

Software User's Guide

A module of the TL-HEX Software Version 2.2

myHEXplan™ Software User's Guide: A module of the TL-HEX software version 2.2

The applicable End User License Agreement can be found at: <http://tlhex.com/policies/Eulapolicy.html>

The applicable privacy policy can be found at: <http://tlhex.com/policies/privacypolicy.html>

Security Precautions:

User is advised to clear the browser history (temporary internet files, cookies, etc.) after logging out of the TL-HEX application.

Computer System Requirements

Display Settings:

Screen resolution of 1280 x 768 pixels or higher.

Supported Browsers:

Microsoft Internet Explorer®: Version 11, Edge: Version 11

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Safari® 11

Safari is trademark of Apple Inc., registered in the U.S. and other countries. HomeKit is a trademark of Apple Inc.

Google Chrome™ Browser 62 or higher

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Google Chrome is made possible by the [Chromium](#) open source project and other [open source software](#).

Mobile Safari® 10.3+

Safari is trademark of Apple Inc., registered in the U.S. and other countries. HomeKit is a trademark of Apple Inc.

Other Requirements:

Web Graphics Library (WebGL) availability and minimum screen resolution are checked at login time in order to provide access to HEX-ray. (See Annex A on HEX-ray Software User's Guide on how to configure the browser)

Internet Connection:

Minimum required internet connectivity speed is of 512kbps.

Recommended internet connectivity speed is of 3mbps or higher.

My Username:

My Password:

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INTRODUCTION

A successful treatment with the TL-HEX system is not simply a matter of correct struts adjustment. The myHEXplan mobile app acts in addition with the standard treatment approach, to support your TL-HEX patient from the first day after surgery, through removal of the device and all the treatment phases.

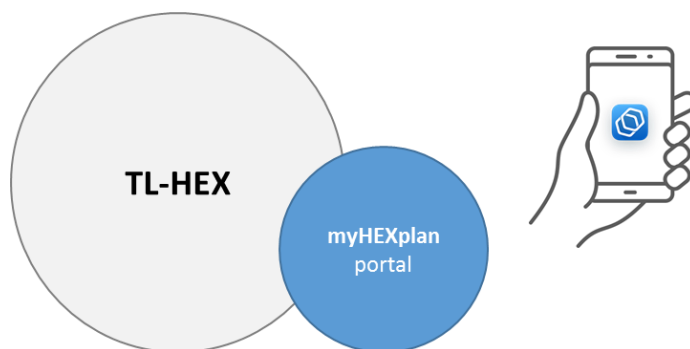
With only a few steps added to the standard flow with which you have become familiar, the myHEXplan app will enrich your clinical practice by providing:

- A remote view of your patient's post-operative treatment actions on the mobile app
- Patient educational and motivational support in between the scheduled check-up visits.

In addition, the myHEXplan mobile app will provide your patient:

- Access to their treatment(s) schedule on a smartphone, in addition to the current paper one(s)
- Reminders for struts adjustment and pin site care
- Access to educational materials about treatment with the TL-HEX system
- Educational and Motivational support and other useful features.

The myHEXplan system consists of a mobile app and a new web portal, in addition to www.tlhex.com.



The current TL-HEX treatment calculation software is enriched with:

- Patient eligibility and digital prescription publishing feature, permitting the patient to receive the digital prescription on her/his smartphone through the new myHEXplan mobile app in addition to the paper one.

The new myHEXplan web portal adds more functionalities like:

- A Dashboard with patient and published cases status
- Patient's History of the actions done on the mobile app
- Case and Patient settings review and update.

The new myHEXplan mobile application provides the patient:

PATIENT

BASIC VERSION OF MYHEXPLAN – The myHEXplan mobile app comes with some general functionalities (e.g. Pin site care, Digital prescription activation)

DIGITAL PRESCRIPTION ACTIVATION – Once the patients have installed the myHEXplan mobile app, they will be asked to “Tap here to get started” and then “Scan your QR code” in order to download and activate the digital prescription.

- The QR Code is associated with the patient and not with the case, so the patient is asked to scan the QR Code only for the first prescription. In the case of multiple frames, the patient will receive automatic notifications as soon as their mobile app is synchronized with the myHEXplan portal

Activating the digital prescription will enable more functionalities within myHEXplan mobile app, including Prescription overview, Struts adjustment with related reminders, All my daily tasks, My diary and Educational / Motivational messages reception.

STRUTS ADJUSTMENT – For each frame (identified by the Frame ID letter), struts adjustment daily reminders will be automatically sent to the myHEXplan mobile app, as scheduled in the paper prescription. At the prescribed time, the patient will receive a reminder. Tapping on STRUT ADJUST will open the prescribed schedule, where the patient will be able to mark the struts adjustment as complete.

PIN SITE CARE – If you have chosen to set pin site care reminders for your patient, he/she will also be able to mark this activity as complete


MY DIARY – All patient interactions will be tracked in the “diary” and your account in the myHEXplan portal will be synchronized. Notifications of missed adjustments will be sent to the email contact according to the notification threshold set by you within the myHEXplan case settings.

OTHER - The patient will be able to load a personal photo, enter a nickname and a personal treatment goal. He/she will also be able to set a preferred time for pin site care alert notifications (by default, time of reminders is set at 9:00am). The patient has the ability to change only the timing of reminders, the frequency will remain unchanged as per surgeon setting.

NOTES

- The myHEXplan system is not intended for the diagnosis of disease or other conditions, or the cure, mitigation, treatment, or prevention of disease, or is intended to affect the structure or any function of the human body
- The myHEXplan system does not substitute the paper treatment plan provided to the patient by the surgeon
- The information visualized on the myHEXplan system does not substitute the scheduled check-up visits with the surgeon
- Any changes on the paper treatment plan will be provided to the patient by the surgeon during the check-up visit
- If any malfunctioning of myHEXplan system occurs, please always remind the patient to continue the daily struts adjustment program according to the provided printed treatment plan.


ONLINE HELP

Online help is available by clicking on  icons where applicable; the surgeon will be able to view relevant help information.

TREATMENT PUBLISHING FLOW

Here below is described the flow to publish a new case on the myHEXplan mobile application.

MAIN STEPS SUMMARY				
PATIENT ELIGIBLE	FRAME ID	PUBLISH	SETTINGS	PRINT PRESCRIPTION

- **LOGIN** - Login to TL-HEX software on tlhex.com
- **PATIENT ELIGIBILITY** - Mark the patient as eligible for the myHEXplan app; this will enable the myHEXplan associated functionalities, exclusively for that patient (see [ADD OR MODIFY A PATIENT](#))
- **NEW CASE and FRAME ID** - Create a new case and assign a letter (Frame ID) to the frame. This same letter will be included in the printed prescription and also in the myHEXplan mobile app, to help the patient associate the struts adjustment notified with the corresponding frame, in case of multiple frames at same time.
- **CASE DATA** – Enter all the required case data to permit software to calculate the treatment plan.
- **TREATMENT PUBLISHING** - From the Report tab, click on  [Publish for myHEXplan™] button to complete the settings of myHEXplan mobile app for your patient and case (see [PUBLISH FOR myHEXplan](#)) :


CASE SETTINGS tab

- **Treatment timeline:** The timeline helps visualizing the treatment progress and phases and will determine the delivery of motivational messages. Latency and Correction phases duration are automatically populated from TL-HEX software.
- **Notification threshold for skipped days of Struts adjustment:** Set the threshold in days for email notification of your patient's missed struts adjustment. For example, if you want to be notified after 1 day of missed set of six struts adjustment, you must choose "1" as the notification threshold.

(see [CASE SETTINGS TAB](#))

PATIENT SETTINGS tab

- **Pin site care – reminders starting date and frequency:** Set the First Day on which the reminders will be sent and the related weekdays.
Time of alert notification is set by default at 9:00am, and can be changed by the patient in the myHEXplan mobile app. You also have the ability to disable these reminders for the myHEXplan mobile app.
- **Notification contact info:** the myHEXplan portal has the ability to send you, or someone from your office, a notification of skipped days of struts adjustment when threshold set is reached. Here you can insert the email address of the person who will receive these notifications.
- **Educational and Motivational messages:** The messages are organized in educational categories (Struts adjustment, Pin site care and Physical therapy) and in the Living with your fixator category (motivational). By default all messages are selected and it is possible to review the selection. You also have the ability to disable the messages for the myHEXplan mobile app.

