ALLUX™

Instruction Manual

For Prosthetists

Product Type：NE-Z4, NE-Z4SH
Document Number：81-SS00098E
Date of issue：June 1.2017

⚠ CAUTION

- 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 ALLUX™.

ALLUX™ is an electronically controlled Prosthetic knee joint with four-bar linkage which provides safe and comfortable walking through a combination of hydraulic control and computer control.

This instruction manual (hereinafter, referred to as this document) was prepared to ensure that the persons who have participated in a Nabtesco ALLUX™ license seminar and are certified can assemble and adjust ALLUX™ safely.

This document describes matters concerning typical usage such as fitting and walking, maintenance, operation procedures including adjustment and replacement of service part, trouble shooting, and cautionary notes.

Explain the cautions for use to the user, and hand User's Guide to him/her.

Important Information

Purpose of ALLUX™

ALLUX ™ was designed and is manufactured for use as an artificial knee joint by above-knee, knee disarticulation,hip disarticulation. Do not use ALLUX™ for any other purposes. For hip prostheses, it is recommended to use a torsion adapter to prevent application of large torsion to ALLUX™.
For the specifications for ALLUX™, see 2.Product Overview.

WARNING

■Do not use ALLUX™ outside of the specification range. Do not modify the main body or parts.
Doing so can cause injury or damage ALLUX™.

Cautions for handling ALLUX™ safely

Nabtesco Corporation (hereinafter, referred to as Nabtesco) cannot foresee all of potential residual risks of ALLUX™ and risks resulting from human errors and usage environment.

Although there are a lot of instructions and prohibitions for handling ALLUX™ (assembling, adjusting and maintaining the prosthesis), all these matters cannot be described in this document or on the warning labels on the body of ALLUX™.

Therefore, when handling ALLUX™, it is necessary not only to observe the precautions stated in this document, but also to take safety measures necessary for prosthesis knee joint.

Particularly important matters concerning the safe handling of ALLUX™ are described below. These matters apply to the persons who assemble and adjust ALLUX™.

Read this document thoroughly

Before handling ALLUX™, thoroughly read this document, and sufficiently understand the contents. Strictly observe the safety precautions stated in the document.

Qualification of assemblers and adjusters

Anyone assembling or adjusting the ALLUX™ must have attended ALLUX™ license seminars and be a licensed prosthetist. Outsourcing to anyone else is strictly prohibited.

About This Document

Target of this document

This document is intended for the persons (prosthetists, etc.) who have attended and completed ALLUX™ license seminar to fit the product for prosthetic users.

Copyright

When this document is lost or damaged

If this document or any related document is lost or damaged, immediately ask the Local sales representative or Distributor(hereinafter,referred to as the Distributor) to reissue it.
Handling ALLUX™ without this document can cause accidents.

Information

The information on this manual is subject to change without prior notice for product improvement.

Structure of This Document

This document consists of the following chapters.

Title of chapter	Contents
Introduction	Outline and purposes of this document
Important information	Purpose of use, information for safe handling of ALLUX™
About This Document	Notes on this document
Structure of this document	Contents of each chapter in this document
1. Safety precautions	Safety precautions
2. Product Overview	Specifications for ALLUX™
3. Before use	Names and models of ALLUX™ and accessories Procedures for installing and uninstalling ALLUX™ software Procedures for starting ALLUX™ software Procedures for communicating with ALLUX™
4. Assembly procedures	Aligning method Interference with socket at maximum flexion angle
5. Selective modes by remote controller	Explanation of selective modes by remote controller
6. Adjustment procedures	Safe posture and condition ready for communication Procedures for adjusting on ALLUX™ software Synchronization with remote controller Calibration procedures Explanation about vibration Various adjustments and data saving Procedures for checking walking data
7. States of ALLUX™	Explanation of states of ALLUX™ and vibration alert pattern
8. Charging procedures	Procedures for charging ALLUX™ and backup battery
9. Maintenance Parts	Explanation of service and replacement parts and cautions Procedures for replacing extension rubber stopper
10. Troubleshooting	Possible troubles during assembly and adjustment, and procedures for adjustment to solve the trauble of user
11. Disposal	Explanation about method of disposal of ALLUX™
12. Periodic inspection	Explanation about periodic inspection and warranty period
13. Warranty	Explanation about warranty

Table of Contents

Table of Contents

1 Safety Precautions

1.1 Definition of symbols

Throughout this manual, the following signal words are used to classify and explain the hazards and damages which may be caused by improper usage not conforming to the instructions.

WARNING	Indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.
CAUTION	Indicates a potentially hazardous situation which, if not avoided, could result in minor or moderate injury.
NOTICE	Damage only.

As protective measure above-mentioned, the instructions to be observed are classified and explained by using the following pictograms.

	Indicates actions that you must not do when handling the product.
	Indicates actions that you must do based on instructions when handling the product.

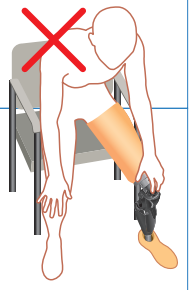
1.2 Warning

Strictly observe the following instructions to use the product safely.

WARNING

- Be sure to hand the separate User's Guide to the user, and explain precautions for use.
  Incorrect use, the parts could be damaged or broken, thus resulting in a fall.
- When detecting abnormal noise, play or reduction in hydraulic resistance, discontinue the use, and contact the Distributor.
  Use when it feels abnormal, the parts could be damaged or broken, thus resulting in a fall.

- Do not use for a user who weighs more than 125 kg.
  Use when the weight limit is exceeded, the parts could be damaged or broken, thus resulting in a fall.
- Do not use if the user is not in a condition to use the prosthesis knee joint.
  This could get aggravation of symptoms.
- Do not use for sports.
- Do not use for any purpose other than prosthesis knee joint.
  The parts could be damaged or broken, thus resulting in a fall.



- When bending the prosthesis knee joint, do not put your hand behind the knee.
- When extending the prosthesis knee joint, do not touch the knee.
  This can cause injury from your hand being caught in the knee joint.

1 Safety Precautions

1.3 Caution

Strictly observe the following instructions to use the product safely.

⚠CAUTION

- The adjustment of ALLUX™ must be done by a certified prosthetist of ALLUX™ handling.
  Incorrect adjustment could impair walking safety and comfort.
- Charge the main body of ALLUX™ before using it.
  Normal walking will be impossible if the battery runs out during use.
- After adjusting it in the communication state for a long time, charge it.
  Communication requires more power and thus depletes the battery faster.
- Adjust ALLUX™ in an environment with a temperature from 0˚C /+32˚F to +40˚C/+104˚F(Recommended:+20˚C/+68˚F)
  The temperature can affect the flex/extension resistance.

- Never attempt to disassemble or modify the product.
  The parts could be damaged or broken, thus resulting in a fall.

- Do not put a magnet closer or use in a magnetic field or in an environment with strong electromagnetic waves(e.g. MRI).
  Could result in a malfunction.
- Do not give a strong impact to the product by dropping it from a height.
  The parts could be damaged or broken, thus resulting in a fall.
- Do not use in an environment with a temperature of less than -10˚C/+14˚F or more than +40˚C/+104˚F
  The flexural extension resistance may change, resulting in a fall.
- Do not charge with anything other than the designated charger.
  Abnormal voltage use, could result in a malfunction.

- Never attempt to disassemble, heat, short-circuit or put the battery in a fire.
  Could result in deforming the plastic parts, could result in a malfunction.
- Do not expose to heaters.

- Do not immerse the product in liquids, such as water and seawater, or pour any liquid over it.
  Could result in rusting etc. of the parts, could result in a malfunction.
- Do not use any detergent or solvent (thinner) for cleaning it.
  Discoloration, desiccation of the grease, and abnormal noises.

1.4 Notice

Strictly observe the following instructions.

NOTICE

- Do not leave or store in an environment with a temperature of less than -20˚C/-4˚F or more than +60˚C/140˚F
- Do not charge outdoors.
  Could result in a malfunction.

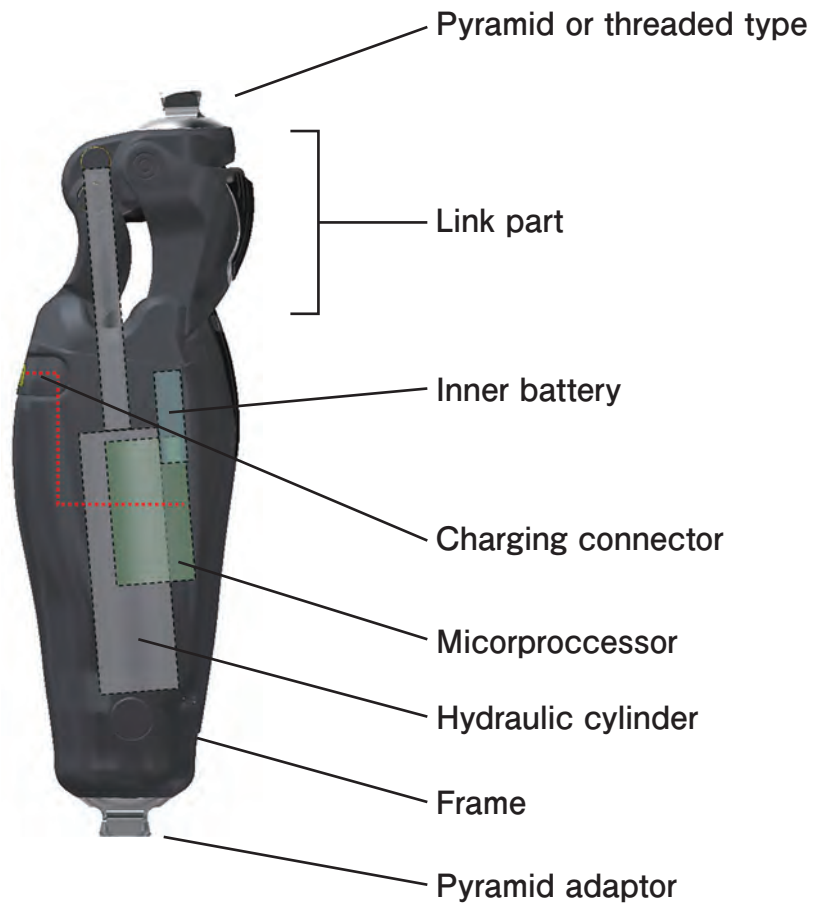
2 Product Overview

2.1 Overview of ALLUX™

ALLUX™ is a knee joint with a four-Bar linkage mechanism to electronically control the stance and swing phases. It provides smooth walking according to the walking speed and enables yielding required for descending a slope or stairs. The safety lock function can be used to stop the knee suddenly bending and as an anti-stumbling function for when the toes get stubbed on the ground etc. The internal power supply supports use of the prosthesis for 5000 steps per day over a period of 4 days(Only a guide as it can vary with the usage conditions).

2.2 Basic structure

ALLUX™ has a pyramid adapter at the bottom and either a pyramid or threaded adapter at the top. The frame is made of carbon, and the link parts are made of an aluminum alloy. The stance and swing phase control is performed by a hydraulic cylinder.



2 Product Overview

2.3 Certification of International Standard

●Certification of International Standard

ALLUX™ was tested for 3 million walking cycles with load of 125kg which corresponds to the average working distance within about 3 years. We will not assume liability for ageing or damage of the product.
*for products with extended warranty: Exchange of structural parts is covered by the warranty.

ISO10328-P6-125kg*)

*) Body mass limit not to be exceeded. For specific conditions and limitations of use see manufacturer's written instructions on intended use.

●K Level(MOB)

K1 Level(MOB1): User can move to a bed or chair, and can walk on a flat surface indoors at a constant speed.
K2 Level(MOB2): User can handle small environmental barriers such as curbs, steps, or irregular ground both indoors and around the home.
K3 Level(MOB3): User can handle most environmental barriers, and can walk at different speeds. In addition to simple walking, he/she can do light work and exercise as well.
K4 Level(MOB4): User has physical abilities higher than basic walking; children, athletes, etc.

●EMC Information

ALLUX™belongs to Group 1 and Class A equipment in accordance with IEC/EN60601-1-2.
ALLUX™requires special precautions regarding EMC (Electromagnetic Compatibility) and need to be installed, put into service and used according to the following information.

CAUTION

- Do not use any cables other than the cables that provided or specified by the manufacturer, Nabtesco Corporation.
- Do not use the peripheral devices other than those specified, with the exception of transducers and cables sold by Nabtesco Corporation as replacement parts for internal components.
  That may result in increased emissions or decreased immunity of the ALLUX™.
- Do not use ALLUX™ adjacent to other equipment. Portable and mobile RF communications equipment can affect the ALLUX™. If adjacent use is necessary, take care.
- Please carefully read this instruction manual to avoid the risk of ignition or electric shock.

●Declaration of Conformity

Nabtesco Corporation, hereby declare that following Class I medical device complies with the essential health and safety requirements of the Medical Devices Directive 93/42/EEC as amended by 2007/42/EC and the R&TTE(Radio and Telecommunications Terminal Equipment) Directive 1999/5/EC.

