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Adjustment App Instruction Manual

(iOS Version)

For Prosthetists

Product Type: NE-Z41, NE-Z41SH

Document Number: 81-SS00127 (ver.5)

Application Ver. 0.4.12 or later

Date of issue: 2024-04-01

Language: English



Carefully read the instruction manual prior to use.

Adjust the knee joint to the user in a place where the user's safety can be ensured.

■Keep this instruction manual for future reference.

Nabtesco

Nablesco Corporation



Introduction

Thank you for purchasing Nabtesco's ALLUXTM.

ALLUXTM can be assembled and adjusted only by the persons who have participated in a Nabtesco ALLUXTM certification seminar and are certified. Matters concerning typical usage such as walking, maintenance, operation procedures including replacement of service part, trouble shooting, and cautionary notes are described in the instruction manual that comes with an ALLUXTM (hereinafter referred to as the ALLUXTM Instruction Manual).

This Adjustment App Instruction Manual describes how to install and use the Adjustment App (hereinafter referred to as this App) in the iOS system environment.

Before adjusting ALLUXTM, thoroughly read the ALLUXTM Instruction Manual mentioned above and the Adjustment App Instruction Manual, sufficiently understand the contents, and strictly observe the safety precautions stated in these manuals.

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Supported model and operating environment

- ALLUXTM (type: NE-Z41)
 - * ALLUXTM (type: NE-Z4) is not supported.

The model can be identified by the design of the front link pad.

It can also be identified by the indication on the charging port.



NE-Z41 (Supported type)



NE-Z4 (Non-supported type)



NE-Z41 (Supported type)



NE-Z4 (Non-supported type)

Compatible OS: iPhone running iOS 13 or later

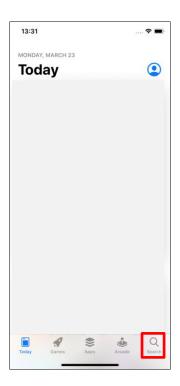
Bluetooth[®]

Precautions on Bluetooth

- Radio waves emitted by a Bluetooth device may affect the operation of electronic devices and other devices. Turn off Bluetooth devices when near priority seats in trains, in areas where flammable gas is generated such as in airplanes near automatic doors and fire alarm devices, as it may cause an accident.
- We do not take any responsibility for the leakage of information when using Bluetooth technology.
- This product does not guarantee wireless connection with all Bluetooth devices. The Bluetooth device to be connected must comply with the Bluetooth standard specified by Bluetooth SIG and must have obtained at least a certification. In addition, even if the device to be connected complies with the Bluetooth standard, phenomena such as inability to connect or different display/operation may occur, depending on the characteristics and specifications of the device.
- Do not disassemble or modify this product as the wireless functionality of this product has been certified to meet technical standards.

Install procedures and initial settings

- 1. Sign in with your Apple ID.
 - Tap the search icon Q in the bottom right corner of the "App Store" screen.
- 2. Type the App name "ALLUX2" into the Search field. Tap the "Search" button on the keyboard.





The following QR code can be used to install.



3. After the search results are displayed, tap the target App as shown below.



- 4. Tap the "GET" button, then tap the "INSTALL" button.
- 5. After the installation is completed, the icon of the App is created on the home screen of the smartphone.
- 6. Tap the icon to start the App.

Initial settings 3

Tap the icon of this App to start.

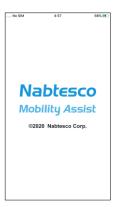


When you first start the App, you will need permission to use Bluetooth. 2)

When the following popup is displayed, tap Allow or OK.



- * The popup screen will vary depending on the smartphone you are using.
- 3) After the company logo is displayed on screen for a second, this screen automatically changed to the next screen.

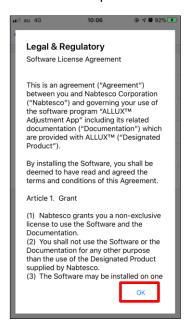


"Enter Password" screen is displayed. Enter the indicated password in the instruction manual. If you fail in entering the password 3 times, you need to restart this App.





The "Legal & Regulatory" dialog is displayed. Read it and tap the "OK" button.



The "App user profile" is displayed. Enter each information and tap the "OK" button.



Company name:

Enter the P&O Clinic name or company that App user works for.

Age:

Select the age of the adjuster from the list.

Gender:

Select the gender of the adjuster from the list.

Initial settings

The "Connection to ALLUXTM" screen is displayed.



- 1. On the "Connection to ALLUXTM" screen, scanning for wireless devices automatically starts.
- 2. The devices related to ALLUXTM are listed up. The indicated characters vary based on the serial number of ALLUXTM. The third line indicates the connection state.
 - Disconnected
 - Connecting
 - Connected
- 3. "ALLUX: Serial No" is displayed. If more than one device is listed up, according to the Serial No. of your own ALLUXTM, select the appropriate wireless device.
- 4. If the wireless device for ALLUXTM is not listed, the wireless connection of ALLUXTM may be in sleep mode. Try to activate the wireless connection with slightly flexing and extending ALLUXTM or applying user's body weight on ALLUXTM. After that, tap the "Cancel" button and then tap the "Scan" button displayed in that position to search for wireless devices again.
- 5. Tap the wireless device on the list. If the wireless connection is successfully done, "Connection to ALLUXTM" screen is displayed automatically. For consecutive connections, the "Connection to ALLUXTM screen is skipped and the initial startup screen is displayed.
- "Connection to ALLUXTM" screen is displayed.

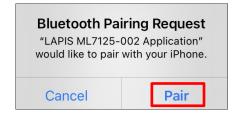
On the "Connection to ALLUXTM", you need to enter the password that comes with ALLUXTM. The password is indicated on the charging port of ALLUXTM.

If you fail in entering the password 3 times, you need to restart this App.

When connecting for the first time, Bluetooth pairing to a smartphone is required. Tap Pair to allow it.







Safe posture

Before changing the operational mode of ALLUXTM using the Application Remote Control or before adjusting or setting ALLUXTM using this App, the user needs to take a posture which is safe even if hydraulic resistance changes. This posture is referred to as 'safe posture'. Explain to the user about safe posture.



