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Adjustment App Instruction Manual

(iOS Version)

For Prosthetists

Product Type: NE-Z41, NE-Z41SH Document Number: 81-SS00127(ver.4) Application Ver. 0.4.11 or later Date of issue: 2023-10-01

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

Nabtesco Corporation

Introduction

Thank you for purchasing Nabtesco's ALLUX[™].

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 ALLUX[™], thoroughly read the ALLUX[™] 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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1

Supported model and operating environment

● ALLUX[™] (type: NE-Z41)

* ALLUX[™] (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

移 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.

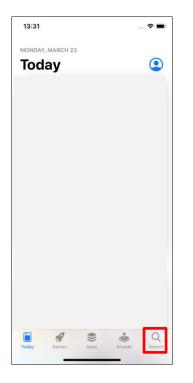
Install procedures and initial settings

1. Sign in with your Apple ID.

2

Tap the search icon \bigcirc 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.





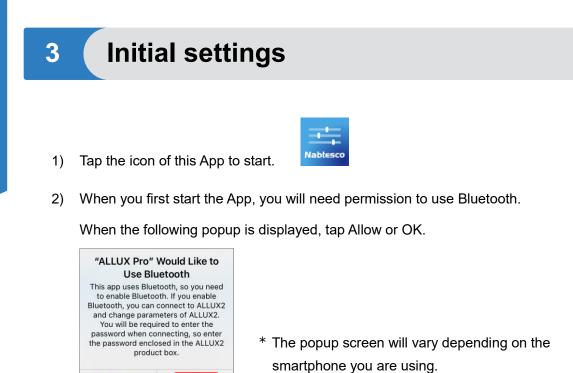
The following QR code can be used to install.



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.



3) After the company logo is displayed on screen for a second, this screen automatically changed to the next screen.



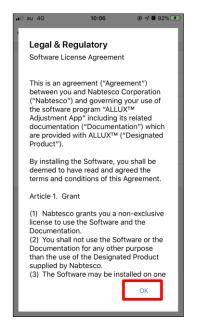
Don't Allow

OK

4) "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.



6) The "App user profile" is displayed.

Enter each information and tap the "OK" button.

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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.

3 Initial settings

7) The "Connection to ALLUXTM" screen is displayed.



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

For consecutive connections, the "Connection to ALLUX[™] screen is skipped and the initial startup screen is displayed.

8) "Connection to ALLUXTM" screen is displayed.

No SIM

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

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.

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| Bluetooth Pairing Request "LAPIS ML7125-002 Application" would like to pair with your iPhone. | | |
|---|------|--|
| Cancel | Pair | |

4 Safe posture

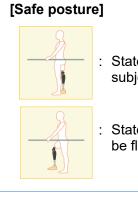
Before changing the operational mode of ALLUX[™] using the Application Remote Control or before adjusting or setting ALLUX[™] using this App, the user needs to take a posture which is safe even if hydraulic resistance changes. This posture is referred to as 'safe posture'. Explain to the user about safe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

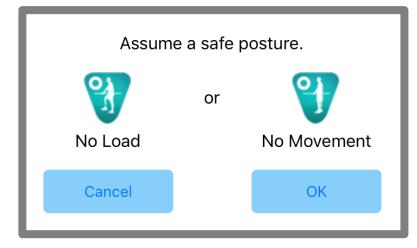


: State where ALLUX[™] is stationary, straight, and vertical and may be subject to weight loading

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

[Request for safe posture]

If ALLUX[™] is not in the safe posture when adjusting or setting ALLUX[™], 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

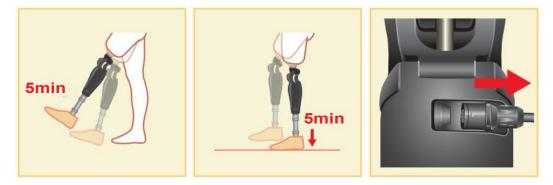
In order to conserve power, ALLUX[™] is not always in communication mode.

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

Once ALLUX[™] communication is established using this App, this state lasts until communication is disconnected.

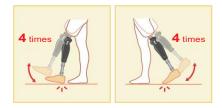
[Communication mode enabled]

- 1. For 5 minutes after ALLUX[™] 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 ALLUX[™]



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.