2 Product Overview

2.4 Specifications

- Type：NE-Z4 (pyramid), NE-Z4SH (threaded)
- Application range & Weight limit: ～K3(MOB3):125kg(275 lb)
  K4(MOB4):100kg(220 lb)
- Weight: 1510g(NE-Z4)/1500g(NE-Z4SH)
- Maximum flexion angle: 155°
- Water resistance: IP42
- Internal power supply: Lithium ion battery
- Communication distance: Within 2 m
- Usage temperature: -10℃/+14℉ ～ +40℃/+104℉

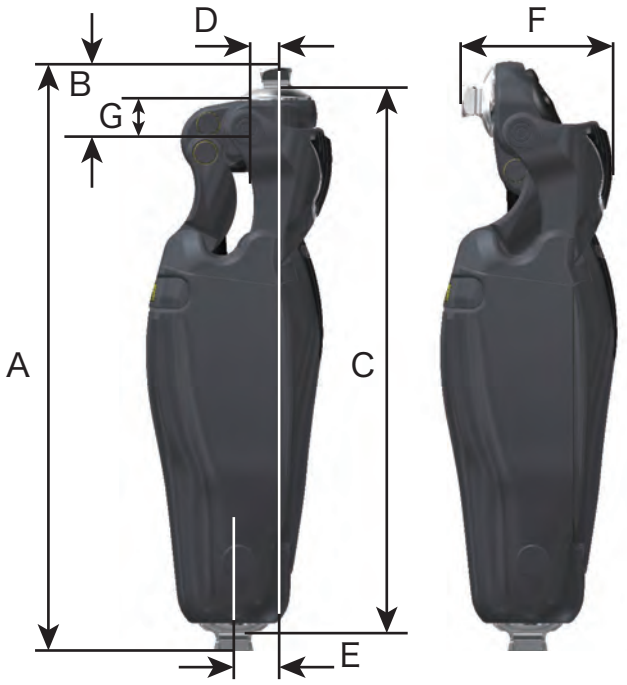
CAUTION

■Note that with the above temperature operating range the hydraulic resistance will decrease at higher temperatures and increase at lower temperatures.
Normal walking will not be supported, possibly resulting in a fall.

- Dimensions：

	NE-Z4	NE-Z4SH
A	295mm	287mm
B	30mm	22mm
C	268mm	266mm
D	15mm	15mm
E	21mm	21mm
F	76mm	68mm
G	16.5mm	14mm

※ 1 inch = 25.4mm



※ The above specifications are subject to change without prior notice for product improvement.

3 Before Use

3.1 Parts list

The package of ALLUX™ contains the following parts. Confirm whether everything is included.

【Main body and accessories】

ALLUX™ NE-Z4	1 pc.	
Instruction manual	1 copy	81-SS00098E(this document)
User's Guide	1 copy	81-SS00099E
Backup battery case NE-SC01	1 pc.	

【Designated devices】

Remote controller NE-RC02	1 pc.	
Charging port cap NE-CC01	1 pc.	
Power OFF cap NE-CC02	1 pc.	
Backup battery NE-SB01	1 pc.	
Extension cable NE-CL02	1 pc.	
Charger NE-BC01	1 pc.	
AC adapter NE-AD01	1 pc.	
Plug adapter(UL) NE-PA01	1 pc.	
Backup batterycharging cable NE-CL01	1 pc.	

NOTICE ■Do not use non-designated peripheral devices.
That might cause a crash of ALLUX™.

3 Before Use

3.2 Preparation for adjustment

Install ALLUX™ software on the personal computer to be used for adjustment of ALLUX™.

3.2.1 Usage environment of ALLUX™ software

●Compatible OS
- Windows 7, Windows 8, Windows 8.1, Windows10

●Hardware
- A set of personal computer on which Microsoft Windows 7 or later can operate.
- A monitor which can display at a resolution of 1024 × 768 dots or more
- One free USB port compatible with USB1.1 or later
- Intel Core i3 CPU or later
- Built-in memory: 4GB or more
- Hard disk in C drive

  For 32-bit Windows: 700MB or more

  For 64-bit Windows: 1.6GB or more

  Note) If Net Framework has been installed, free space of 100MB or more is required.

NOTICE ■An environment other than those outlined above may cause software issues.

3.2.2 Preparation of ALLUX™ software

The following accessories are required to adjust ALLUX™.

●Instruction manual (this document)

●USB for installation of ALLUX™ software

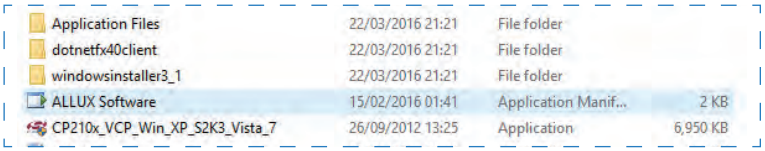
●Wireless dongle

NE-UD02	1 pc.	

3 Before Use

3.2.3 Installing the ALLUX™ software

●Opening the attached folder reveals the following files.



●Open the "CP210x_Windows_Drivers" folder.

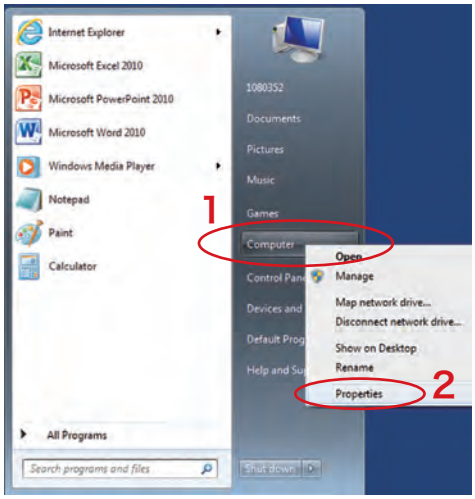
●If your computer environment is 32 bit then double click "CP210xVCPInstaller_x86.exe" to install. If your computer environment is 64 bit then double click "CP210xVCPInstaller_x64.exe" to install.

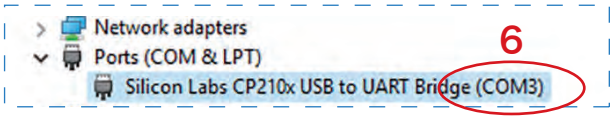
●The installation will require the computer to be rebooted.

●Insert the wireless dongle into a USB port on the computer and verify that it has been recognized by the device manager. More specifically, verify that "Silicon Labs CP210x USB to UART Bridge" is displayed next to the com port within Ports (COM & LPT).

■Confirming the OS bit number and COM port (can vary depending on the computer environment).
With Windows 7 and 8:

1. Click the 'Start' button and then right click on 'Computer'.
2. Click 'Property'.
3. Check the number of bits described to the right of "System type".
4. Insert the wireless dongle.
5. Click Device Manager.



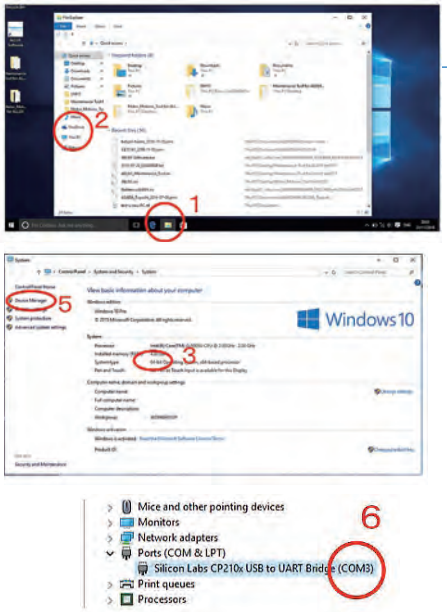


6. Check the COM port to the right of "Silicon Labs CP210x USB to UART Bridge".

3 Before Use

With Windows 10:

1. Click the folder icon on the task bar.
2. Right click "This PC" on the left of the screen and click "Properties".
3. Check the number of bits described to the right of "System type".
4. Insert the wireless dongle.
5. Click Device Manager
6. Check the COM port to the right of "Silicon Labs CP210x USB to UART Bridge".



●The files are available in various languages. Select the file in the language to be used from the following list.

File name	Language	File name	Language
setup.exe	English	setup_ko.exe	Korean
Setup_da.exe	Danish	setup_nl.exe	Dutch
setup_de.exe	German	setup_no.exe	Norwegian
setup_es.exe	Spanish	setup_pt-BR.exe	Portuguese
setup_fi.exe	Finnish	setup_ru.exe	Russian
setup_fr.exe	French	setup_sv.exe	Swedish
setup_it.exe	Italian	setup_tr.exe	Turkish
setup_ja.exe	Japanese	setup_zh-Hans.exe	Chinese

●Click “setup_**.exe,” and install ALLUX™ software.
●Microsoft NET Framework will be simultaneously installed.
*If it has been installed, the installation will be completed in a few seconds.
*If it has not been installed, it may take several tens of minutes, and it may be required to restart the PC.
●After the completion of installation, select the language on the language selection screen.
*The “language” refers to the language to be used on ALLUX™ software.
●ALLUX™ software will automatically start.
*The language can be selected later.
*The shortcut to ALLUX™ software will be automatically created on the desktop.

3.2.4 When Uninstalling the ALLUX™ software

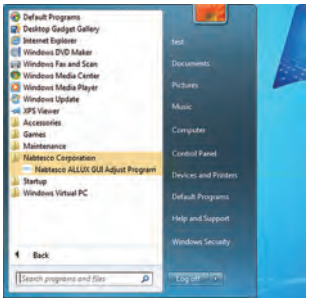
●Start Uninstall Programs in the control panel.
●Select “ALLUX Software” and execute Uninstall and Change.
*The wireless dongle driver and “.NET Framework” will not be deleted.
*The wearer information created by ALLUX™ software will not be deleted.
*The wearer information can be deleted by opening My Documents folder and deleting the folder “ALLUXDATA.”

3 Before Use

3.2.5 Starting the ALLUX™ software

- Insert the wireless dongle into the USB port of the PC.
- Start ALLUX™ software. (Double-click the “ALLUX Software” icon, or start from “Nabtesco Corporation” in the Start Menu.)
  *If the wireless dongle is removed while ALLUX™ software is starting, an error will occur. Restart ALLUX™ software after inserting the wireless dongle.

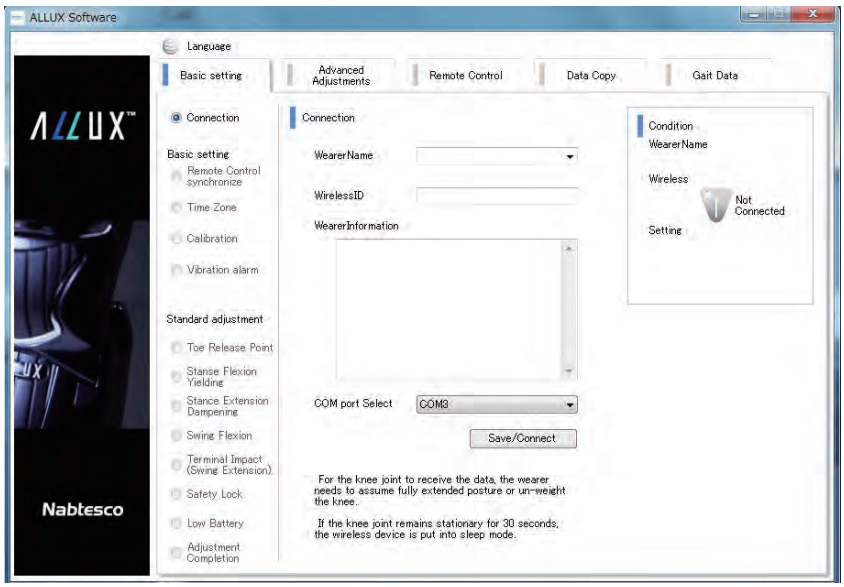
Shortcut on desktop



All Programs in Start Menu

- The following window will appear. Press Enter.

- ALLUX™ software will start, and the following screen will appear.
  If the data on the screen are displayed in a language other than English, press the Language button in the upper left corner, and change the language.



3 Before Use

3.2.6 Connecting the communication with ALLUX™

- Enter the name of user of ALLUX™ or an identifiable name in the “Wearer Name” field.
- Enter the wireless ID shown on the warranty.
  *Enter the Wearer Name, and click Save/Connect. Then, the wireless ID and user name will be automatically saved in the “Wearer Name” folder.
  *Once the name is entered, it can be selected from the combo box from the next time.
  *It is also possible to select a displayed wearer and change the ID.
  *Another person with an identical name cannot use the folder.
- Enter any comments in “Wearer Information.”
  *Adjustment work can be performed even if no comments are entered.
- Select the port connected with the wireless dongle from the “COM port Select” combo box.
  * If the COM port is unknown, check the Windows device driver.
- Press the Save/Connect button.
- The icon being connected will be displayed on the status sheet in the upper right, and the screen will change to another.
  * The screen does not change in the following cases. Check, and reconnect them.
  ① ALLUX™ is in the sleep mode.
  ⇒Flex and extend ALLUX™ to make ALLUX™ ready for wireless communication.
  Or, insert and remove the power OFF cap, and then wait for 5 seconds to make ALLUX™ ready for wireless communication.
  ② The COM port Select is incorrect.
  ⇒The COM port can be found in the Windows device driver.
  ③ The wireless ID is incorrect.
  ⇒Check the wireless ID shown on the warranty.
  ④ The distance between ALLUX™ and wireless dongle is long.
  ⇒Communication can be established when the distance is less than 2 m.

3.2.7 When communication with ALLUX™ is disconnected

Communication is easily disconnected in places, such as TV towers and airports, where the communication radio wave intensity is high, or around medical devices which emit strong electromagnetic waves. If ALLUX™ is adjusted in such a place, keep the knee joint at a distance of less than 2 m from the personal computer for adjustment, and press Reconnection. (For the connecting method, see 3.2.6.)
If the battery level in the main body of ALLUX™ is low, communication may be frequently disconnected. If the battery level is low, charge the battery before starting the communication.
※If the knee is disconnected and goes to sleep,flex and extend the knee.