- Explain to the user about the safe posture, and ensure that the user understands it.
- When the user takes the safe posture without applying the body weight to ALLUXTM, he/she must hold a handrail or sit down.

Flexion/extension resistance may suddenly change, leading to a fall.

[Safe posture]



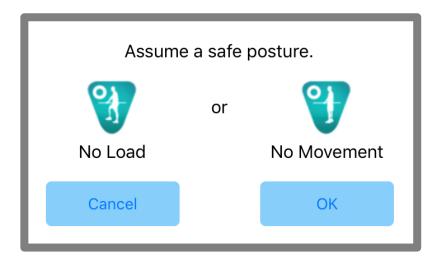
: State where ALLUXTM is stationary, straight, and vertical and may be subject to weight loading



State where ALLUXTM is not subject to weight bearing and the knee may be flexed and stationary.

[Request for safe posture]

If ALLUXTM is not in the safe posture when adjusting or setting ALLUXTM, a popup is displayed. Make sure that the user is in a safe posture, and then tap the "OK" button to reflect the adjustments or settings. If you tap the "Cancel" button, the adjustments or settings will be cancelled.



5 Communication mode and how to connect Bluetooth

In order to conserve power, ALLUXTM is not always in communication mode.

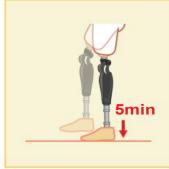
In order to enable the communication mode, you need to perform the following operations.

Once ALLUXTM communication is established using this App, this state lasts until communication is disconnected.

[Communication mode enabled]

- 1. For 5 minutes after ALLUXTM is slightly flexed and extended
- 2. For 5 minutes after you apply your body weight to ALLUX™
- 3. For 5 minutes after the charger or the power OFF cap is disconnected from ALLUXTM







With the Application Remote Control, it is possible to turn OFF wireless connection when the user gets on a plane, etc. To restore wireless connection from that state, the actions such as the one shown below are required.

- 1. Disconnect the charger or the power OFF cap form ALLUX™.
- 2. "Apply a load on the heel 4 times intermittently" or "Apply a load on the toe 4 times intermittently". *You can switch to either one you like with the Application Remote Control.



- *Just starting this App does not connect to ALLUX™. Tap the Bluetooth icon on the initial startup screen (Refer to page 10) to connect to ALLUX™.
- *Just tapping the home button etc. on the smartphone does not disconnect communication with ALLUX™ and this App keeps working behind the screen. If you tap the icon of this App again, it starts in the connected state.



Do not force-quit this App by turning off the smartphone. Doing so may cause adjustment values to turn into an unintended state and result in a fall.

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Common operation as to the initial startup and each screen

At the first start-up, the initial startup screen is displayed after the "Connection to ALLUXTM" screen. At the second and subsequent startups in the normal state, the initial startup screen is displayed after the company logo.



Bluetooth icon:

Tap this icon to display the "Connection to ALLUXTM" screen. The icon changes depending on the connection state. When it is in a disconnected state, tap the icon to enable connection.





Disconnected

General icon:

Tap this icon to display the "General" screen.

Standby mark:



While this App is communicating with ALLUXTM or performing other processing, a circle standby mark is displayed. While this mark is displayed, all on-screen operations are disabled.

Latest adjustment date:

It shows the date when ALLUX $^{\text{TM}}$ was in last adjusted.

Battery level:

It shows the battery level of ALLUXTM.









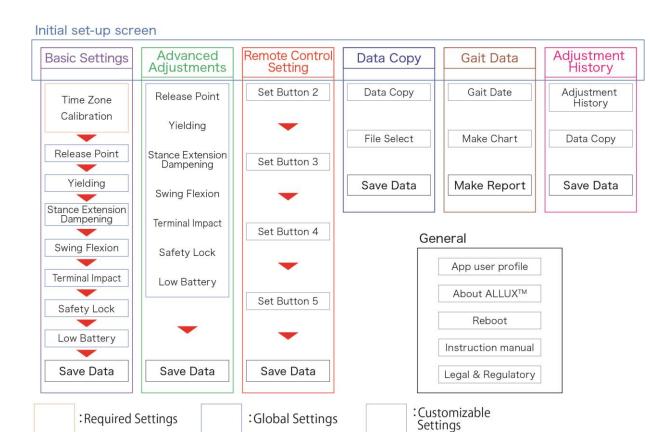
10% or less 10~40%

40~70% 70% or more

- Basic setting button: Tap this button to display the "Basic setting" screen (page 12).
- Advanced Adjustments button: Tap this button to display the "Advanced Adjustments" screen (page 23).
- Remote Control button: Tap this button to display the "Remote Control" screen (page 24).
- Data Copy button: Tap this button to display the "Data Copy" screen (page 29).
- Gait Data button: Tap this button to display the "Gait Data" screen (page 30).
- Adjustment History button: Tap this button to display the "Adjustment History" screen (page 33).

Adjustment procedure

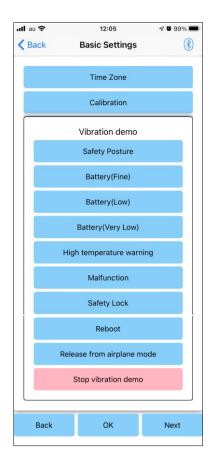
Adjustments are undertaken in the following steps.



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Basic Settings 8

*When this screen is displayed, the setting items in the lower part may not be displayed. Swipe the screen upward to display those setting items.



- Time Zone: Tap this button to display the "Time Zone" screen (page 13).
- Calibration: Tap this button to display the popup for calibration dialog (page 14).
- Vibration demo:

ALLUXTM vibrates to give information and warnings to the user. By tapping these buttons, the user can recognize vibration patterns. Please have the user understand the types and meanings of the vibration alarm patterns.

When you tap each button, the popup for a vibration alarm pattern corresponding to the button is displayed. Tap the "OK" button to vibrate ALLUXTM.