When settings is complete click on  [Publish Case] button to complete the treatment publishing and return back to the Report tab (see [PATIENT SETTINGS TAB](#)).

- **PRESCRIPTION FOR PATIENT PRINT** – By publishing the settings, a unique QR code is generated for the patient and you must print and provide the paper prescription to your patient. The paper prescription now includes the generated QR code and instructions on how to install the myHEXplan app (see [REPORT](#)).

Notice that the status of the case has changed to “Published” and it is no longer editable, this is to ensure that the prescription is synchronized with the patient’s myHEXplan treatment schedule.

- **CHECK THE STATUS** – Check in your Patient’s History the status of the assigned digital prescription (see [DASHBOARD](#))

PUBLISHED TREATMENT UPDATE FLOW

There are two ways to update a published treatment:

1) CHECK-UP OF THE PUBLISHED CASE

MAIN STEPS SUMMARY			
CASE CHECK-UP	PUBLISH	UPDATE SETTINGS	PRINT PRESCRIPTION

- **CHECK-UP** of the published case - You can check up a published case and when the treatment publishing flow is completed, the prescription currently loaded on the patient’s myHEXplan mobile app will be updated.
Now you can print the prescription and provide it to the patient, as per usual practice.

NOTE: The patient will not be asked to scan the QR Code again; the updated prescription will automatically download in your patient’s myHEXplan mobile application.

2) CREATE A NEW CASE WITH THE SAME FRAME ID

MAIN STEPS SUMMARY				
NEW CASE	SAME FRAME ID	PUBLISH	UPDATE SETTINGS	PRINT PRESCRIPTION

- **NEW CASE with same FRAME ID** - Create a new case and, in order to replace the prescription currently available in your patient’s myHEXplan mobile app, you must use the same Frame ID. In the publishing phase, you will be asked to confirm the substitution of the previous prescription.

Unless you need to update the patient and case settings, you can skip all intermediate steps and go straight to publication. By confirming the publication, you will be brought back to the Report tab. Now you can print the prescription. The patient will not be asked to scan the QR Code again: the new prescription will automatically download to your patient’s myHEXplan mobile app and will replace the previous prescription with the same Frame ID. Track the status of the new prescription in your patient’s Diary, as previously described.

myHEXplan MODULE FEATURES OVERVIEW

In this section are described the myHEXplan additional features and options to the TL-HEX Treatment Calculation software.

ADD OR MODIFY A PATIENT

When Add a New Patient or Modify an existing one, the myHEXplan Eligible flag is present. The flag permits to publish treatments to the myHEXplan mobile app for that patient. The flag can be set anytime, also after having already created a case for that patient.

The screenshot shows the 'Add New Patient' form. It contains the following elements:

- Patient ID ***: A text input field with a help icon.
- Patient Initials ***: A text input field.
- Gender ***: Radio buttons for 'Male' and 'Female'.
- myHEXplan™ Eligible**: A checkbox with a help icon.
- Warning**: A light blue box with a warning icon and text: "You are not allowed to enter or provide any information that allows, directly or indirectly, the identification of your patient (e.g. name, birth date, address, email-address, phone number etc.). Please use only an internal confidential code to identify your patient record when using this Software."
- Prescription Preferences**: A dark blue bar with a right-pointing arrow.
- Buttons**: 'Save Patient', 'Save & Create Case', and 'Cancel'.

For each new patient, the surgeon should provide the following information

- unique Patient ID
- Patient Initials
- Gender
- myHEXplan Eligible


Warning: Under the Orthofix Terms of Use (End User License Agreement and Privacy Policy), the surgeon shall never enter information that directly identifies a patient. The patient number is intended to be used as an identifying link to the patient within the surgeon's patient management system.

Clicking on the **Save Patient** button will complete the creation process and open the "List of patients" screen, which will include all previously entered patients as well as the newly created one.

On the other hand, clicking on the **Save & Create Case** button will save the new patient and will open a new ready-to-use case that is already associated to the newly created patient.

LIST PATIENTS AND CASES




















In the List of Patients the myHEXplan eligible patients are highlighted with the  icon.

List of Patients

Search ▶

Add new Patient ?

	Patient ID ↑	Initials	Gender	Last Case Planned	Active Cases	Actions
▶ 	HEX-ray Guide	HEX-ray Guide	Male	30/05/2017	20	 
▶ 	HEX-ray HELP Content test	Help Content Test	Male	04/03/2017	4	 
▶	Received_Cases	RC	N/A	22/12/2017	0	
▶	SW User's Guide	SW User's Guide	Male	10/01/2018	6	 
▶ 	Test 1	APP	Male	09/01/2018	4	  
▶ 	Test 2	Candidate 1	Male	12/01/2018	1	  

◀◀◀ 1 ▶▶▶ ALL ▼

6 items in 1 pages

























































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Click on the  [arrow] icon near a Patient ID to expand the list of cases related to it grouped by Frame IDs.


List of Patients

Search ▶

Add new Patient ?

	Patient ID ↑	Initials	Gender	Last Case Planned	Active Cases	Actions																																																												
▶ 	HEX-ray Guide	HEX-ray Guide	Male	30/05/2017	20	 																																																												
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



















In the List of Cases the eligible patients to myHEXplan patients have been highlighted with the  icon.

List of Cases

Search ▶

Add new Patient Add new Case ?





Patient ID	Frame ID	Case ID	Case Description	Status	Case Type	Bone Type	Side	Planning Created ↓	Days Left	Actions
 Test 2	H	Caso 1		Revoked	 Deformity	Tibia	Left	12/01/2018	1	  
SW User's Guide	N/A	prova2_10/01/2...	prpv	Active	Deformity	Long Bone	Left	10/01/2018	0	   
 Test 1	B	Prova		Active	 Deformity	Tibia	Left	09/01/2018	12	  
 Test 1	B	sostituzione		Active	Deformity	Tibia	Left	09/01/2018	6	   
 Test 1	H	secondo caso 1.0.14		Active	Fracture	Hindfoot	Right	09/01/2018	0	   
 Test 1	E	terzo on IE		Active	Fracture	Long Bone	Left	09/01/2018	1	   
Received_Cases	C	Case from andreaforcolin... 09:39:32	Case from andreaforcolin...	Received	Deformity	Tibia	Left	22/12/2017	0	  
 HEX-ray Guide	A	Tibia Left Black		Active	Deformity	Tibia	Left	30/05/2017	0	   
 HEX-ray Guide	E	Tools black		Active	Fracture	Tibia	Left	30/05/2017	0	   
 HEX-ray Guide	C	Tools		Active	Deformity	Tibia	Left	09/05/2017	0	   

« « 1 » » 10 36 items in 4 pages

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STATUS ICONS

The status icons present on the List of Patients and List of Cases are described in the following table:

Tlhex.com	
	myHEXplan ELIGIBLE The icon identifies myHEXplan eligible patients.
	FRAME WITH PUBLISHED CASE The icon identifies a frame with published case.
	PUBLISHED CASE With reference to all the cases of the same Frame ID, the icon identifies published Active or AdjustedReport cases to myHEXplan mobile application. When published the case is no longer editable.
	REVOKED CASE The icons identify prescription that has withdrawn from your patient's myHEXplan mobile app. When revoked the case is read-only and it can be viewed, sent or myHEXplan™ Case Settings can be viewed.

ACTIONS

Actions that can be performed on a patient or case are:



ADD NEW CASE

Create a new case related to this patient in one click by selecting this icon

DELETE A PATIENT

By selecting this option, the patient and all his/her related cases will be deleted.



The popup window will appear to confirm the removal of the patient. Click on 'Delete' to move on. A warning pop up reminds that the action cannot be reverted, once a patient is deleted. Patients with published or revoked cases cannot be deleted.