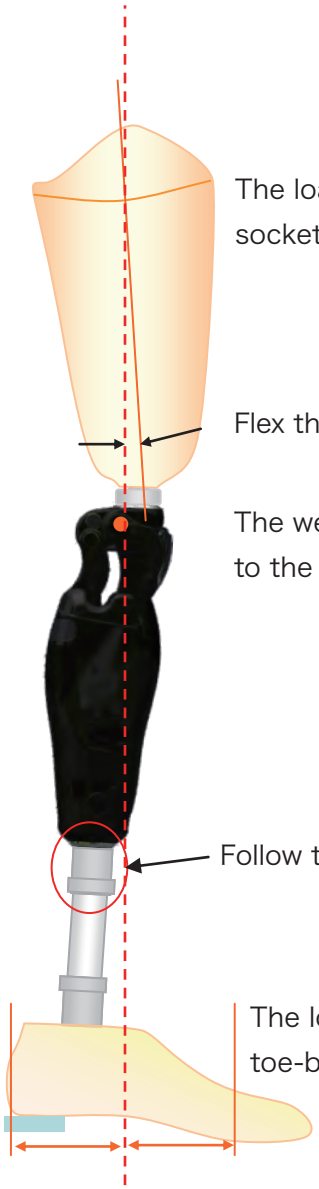
4 Assembly Procedures

4.1 Static alignment

With load and fully extended (assembled using the bench alignment shown in the figure below.
Assemble according to the bench alignment shown below.

CAUTION

■Assemble the adapter under the knee joint straight without adjusting the angle.
If the adapter is contacted to the frame while assembling, the user may not walk normally.



The load line must pass through mid line of the socket at the top of the socket.

Flex the longitudinal axis of the socket at an angle of 3 to 5º.

The weight line must pass 0 ± 5 mm anterior or posterior to the knee axis (upper front axis).

Follow the distal pyramid angle.

The load line passes through the center between the toe-break and the heel end.

4 Assembly Procedures

4.2 Contact with socket at maximum flexion angle

The maximum flexion angle of ALLUX™ is 155º.

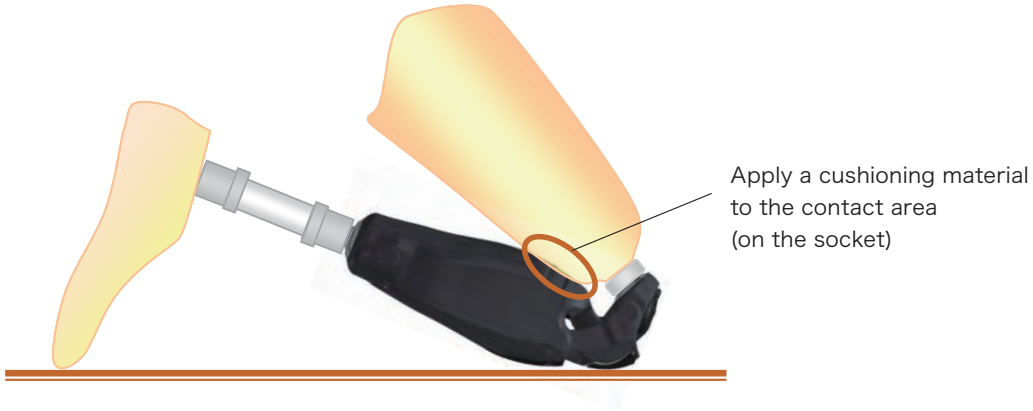
NOTICE

- Design the socket to ensure that the user's foot is in contact with his/her buttock at the maximum flexion angle.
- When inevitable that an adapter such as a socket or pipe will come in contact with the knee joint then ensure to use some form of cushioning (elastic material such as rubber) in the socket to avoid any direct contact.

If any of the above requirements cannot be met, give the following instructions to the user.

(1) Do not apply a strong impact to the knee joint at bending the knee in the maximum flexion angle.

(2) Do not apply a load heavier than the body weight at bending the knee in the maximum flexion angle.



4.3 Using the extension cable

When a foam cover is used then the connectors can be used without having to remove the cover via the included extension cable (NE-CL02).
Charging and auxiliary battery can be used via an extension cable.

NOTICE

- Make sure that the extension cable end is not exposed to water.
- Connect the extension cable so that the cable will not get caught when the knee joint is flexed.
  The battery may short-circuit, could result in a malfunction.

5 Selective Modes by Remote Controller

5.1 ALLUX™ operational modes

ALLUX™ has five operational modes.

1.Normal 2.Flexion angle limit 3.Variable selective flexion lock
4.Full extension lock 5.Free swing

Use the remote controller to change the operational modes. The optional buttons on the remote controller can be customized as appropriate.

5.2 Operation with the remote controller

The operational mode can be selected with the remote controller (NE-RC02). To change modes, hold the button on the remote controller for longer than 1.5 seconds within 120 seconds of bending and stretching the knee or removing the body weight and then applying it while standing in safe posture.(See 6.1) To return to the normal mode, press the '1' button on the remote controller. The remote controller requires two AAA batteries. Please replace the batteries if the remote controller does not work properly, or within a year.

WARNING

- Wear the remote controller to avoid the button from being pressed accidentally.
  Unintentional switching of the mode could result in falling over.
  * A vibratory alert will occur when the mode is switched. If an unintentional vibratory alert occurs then ensure to verify whether a remote control malfunction has occurred.

NOTICE

- Please do not use the remote control anywhere radio waves are prohibited, for example aircraft etc.
- Connecting and disconnecting the charger or power off cap will result in the ALLUX ™ returning to the normal mode set using the '1' button on the remote controller.
  Please exercise caution as the status may differ before and after charging.

- Assume safe posture. (See 6.1. Safe posture)
- Push an optional button (1-5) of the remote controller for over 1.5 seconds, vibration will sounds for 2 seconds.
- The selected mode is applied.

5 Selective Modes by Remote Controller

5.3 Normal Mode

5.3.1 Overview

The normal mode is adjusted for normal walking. Judging various walking situations and normal motions with the sensor, ALLUX™ automatically adjusts the bending or stretching resistance.

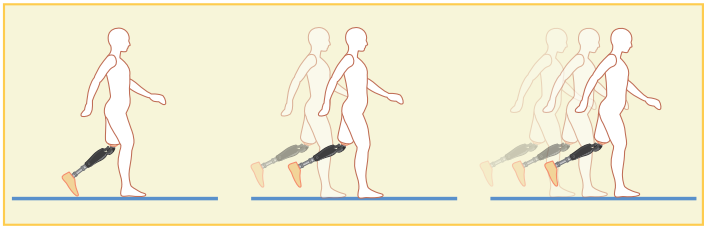
5.3.2 Yield Function

In the following situations, ALLUX™ yields, increasing bending resistance and allowing knees to bend slowly.

Standing | Sitting down | Standing up | Going down steps | Going downhill

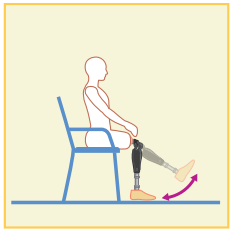
5.3.3 Walking speed auto-adjust function

ALLUX™ automatically adjusts the bending and stretching resistance according to walking speed.



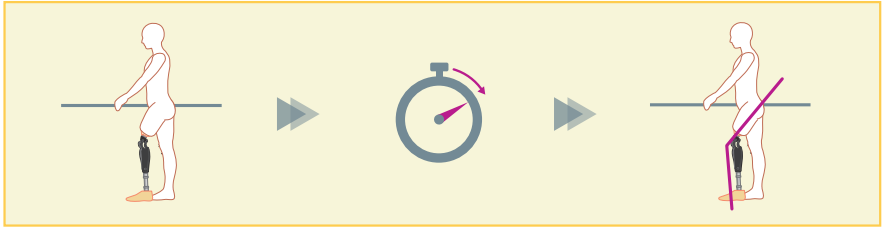
5.3.4 Seated position

When in a seated position, ALLUX™ maintains no resistance in bending or stretching.



5.3.5 Safety lock

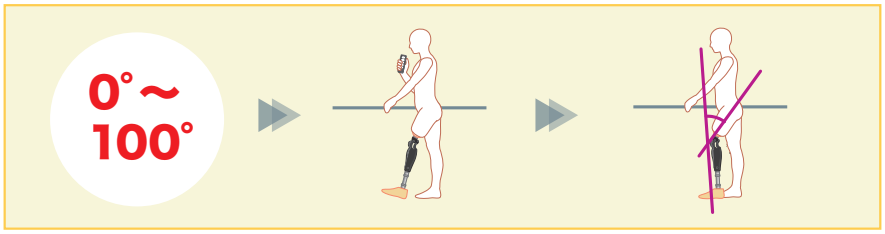
When under a burden and knees are bent continually for a few seconds, ALLUX™ locks the bending resistance at a certain angle. (This function can be turned off or the sensitivity can be adjusted.See 6.12)



5 Selective Modes by Remote Controller

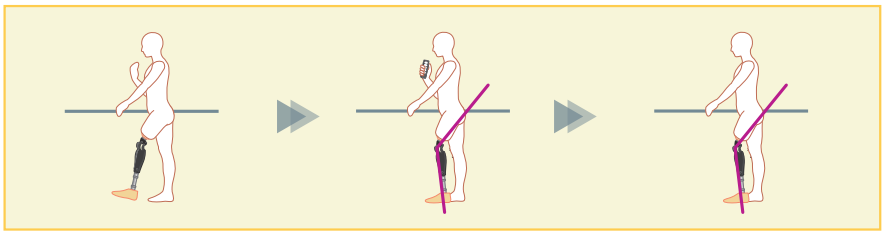
5.4 Flexion angle limit mode

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



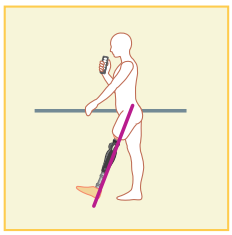
5.5 Variable selective flexion lock mode

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



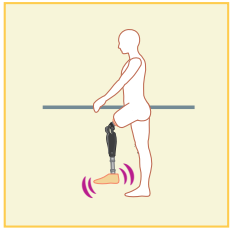
5.6 Full extension lock mode

Knees are locked in a fully extended state. To change modes using the remote controller once locked, put your weight on the ALLUX™ and then remove it.



5.7 Free swing mode

In free swing mode, the knee is kept free.

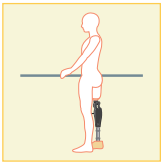


6 Adjustment Procedures

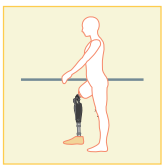
6.1 Safe posture and condition ready for communication

'Safe posture' refers to the posture taken in order to change the mode before using the remote controller or communicating with the ALLUX™ software. Explain to the user about safe posture.

【Safe posture】



:State where ALLUX™ is straight and upstanding and may be subject to weight loading



:State where ALLUX™ is not subject to weight bearing and the knee may be flexed

【Request for safe posture】

If ALLUX™ is not in the safe posture when data is transmitted during adjustment, a popup will be displayed. Make sure the user is demonstrating safe posture, and press OK.

CAUTION

- 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 ALLUX™, he/she must hold a handrail or sit down. Flexion/extension resistance may suddenly change, leading to a fall.

ALLUX™ software displays the safety icons as below.

6 Adjustment Procedures

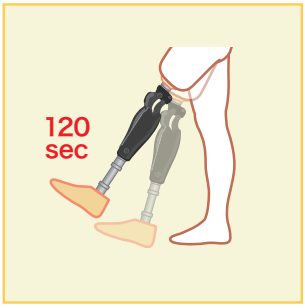
In order to conserve power, ALLUX™ is not always in communication mode. Communication mode is activated in ALLUX™ 120 seconds after lightly bending and extending, or 120 seconds after applying your body weight and then removing it. Communication cannot be established while walking. Once ALLUX™ communication is established, this state lasts until communication is disconnected.

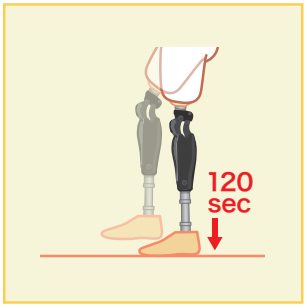
【Communication mode enabled:】

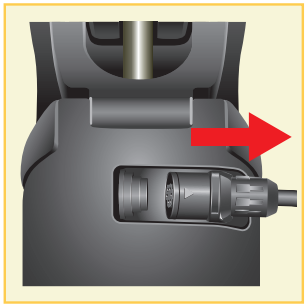
①For 120 seconds after ALLUX™ is slightly flexed and extended

②For 120 seconds after the user applies his/her body weight to ALLUX™

③For 120 seconds after the charger or power OFF cap is disconnected from ALLUX™







ALLUX™ software displays the communication state icons as below.