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.

| •II au 4G | ^{13:49} Adjustment menu | |
|----------------------|-------------------------------------|--------|
| | Basic Settings | |
| | Advanced Adjustments | s |
| | Remote Control | |
| | Data Copy | |
| | Gait Data | |
| | Adjustment History | |
| | | |
| | | |
| | | |
| Latest adju date: | stment 2020/10/22 step]:272 | [Total |
| | | |

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Bluetooth icon:

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



Disconnected

d Connected

General icon:

Tap this icon i 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 ALLUXTM was in last adjusted.

Battery level:

It shows the battery level of ALLUX[™].



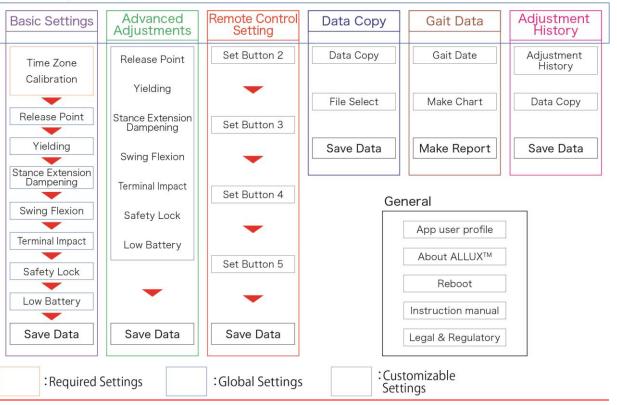
Basic setting button: Tap this button to display the "Basic setting" screen (page 12).

- 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).

7 Adjustment procedure

Adjustments are undertaken in the following steps.

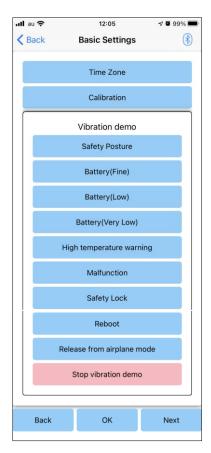
Initial set-up screen



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:

ALLUX[™] 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): ALLUX[™] vibrates when the remaining battery level is insufficient and normal walking is impossible.
- High temp warning: ALLUX[™] vibrates when the knee joint is in high temperature.
- Malfunction: ALLUX[™] vibrates when the knee joint needs service.
- Safety Lock: ALLUXTM vibrates when the safety lock is turned on.
- Reboot: ALLUX[™] vibrates when ALLUX[™] is rebooted.
- Release from airplane mode: ALLUXTM vibrates when the airplane mode is turned off. (page 9)
- Stop vibration demo: ALLUX[™] stops vibration.



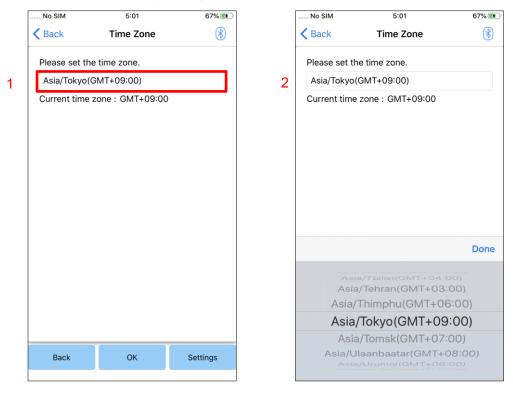
Make sure the user recognizes all vibration patterns and understands the differences. If the user uses ALLUXTM without understanding the meanings of the vibrations, he/she may not be in a safe posture against a warning about failure or high temperature and may fall because the ALLUXTM is locked when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

ALLUX[™] 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.

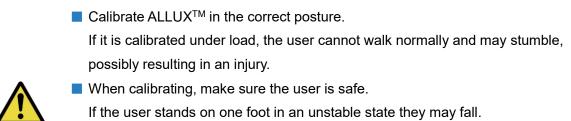
- 1. Tap the Time Zone picker to display the time zone list.
- 2. Select the time zone of user's location.
- 3. Tap the "Settings" button to send the time zone to ALLUX[™].
- *Once selected, it is unnecessary to repeat this step unless there is a permanent relocation to another time zone. It is also 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 ALLUX[™].

10 Calibration

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





- 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.

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| Basic | setting | ۲ |
| Time | Zone | |
| Calib | ration | |
| Vibration a | ılarm dem | 10 |
| Safety | Posture | |
| Confirm Lifting up the prosthesis with a safe posture and tap "OK" with keeping the state. | | |
| Cancel | C | ж |
| High temperature warning | | |
| Malfunction | | |
| Safety Lock | | |
| k C | ж | Next |
| | Basic : Time Calib Vibration a Safety Con Lifting up the pro- posture and tap "O star Cancel High tempera Malfu Safety | Lifting up the prosthesis with posture and tap "OK" with kee state. Cancel C High temperature warn Malfunction Safety Lock |

- 1. Tap the "Calibration" button on the "Basic setting" screen, a popup is displayed.
- Have the user lift his/her foot to keep ALLUX[™] 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.
- 4. The popup closes and the screen returns to the "Basic setting" screen.