PATIENT HISTORY



This section reports the patient's history of actions done on myHEXplan mobile application. This section reports also events when actions are not done (e.g. pin site care not done, struts adjustment not done ...).

PATIENT SETTINGS



Any time during the treatment, or following the check-up visits, you have the ability to view / edit:

- Pin site care frequency
- Email address for receiving skipped struts adjustment notification
- Educational and Motivational messages selection
- Progress of cases

CASE SETTINGS



Any time during the treatment, or following the check-up visits, you have the ability to view / edit:

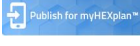
- Consolidation phase duration: modifying this period will extend or reduce the period during which the motivational messages are sent to the patient through the myHEXplan mobile app
- Notification threshold of missed struts adjustment
- The threshold in days for email notification of patient's missed struts adjustment

TREATMENT PUBLISHING IN DETAIL

PUBLISH FOR myHEXplan

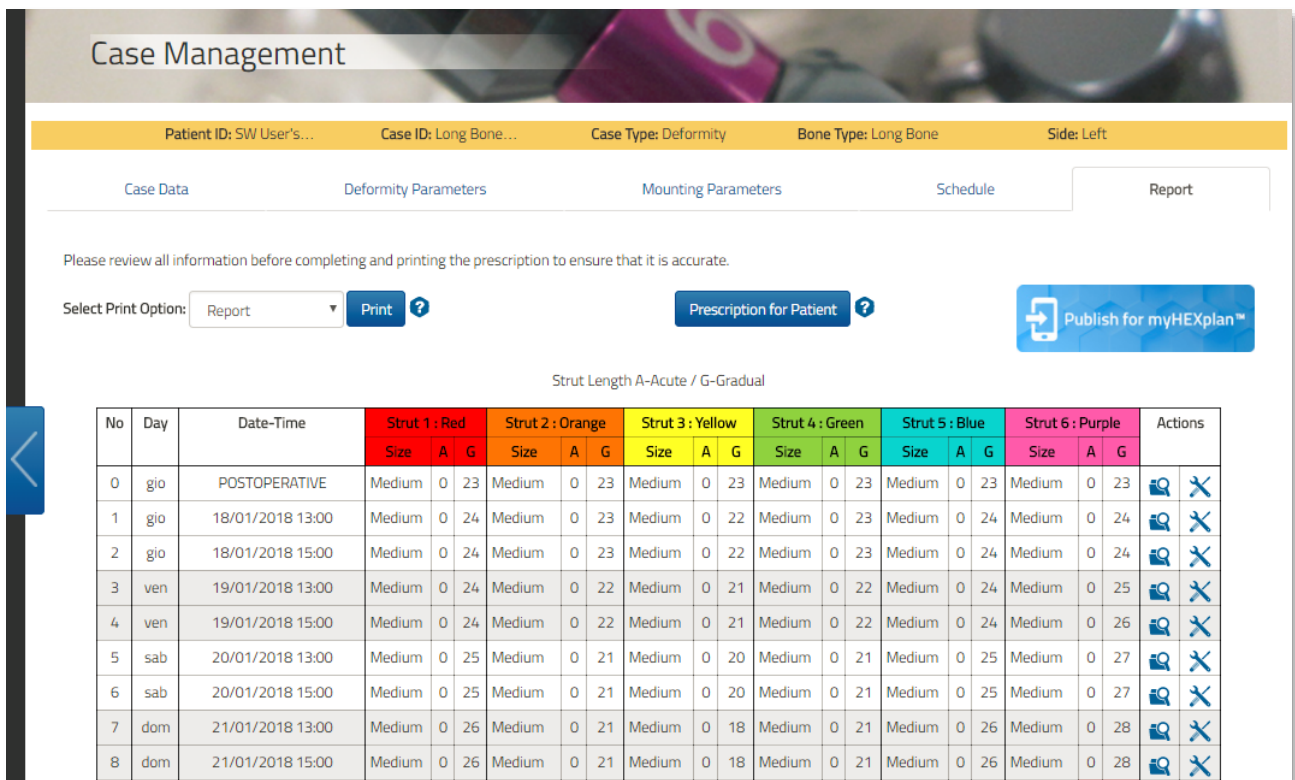
In the Report tab for eligible patients, the button  [Publish for myHEXplan™] is displayed.

Here you have the option to print the prescription pressing the  [Prescription for Patient] button.

Press  [Publish for myHEXplan™] button to publish the case to patient's mobile after having entered myHEXplan case and patient settings.

When the Treatment Publishing flow is completed, the prescriptions for patient displays a QrCode which should be scanned the first time from the patient to download the related published prescriptions. QrCode is unique for each patient.

NOTE: If another case has been published for this patient on the same Frame ID, publishing the current case on the same Frame ID will withdraw the previous one with all the struts adjustments and reminders which will be updated with the new ones.



The screenshot shows the 'Case Management' interface. At the top, patient details are displayed: Patient ID: SW User's..., Case ID: Long Bone..., Case Type: Deformity, Bone Type: Long Bone, Side: Left. Below this are tabs for Case Data, Deformity Parameters, Mounting Parameters, Schedule, and Report. A message states: 'Please review all information before completing and printing the prescription to ensure that it is accurate.' Below the message are three buttons: 'Select Print Option: Report' (dropdown), 'Print' (button), 'Prescription for Patient' (button), and 'Publish for myHEXplan™' (button). Below the buttons is a table titled 'Strut Length A-Acute / G-Gradual'.

No	Day	Date-Time	Strut 1 : Red			Strut 2 : Orange			Strut 3 : Yellow			Strut 4 : Green			Strut 5 : Blue			Strut 6 : Purple			Actions	
			Size	A	G	Size	A	G	Size	A	G	Size	A	G	Size	A	G	Size	A	G		
0	gio	POSTOPERATIVE	Medium	0	23	Medium	0	23	Medium	0	23	Medium	0	23	Medium	0	23	Medium	0	23		
1	gio	18/01/2018 13:00	Medium	0	24	Medium	0	23	Medium	0	22	Medium	0	23	Medium	0	24	Medium	0	24		
2	gio	18/01/2018 15:00	Medium	0	24	Medium	0	23	Medium	0	22	Medium	0	23	Medium	0	24	Medium	0	24		
3	ven	19/01/2018 13:00	Medium	0	24	Medium	0	22	Medium	0	21	Medium	0	22	Medium	0	24	Medium	0	25		
4	ven	19/01/2018 15:00	Medium	0	24	Medium	0	22	Medium	0	21	Medium	0	22	Medium	0	24	Medium	0	26		
5	sab	20/01/2018 13:00	Medium	0	25	Medium	0	21	Medium	0	20	Medium	0	21	Medium	0	25	Medium	0	27		
6	sab	20/01/2018 15:00	Medium	0	25	Medium	0	21	Medium	0	20	Medium	0	21	Medium	0	25	Medium	0	27		
7	dom	21/01/2018 13:00	Medium	0	26	Medium	0	21	Medium	0	18	Medium	0	21	Medium	0	26	Medium	0	28		
8	dom	21/01/2018 15:00	Medium	0	26	Medium	0	21	Medium	0	18	Medium	0	21	Medium	0	26	Medium	0	28		

The [Publish for myHEXplan™] button is disabled when:

- The prescription has already been completed
- The assigned frame ID is N/A.

CASE SETTINGS TAB

After having pressed the [Publish for myHEXplan] button, the first step in the Treatment Publishing flow is the Case Settings. The step is composed by three sections:

- Treatment timeline
- Notification Threshold
- Published Cases Progress to Date.