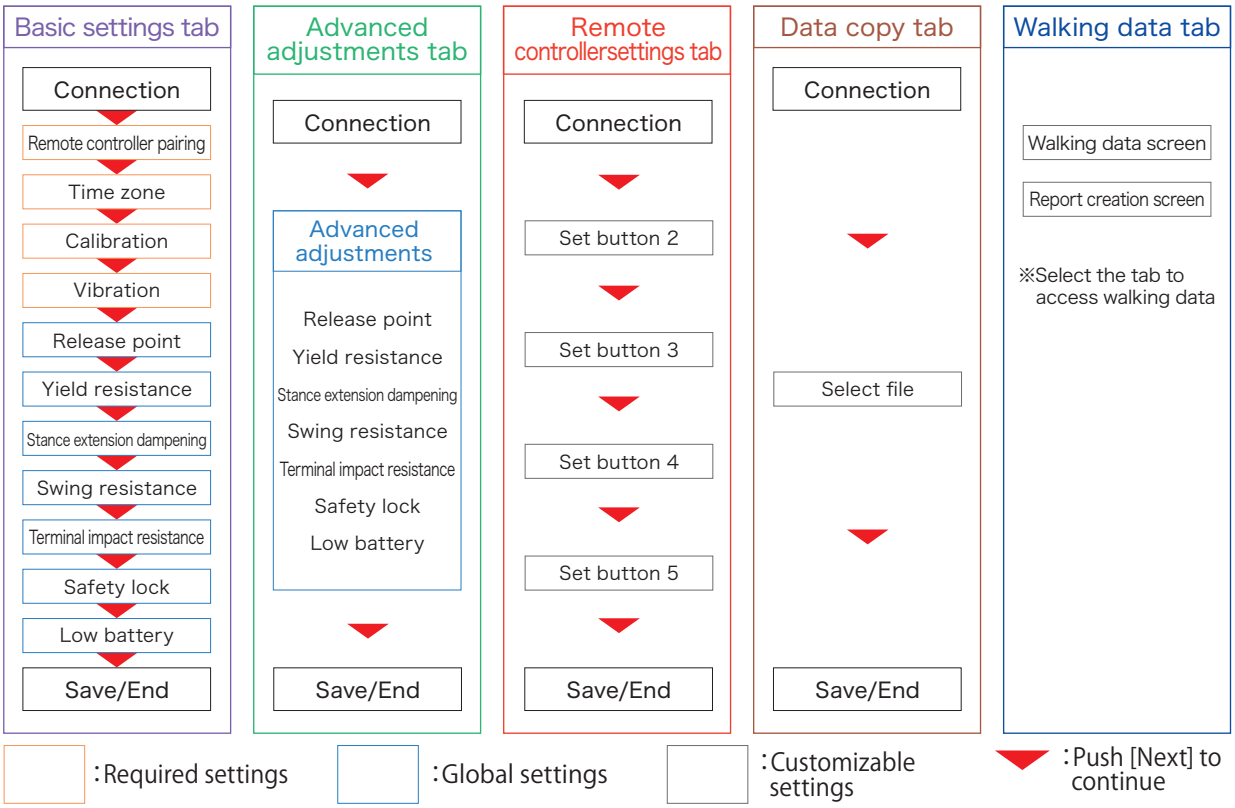
Not connected

Connected

6 Adjustment Procedures

6.2 Adjustment Procedures

Adjustments are undertaken in the following steps.



After the initial settings are completed adjustments can be made from the 6.15 Collective Setting Screen.

Default remote controller configuration:
Button 1: Normal mode
Button 2: Flexion angle limit mode
Button 3: Variable selective flexion lock mode
Button 4: Full extension lock mode
Button 5: Free swing mode

Adjustment is not necessary when the default setting is used.
6.16 “Remote controller settings” explains how to change the remote controller settings.
6.17 data copy to used to apply previously adjusted data.
6.18 “Walking data” shows the number of steps for each walking speed.

6 Adjustment Procedures

6.3 Pairing with remote controller

When using ALLUX™ for the first time, it is necessary to synchronize the remote controller and the prosthesis. When a bilateral leg amputee uses two ALLUX™, it is necessary to pair each of them with a remote controller, and two remote controllers are used.

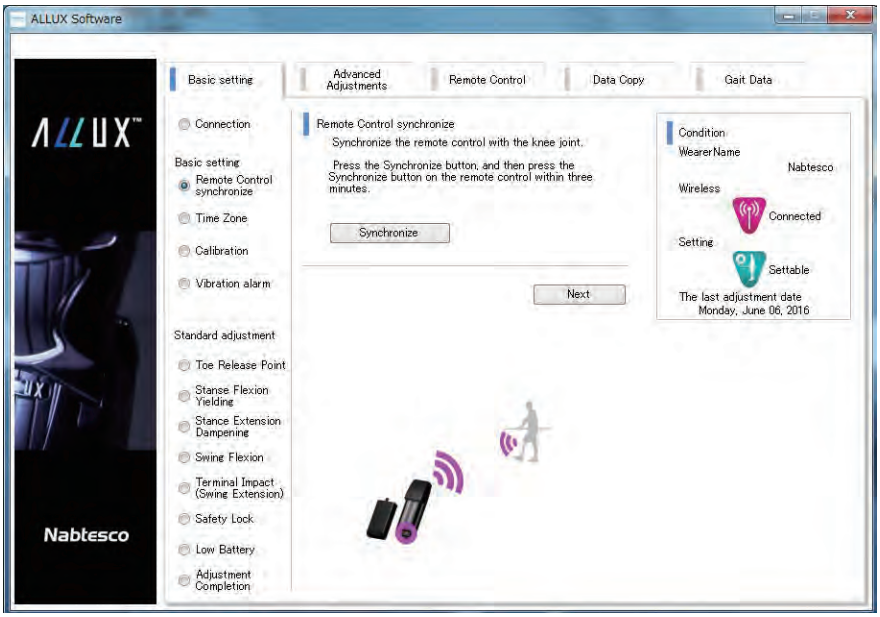
- Remove the remote controller battery cover.
- Press the remote controller synchronize button in the Basic setting tab.
- After a popup appears, hold down the remote controller pairing button for 1.5 seconds or more.

  *Pairing button: Red button on remote controller shown on the ALLUX™ software screen

- The ALLUX™ will vibrate.

  *If ALLUX™ and wireless dongle are apart from each other, radio waves cannot be received, and ALLUX™ and remote controller cannot be paired. Keep them at a distance within 2 m.
- Press the OK button in the popup.

  Once they are synchronized, it is unnecessary to synchronize them again.

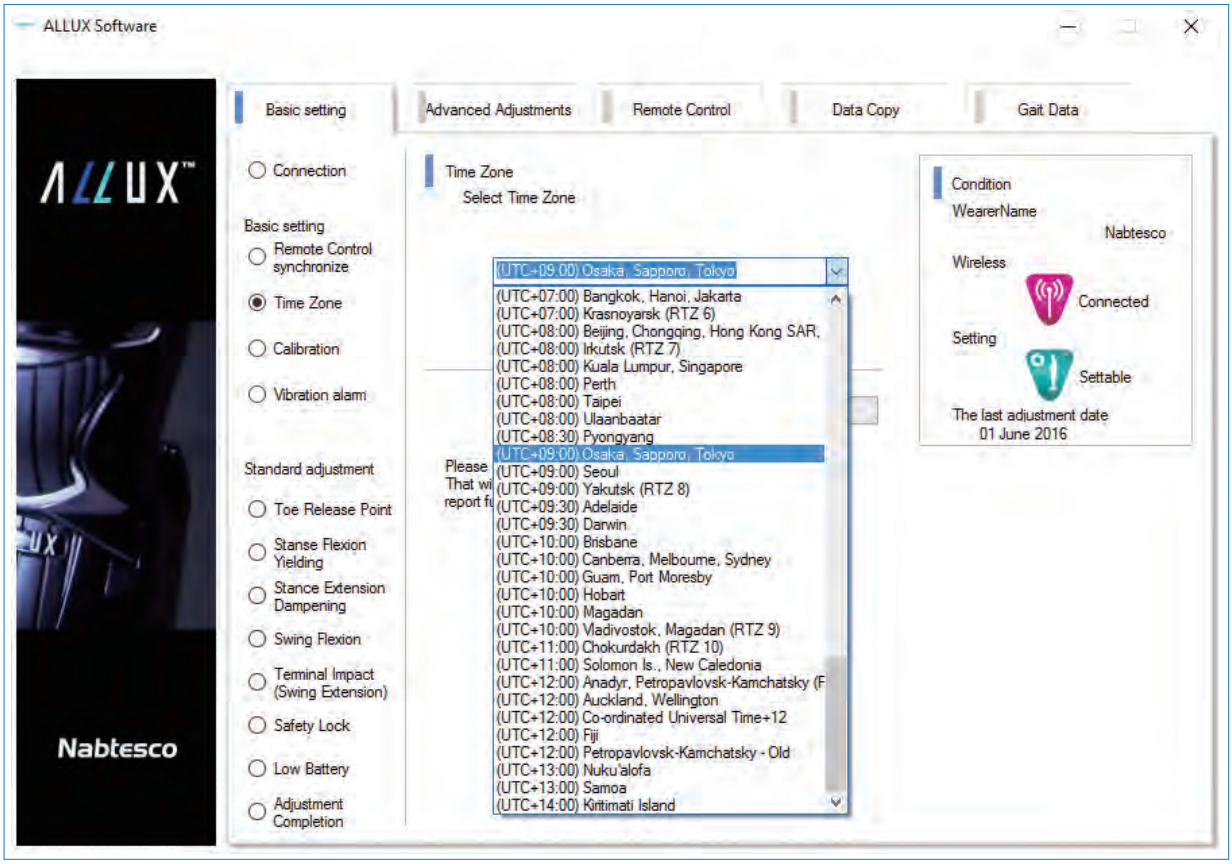


6 Adjustment Procedures

6.4 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). When used outside Japan, please change the time zone to reflect the local time.

●Select the local time zone from the time zone list.



Once the time zone is set, the setting is maintained. Overseas trips will not require the time zone being reset but the change in date will be based on the time zone selected here.

6 Adjustment Procedures

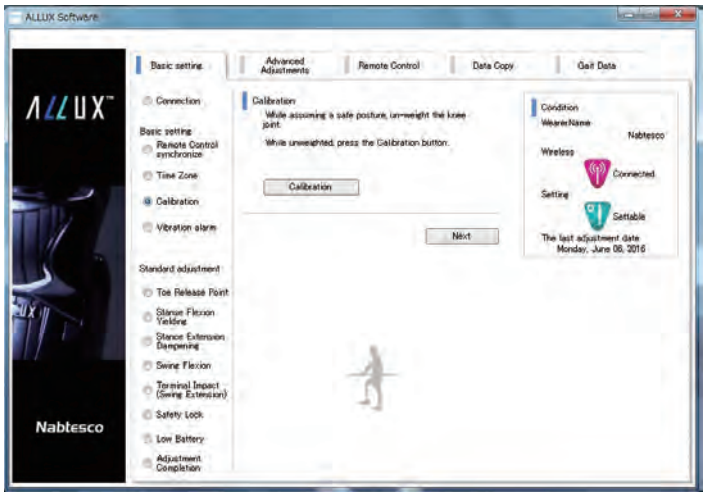
6.5 Calibration

When ALLUX™ is used for the first time or re-aligned or the foot part is replaced, perform calibration again.

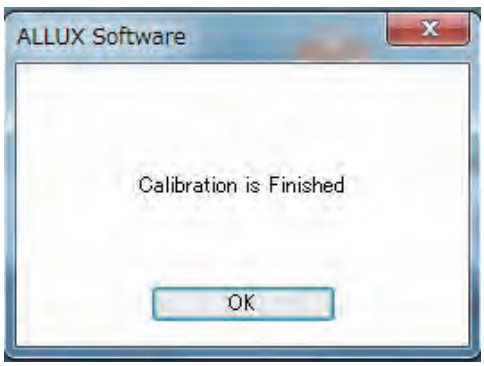
WARNING

- Calibrate ALLUX™ in the correct posture.
  If it is calibrated under load, the user cannot walk normally and may tumble, resulting in a serious accident.
- When calibrating, ensure the user's safety.
  The user must stand on one foot in an unstable state and may tumble.
- Calibrate in a state that is as close as possible to that of normal use.
  If conditions are not the same, ALLUX™ may not work properly.
- Apply the release point setting (see 6.7) after calibration.
  The setting value of the optimal release point may change and normal walking may be impossible.

- Press the Calibration button in the Basic setting tab.
- Keep ALLUX™ free from load.
  *The user must hold parallel bar type handrails or sit in a chair to ensure his/her safety.
- Press the Calibration button.



- The calibration completion popup will appear.
- Press the OK button.



6 Adjustment Procedures

6.6 Confirmation of vibration

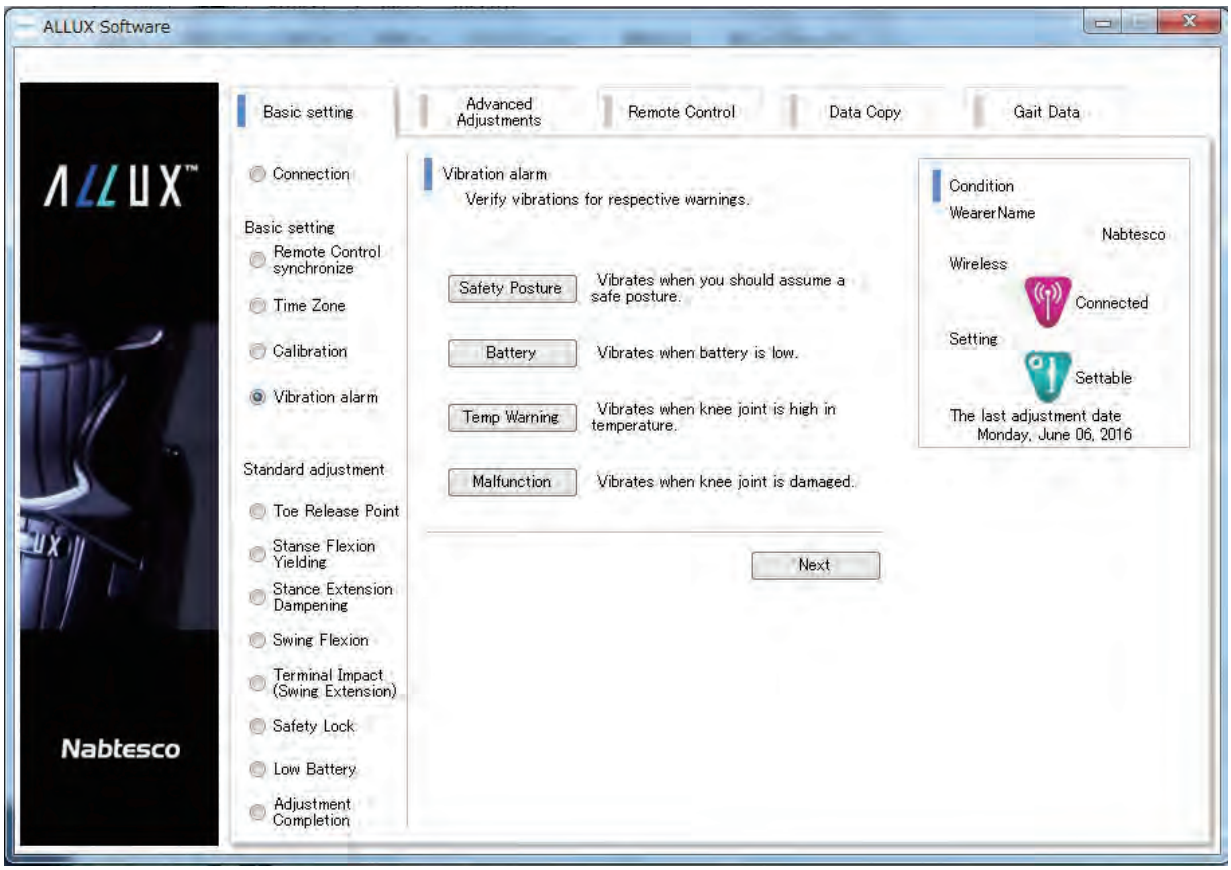
ALLUX™ vibrates with various intensity to notify or warn the user. Ensure that the user understands the various vibrations.