- Safety Posture: ALLUX[™] vibrates when the user should take a safe posture.
- Battery (Fine): ALLUXTM vibrates when the remaining battery level is 3 hours or more.
- Battery (Low): ALLUXTM vibrates when the remaining battery level is less than 3 hours.
- Battery (Very Low): ALLUXTM vibrates when the remaining battery level is insufficient and normal walking is impossible.
- High temp warning: ALLUXTM vibrates when the knee joint is in high temperature.
- Malfunction: ALLUXTM vibrates when the knee joint needs service.
- Safety Lock: ALLUXTM vibrates when the safety lock is turned on.
- Reboot: ALLUXTM vibrates when ALLUXTM is rebooted.
- Release from airplane mode: ALLUXTM vibrates when the airplane mode is turned off. (page 9)
- Stop vibration demo: ALLUXTM stops vibration.



■ Make sure the user recognizes all vibration patterns and understands the differences. If the user uses ALLUXTM without understanding the meanings of the vibrations, he/she may not be in a safe posture against a warning about failure or high temperature and may fall because the ALLUXTM is locked when he/she tries to walk.

- Back button: Tap this button to display the initial startup screen.
- OK button: Tap this button to display the initial startup screen.
- Next button: Tap this button to display the "Toe Release Point" adjustment screen.

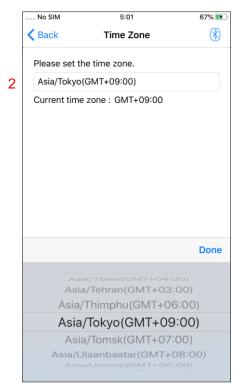
9

Setting the Time Zone

ALLUXTM contains an internal clock used to keep records of the number of steps taken per day. The default setting is Japan Standard Time (GMT+09:00). Please change the time zone to reflect the local time.

- 1. Tap the Time Zone picker to display the time zone list.
- 2. Select the time zone of user's location.
- 3. Tap the "Settings" button to send the time zone to ALLUXTM.
 - *Once selected, it is unnecessary to repeat this step unless there is a permanent relocation to another time zone. It is also unnecessary to select it again when the user travels overseas for a short period of time. Note, however, that the time zone selected here becomes the standard time zone for when the day changes.





- Back button: Tap this button to display the "Basic setting" screen.
- OK button: Tap this button to display the initial startup screen.
- Settings button: Tap this button to send the time zone to ALLUXTM.

Calibration 10

When ALLUXTM is used for the first time or re-aligned or the foot part is replaced, ALLUXTM will need to be calibrated.

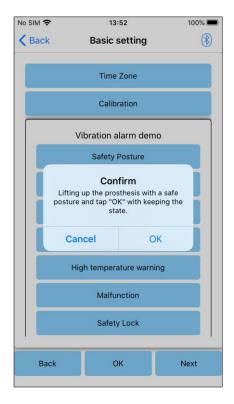
> ■ Calibrate ALLUXTM in the correct posture. If it is calibrated under load, the user cannot walk normally and may stumble, possibly resulting in an injury.



WARNING

When calibrating, make sure the user is safe. If the user stands on one foot in an unstable state they may fall.

- Calibrate with definitive components attached and fully tightened. If alignment adjustments are made, ALLUXTM may not work properly.
- Apply the toe release point setting (see Chapter 11) after calibration. The setting the Toe Release Point prior to calibration may make normal walking impossible or unsafe.



- Tap the "Calibration" button on the "Basic setting" screen, a popup is displayed.
- 2. Have the user lift his/her foot to keep ALLUXTM free from load.
 - * Have the user hold a handrail in parallel bars or sit on a chair to ensure his/her safety.
- 3. Tap the "OK" button on the popup.
- The popup closes and the screen returns to the "Basic setting" screen.

Adjusting the Toe Release Point

Factory default setting = 80

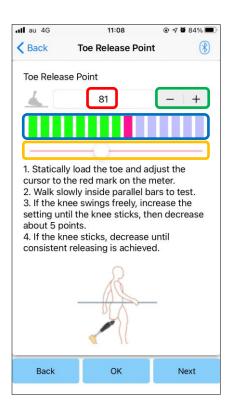
Set the Toe Release Point for transition to the swing phase. Check the walking condition in parallel bars where the user's safety can be ensured.



Check the walking condition in a place, e.g. in parallel bars, where the user's safety can be ensured.

If ALLUXTM cannot smoothly shift to swing phase, user may fall.

- 1. Have the user stand in parallel bars and place the prosthetic foot behind them and load the prosthesis simulating terminal stance.
- 2. The amount of toe load will be displayed on the display bar.
- 3. Set the adjustment value to the maximum sensor output value (It is indicated as a red line).
- 4. Test by having the user walk slowly.
 - *If ALLUXTM releases with every step, gradually increase until it sticks, then reduce approximately five points.
 - *If ALLUXTM fails to release with every step, reduce the value until it releases with every step when walking slowly.
- 5. When complete, tap "Next" button to move to the "Stance Flexion Yielding" adjustment screen.



Adjustment value (min: 0, max: 200):

A toe release point adjustment value is displayed and entered in figures.

Adjustment value stepper:

These buttons increase or decrease the adjustment value in increments of 1.

Bar meter box view:

It shows the sensor output during ambulation.

Adjustment value slider:

- *Adjustments can be made by any of the three options: direct number input, + or - buttons, or click and drag.
- Back button: Tap this button to display the "Basic setting" screen.
- OK button: Tap this button to display the initial startup
- Next button: Tap this button to display the "Stance Flexion Yielding" adjustment screen.

Adjusting the Stance Flexion Yielding

Factory default setting = 25 (Standard value: 20 ~ 30)

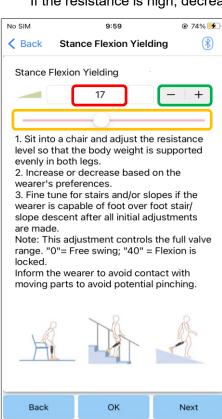
Adjust the yielding resistance so that the user feels balanced when sitting into a chair, or walking down stairs and slopes. Gradually increase or decrease the value according to the user's preference and always ensure they are standing safely prior to making adjustments. It is recommended to adjust the resistance at a normal temperature (+20°C/+68°F).