The screenshot displays the 'Treatment Publishing' interface. At the top, patient details are shown: Patient ID: Bug retest, Case ID: e3, Case Type: Deformity, Bone Type: Ankle, Side: Right. Below this, the 'Case Settings' tab is active, showing 'TREATMENT SETTINGS FOR CURRENT CASE'. The 'Consolidation Phase Duration' is set to 30 days. A timeline for Frame ID E shows three phases: Latency (5 d), Correction (15 d), and Consolidation (30 d). Key dates include Surgery on 18/01/2018, Surgery on 23/01/2018, Surgery on 07/02/2018, and Approximate Removal on 09/03/2018. The 'NOTIFICATION THRESHOLD' section shows 'Skipped days of Struts Adjustment' set to 'Not set'. A note states: 'NOTE: Number of days after which you want to be notified by email that patient is not doing his struts adjustment'. The 'PUBLISHED CASES PROGRESS TO DATE' section shows a legend for Latency (blue), Correction (yellow), and Consolidation (green). Below, Frame ID B has Surgery on 08/01/2018 and Approximate Removal on 22/02/2018. A progress bar for Case ID B shows 5 d of Latency and 30 d of Consolidation. At the bottom, there are links for Privacy Policy, EULA, and Cookies.

Treatment Timeline

The timeline helps visualizing the treatment progress and phases and will determine the delivery of motivational messages only. Latency and Correction phases' duration are automatically populated from TL-HEX software. Consolidation Phase Duration is calculated by default, as triple the duration of the correction phase if correction lasts more than 30 days (otherwise, the consolidation duration defaults to 30 days). However, the value can be updated and changed anytime also during the treatment. This also estimates an approximate removal date of the frame.

NOTE: Approximate removal date value will not be made available to the patient in any way.

Notification Threshold

Set the threshold in days for email notification of patient's missed struts adjustment on myHEXplan patient mobile application in relation to this case. A notification email will be sent to the email address entered for this patient settings after the number of days of skipped struts adjustment specified.

A different value can be set for each case of the patient and can be updated any time during the treatment.

Published Cases Progress to Date

This section shows the treatment timelines of already published cases (if present) for this patient, updated at the current day.

To continue the Treatment Publishing flow press on the side arrow or on the 'Patient Settings' tab.



PATIENT SETTINGS TAB

The second step in the Treatment Publishing flow is the Patient Settings. The step is composed by four sections:

- Pin site care
- Contact info
- Educational and Motivational messages
- Publish Case.

For subsequent treatment publishing, the saved Patient settings for the current patient are displayed.

Pin Site Care

The section can be enabled  or disabled ; disabling means that this patient will not receive any reminders about pin site care on myHEXplan mobile application.

If enabled, selection of First Day and Frequency of Pin Site care reminders for this patient is mandatory and define, respectively, when patient will start to receive Pin Site Care reminders and with which frequency.

“Select all days” will automatically select all the days resulting in a frequency of once a day.

The patient will start receiving the set reminder as soon as he will activate the prescription on myHEXplan mobile application.

It can be changed anytime during the treatment.

Contact Info

Email address where to receive the notifications about Skipped Struts Adjustments if a threshold has been set. To set the notification threshold refer to the ‘Treatment Publishing – Case Settings, Notification Threshold’ field.

It defaults to TL-HEX registration email address, but this information will not be given in any way to the patient.

It can be changed to another email address, for example the one of a nurse of another care team member.

It can be change anytime during the treatment.

NOTE: It is possible to customize a different email address for each patient.





NOTE: Other contact info different from email address and that were entered in TL-HEX software will be printed on the hard-copy of the prescription and will also be made available in your patient's myHEXplan mobile application, under the "My surgeon" info in the "User profile" section.



Educational and Motivational Messages

The Educational and Motivational messages can be set during treatment publishing and reviewed and modified anytime from myHEXplan Patient Settings during the treatment.

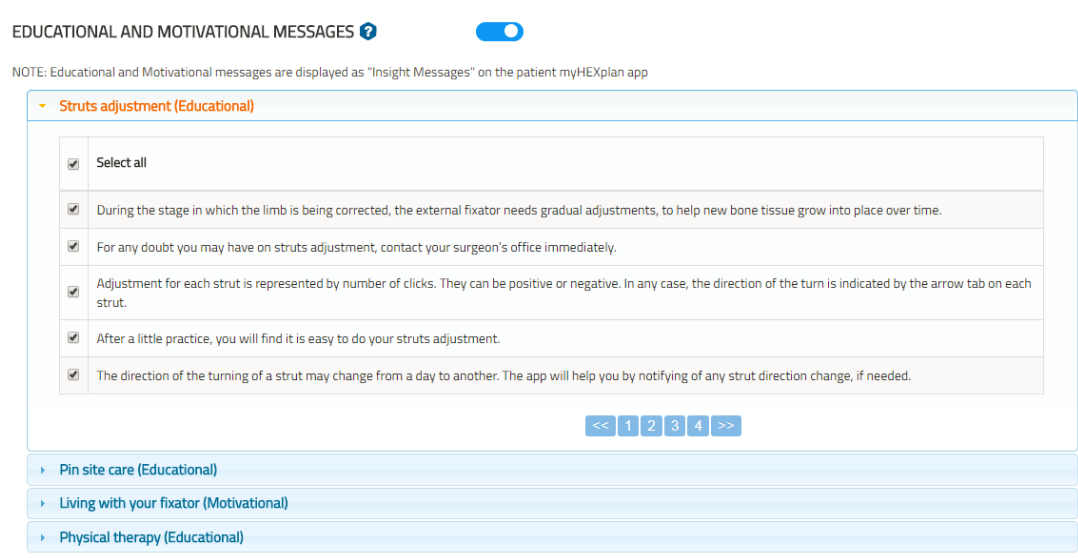
The messages setting is directly connected with a patient, so any patient can have different messages setting.

The messages Categories are the following:

EDUCATIONAL		MOTIVATIONAL	
 Pin site care	 Struts Adjustment	 Physical Therapy	 Living with your fixator

The section can be enabled  or disabled ; disabling means that this patient will not receive any educational and motivational message reminder on myHEXplan mobile application.

If enabled, the set of messages to be sent to myHEXplan mobile application defaults to all messages for all 4 categories.



Pressing on 'Select all', it is possible to unselect or select all messages simultaneously for a chosen category. Otherwise, it is possible to choose the set of messages more suitable for the current patient.

NOTE: Educational and Motivational messages are displayed as "Insight Messages" on the patient myHEXplan app and the patient has the option to enable or disable them.

The patient will start receiving the set messages as soon as they activate the prescription on myHEXplan mobile application and the delivery of the messages is related to the phase of the treatment.

NOTE: The settings for motivational and educational messages can be changed anytime during the treatment.

Insight messages sequence and frequency

According to the treatment phase, the selected insight messages for a patient will be delivered with a top to bottom approach and following the sequence and frequency below:

- **Latency phase** (Frequency: one message every 3 days)
 1. Pin site Care
 2. Living with your fixator

- **Adjustment phase** (Frequency: one message every 3 days)
 1. Struts Adjustment
 2. Pin site Care
 3. Struts Adjustment
 4. Struts Adjustment
 5. Living with your fixator
 6. Struts Adjustment
 7. Struts Adjustment
 8. Physical Therapy
 9. Struts Adjustment


- **Consolidation phase** (Frequency: one message every 2 days)
 1. Pin site Care
 2. Living with your fixator
 3. Physical Therapy

In case the selected insight messages for a category will finish before the completion of the treatment, the messages delivery will restart from the selected top one.

The messages delivered to a patient will be listed in the 'Patient History' in myHEXplan portal, accessible clicking

on  icon.

Publish Case

Click on  [Publish Case] to finalize the treatment publishing process of the current case.

The Case on TL-HEX will be read-only apart from the Report tab. The QR code will be printed on the pdf of the prescription.

The hard-copy of the prescription should always be issued to the patient.

NOTE: Patient must scan the QR Code only the first time in order to download the available published prescriptions on his mobile application. After that, the myHEXplan mobile application will synchronize automatically with the TL-HEX software and portal.

There can be a little delay between publishing and synchronization: make sure that the patient is always up-to-date also during check-up visits.

Cancel

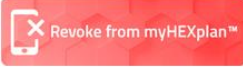

Click on  [Cancel] to abort the current publication of the case. The case will not be published.

REPORT

When Treatment Publishing is successfully completed, the Report tab will be presented.

When a case has been published, it is NOT editable and the Adjust option is disabled. To update the case, you can perform a CHECK-UP and publish the new case (see [PUBLISHED TREATMENT UPDATE FLOW](#)).