WARNING

■Make sure the user vibrations and understands the differences. If the user uses ALLUX™ 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 knee is locked when he/she tries to walk.

- ●Press the Vibration alarm button in the Basic setting tab.
- ●Press Safety Posture, and confirm the vibration.
- ●Press Battery, and confirm the vibration.
- ●Press Temp Warning, and confirm the vibration.
- ●Press Malfunction, and confirm the vibration.

*Each vibration is explained on the displayed screen. For the details, see 7.4.



6 Adjustment Procedures

6.7 Setting 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.

CAUTION

■Check the walking condition in a place, e.g. in parallel bars, where the user's safety can be ensured.
If the knee cannot smoothly shift to swing phase, user may fall.

●Press the Toe Release Point button in the Basic setting tab.

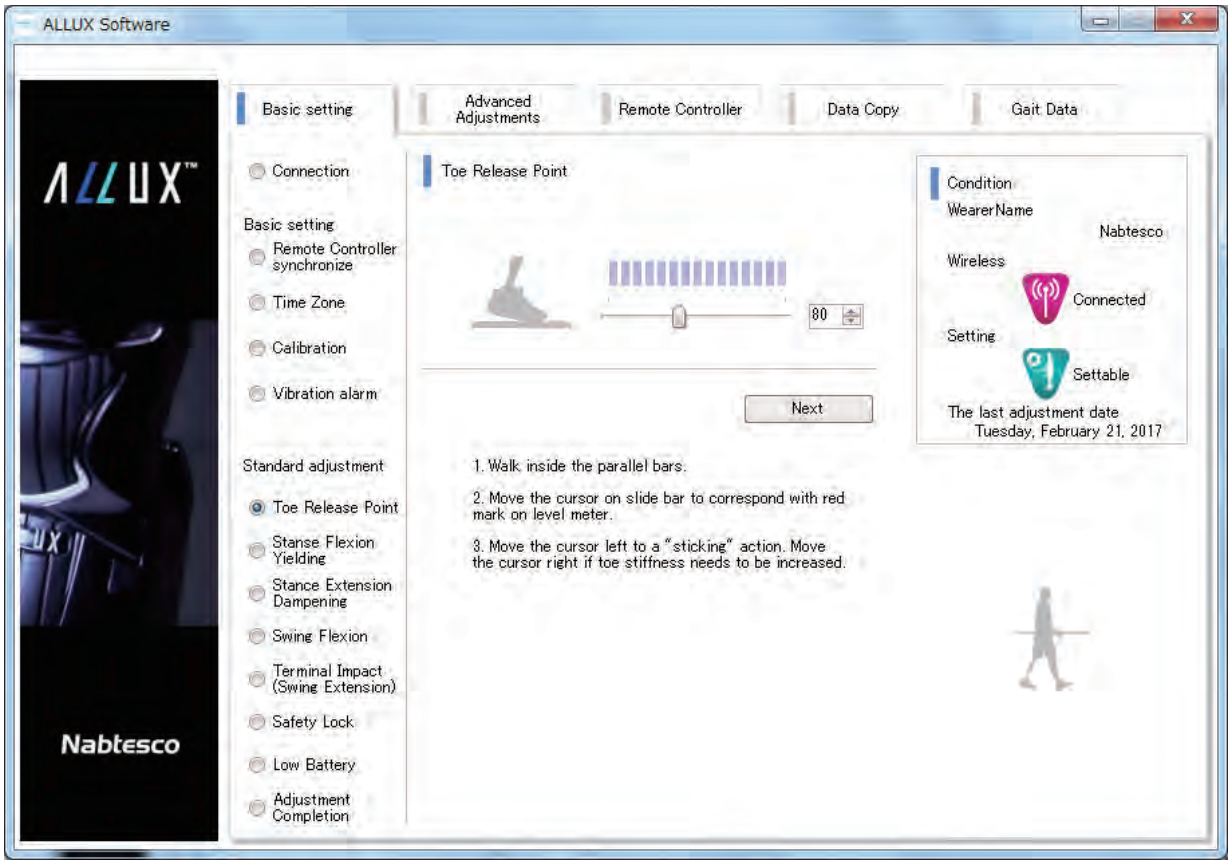
●Make the user walk in the parallel bars.

●Set the cursor under the red line displayed in the release point gauge.

*If the user walks with small strides and the knee jams easily, move the cursor to the left.

*If the knee flexes earlier and is unstable at the heel-off phase, move the cursor to the right.

●After the completion of adjustment, press Next.



6 Adjustment Procedures

6.8 Setting the yielding resistance

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

Adjust the yielding resistance so that the user's weight is applied equally to both feet when the user sits on a chair. If the resistance is high when the user goes down a slope or stairs, gradually decrease the resistance in a state where the user's safety is ensured. It is recommended to adjust the resistance at a normal temperature (+20℃/+68℉).

WARNING

■When ALLUX™ is used in a low-temperature environment (0℃/+32℉ or less), the yielding resistance may be increased. Check the yielding resistance before starting use in a low-temperature environment. Since the knee cannot be easily flexed, the user may fall when walking down stairs.

CAUTION

■Do not touch any moving part when the user stands up.
Risk of injury from your hand being caught in the knee joint.

■Test it on stairs or slopes after the completion of all adjustments.
If the adjustments have not been made sufficiently, the user may fall.

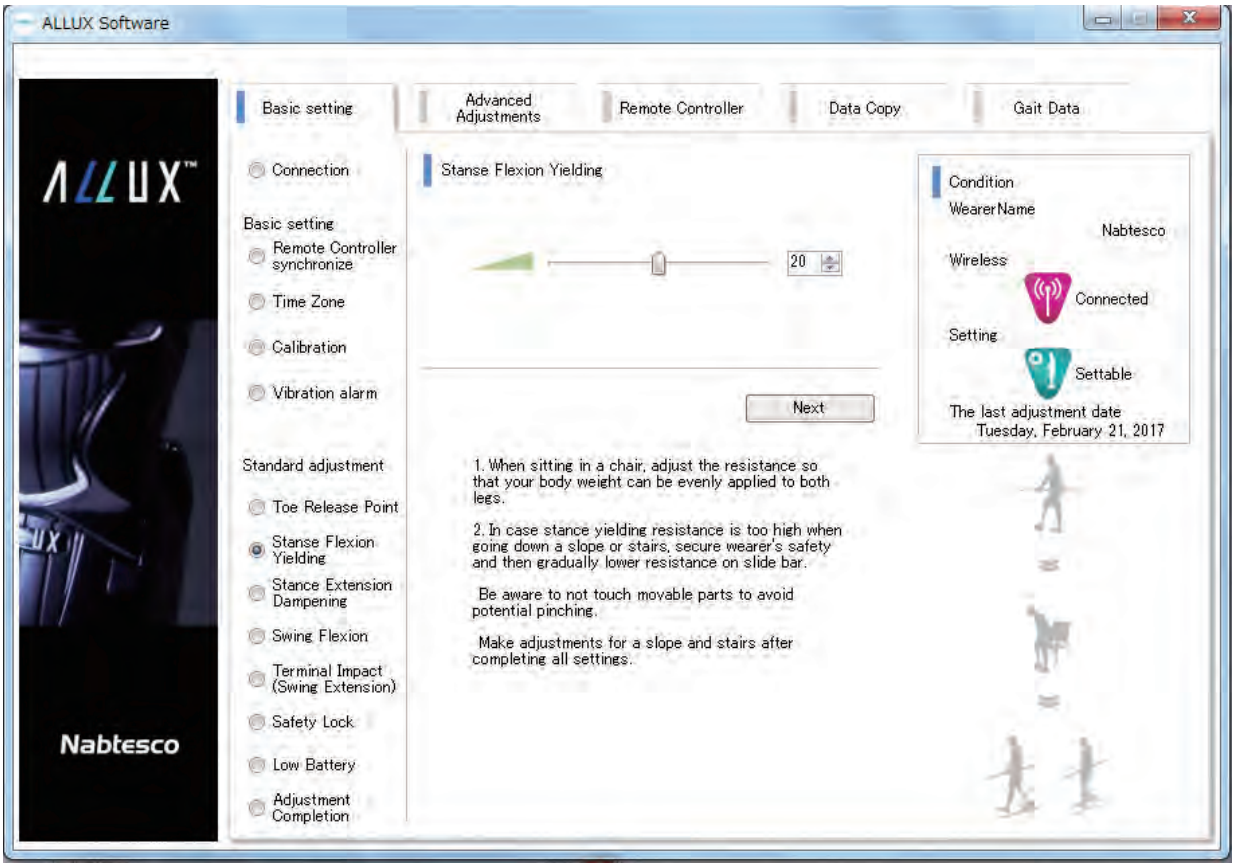
●Press the Stance Flexion Yielding button in the Basic setting tab.

●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, move the cursor to the right.
* If the resistance is high, move the cursor to the left.

6 Adjustment Procedures

●After the completion of adjustment, press Next.



6 Adjustment Procedures

6.9 Setting the stance extension dampening

Factory default setting = 5 (Standard value:5～15)

Normally, set the extension resistance in stance phase to 5, no resistance state. Adjust the resistance only when the user uses the double knee motion. It is recommended to adjust the resistance at a normal temperature (+20˚C/+68˚F).

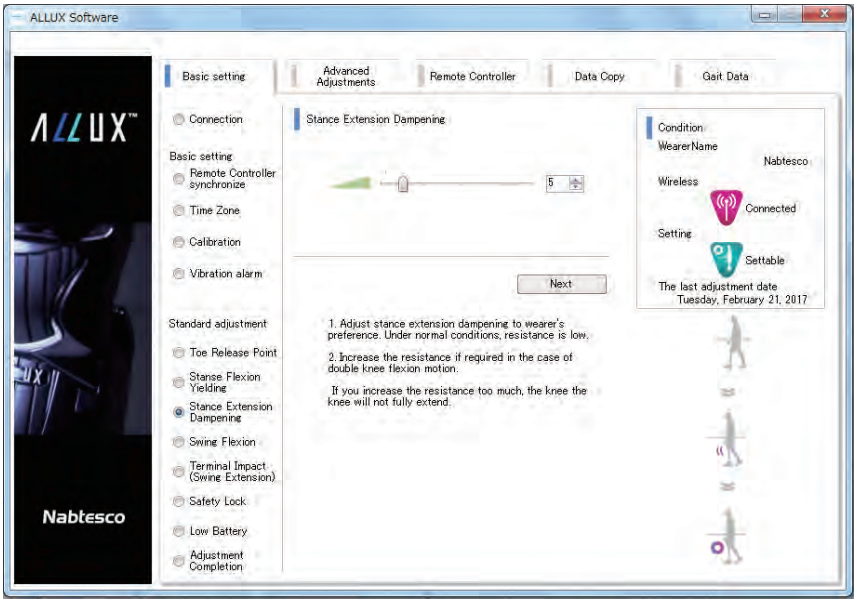
WARNING

- When ALLUX™ is used in a low-temperature environment (0˚C/+32˚F or less), the stance extension dampening may be increased. Check the double knee resistance before starting use in a low-temperature environment. Since the knee cannot be easily extended, ALLUX™ may jam when shifting to the swing phase.

CAUTION

- 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. ALLUX™ cannot shift to the swing phase in the flexed state for double knee motion, and the user may fall if it jams.

- Press the Stance Extension Dampening button in the Basic setting tab.
- Adjust the resistance for stance extension dampening.
  * If the resistance is low, move the cursor to the right.
  * If the resistance is high, move the cursor to the left.
- After the completion of adjustment, press Next.