■ When ALLUXTM is used in a low-temperature environment (0°C/+32°F or less), the yielding resistance may be higher. Check the yielding resistance before starting use in a low-temperature environment. Since ALLUX™ cannot be easily flexed, the user may fall on stairs or slope.



- Do not touch the linkage parts on ALLUXTM when standing up to avoid potential pinching.
- The yielding resistance, for walking downstairs or slopes, should be adjusted after completion of all adjustment. If the adjustments have not been made sufficiently, the user may fall on stairs or slopes.
- 1. Adjust the resistance so that the user's weight is applied equally to both feet when the user sits on a chair.
 - *If the resistance is low, increase the adjustment value.
 - *If the resistance is high, decrease the adjustment value.



Adjustment value (min: 0, max: 40):

A stance flexion yielding adjustment value is displayed and entered in figures.

Adjustment value stepper:

These buttons increase or decrease the adjustment value in increments of 1.

Adjustment value slider:

- Back button: Tap this button to display the "Toe Release" Point" adjustment screen.
- OK button: Tap this button to display the initial startup screen.
- Next button: Tap this button to display the "Stance Extension Dampening" adjustment screen.

Adjusting the Stance Extension Dampening

Factory default setting = 5 (Standard value: 0 ~ 25)

Normally, set the extension resistance in stance phase to 5, no resistance state. Adjust the resistance only when the user walks with stance flexion. It is recommended to adjust the resistance at a normal temperature (+20°C/+68°F).



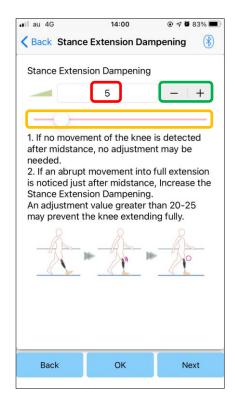
■ When ALLUXTM is used in a low-temperature environment (0°C/+32°F or less), the stance extension dampening may be increased. Check the extension resistance before starting use in a low-temperature environment. Since ALLUXTM cannot be easily extended, the user may stumble and then fall when initiating swing phase.



- Check the walking condition in a place, e.g. in parallel bars, where the user's safety can be ensured.
- The user must walk in such a way that the knee shifts to the swing phase after it is extended.

Since ALLUXTM cannot shift to the swing phase in flexed state for double knee motion, the user may stumble and then fall.

- 1. Adjust the resistance for stance extension dampening.
 - *If the resistance is low, increase the adjustment value.
 - *If the resistance is high, decrease the adjustment value.



Adjustment value (min: 0, max: 40):

A stance extension dampening adjustment value is displayed and entered in figures.

Adjustment value stepper:

These buttons increase or decrease the adjustment value in increments of 1.

Adjustment value slider.

- Back button: Tap this button to display the "Stance Flexion Yielding" adjustment screen.
- OK button: Tap this button to display the initial startup screen.
- Next button: Tap this button to display the "Swing Flexion" adjustment screen.

Adjusting the Swing Flexion Resistance

Factory default setting = 20 (Standard value: 15 ~ 35)

Adjusts the flexion resistance during swing phase. After the resistance is adjusted, based on normal walking, the knee joint will automatically adjust the flexion resistance according to the walking speed.

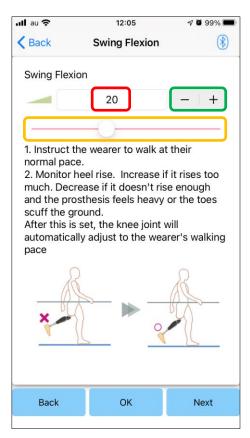


Evaluate the walking function in a place, e.g. in parallel bars, where the user's safety can be ensured.

If ALLUXTM cannot smoothly shift to swing phase, the user may fall.

*If the foot scuffs the floor because ALLUXTM didn't trigger swing phase, re-adjust the Toe Release Point as stated in "Adjusting the Toe Release Point" (page 15).

- 1. Adjust the Swing Flexion Resistance for normal walking speeds.
 - *If there is excessive heel rise, the resistance is low, increase the adjustment value.
 - *If the toes scuff the ground, the resistance is high, decrease the adjustment value.



Adjustment value (min: 1, max: 50):

A swing flexion resistance adjustment value is displayed and entered in figures.

Adjustment value stepper:

These buttons increase or decrease the adjustment value in increments of 1.

Adjustment value slider:

- Back button: Tap this button to display the "Stance Extension Dampening" adjustment screen.
- OK button: Tap this button to display the initial startup screen.
- Next button: Tap this button to display the "Terminal Impact" adjustment screen.

Adjusting the Terminal Impact

Factory default setting = 5 (Standard value: 0 ~ 25)

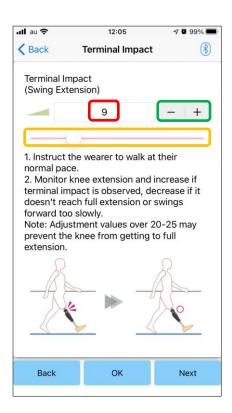
Adjust the extension resistance during swing phase. If terminal impact occurs, gradually increase it. After the resistance is adjusted based on the normal walking, ALLUXTM will automatically adjust the extension resistance according to the walking speed.



Evaluate the walking function in a place, e.g. in parallel bars, where the user's safety can be ensured.

If the resistance is set too high, ALLUXTM cannot extend completely, and the user may fall.

- 1. Adjust the terminal impact resistance for normal walking speed.
 - *If the resistance is low, increase the adjustment value.
 - *If the resistance is high, decrease the adjustment value.



Adjustment value (min: 0, max: 40):

A terminal impact adjustment value is displayed and entered in figures.

Adjustment value stepper:

These buttons increases or decreases the adjustment value in increments of 1.