The Report tab now provides the following features:


	<p>The Published cases to myHEXplan mobile application, can be revoked using the [Revoke from myHEXplan™] button, allowing to withdraw from the patient's mobile the case along with all struts adjustment details and reminders.</p> <p>NOTE: Once revoked, the case will become read-only and it is not possible to modify or publish it again. Please, be careful before revoking a case.</p>
	<p>Click on [Prescription for Patient] to generate a prescription in pdf format. This document must then be printed and the hard copy must be issued to the patient and can also be saved for the record.</p> <p>On the generated pdf prescription, the QR code for the patient to scan will be displayed together with the instructions about how to download myHEXplan™ mobile application and activate it using the provided unique QrCode.</p> <p>NOTE: myHEXplan system does not substitute the paper treatment plan provided to the patient by the surgeon.</p> <p>Any changes on the paper treatment plan will be provided to the patient by the surgeon during the check-up visit.</p> <p>If any malfunctioning of myHEXplan system occurs, please always remind the patient to continue the daily struts adjustment program according to the provided printed treatment plan.</p>

Case Management

Patient ID: SW User's...
 Case ID: Long Bone...
 Case Type: Deformity
 Bone Type: Long Bone
 Side: Left






















Case Data
Deformity Parameters
Mounting Parameters
Schedule
Report

Please review all information before completing and printing the prescription to ensure that it is accurate. View Case

Select Print Option: Report Print ?
Prescription for Patient 
Revoke from myHEXplan™

This case has been published and it is NOT editable. To update this case, you can perform a CHECK-UP and publish the new case. Remember to print the Prescription for Patient with the QR code.

Strut Length A-Acute / G-Gradual

No	Day	Date-Time	Strut 1 : Red			Strut 2 : Orange			Strut 3 : Yellow			Strut 4 : Green			Strut 5 : Blue			Strut 6 : Purple			Actions
			Size	A	G	Size	A	G	Size	A	G	Size	A	G	Size	A	G	Size	A	G	
0	gio	POSTOPERATIVE	Medium	0	23	Medium	0	23	Medium	0	23	Medium	0	23	Medium	0	23	Medium	0	23	  
1	gio	18/01/2018 13:00	Medium	0	24	Medium	0	23	Medium	0	22	Medium	0	23	Medium	0	24	Medium	0	24	  
2	gio	18/01/2018 15:00	Medium	0	24	Medium	0	23	Medium	0	22	Medium	0	23	Medium	0	24	Medium	0	24	  
3	ven	19/01/2018 13:00	Medium	0	24	Medium	0	22	Medium	0	21	Medium	0	22	Medium	0	24	Medium	0	25	  
4	ven	19/01/2018 15:00	Medium	0	24	Medium	0	22	Medium	0	21	Medium	0	22	Medium	0	24	Medium	0	26	  
5	sab	20/01/2018 13:00	Medium	0	25	Medium	0	21	Medium	0	20	Medium	0	21	Medium	0	25	Medium	0	27	  
6	sab	20/01/2018 15:00	Medium	0	25	Medium	0	21	Medium	0	20	Medium	0	21	Medium	0	25	Medium	0	27	  

PRESCRIPTION FOR PATIENT

The 'Prescription' PDF file displays the adjustment schedule for the patient; each row describes the strut adjustment to be made by the patient for each deformity correction step as specified in the schedule. This document must then be printed and the hard copy should be issued to the patient and can also be saved for the record.

NOTE: The print-out should be checked for correctness and readability and the patient should be instructed to contact the surgeon in case the prescription becomes lost or damaged.

NOTE: All information must be reviewed by the surgeon before completing and printing the prescription to ensure it is accurate.

Adjustment for each strut is represented by the number of clicks (1/2 rotation of the strut adjustment knob that is 1/2mm) and can be positive (if strut length increases) or negative (when the strut length decreases). In addition, the gradual adjustment scale value in millimeters is displayed as a reference for each strut.


In addition to adjustment schedule, the following info are included to the paper prescription:

- The myHEXplan mobile app icon on each page of the prescription
- QR Code printed on the last page of the prescription. The QR Code is associated with the individual patient, therefore all cases for that patient will generate the same QR Code
- Instructions on how to install the myHEXplan app and load the treatment schedule onto their mobile device.

Dr. Orthofix
via delle Nazioni, 9
Bussolengo, Verona, Italy, 37012
+390456719000,

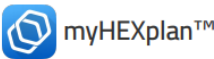
Print date: 16/01/2018, 21:51:57
Case ID: Long Bone 2
Case Description: Long Bone
Patient ID: SW User's Guide
Side: Left
Bone Type: Long Bone

Page 1
Check the last page to download
prescription(s) on your smartphone



Frame ID: B

No	Day	Date-Time	Strut Adjustment in 'CLICKS' (a)						Strut Reference Length (b)						
			RED	ORANGE	YELLOW	GREEN	BLUE	PURPLE	RED	ORANGE	YELLOW	GREEN	BLUE	PURPLE	
			1	2	3	4	5	6	1	2	3	4	5	6	
0	gio	POSTOPERATIVE	0	0	0	0	0	0	<input type="checkbox"/>	23	23	23	23	23	23
1	gio	18/01/2018 13:00	-1	1	2	1	-1	-2	<input type="checkbox"/>	24	23	22	23	24	24
2	gio	18/01/2018 15:00	0	0	0	0	0	0	<input type="checkbox"/>	24	23	22	23	24	24



From the first day after surgery until the device removal, through all the phases, you are the driver of your treatment

4 steps to get your TL-HEX prescription on your iPhone:

1. Go to the App Store
2. Search for myHEXplan™
3. Install myHEXplan™ on your iPhone
4. Launch myHEXplan™, scan the QR code, set your preferences...


...and let your journey begin!

To learn more about your medical device and to find out other Patient Stories:
www.limbhealing.com

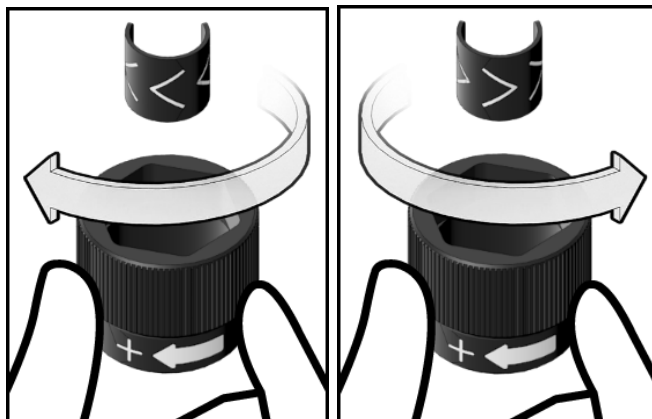
© Orthofix Srl

The iPhone models currently supported are 6 or higher, iOS version 10.3 or higher

Scan QRcode



The direction clips are then applied to the rod end joints according to the prescription. If strut elongation is required (positive numbers in the prescription), the arrow on the clip should point in the same direction as the reference arrow on the adjustment knob (Fig. a). If strut shortening is required (negative numbers in the prescription), the clip should be applied with the arrow pointing in the opposite direction of the arrow on the adjustment knob (Fig. b).



Strut Adjustments direction change

In most of the cases, the orientation of direction clips remains the same throughout the treatment. In some cases with a rotational deformity correction, the direction of strut adjustments in the prescription may change from positive to negative or vice versa. In this situation, the surgeon should instruct the patient about the day the change of direction occurs and either schedule a clinic visit for the orientation change of the direction clip or instruct the patient on how to make this orientation change to the direction clip themselves.

In the prescription, any direction change is highlighted with a couple of << >> characters around the number(s) where the direction change happens.