6 Adjustment Procedures

6.10 Setting the swing resistance

Factory default setting = 20 (Standard value:15~30)

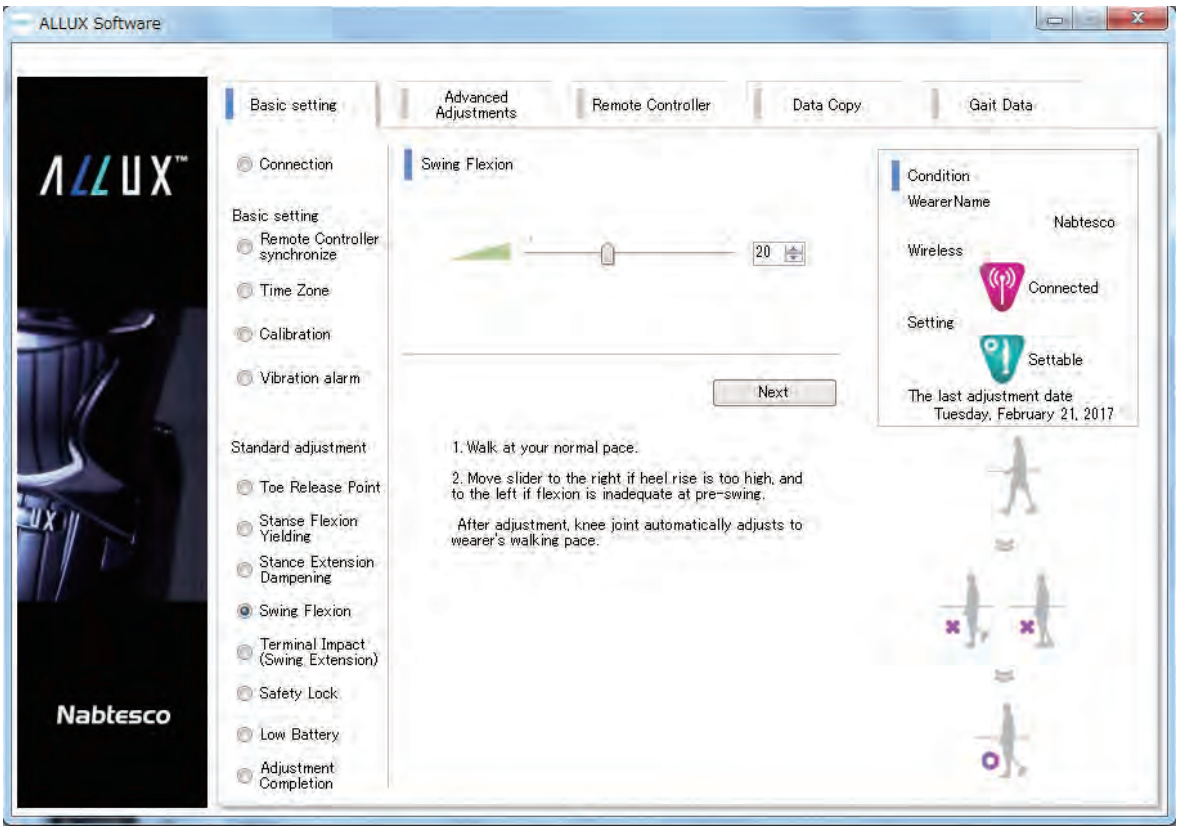
Adjust the flexion resistance in the swing phase. After the resistance is adjusted based on the normal walking speed, the knee joint will automatically adjust the flexion resistance according to the walking speed.

CAUTION

■Check the walking condition in a place, e.g. in parallel bars, where the user's safety can be ensured.
When the user walks faster, ALLUX™ cannot shift to the swing phase, and the user may fall if it jams.

*If ALLUX™ jams (cannot shift to the swing phase) and the user cannot walk, re-adjust the toe release point as stated in 6.7

●Press the Swing (Swing Flexion) in the Basic setting tab.
●Adjust the swing resistance for normal walking speed.
* If the resistance is low, move the cursor to the right.
* If the resistance is high, move the cursor to the left.
●After the completion of adjustment, press Next.



6 Adjustment Procedures

6.11 Setting the terminal impact

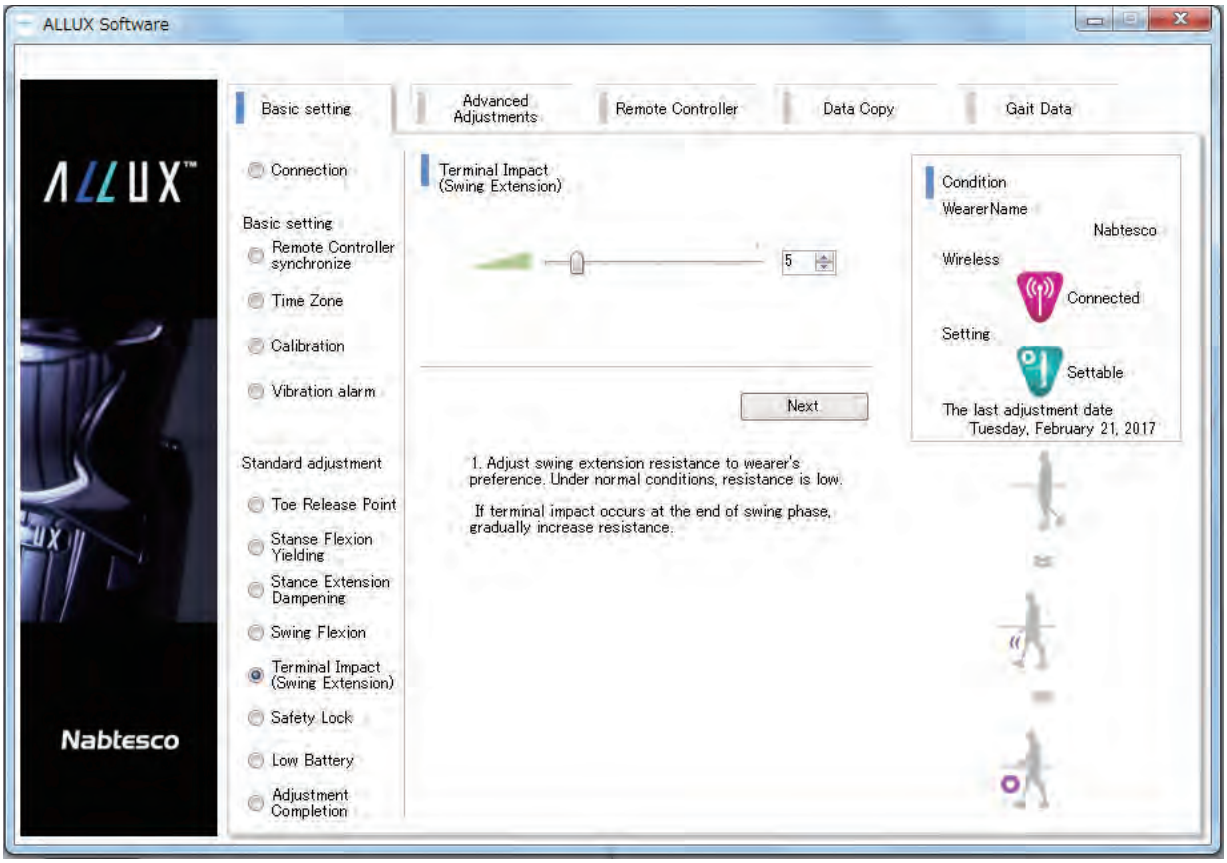
Factory default setting = 5 (Standard value:5～15)

Adjust the extension resistance in the swing phase. If terminal impact occurs, set the resistance gradually increasing it. After the resistance is adjusted based on the normal walking speed, the knee joint will automatically adjust the extension resistance according to the walking speed.

CAUTION

■Check the walking condition in a place, e.g. in parallel bars, where the user's safety can be ensured.
If the resistance is set too high, the knee cannot extend completely, and the user may fall.

●Press the Terminal Impact (Swing Extension) button in the Basic setting tab.
●Adjust the terminal impact resistance for normal walking speed.
* If the resistance is low, move the cursor to the right.
* If the resistance is high, move the cursor to the left.
●After the completion of adjustment, press Next.



6 Adjustment Procedures

6.12 Setting the safety lock

Factory default setting = Invalid

The safety lock is designed to lock the knee at a flexed angle in which the user stops for a certain time with the knee bent under a certain level of weight. To use the safety lock, enable it.

CAUTION

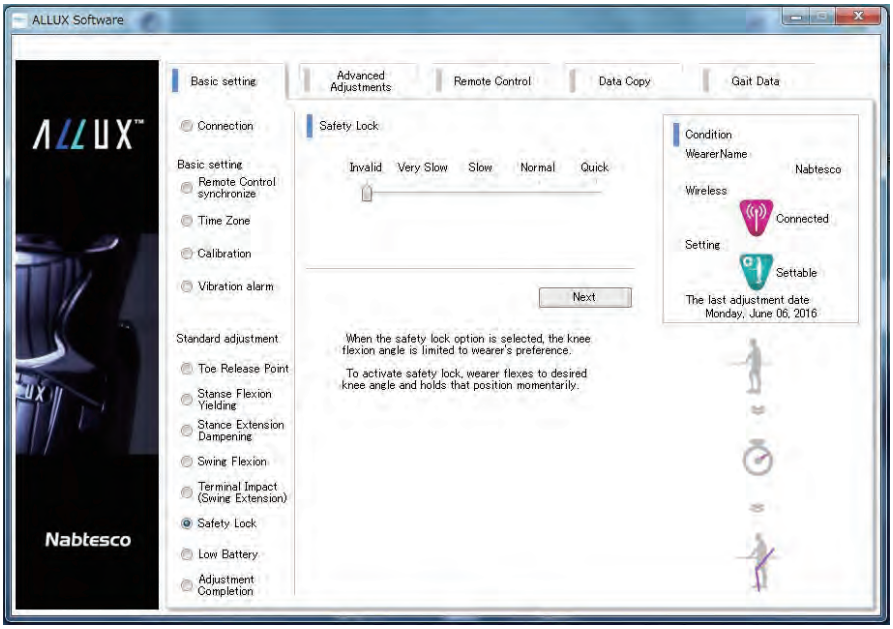
■Check the function in a place, e.g. in parallel bars, where the user's safety can be ensured.
If the user is not familiar with the safety lock, he/she cannot lock the knee joint, and his/her knee may be bent.

*Before setting the safety lock, ensure that the user understands the function and is sufficiently trained.

●Press the Safety Lock button in the Basic setting tab.
●Adjust the sensitivity of the safety lock. If Quick is pressed, the knee will lock even with a short-term suspension.
* If Deactivated is pressed, the safety lock will not function.
●After the completion of adjustment, press Next.

CAUTION

■Test normal motions and see if it works properly for use.
If Quick is pressed, the knee may lock when seated.



6 Adjustment Procedures

6.13 Low battery settings

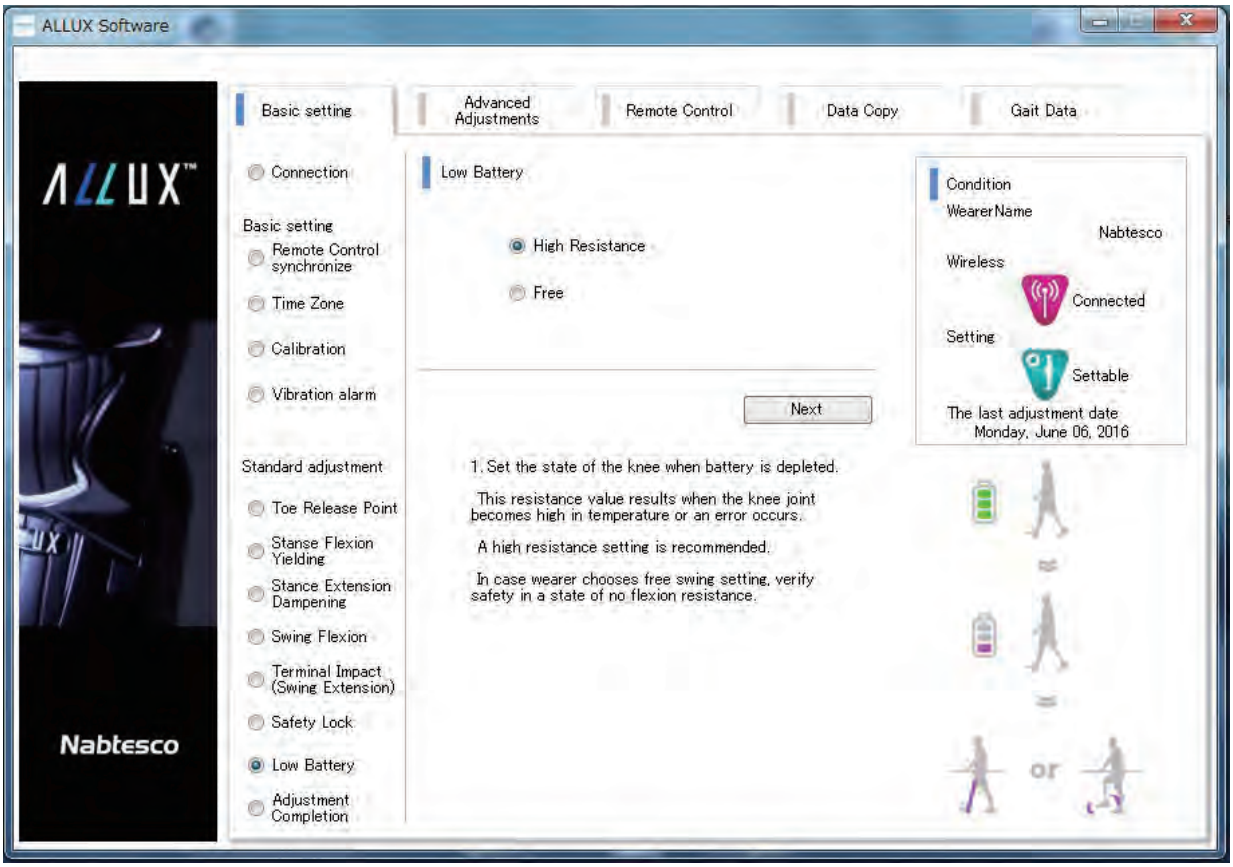
Factory default setting = High Resistance

Adjust the settings for low battery situations.

CAUTION

■If Free is pressed, 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 controller.
The user may not be able to move to a safe place because of the low battery.

●Select Low Battery Settings in the Basic settings tab.
●Adjust the low battery settings.
●After the completion of adjustment, select Next.