11 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.

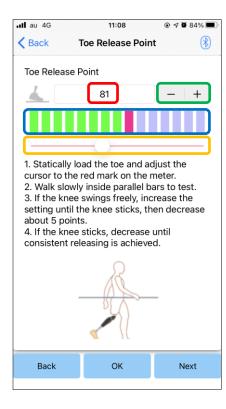
If ALLUX[™] cannot smoothly shift to swing phase, user may fall.

- 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 ALLUX[™] releases with every step, gradually increase until it sticks, then reduce approximately five points.

*If ALLUX[™] 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:

This slider is used to set an adjustment value.

*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 screen.
- Next button: Tap this button to display the "Stance Flexion Yielding" adjustment screen.

12 Adjusting the Stance Flexion Yielding

Factory default setting = 20 (Standard value: 15 ~ 25)

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 ALLUX[™] 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.

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| level so that t evenly in both 2. Increase or wearer's pref 3. Fine tune f wearer is cap slope descen are made. Note: This ad range. "0"= F locked. Inform the we | r decrease based | s supported on the opes if the foot stair/ djustments s the full valve : Flexion is tact with |
| Back | ок | Next |

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.

13 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 ($+20^{\circ}C/+68^{\circ}F$).



When ALLUX[™] 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 ALLUX[™] 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 ALLUX[™] 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.

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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.

14

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 ALLUX[™] cannot smoothly shift to swing phase, the user may fall.

*If the foot scuffs the floor because ALLUX[™] 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.

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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.

15 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, ALLUX[™] 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.

| ull au 🗢 | 12:05 | 1 🖉 99% 🔳 | |
|--|-----------------|-----------|--|
| K Back | Terminal Impact | ۲ | |
| Terminal Ir (Swing Ext | | | |
| (Swing Ext | ension) | | |
| | 9 | - + | |
| | 0 | | |
| normal pace. 2. Monitor knee extension and increase if terminal impact is observed, decrease if it doesn't reach full extension or swings forward too slowly. Note: Adjustment values over 20-25 may prevent the knee from getting to full extension. | | | |
| | | | |
| Back | ОК | Next | |

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.

16 Adjusting the Safety Lock

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 ALLUX[™] flexed under a certain level of weight. To use the Safety Lock, adjust the slider to set the activation time.





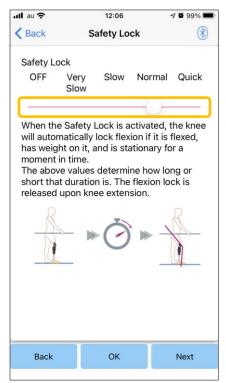
Check the function in a place, e.g. in parallel bars, where the user's safety can be ensured.

If the user is not familiar with the safety lock, he/she may inadvertently unlock the ALLUX[™], and ALLUX[™] 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.

17 Low Battery settings

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

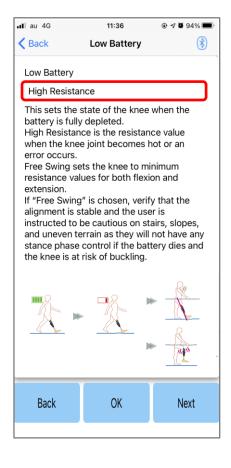
Adjust the settings for low battery situations.



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.

18 Saving the adjustment data

The adjustment or set data is automatically stored in ALLUX[™].

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).

Save data button:

- 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.

| ull au 🗢 | 12:06 | 🕫 🖉 99% 🔲 |
|-------------------------------|---------------------|---------------|
| K Back | Save data | (*) |
| | | |
| | Save data | |
| Save the adju | ustment data in the | local folder. |
| | Close | |
| Close the app is completed | o as the adjustmen | t procedure |
| | | |
| | | |
| | | |
| Back | ок | |

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 $ALLUX^{TM}$ 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.