The Prescription Preferences previously entered and associated to a specific patient will be printed in the upper-left corner of this file and Prescription Notes entered in the Schedule tab will be printed in the upper-right corner. The Prescription file has been optimized for black and white printing. In order to distinguish between blue and red shaded rows, a black contour has been added to the red cells. This document must then be printed and the hard copy must be issued to the patient and can also be saved for recording purposes. The print-out should be checked for correctness and readability, and the patient should be instructed to contact the surgeon in case the prescription becomes lost or damaged.

myHEXplan™ PORTAL

OBTAINING ACCESS AND INFORMATION

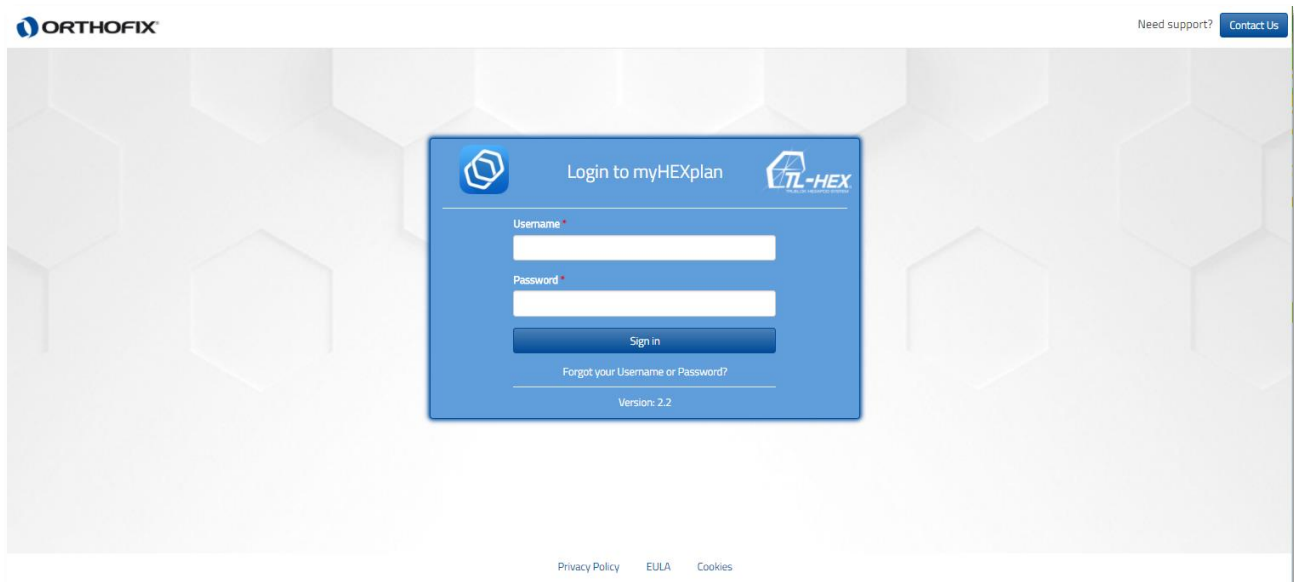
Access to myHEXplan portal is controlled by the same TL-HEX software 2.2 Username and Password obtained at www.tlhex.com and may not be available in all countries. Please contact your sales representatives for availability..

For further information and support, please, send an email to tlhexcustomercare@orthofix.com.

GETTING STARTED ... HOW TO LOG IN

Go to: myhexplan.tlhex.com

This location provides the login screen. Enter TL-HEX username and password and click 'Sign in'. Mandatory fields are marked with a *.



NAVIGATION MENU



The software header allows the user to recall the following menu functions anywhere within the application:

- List of Patients
- Dashboard


In addition to this two menus, the icons on the right-hand-side identify the following actions:





MANAGE ACCOUNT

Where the user can change the password.

NOTE: the password will be changed also in TL-HEX.


- 

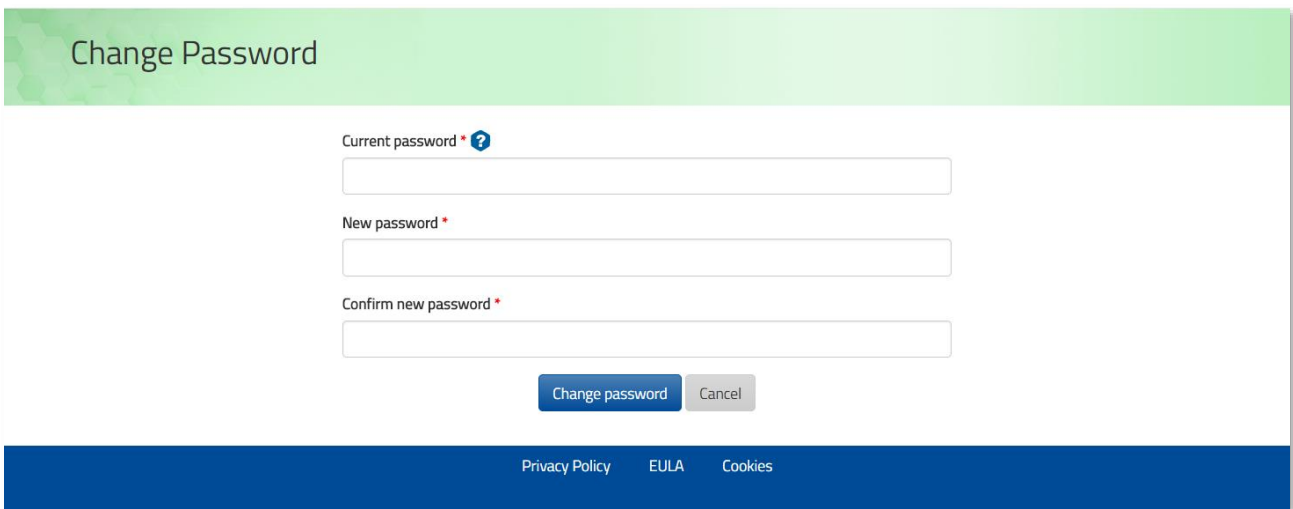
CONTACT US
A quick link to access the support or obtain more information on the TL-HEX System, both software and hardware, is available by clicking on this icon. This will display the instructions on how being in contact with the TL-HEX Customer Care.
- 

INSTRUCTIONS FOR USE
By clicking on the icon the user is forwarded to the Instruction for Use section where he/she can find the available support material on product usage and additional resources.
- 

LOG OUT
To log out, just click on the icon.

MANAGE ACCOUNT - Change Password

In this section, clicking on  [Manage account] icon, the user can 'Change Password'.




TL-HEX and myHEXplan shares the same credentials. Changing the password in myHEXplan will affect also TL-HEX and viceversa.

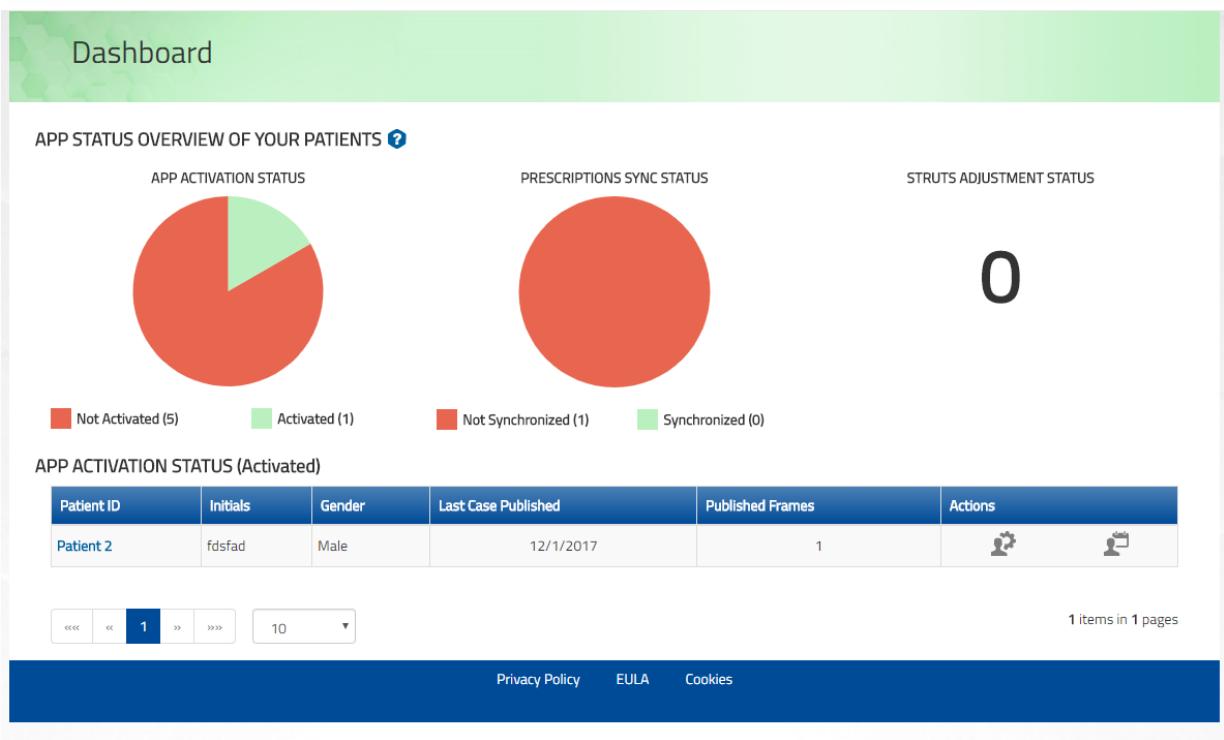
Simply enter the current password, followed by entering and confirming the new password, then click Change Password. Password must be six or more characters and it is case sensitive.