6 Adjustment Procedures

6.14 Saving the settings and completing the adjustment

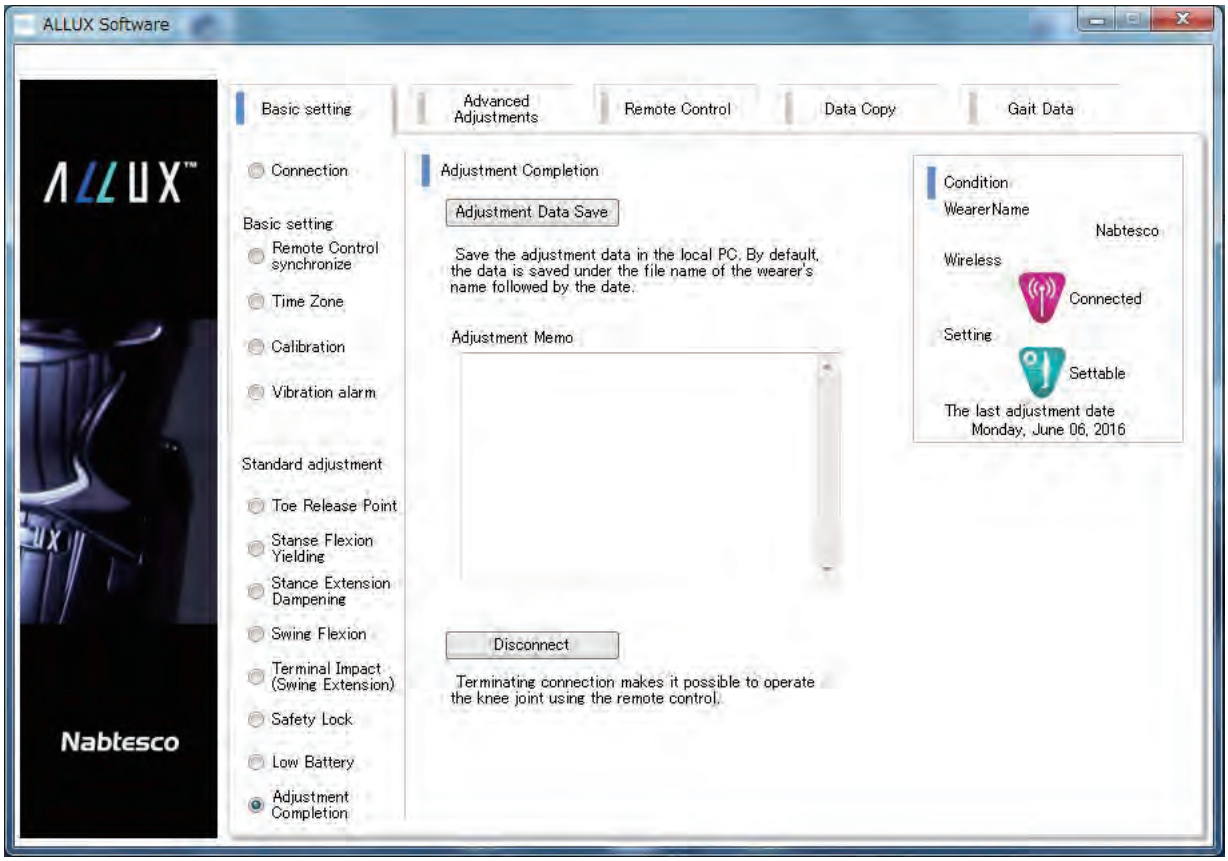
The adjustment setting data is automatically stored in ALLUX™. The adjustment data can be saved in the computer used.

- Press the Adjustment Completion button in the Basic setting tab.
- Press the Adjustment Data Save button.

  *The data will be saved in the “Wearer Name” folder in the ALLUXDATA folder in My Documents.

  *The contents entered in Adjustment Memo will be simultaneously saved.
- After saving the data, press Disconnect.

  *The connection can be disconnected by pressing Disconnect button without saving the data.

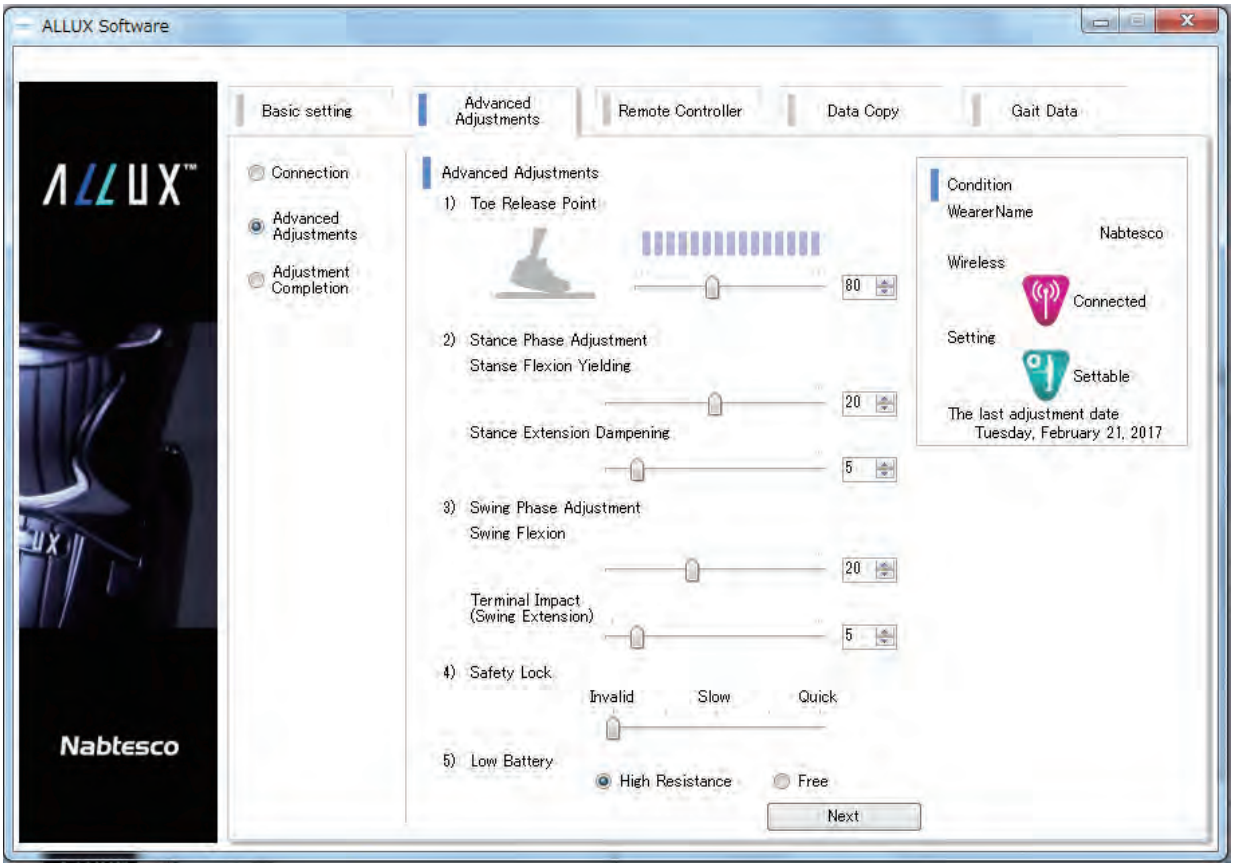


6 Adjustment Procedures

6.15 Advanced adjustments

The setting items adjusted in 6.7 to 6.13 can be collectively adjusted, however the collective setting is not always required to be done.

- Press the Advanced adjustments tab.
- Adjust the set values or cursor positions.
  * See 6.7 to 6.13 for the cautions for adjustment.
- After completing the adjustments, press Next.



6 Adjustment Procedures

6.16 Setting the remote controller

The mode can be changed remotely by assigning modes to the buttons on the remote controller. There are five modes on the remote controller, and four of them can be set.

CAUTION

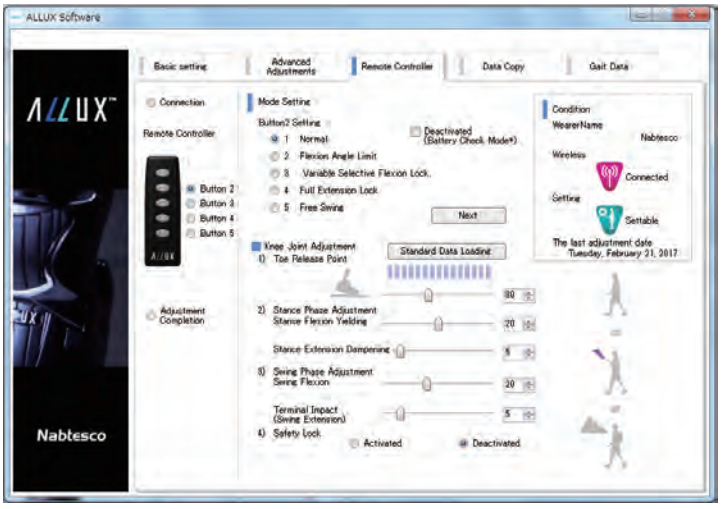
■Check the operation in a place, e.g. in parallel bars, where the user's safety can be ensured. If the mode is changed during the button adjustment, the knee may suddenly bend, and the user may fall.
※When the remote controller settings tab is selected, ALLUX™ is automatically switched to the mode set to button 2.

*When the PC and ALLUX™ are connected, the remote controller cannot be used. The remote controller will be enabled after the connection is terminated. The procedures for operating the remote controller are explained in 6 "Explanation of functions."

●Press the Remote controller tab.
●Select a mode from (1) to (5) for the button * in the remote controller setting area.

① Normal mode: For normal walking

・Adjust the values in the same manner as in 6.15 "Collective Adjustments."
・The adjustment values set in the Basic setting tab can be loaded by pressing Standard Data Loading button.

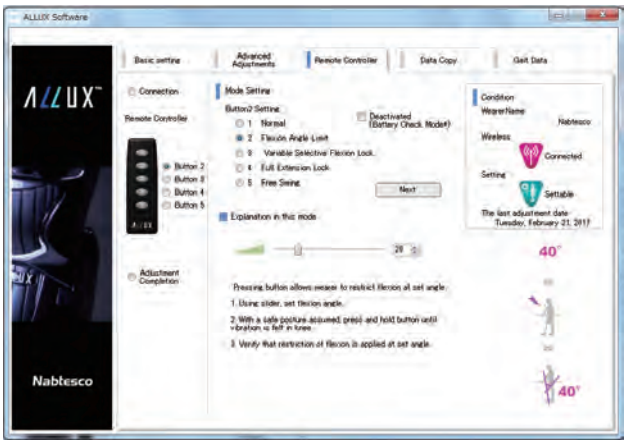


■ Press Copy, and the data will be changed to the adjustment values set in the Basic setting tab.

6 Adjustment Procedures

②Flexion Angle Limited mode : The knee will be locked at the specified knee angle.

・Adjust the locking angle with the cursor.
*If the knee is flexed significantly quickly or flexed quickly from a halfway angle, the knee will be locked at an angle deviating from the specified angle. This is not a defect. To lock it at the specified angle, slowly flex the knee again to lock it.



③Variable Selective Flexion Lock mode : The knee will be locked at the knee angle when the remote controller is operated.

④Full Extension Lock mode : The knee will be locked in the full extension state.

⑤Free Swing mode : The flexion and extension resistances of knee will be minimized.

●Pressing Next will change the screen to the next button setting screen.
Pressing Next in the button 5 screen will change the screen to the Adjustment Completion screen. (See 6.14)

NOTICE

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

⑥Deactivated (battery level confirmation*): The mode does not change even when the remote controller button is pressed.

When the remote controller button is set to 'not in use' then pushing the button will result in the remaining battery level being indicated by vibration patterns.

Estimated number of steps※	Vibration patterns	
About 30,000 steps	1second x 4 times	
About 20,000 steps	1second x 3 times	
About 10,000 steps	1second x 2 times	
Will soon no longer be capable of walking.	0.5 seconds × 8 times	

※Number of steps using the prosthesis, but double if both sides.
Only a guide as it can vary with the usage conditions.

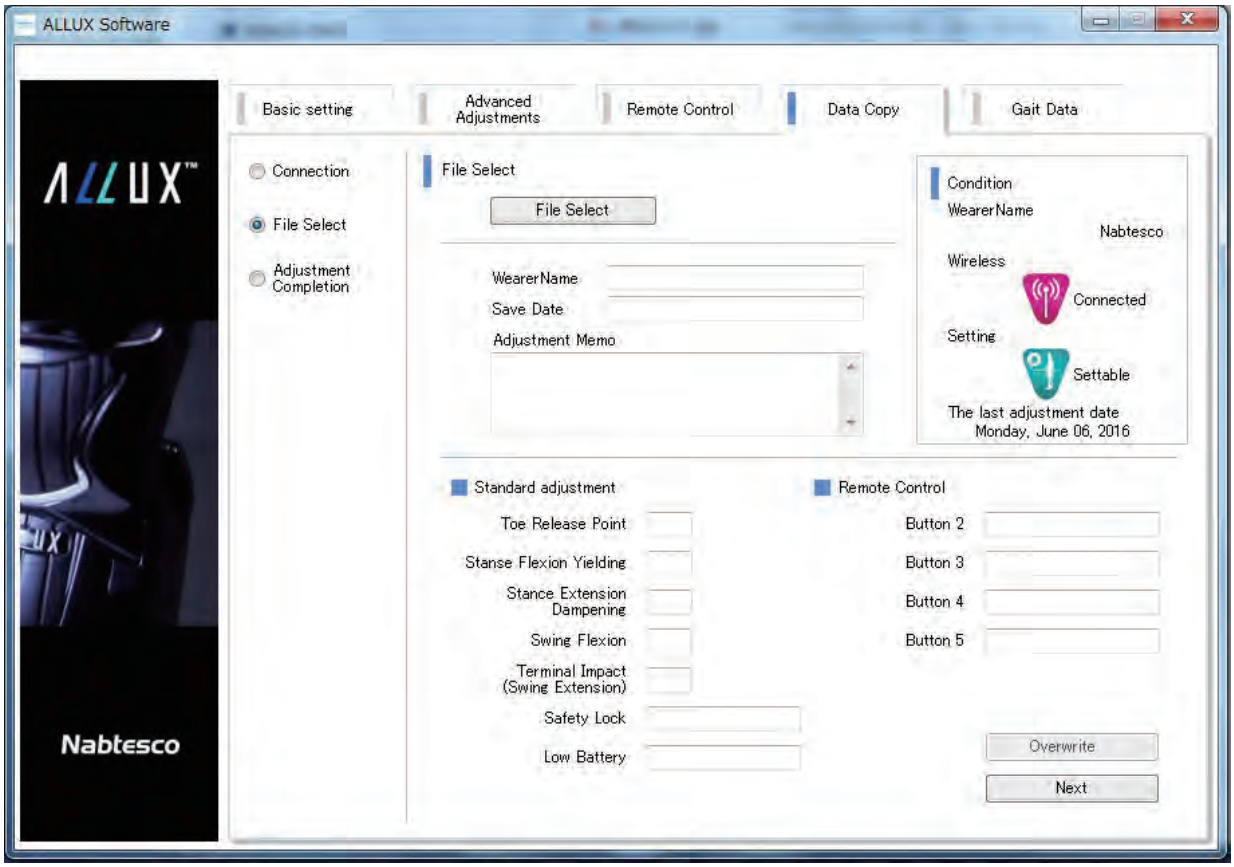
6 Adjustment Procedures

6.17 Copying the data

The data saved in the computer can be loaded to rewrite the settings of ALLUX™.

