     | Test level in V/m | Polarization | Modulation           |
|----------------------|-------------------|--------------|----------------------|
| 385                  | 27                | H/V          | PM 18 Hz,<br>DC 50%  |
| 450                  | 28                | H/V          | PM 18 Hz,<br>DC 50%  |
| 710<br>745<br>780    | 9                 | H/V          | PM 217 Hz,<br>DC 50% |
| 810<br>870<br>930    | 28                | H/V          | PM 18 Hz,<br>DC 50%  |
| 1720<br>1845<br>1970 | 28                | H/V          | PM 217 Hz,<br>DC 50% |
| 2450                 | 28                | H/V          | PM 217 Hz,<br>DC 50% |
| 5240<br>5500<br>5785 | 9                 | H/V          | PM 217 Hz,<br>DC 50% |

## Trauma & Extremities

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This document is intended solely for the use of healthcare professionals. A surgeon must always rely on his or her own professional clinical judgment when deciding whether to use a particular product when treating a particular patient. Stryker does not dispense medical advice and recommends that surgeons be trained in the use of any particular product before using it in surgery.

The information presented is intended to demonstrate a Stryker product. A surgeon must always refer to the package insert, product label and/or instructions for use, including the instructions for cleaning and sterilization (if applicable), before using any Stryker product. Products may not be available in all markets because product availability is subject to the regulatory and/or medical practices in individual markets. Please contact your Stryker representative if you have questions about the availability of Stryker products in your area.

Operative techniques, patient information leaflets and other associated documents may be requested online at [www.stryker.com](http://www.stryker.com). If saving the Instructions for Use, operative techniques, or cleaning instructions, please make sure you always have the most up to date version prior to use.

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