19 Advanced Adjustments

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.

| o SIM | 10:04 | @ 76% 🗭 | Calibration: (page 14) |
|----------------------|----------------------|---------|---|
| C Back | Advanced Adjustm | ents 🛞 | Performs calibration. |
| | Calibration | | |
| Too Polo: | ase Point | | Toe Release Point: (page 15) |
| TOP Relea | 92 | - + | Changes the toe release point adjustment value. |
| | | | Stance Phase Adjustment(Yielding): (page 16) |
| | | | Changes the stance flexion yielding adjustment value. |
| Stance P | Phase Adjustment | | |
| | 17 | - + | Stance Extension Dampening: (page 17) |
| | | | Changes the stance extension dampening adjustment |
| Stance E | extension Dampening | | value. |
| | 14 | - + | value. |
| | -0 | | Swing Flexion: (page 18) |
| Swing Fle | exion | | Changes the swing flexion resistance adjustment value. |
| | 4 | - + | |
| | | | Terminal Impact: (page 19) |
| | | | Changes the terminal impact adjustment value. |
| Terminal (Swing E | Impact extension) | | |
| (onlight) | 0 | - + | Safety Lock: (page 20) |
| | v | | Selects the sensitivity of the safety lock. |
| 0 | | | |
| Safety Lo | Slow | Quick | Low Battery: (page 21) |
| OFF | Slow | Quick | Selects the flexion resistance when the battery is low. |
| Low Batte | en | \sim | |
| (| | | Pack button: Tan this button to display the initial startup |
| High Ke | sistance | | Back button: Tap this button to display the initial startup |
| Deak | 04 | blout | screen. |
| Back | OK | Next | 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

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, ALLUX[™] 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.



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]

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



[Free swing mode]

In free swing mode, ALLUX[™] 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

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.

| No SIM | 5:04 | 68% 📢 | | | |
|--------------------------------|----------------|-------|--|--|--|
| K Back | Remote Control | (*) | | | |
| Remote Control | | | | | |
| Button 2 | | | | | |
| Mode Setting Button2 Settir | ng | | | | |
| 2 Flexion Ang | gle Limit | | | | |
| Deactivated | | | | | |
| Explanation in | this mode | | | | |
| | 20 | - + | | | |
| | | | | | |
| Back OK Next | | | | | |

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]

| No SIM 奈 | 13:59 | | 100% 🗖 | | |
|-----------------------------|----------------------|---|------------|--|--|
| Back Remote Control | | | | | |
| Remote Contro | ol | | | | |
| Button 2 | | | | | |
| Mode Setting | | | | | |
| Button2 Setting | | | | | |
| 1 Normal | | | | | |
| Deactivated | | | \bigcirc | | |
| L | oading standard data | | | | |
| Toe Release P | oint | | | | |
| | 80 | - | + | | |
| | | | | | |
| | | | | | |
| Stance Flexior | Violding | | _ | | |
| Stance Flexion | 20 | | + | | |
| | 20 | _ | . т | | |
| | 0 | | _ | | |
| Stance Extens | ion Dampening | | | | |
| | 5 | - | + | | |
| -0- | | | | | |
| Swing Flexion | | | | | |
| | 20 | - | + | | |
| | 0 | | | | |
| Terminal Impa | | | | | |
| (Swing Extens | | | _ | | |
| | 5 | - | + | | |
| -0- | | | — | | |
| Safety Lock | | | | | |
| Deactivated Activated | | | | | |
| | | | | | |
| Deck | | | | | |
| Back | Back OK Next | | | | |

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.



[Adjustment field for Flexion Angle Limited mode]

| No SIM | 5:04 | 68% 💓 | | | | |
|----------------|---------------------------------|-------|--|--|--|--|
| K Back | Remote Control | () | | | | |
| Remote Control | | | | | | |
| Button 2 | Button 2 | | | | | |
| | Mode Setting Button2 Setting | | | | | |
| 2 Flexion A | ngle Limit | | | | | |
| Deactivated | 1 | | | | | |
| 20 - + | | | | | | |
| Back OK Next | | | | | | |
| Buok | U.K. | Hert | | | | |

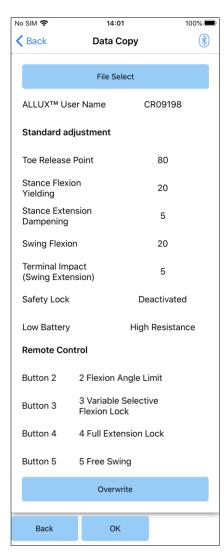
Locking Angle:

ALLUX[™] is locked at the set angle.

21 Data Copy

The data saved in the "Save data" screen (page 22) can be loaded to rewrite the settings of ALLUXTM.