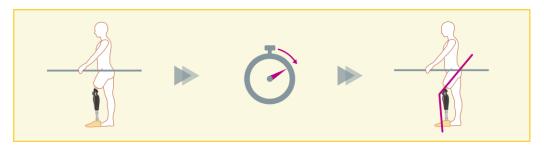
Adjustment value slider:

- Back button: Tap this button to display the "Swing" Flexion" adjustment screen.
- OK button: Tap this button to display the initial startup screen.
- Next button: Tap this button to display the "Safety Lock" adjustment screen.

Adjusting the Safety Lock 16

Factory default setting = Invalid

The Safety Lock is designed to lock ALLUX™ at a flexed angle in which the user stops for a certain time with ALLUXTM flexed under a certain level of weight. To use the Safety Lock, adjust the slider to set the activation time.

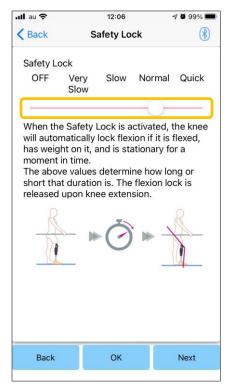




Check the function in a place, e.g. in parallel bars, where the user's safety can be ensured.

If the user is not familiar with the safety lock, he/she may inadvertently unlock the ALLUXTM, and ALLUXTM may buckle.

- *Before setting the safety lock, ensure that the user understands the function and is sufficiently trained.
- 1. Adjust the sensitivity of the safety lock. If Quick is selected, the knee will lock even with a short-term suspension.
 - *If Deactivated is selected, the safety lock will not function.



Adjustment value slider.

This slider is used to set an approximate time (See below.) to activate the safety lock.

- Very Slow: About 3 seconds
- Slow: About 2 seconds
- Normal: About 1.5 seconds
- Quick: About 1 second
- Back button: Tap this button to display the "Terminal Impact" adjustment screen.
- OK button: Tap this button to display the initial startup screen.
- Next button: Tap this button to display the "Low Battery" setting screen.

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Low Battery settings

Factory default setting = High Resistance (Equivalent to the flexion resistance 30)

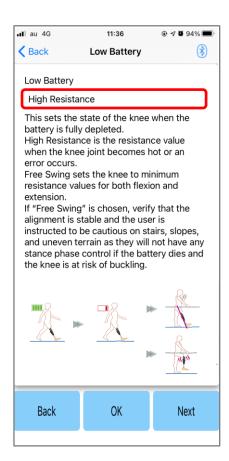
Adjust the settings for low battery situations.



If Free is selected, make sure the user can walk in a free swing state. The user can test the free swing state by selecting the free swing mode on the Remote Control Screen.

The user may not be able to move to a safe place because of the low battery.

1. Select the flexion resistance when the battery is almost depleted.



Low Battery setting picker:

Tap this picker to select a resistance when the battery is low from the following options.

- High Resistance (recommended): The flexion resistance is equivalent to the stance flexion yielding adjustment value 30.
- Free:

There is no flexion resistance.

*Whichever you select, the extension resistance becomes free.

- Back button: Tap this button to display the "Safety Lock" adjustment screen.
- OK button: Tap this button to display the initial startup screen.
- Next button: Tap this button to display the "Save data" screen.

Saving the adjustment data 18

The adjustment or set data is automatically stored in ALLUXTM.

These data can be saved to a folder on the smartphone.

The saved data can be used by copying the data (page 29).

Even if the setting data is not saved, the setting data for the past 5 days is automatically saved in the Adjustment History (Refer to page 33).

- 1. Tap the "Save data" button.
- 2. While it is saving, a standby mark is displayed and any operation is not accepted.
- 3. After the saving is completed, a popup is displayed.
- 4. Tap the "OK" button to return to the "Save data" screen.



Save data button:

Tap this button to save data.

The saved data can be used from the "Data Copy" screen (Refer to page 29).

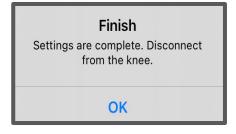
<<Storage location of the created data>>

*Smartphone "Files" > "Browse" > "On My iPhone" > "ALLUX Pro" > "data folder"

Close button:

Tap this button to terminate the connection with ALLUX[™] and exit this App.

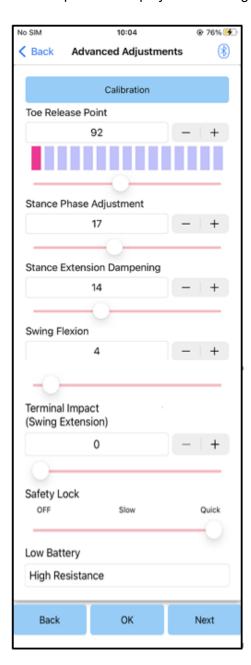
- Back button: Tap this button to return to the previous screen.
- OK button: Tap this button to display the initial startup screen.



Advanced Adjustments 19

The settings previously described in Chapters 10 to 17 can be collectively adjusted on this screen. We recommend you make the first adjustments on the "Basic setting" screen and make readjustments on the "Advanced Adjustments" screen from the second time. Refer to each screen described in Chapters 10 to 17 for the explanation, warnings, and cautions of each item.

*When this screen is displayed, the setting items in the lower part may not be displayed. Swipe the screen upward to display those setting items.



- Calibration: (page 14) Performs calibration.
- Toe Release Point: (page 15) Changes the toe release point adjustment value.
- Stance Phase Adjustment (Yielding): (page 16) Changes the stance flexion yielding adjustment value.
- Stance Extension Dampening: (page 17) Changes the stance extension dampening adjustment value.
- Swing Flexion: (page 18) Changes the swing flexion resistance adjustment value.
- Terminal Impact: (page 19) Changes the terminal impact adjustment value.
- Safety Lock: (page 20) Selects the sensitivity of the safety lock.
- Low Battery: (page 21) Selects the flexion resistance when the battery is low.
- Back button: Tap this button to display the initial startup screen.
- OK button: Tap this button to display the initial startup
- Next button: Tap this button to display the "Save data" screen.