It is important to remember that the surgeon remains ultimately responsible for the confidentiality of the information entered into the software. One of the ways to guarantee confidentiality is to ensure password integrity by changing it at regular intervals and by keeping the password as secure as possible.

ONLINE HELP

Online help is available by clicking on  icons where applicable; the surgeon will be able to view relevant help information.

DASHBOARD



The Dashboard can be reached by clicking [[Dashboard](#)] and it is the homepage of the software. It offers a general graphical overview of the status of eligible patients considering patient application activation, prescriptions synchronization and struts adjustment progress.

By clicking on the corresponding colored section, the list of patient IDs in the related status is displayed.

This helps in identifying patients who, for various reasons, are not following their treatment schedules on myHEXplan patient app.

APP ACTIVATION STATUS

First pie chart considers the total number of eligible patients on the list of patients and displays in

green: patients which have downloaded and activated myHEXplan patient application scanning the QR code on the prescription: Activated (in brackets the number of them)

red: patients which have not yet activated myHEXplan patient application scanning the QR code on the prescription: Not Activated (in brackets their number)

NOTE: 0 is displayed when the list of patients of the portal is empty.

PRESCRIPTION SYNC STATUS

Second pie chart considers the subset of eligible patients with the app activated by scanning the QR code and displays in:

green: patients which have correctly synchronized myHEXplan patient application with the TL-HEX software and portal and have the updated digital prescriptions: Synchronized (in brackets the number of them)

red: patients which have not synchronized myHEXplan patient application with the TL-HEX software and portal and potentially can have the digital prescriptions not updated: Not Synchronized (in brackets their number)

For example, this may happen if the patient is not on line when the update of a prescription is published to myHEXplan.

STRUTS ADJUSTMENT STATUS

Third pie chart considers the subset of eligible patients with the app activated and which are correctly synchronized and displays in

green: patients which have confirmed their struts adjustment on myHEXplan patient application and they are on schedule with their digital prescriptions: On Schedule (in brackets the number of them)

red: patients which have not confirmed or postponed their struts adjustment on myHEXplan patient application in the last 24 hours and they are no longer on schedule with their digital prescriptions: Not On Schedule (in brackets the number of them)

For example, this may happen for different reasons that may be investigated with the patient: maybe the patient is no longer using the app and he is just confirming the adjustment on the paper prescription or he has stopped turning the struts and he is not following the treatment at all.

LIST OF PATIENTS

The screenshot shows a web interface titled "List of Patients". At the top is a search bar with a magnifying glass icon and a right-pointing arrow. Below the search bar is a table with a question mark icon in the top-left corner. The table has the following columns: Patient ID, Initials, Gender, Last Case Published (with a downward arrow), Published Frames, and Actions. There are two rows of data:

Patient ID	Initials	Gender	Last Case Published	Published Frames	Actions
Patient 2	SD	Male	1/18/2018	1	
Patient 4	DD	Male	1/18/2018	1	

Below the table is a pagination control with arrows for navigation and a dropdown menu set to "10". To the right of the pagination, it says "2 items in 1 pages". At the bottom of the interface, there are three links: "Privacy Policy", "EULA", and "Cookies".

The List of Patients can be reached by clicking [[List of Patients](#)] and lists all the eligible patients with at least a published or revoked case, otherwise the list is empty.

By default patients are sorted based on the case publishing date, in decreasing order.

The List of Patients can also be sorted in ascending or descending order by clicking on any of the headers (a part from "Actions").

myHEXplan Patient records are paginated and it is possible to navigate between the different pages by selecting the desired page below the list. The user can also change the number of records displayed per page [10 – 25 – 50 – ALL].

SEARCH

List of Patients

Search ▼

Patient ID ?

Status

 ▼

Publish date

 ▼

Case ID

Side

 ▼

Case Description

Bone Type

 ▼

Frame ID

To search a Patient or Case, expand the search bar to search the content based on specific criteria. Enter the search criteria in the relevant field and press the Search button.

User can search by Patient ID, Status, Frame ID, Case ID, Side, Case Description, Bone Type and Planning Created (using the "This Date", "After This Date" or "Before This Date" logic).

To remove any filter, click the Clear button.

Patient ID	Initials	Gender	Last Case Published	Published Frames	Actions			
▼ Patient 2	SD	Male	1/18/2018	1				
Frame ID								
▼	B							
	Case ID	Case Description	Bone Type	Side	Status	Status Change Date	↓	Actions
	Case 1		Ankle	Left	Published	1/18/2018 12:42:42		
▶ Patient 4	DD	Male	1/18/2018	1				

<<< < 1 > >>>

▼

2 items in 1 pages

Click on the icon related to each patient in the list to expand the list of cases related to this patient grouped by Frame ID.

identifies a Frame ID with a published case to myHEXplan mobile application.

myHEXplan PATIENT ACTIONS

Actions that can be performed on a patient are:

myHEXplan PATIENT SETTINGS



Click on Patient ID or on this icon any time during the treatment, or following the check-up visits, to view/edit related patient's settings for myHEXplan mobile application:

- Pin-site care frequency
- Email address for receiving skipped struts adjustment notification
- Educational and Motivational Messages
- Progress of cases

myHEXplan Patient History





Click on this icon to view the related patient's history of actions done on myHEXplan mobile application.

This section reports also events when actions are not done (e.g. pin site care not done, struts adjustment not done ...).

myHEXplan CASE STATUS

Cases displayed in myHEXPlan portal are only a subset of all TL-HEX cases.

They can be **Published**  if has been published to myHEXplan mobile application for the patient or **Revoked**  when the case has been withdrawn.

myHEXplan CASE ACTIONS

Actions that can be performed on a case are:

myHEXplan CASE SETTINGS



Click on this icon any time during the treatment to view/edit settings or to revoke a published case. For revoked cases, it allows only view settings.

myHEXplan VIEW CASE IN TL-HEX



Click on this icon to go back to TL-HEX. Published case will land on TL-HEX case Report tab. Revoked case will land on the TL-HEX list of patients.



Login may be needed to access TL-HEX.

myHEXplan PATIENT SETTINGS

The screenshot displays the 'Patient Settings' page for 'Patient ID: Patient 1'. It includes sections for 'PIN SITE CARE' (with a toggle, 'First Day' date, and 'Frequency' days), 'CONTACT INFO' (with an email address and 'Edit' button), 'EDUCATIONAL AND MOTIVATIONAL MESSAGES' (with a toggle and a list of message categories), and 'PUBLISHED CASES PROGRESS TO DATE' (with a legend and a progress bar for 'Case ID CopyOf_test').

Pin Site Care

It displays the Pin Site Care settings for this patient set during the treatment publishing and that can be viewed and changed anytime during the treatment.