- 1. Tap the "File Select" button to display the "File Select" screen.
- 2. Select the data that you want to use.
- 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.



| o SIM | 15:41 | 77% 🔳 | |
|-----------------------------|-----------------|-------|--|
| C Back | File Select | | |
| CS05147 | | | |
| CS05147_20230620_153511.xml | | | |
| CS05147_202 | 30620_153504.x | ml | |
| CS05147_202 | 30620_153507.xi | ml | |
| CS05147_20230620_153518.xml | | | |
| CS05147_202 | 30620_153509.x | ml | |
| CR09191 | | | |
| CR09191_202 | 30620_153713.xi | ml | |
| CR09191_202 | 30620_153710.xi | ml | |
| CR09191_20230620_153716.xml | | | |
| | | | |
| | | | |
| | Cancel | ОК | |

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.

Gait Data

22

ALLUX[™] 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.

22.1 Gait data screen

| No SIM 🗢 | 14:02 | 100% 🔲 |
|------------|-------------|-------------------|
| K Back | Gait Data | (*) |
| Gait Data | | [Total step]:3247 |
| Recording | | |
| Enable | | |
| Range | | |
| Month | | |
| Form | | |
| Bar Chart | | |
| Period | | |
| From | | |
| 2020/06/27 | | |
| То | | |
| 2020/07/27 | | |
| | Make Chart | |
| Output | | |
| | Make Report | |
| Back | ОК | |

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.

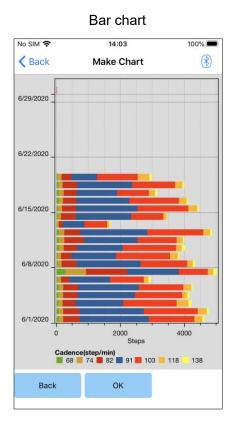
- Back button: Tap this button to display the initial startup screen.
- OK button: Tap this button to display the initial startup screen.

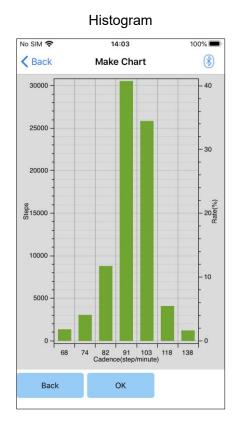
22.2 Make chart screen

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.





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.

| No SIM 奈 | 14:04 | 100% 📼 | | | |
|--|---------------|--------------|--|--|--|
| K Back | Make Report | () | | | |
| User Information | | | | | |
| ALLUX™ User Height[cm] : Weight[kg] : Age : Active Lebel: Foot module : | r Name : | | | | |
| Person in char | ge | | | | |
| | | | | | |
| ALLUX™ Setti | ng | | | | |
| Toe Release Po | pint | 80 | | | |
| Stanse Flexion Yielding | | 20 | | | |
| Stance Extensi Dampening | ion | 5 | | | |
| Swing Flexion | | 20 | | | |
| Terminal Impac | ct | 5 | | | |
| Safety Lock | De | eactivated | | | |
| Low Battery | High | n Resistance | | | |
| Comments | | | | | |
| | | | | | |
| Back | Make a report | | | | |

Image of a created report

| | SUMMARY REPORT ALLUX™ |
|--|-----------------------|
| Date of the Report Department data or | ATTO00 16:0037 AM |
| Num A/140022 10 | 10.5 Take |
| 1. ALLUX [®] | USER INFORMATION |
| ALL LOC" LOGI MARK | |
| any or a | |
| Age : | |
| NOOF ITTO BURK (| |
| 2. STAND | ARD ADJUSTMENT |
| toe Release point of | |
| Name Reads they | engins angenings |
| twing Record 51 | |
| Softing Lock 1244 | |
| townshinery stight | landour of |
| 2 COMMA | |
| 5. COMM | ENTS OF PROSTHETIST |
| 3. COMM | ENTS OF PROSTNETIST |
| 3. Comme | NTS OF PROSTNETIST |

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 ALLUX[™] and displayed automatically.

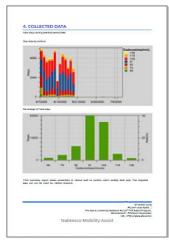
Comments:

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.