Setting the remote control 20

20.1 ALLUX[™] operational modes

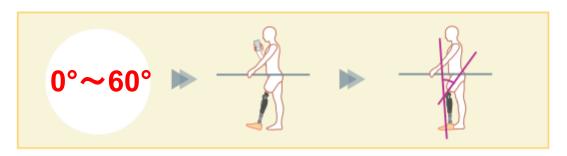
ALLUXTM has the following five operational modes.

[Normal mode]

The normal mode is adjusted for normal walking. Judging various walking situations and normal motions with the sensor, ALLUXTM automatically adjusts the flexion and extension.

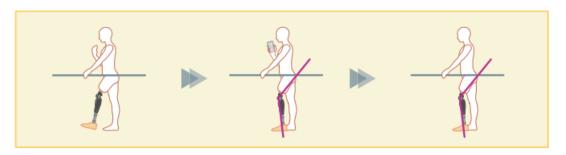
[Flexion angle limit mode]

In flexion angle limit mode, flexion resistance is locked at a designated angle while extension resistance remains free.



[Variable selective flexion lock mode]

ALLUX[™] remembers the angle at which variable selective flexion lock mode is turned on. Flexion resistance is locked when it reaches that angle while extension resistance remains free.



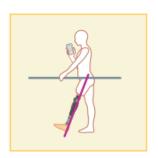
NOTICE

■ When the flexion angle limit mode or variable selective flexion lock mode is used, do not apply excessive force to ALLUXTM when contacting the stop. If an excessive impact force is applied to ALLUXTM, it may be damaged.

20) Setting the remote control

[Full extension lock mode]

ALLUXTM is locked in a fully extended state. (When activated with knee flexion, it will allow extension until ALLUXTM reached the extension stop). This can be used as a "Sit to Stand" feature.



[Free swing mode]

In free swing mode, ALLUXTM is kept free (resistance-free state).



20.2 Assigning operational modes to the buttons on the Application Remote Control

The above operational modes can be assigned to the buttons on the Application Remote Control. The normal mode is always assigned to Button 1 on the Application Remote Control, and the settings of this mode are those adjusted on the "Basic setting" screen or the "Advanced Adjustments" screen.

You can freely assign the five operational modes above to buttons 2 to 5 on the Application Remote Control.

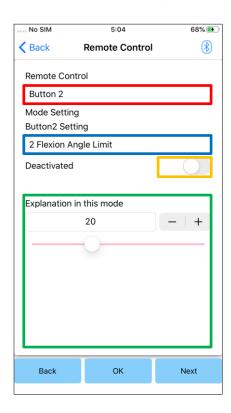
Default remote controller configuration:

- Button 2: Flexion Angle Limited mode
- Button 3: Variable Selective Flexion Lock mode
- Button 4: Full Extension Lock mode
- Button 5: Free Swing mode

Setting the remote control

20.3 Remote control setting screen

*When this screen is displayed, the setting items in the lower part may not be displayed. Swipe the screen upward to display those setting items.



Remote Control setting picker:

Tap this picker to change the button to set.

Select a button from the following list.

- Button 2
- Button 3
- Button 4
- Button 5

Mode Setting picker:

You can select the mode to assign to the selected button. Select a mode from the following list.

- Normal mode
- Flexion Angle Limited mode
- Variable Selective Flexion Lock mode
- Full Extension Lock mode
- Free Swing mode

Deactivated switch:

When this switch is turned ON, the selected button does not work even if it is tapped on the Application Remote Control.

In addition, the adjustment field for each mode is hidden.

Adjustment field for each mode:

In Normal mode and Flexion Angle Limited mode, the adjustment field is displayed.

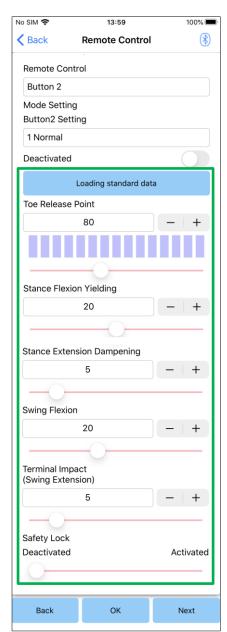
In Variable Selective Flexion Lock mode, Full Extension Lock mode, and Free Swing mode, the adjustment field is not displayed.

- Back button: Tap this button to display the initial startup screen.
- OK button: Tap this button to display the initial startup screen.
- Next button: Tap this button to display the "Save data" screen.



20) Setting the remote control

[Adjustment field for Normal mode]



Loading standard data button:

The adjustment values set in the Button 1 (adjustment values set in the "Basic setting" screen or the "Advanced adjustments" screen) can be loaded by tapping this button.

Toe Release Point:

Changes the toe release adjustment value.

Stance Flexion Yielding:

Changes the stance flexion yielding adjustment value.

Stance Extension Dampening:

Changes the stance extension dampening adjustment value.

Swing Flexion:

Changes the swing flexion resistance adjustment value.

Terminal Impact:

Changes the terminal impact adjustment value.

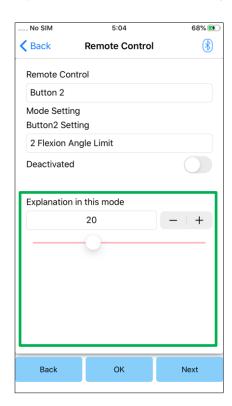
Safety Lock:

Selects whether to enable or disable the safety lock. To the sensitivity of the safety lock (time to activate the safety lock), the value adjusted on the "Basic setting" screen or the "Advanced adjustments" screen is applied.

*Refer to each screen described in Chapters 11 to 16 for the explanation, warnings, and cautions of each item.