It can be enabled  or disabled , disabling means that this patient will no longer receive any reminders about pin site care on myHEXplan mobile application.

If enabled, selection of First Day and Frequency of Pin Site care reminders for this patient is mandatory and define, respectively, when patient will start to receive Pin Site Care reminders and with which frequency.

“Select all days” will automatically select all the days resulting in a frequency of once a day.

The patient will start receiving the set reminder as soon as he will activate the prescription on myHEXplan mobile application.

The update of pin site care setting will be sent to myHEXplan patient application but the patient will not be directly notified.

Contact Info

It displays the Contact Info settings for this patient set during the treatment publishing and that can be viewed and changed anytime during the treatment.

Email address where to receive the notifications about Skipped Struts Adjustments if a threshold has been set. To set the notification threshold refer to the ‘Treatment Publishing – Case Settings, Notification Threshold’ field.

It defaults to TL-HEX registration email address, but this information will not be given in any way to the patient.



It can be changed to another email address, for example the one of a nurse of another care team member.

NOTE: It is possible to customize a different email address for each patient.

NOTE: Other contact info different from email address and that were entered in TL-HEX software will be printed on the hard-copy of the prescription and will also be made available in your patient's myHEXplan mobile application, under the "My surgeon" info in the "User profile" section.

Educational and Motivational Messages

It displays the Educational and Motivational Messages settings for this patient set during the treatment publishing and that can be viewed and changed anytime during the treatment.

It can be enabled  or disabled , disabling means that this patient will not receive any motivational and educational message reminder on myHEXplan mobile application.

If enabled, the set of messages to be sent to myHEXplan mobile application defaults to all messages for all 4 categories.

Pressing on 'Select all', it is possible to unselect or select all messages simultaneously for a chosen category.

Otherwise, it is possible to choose the set of messages more suitable for the current patient.

The patient will start receiving the set messages as soon as they activate the prescription on myHEXplan mobile application.

The delivery of the messages is related to the phase of the treatment.

NOTE: Educational and Motivational messages are displayed as "Insight Messages" on the patient myHEXplan app and the patient has the option to enable or disable them.

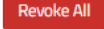
The update of messages setting will be sent to myHEXplan patient application but the patient will not be directly notified.

Published Cases Progress to Date

This section shows the treatment timelines of already published cases (if present) for this patient, updated at the current day.

Revoke All



Be careful when using this functionality, by clicking on  [Revoke All] and confirming all the cases published for this patient will be withdrawn from their mobile.

Patient will be notified and all the struts adjustment reminders will be removed from their smartphone.

Cancel




Click on  [Cancel] to cancel the action and come back to the list of patients.

All the changes done to the page will be lost.

Update



Click on  [Update] to update the changes done to the page. The updates will be received by MyHEXplan mobile application but the patient will not be notified of the updates.

myHEXplan PATIENT HISTORY

Patient History

Patient ID: Patient 1

Last Synchronization Date: 1/18/2018 12:38:56
NOTE: In this section, the displayed date and time are related to the time zone of the patient.

REPORTED EVENTS HISTORY

Pin Site Care Struts Adjustment Prescriptions Sync Date From: Date To: Search

Date	Type	Message
1/18/2018 00:00:00	Pin Site Care	Pin Site Care NOT done
1/17/2018 19:00:00	Struts Adjustment	Struts Adjustment 1/17/2018 7:00:00 PM - A NOT done
1/17/2018 18:00:00	Struts Adjustment	Struts Adjustment 1/17/2018 6:00:00 PM - A NOT done
1/17/2018 17:00:00	Struts Adjustment	Struts Adjustment 1/17/2018 5:00:00 PM - A NOT done

4 items in 1 pages

EVENTS HISTORY

Pin Site Care Prescriptions Sync Struts Adjustment Other Date From: Date To: Search

Date	Type	Message
1/18/2018 12:38:56	App State Changed	App state changed to Synced
1/18/2018 12:38:56	App State Changed	App state changed to Synced

2 items in 1 pages

Cancel

Privacy Policy EULA Cookies

Patient History shows the actions performed or not by this patient on myHEXplan mobile application and it is divided in two parts.

Events History: it shows the list of all the events done or postponed by the patient.

Reported Events History: it shows the list of events which have not been done by this patient on the application and that should be taken into particular consideration.

The actions are displayed with the indication of the date and time in which they have been done.

NOTE: date and time are related to the time zone of the patient

Events History

The type of events registered on the Patient History are:

- **Pin Site Care** : action confirmed by patient on myHEXplan mobile application
- **Prescription Sync**: synchronization successfully done with myHEXplan mobile application of this patient
- **Struts Adjustment**: action confirmed or postponed by the patient on myHEXplan mobile application with the indication of the frame ID and expected date and time in which it should be done.
- **Other**: actions related to other aspects of the treatment that can be set using myHEXplan mobile application (for example, mood self assessment-how are you today, enabling/disabling of insight messages or personal goal...)

Reported Events History

The type of reported events registered on the Patient History are:

- **Pin Site Care not done:** it means that the scheduled action has not been confirmed as done on patient's myHEXplan mobile application.
- **Struts Adjustment not done:** it means that all the scheduled struts adjustment actions of a day has not been confirmed as done or postponed on patient's myHEXplan mobile application. This information come along with the indication of the frame ID and expected date and time in which it should be done.
- **Prescriptions sync not done:** it means that patient has not synchronized myHEXplan patient application with the TL-HEX software and portal in the last 24 h and potentially can have the digital prescriptions not updated.

myHEXplan CASE SETTINGS

The screenshot displays the 'Case Settings' page in the myHEXplan software. At the top, it shows patient and case details: Patient ID: paziente..., Case ID: CopyOf_te..., Case Type: Deformity, Bone Type: Tibia, and Side: Left. Below this, the 'TREATMENT SETTINGS FOR CURRENT CASE' section includes a 'Consolidation Phase Duration' set to 30 days. A timeline visualizes the treatment phases: 'Latency' (5 d), 'Correction' (23 d), and 'Consolidation' (30 d). Key dates are marked: 'Surgery' on 1/18/2018, 'Approximate Removal' on 3/17/2018, and a date of 2/15/2018. The 'NOTIFICATION THRESHOLD' section shows 'Skipped days of Struts Adjustment' set to 'Not set'. At the bottom right, there are 'Revoke', 'Cancel', and 'Update' buttons. The footer contains links for 'Privacy Policy', 'EULA', and 'Cookies'.

Treatment Settings for Current Case

It displays the treatment settings for current case set during the treatment publishing and that can be viewed and changed anytime during the treatment.

The timeline helps visualizing the treatment progress and phases and will determine the delivery of motivational messages only.

Latency and Correction phases duration are automatically populated from TL-HEX software.

Consolidation Phase Duration is calculated by default, as triple the duration of the correction phase if correction lasts more than 30 days (otherwise, the consolidation duration defaults to 30 days). This also estimates an approximate removal date of the frame.

The update of consolidation phase duration setting will be sent to myHEXplan patient application but the patient will not be directly notified,

NOTE: Approximate removal date value will not be made available to the patient in any way.

Notification Threshold


It displays the notification threshold settings for current case set during the treatment publishing and that can be viewed and changed anytime during the treatment.

It defines the threshold in days for email notification of patient's missed struts adjustment on myHxEplan patient mobile application in relation to this case. A notification email will be sent to the email address entered for this patient settings after the number of days of skipped struts adjustment specified.

A different value can be set for each case of the patient.

Revoke




For published cases. Be careful when using this functionality, by clicking on  [Revoke] and confirming the current case published for this patient will be withdrawn from their mobile. Patient will be notified and all the struts adjustment reminders for this case only will be removed from their smartphone.

NOTE: Once revoked, the case will become read-only and it is not possible to modify or publish it again. Please, be careful before revoking a case.


Cancel



Click on  [Cancel] to cancel the action and come back to the list of patients. All the changes done to the page will be lost.

Update



Click on  [Update] to update the changes done to the page. The updates will be received by MyHEXplan mobile application but the patient will not be notified of the updates.



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