23 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 ALLUX[™] devices may be included.
 Please check the data before using it.

| No SIM 奈 | 14:04 | 100% 📟 | | No SIM 奈 | 14:06 | 100% 📟 |
|-------------|-------------------|---------------|----------------------|-------------|-----------------------|--------------|
| < Back | Adjustment histor | у 🛞 | | < Back | Adjustment history | / 🛞 |
| Adjustmer | nt history | | | | | |
| | | | | | 2020 | |
| Item | | | | | 07/27 | |
| Toe Releas | se Point | | | | 80 | |
| Stanse Fle | exion Yielding | | | | 20 | |
| Stance Ext | tension Dampening | | | | 5 | |
| Swing Flex | kion | | | | 20 | |
| Terminal In | mpact | | | | 5 | |
| Safety Loc | :k | De | Horizontal scrolling | b | Deactivate | d |
| Low Batter | ry | High | | nce | High Resista | nce |
| Remote Co | ontrol | | | | | |
| Button 2 | | 2 Flexion Anç | | | 2 Flexion Angle Limit | |
| Button 3 | | 3 Variable Se | | lexion Lock | 3 Variable Selective | Flexion Lock |
| Button 4 | | 4 Full Extens | | | 4 Full Extension Lock | (|
| Button 5 | | 5 Free Swing | | | 5 Free Swing | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| Back | ОК | | | Back | ОК | |
| | | | | | | |

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.

General 24

When you tap the General icon i 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 ALLUX[™].

| No SIM | 11:09 | | App user profile: |
|------------------|--------------------------|--------|---|
| A Back | General | | "App user profile" screen (page 6) is displayed. |
| App user pro | ofile | | ●About ALLUX [™] : |
| About ALLU | Хтм | | "About ALLUX [™] " screen is displayed. |
| Reboot | | | Reboot: |
| Instruction n | manual | | Restarts ALLUX™. |
| | nanuai | | A popup for confirmation is displayed. Tap the "OK" |
| Legal & Reg | ulatory | | button. |
| About APP | | | *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. |
| | LUX [™] screen] | 100% 🗭 | This screen shows the version of ALLUX [™] . |
| 〈 General | About ALLUX™ | | |

App Version:

The version of this App is displayed.

●ALLUX[™] firmware version:

The firmware version of ALLUX[™] is displayed.

Serial No:

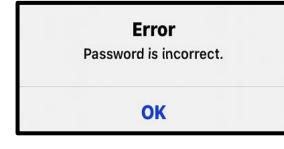
The serial number of the ALLUX[™] is displayed.

[

| | 10.19 | 100% |
|------------------|---------------|------|
| 〈 General | About ALLUX™ | |
| App Version | I | |
| 0.4.0 | | |
| ALLUX™ fir | mware version | |
| 50.36/07.32 | | |
| Serial No. | | |
| CR09198 | | |
| | | |
| | | |
| | | |

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)



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 ALLUX[™]" screen)



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)



25.4 Wireless connection error

Error Connection to Bluetooth was failed. Retry wireless connection. This error occurs if you fail in entering the password 3 times on the "Enter Password" screen or the "Connection to ALLUX[™]" screen. And then this App closes at once. When you start up this App again, you can enter the password again.

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



25.5 Wireless communication error

Error Communication to ALLUX™ was failed. Retry Bluetooth connection to ALLUX™.

Assume a safe posture.

or

No Movement

OK

25.6 Safe posture error

No Load

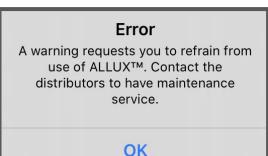
Cancel

This error occurs when communication between ALLUX[™] 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.

If the user does not take a safe posture, ALLUX[™] 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 ALLUX[™] is stopped. Contact the distributor to have maintenance service. 26

Troubleshooting

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 [™] " 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. |
| | Check that ALLUX [™] wireless | Turn ON wireless connection referring to |
| | connection is ON. | (page 9) |
| | Check that battery for ALLUX™ | Charge the battery for ALLUX™. |
| ALLUX [™] is not | has been charged. | |
| indicated on the | Check that multiple Apps work | Close unnecessary Apps. |
| "Connection to | at the same time. | |
| ALLUX™" screen. | Check that the Bluetooth | Turn ON the Bluetooth function. |
| | function is "ON" on the | |
| | smartphone. | |

| Communication between ALLUX [™] and App is easily disconnected. | Check that the battery capacity for ALLUX [™] or smartphone is low battery status. Check ALLUX [™] is used under the specific wireless condition such as beside railway, highway, TV tower, airport, in exhibition and hospital. | Charge the battery for ALLUX [™] or smart phone. 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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