20) Setting the remote control

[Adjustment field for Flexion Angle Limited mode]

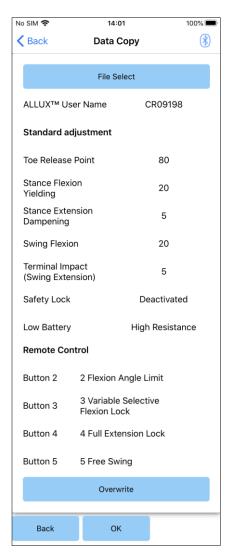


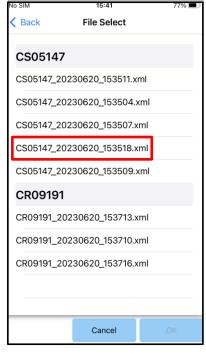
Locking Angle: ALLUXTM is locked at the set angle.

Data Copy

The data saved in the "Save data" screen (page 22) can be loaded to rewrite the settings of $ALLUX^{TM}$.

- 1. Tap the "File Select" button to display the "File Select" screen.
- 2. Select the data that you want to use.
- 3. Tap the "OK" button to return to the "Data Copy" screen. At that time, the past data is loaded and displayed.
- 4. Confirm the data.
- 5. Tap the "Overwrite" button to write the adjustment data.





Data to be used

Data Copy screen

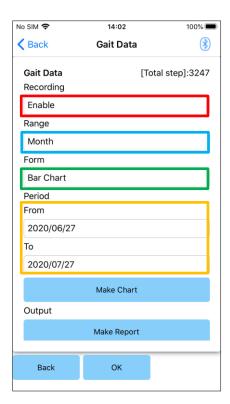
- Back button: Tap this button to display the initial startup screen.
- OK button: Tap this button to display the initial startup screen.
- * If any of the above buttons is tapped without tapping the
- "Overwrite" button first, the data will not be rewritten.

File Select screen

- Cancel button: Tap this button to display the "Data Copy" screen without loading data.
- OK button: Tap this button to display the "Data Copy" screen after loading data.

ALLUXTM records gait history (steps per cadence) for a period of two years and displays that of a designated period as a bar chart or histogram. This gait data can be printed out.

Gait data screen 22.1



Recording picker:

Select whether or not to record data.

- Enable
- Disable/Data Del

*When "Disable/Data Del" is selected, a popup for confirmation is displayed. If you tap the "OK" button, all saved data will be deleted.

Range picker:

Select a period for data to be displayed in a graph.

You can select from the following options.

- Day
- Month
- Half Year
- Two Years

*If 2 years is selected, the period is limited to 2 years prior to the current date.

* When "Bar Chart" is selected with the "Form" picker, you cannot select "Day" with the "Period" picker.

Form picker:

You can select a chart form between "Bar Chart" and "Histogram".

Period selection picker.

Select a start date ("From") and an end date ("To") with the picker. When you select one, the other date automatically changes according to the range selected with the "Period" picker.

- Make Chart button: Tap this button to display the "Make Chart" screen.
- Make Report button: Tap this button to display the "Make Report" screen.
- Back button: Tap this button to display the initial startup screen.
- OK button: Tap this button to display the initial startup screen.

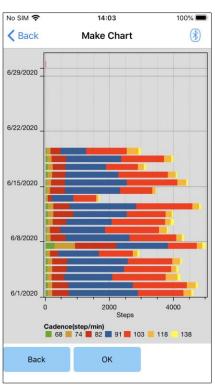
22.2 Make chart screen

A graph is created based on the settings set on the "Gait Data" screen.

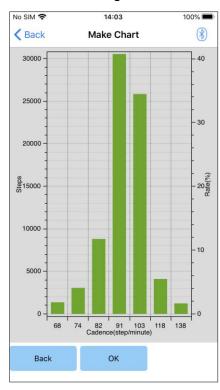
The bar chart is color-coded by cadence.

The histogram shows the aggregated data during the "Period" selected with the picker.

Bar chart



Histogram



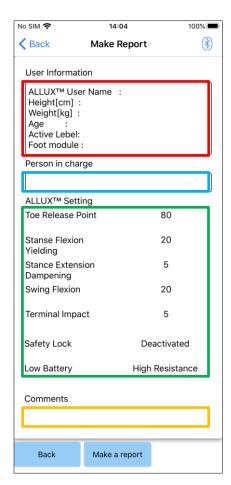
- Back button: Tap this button to display the "Gait Data" screen.
- OK button: Tap this button to display the initial startup screen.

22.3 Creating a report

A report is created for the period set on the "Gait Data" screen.

Both a bar chart and a histogram are put in the report.

You can reflect the user information and comments entered on this screen in the report.



User Information column:

The editor has default settings like the ones shown on the left, but you can delete them or add new settings as you like.

Person in charge column:

Enter the Author (user of this app) information. You can also enter the company name in a few lines.

ALLUX™ Setting:

Gait parameters are loaded from ALLUXTM and displayed automatically.

Comments:

Enter comments as necessary.

- Back button: Tap this button to display the "Gait Data" screen.
- Make a report button: Tap this button to create a report in PDF format.

Tap Files > Browse > On My iPhone > ALLUX Pro > data folder on the smartphone to find the created report.

Image of a created report

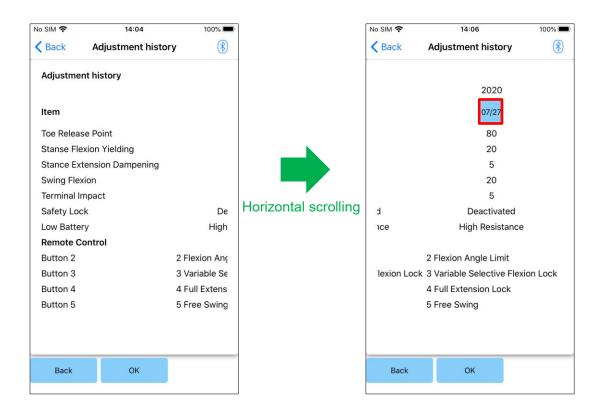




Adjustment History

This App stores the history data of adjustments made in on your smart phone for up to the past 5 days. They are saved separately from the adjustment data in the "Save data" screen (page 22). You can view the history and apply the data to ALLUXTM.

* By scrolling the viewing area horizontally on this screen, you can see previous data. In the previous data, the history of adjustments made with other ALLUXTM devices may be included. Please check the data before using it.



Date button:

When you tap the button, the screen displays the "Data Copy" screen (page 29) and you can send the displayed data at this time to ALLUXTM.

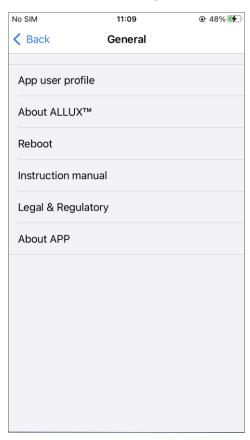
- Back button: Tap this button to display the initial startup screen.
- OK button: Tap this button to display the initial startup screen.

24

General

When you tap the General icon : on the initial startup screen (page 10), the screen displays the "General" screen.

You can redisplay the screen that displays only at the initial startup and you can confirm the software version of ALLUXTM.



- App user profile:
 - "App user profile" screen (page 6) is displayed.
- ■About ALLUXTM: "About ALLUX $^{\text{TM}}$ " screen is displayed.
- Reboot:

Restarts ALLUX™.

A popup for confirmation is displayed. Tap the "OK"

*As the communication is disconnected, you need to enable connection again.

(The same action as removing and inserting the power OFF cap.)

Instruction manual:

Tapping this button links to the download page of the instruction manual. A user name and a password are required.

Legal & Regulatory:

The "Legal & Regulatory" dialog (page 6) is displayed.

About APP:

Displays application name, usage, UDI-DI, etc.

[About ALLUXTM screen]



This screen shows the version of ALLUXTM.

App Version:

The version of this App is displayed.

ALLUXTM firmware version:

The firmware version of ALLUXTM is displayed.

Serial No:

The serial number of the ALLUXTM is displayed.

25 **Error message popup**

If an error occurs during an operation, a popup is displayed.

Please follow the instructions in the popup.

25.1 Password error ("Enter Password" screen)

Error

Password is incorrect.

OK

This error occurs when the wrong password was input on the "Enter Password" screen. Try to enter the password indicated in the instruction manual again. (page 5)

25.2 Password error ("Connection to ALLUXTM" screen)

Error

Password is incorrect.

OK

This error occurs when the wrong password was input on the "Connection to ALLUXTM" screen. Try to enter the password indicated on the charging port again. (page 7)

25.3 Password error (3 times)

Error

Password was wrong 3 times. App closes when the "OK" button is pressed.

OK

This error occurs if you fail in entering the password 3 times on the "Enter Password" screen or the "Connection to ALLUXTM" screen. And then this App closes at once. When you start up this App again, you can enter the password again.

25.4 Wireless connection error

Error

Connection to Bluetooth was failed. Retry wireless connection.

OK

This error occurs when wireless connection between ALLUXTM and Bluetooth on smartphone is failed. Try to turn ON the wireless connection of ALLUXTM referring to page 9.

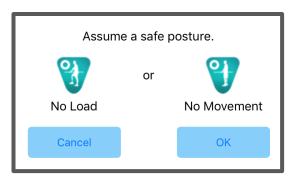
25.5 Wireless communication error



This error occurs when communication between $\mathsf{ALLUX}^\mathsf{TM}$ and App on smartphone is failed. Enable wireless connection again referring to page 10.

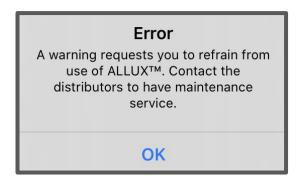
If adjustment is in progress, recheck the adjustment value after reconnection.

25.6 Safe posture error



If the user does not take a safe posture, ALLUXTM cannot change the settings. Have the user take a safe posture referring to page 8.

25.7 Hydraulic control error



Because hydraulic control may be out of order, the control of ALLUXTM is stopped.

Contact the distributor to have maintenance service.

26 Troubleshooting

Problem	Check item	Remedy
	Check that the operating system	Update the operating system to iOS 13 or later.
The Adjustment	version is appropriate.	
App cannot be	Check that the hard disk of the	Increase the free space on the hard disk.
installed.	smartphone etc. has a required	
	free space.	
	Check that ALLUX™ is	Select ALLUX™ on the "Connection to
	recognized on the "Connection	ALLUX™" screen.
	to ALLUX TM " screen (page 7).	
	Check that ALLUX™	ALLUX™ cannot be connected with multiple
	communication is not connected	devices. Try the actions in the following order.
	with multiple devices.	Disconnect from the Application Remote
		Control.
		2. Shut down the Adjustment App and the
		Application Remote Control.
		3. If the user is using the Application Remote
ALLUX™ cannot		Control, ask the user to disconnect it.
be connected.	Check that Bluetooth is "ON" on	Turn ON Bluetooth on the smartphone.
	the smartphone.	
	Cannot be connected even with	Perform the following three steps before
	the above remedies.	reconnecting.
		(1) Reboot the ALLUX™ power supply.
		(Insert the charger or the power OFF cap
		once and then remove it.)
		(2) Turn OFF the smartphone's Bluetooth
		once and then turn it back ON.
		(3) Restart the Adjustment App.
	01 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	
	Check that ALLUX™ wireless	Turn ON wireless connection referring to
	connection is ON.	(page 9)
ALLUX™ is not	Check that battery for ALLUX™	Charge the battery for ALLUX™.
indicated on the	has been charged.	
"Connection to	Check that multiple Apps work	Close unnecessary Apps.
ALLUX TM " screen.	at the same time.	
	Check that the Bluetooth	Turn ON the Bluetooth function.
	function is "ON" on the	
	smartphone.	

	Check that the battery capacity for ALLUX [™] or smartphone is low battery status.	Charge the battery for ALLUX [™] or smart phone.
Communication between ALLUX TM and App is easily disconnected.	Check ALLUX™ is used under the specific wireless condition such as beside railway, highway, TV tower, airport, in exhibition and hospital.	Avoid using the device in an environment where trains or vehicles frequently come and go, or in an environment where there are multiple wireless connections.
	Check if there are huge shields against radio wave around ALLUX™ user.	Remove shields that block radio waves.



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