- Press the Data Copy tab.
- Press the File Select button, and select a file.
- The settings and notes on adjustment will be displayed.
- Press the Overwrite button, and the data will be transmitted to ALLUX™.

  * If the Next button is pressed, the data will not be overwritten.



6 Adjustment Procedures

6.18 Checking the walking data

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

●Select the Walking Data tab.

*The number of steps for the month up until the day will be displayed on the initial screen.

*"Number of steps" refers to that of ALLUX™, not including the steps on the sound side of the patient.

1) Recording

・If Enable is selected, steps taken will be counted in recorded number of steps in the walking data.

・If Disable/Data Del is selected, the number of steps will not be counted in the walking data. The existing walking data will be deleted.
(A confirmation popup window will appear.)

2) Range and Form

・The data for a designated period is displayed as a bar graph or histogram. In the bar graph, the graph for one month will be displayed defined by days, for half a year will be displayed defined by weeks, and for two years will be displayed defined by months.

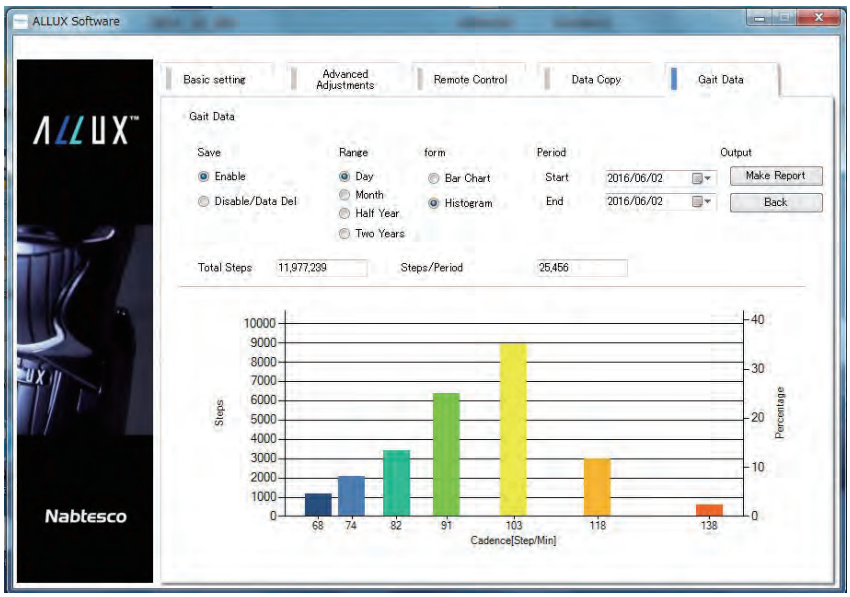
3) Period

・When Daily/Monthly/Half year is selected, the data for a certain period can be selected by specifying either the start or end date.

4) Make Report

・Select the Create Report button to create a report for the designated period. Please follow the steps on the next page.

●Pressing Back will change the screen to the Saving and Completion screen.



6 Adjustment Procedures

6.19 Creating a report

When the Make Report button under Gait Data is selected, the report creation screen will be displayed. Entry items will be reflected in the report.

1) User Information

Fill in the user information. It is a free format, however, the name should be the first line as the first line will be shown on the footer of the report.

2) Report creator's name

Fill in the report creator's name. Once set, this name will be shown automatically on subsequent reports.

3) Font

Select the font in which the report is to be printed. Entry items on this screen will be shown in this font as well.

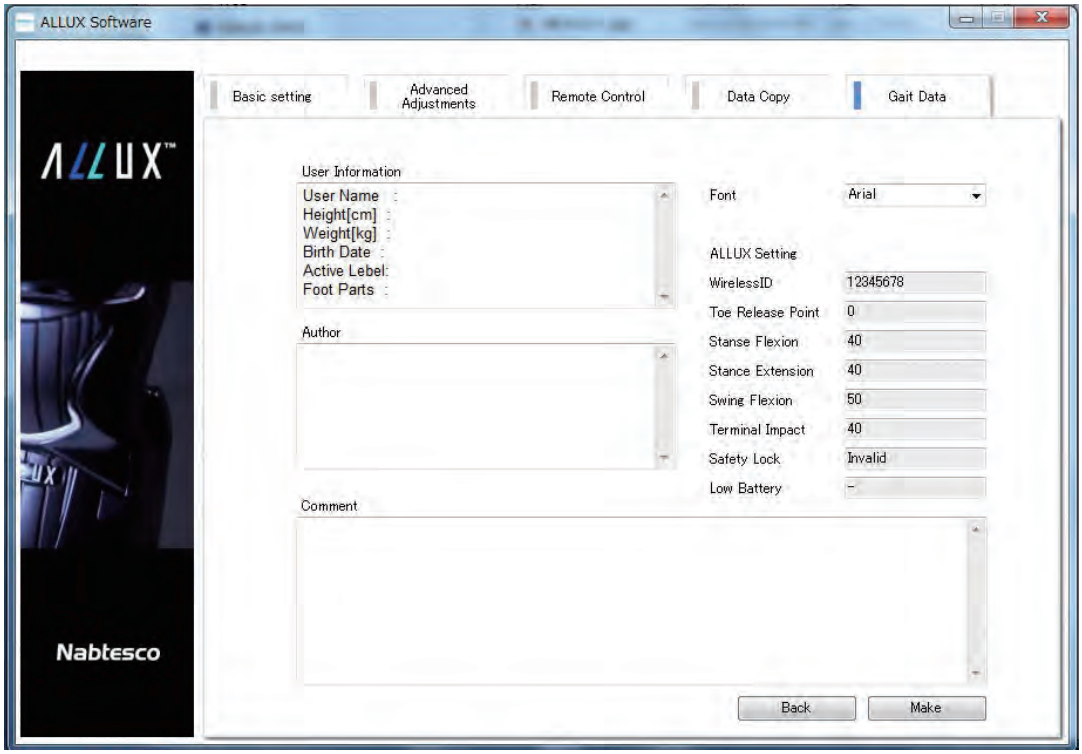
4) ALLUX™ setting

Shows the current ALLUX™ setting. This cannot be changed on this screen.

5) Comment

Write comments as necessary. Comment will be included in the report.

Select the Make button and select a printer.



7 States of ALLUX™

7.1 States of ALLUX™

ALLUX™ has some modes, i.e. charging mode, backup battery connecting mode, modes selected by the remote controller, high-temperature mode and battery empty mode. When the mode is changed to another mode, the vibration will warn the user about the mode change. Vibration patterns can be experienced during adjustment (See 6.6.).
ALLUX™ is designed to be used for 4 days with the internal power supply and the number of steps taken by the prosthesis is 5000/day. When the remaining battery time is less than 3 hours, an alert will be given by vibration. If the backup battery is connected at this time, ALLUX™ can be used for one day. The backup battery is used to supplement the internal power supply. It cannot charge the internal battery.
It is recommended to charge ALLUX™ every day although the battery consumption depends on the amount of activity of the user. (For the charging procedures, see 8 “Charging procedures.”
The internal power supply has three modes: normal mode (where there are 3 or more hours of battery life), a mode in which less than three hours of battery life remain, and a mode in which ALLUX™ cannot be used without charging. If the internal power supply is exhausted the ALLUX™ cannot be used without charging, the user cannot use the ALLUX™ even if the backup battery is connected. When the battery is exhausted, a high yielding resistance (bending resistance value30) or a free state (bending resistance value0) is applied to the flexion resistance (See 6.13 Low Battery Setting).

WARNING	■If the vibration request for safe posture activates during normal use, the user must be in safe posture. Flexion/extension resistance may suddenly change, leading to a fall. ■If the vibration does not activate when the charger is disconnected, discontinue use, and contact the Distributor. The vibrator may be defective. Cautions and warnings cannot be given. Flexion/extension resistance may suddenly change, leading to a fall.
CAUTION	■Charge the battery every day regardless of the usage of ALLUX™. Even when not walking the sensors will be on and draining the battery. Please exercise caution as the status may differ before and after charging. ■Do not routinely exhaust the battery. The vibration notification will not unavailable, flexion/extension resistance may suddenly change, leading to a fall. ■When the knee joint is heated, do not touch any metallic part of its body. and could result in burns. ■When the vibration for warning about battery exhaustion activates, refrain from using ALLUX™, and charge the battery. Normal walking will be impossible if the battery runs out during use. ■When ALLUX™ is used in a low-temperature environment, the flexion and extension resistances may increase. Check the resistances prior to use. Normal walking will not be supported, possibly resulting in a fall. ■When ALLUX™ is used at a high temperature, the flexion and extension resistances decrease. Use it carefully when walking on stairs or a slope. May not support the weight, possibly resulting in a fall.
NOTICE	■Constant use of the backup battery is not recommended. Could hasten battery degradation. * After using the backup battery, charge the internal power supply and backup battery. * The operational duration time may vary due to the temperature, deterioration, or walking conditions.

7 States of ALLUX™

7.2 Normal use state

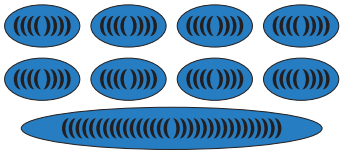
7.2.1 When charger or power OFF cap is disconnected

When the charger (NE-BC01) or the power OFF cap (NE-CC02) is disconnected, ALLUX™ will enter the normal usage condition, and the vibration will activate to indicate the residual capacity of the internal power supply of ALLUX™. After removing the charger and power OFF connector, connect the charging port cap (NE-CC01).

●Disconnect the charger or the power OFF cap. When the vibration does not sound as below, connect the charger or the power OFF cap and disconnect it again.

0.25sec×8times :3hours or more

0.5sec×8times :Less than 3hours



0.75sec8times+(4sec) :No more walk

●Connect the charging port cap.

WARNING

■After disconnecting the charger, connect the charging port cap. (NE-CC01). If the cap is not used and the connector terminal comes into contact with water or another liquid, ALLUX™ may malfunction and enter the charge mode, and the user cannot walk and may be stranded in a dangerous place.

7.2.2 When power is turned off for charging

The power supply turns off when the charger or power off cap are connected.

●Connect the charger

2sec

WARNING

■Do not walk with the power OFF cap connected. Since the walking control is disabled, the user cannot walk normally. If ALLUX™ is used with the cap, the user cannot walk normally and may fall.

Charging port cap NE-CC01	
Power OFF cap NE-CC02	

7 States of ALLUX™

7.2.3 Use of backup battery

When the battery is exhausted, the control of ALLUX™ will be stopped. Connecting the backup battery (NE-SB01) before the internal battery runs out enables the user to use ALLUX™ continuously for one day.

- When the internal battery capacity allows for less than 3 hours of walking, the warning vibration will be activated.

- Remove the Charging port cap.
- Fit the backup battery case (NE-SC01) containing the backup battery on the body of ALLUX™ or the lower leg side of the armoring, such as the foam cover, and secure it with the Velcro tape.
- Connect the backup battery to ALLUX™.

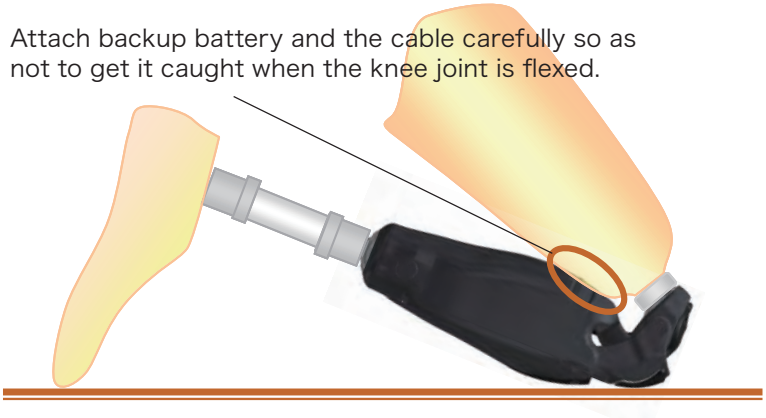
  * ALLUX™ will enter the normal mode stated in 7.2.1, and the vibration for confirmation of backup battery capacity will sound.

* The backup battery must be charged.

【How to use】

Carry the backup battery (NE-SB01) constantly and use if necessary, such as when the warning vibration lets you know the internal battery is low or when the knee locks due to the battery exhaustion. To use, put the backup battery into the backup battery case, wrap it onto the lower leg, and connect it to the ALLUX™.
After use, the backup battery should always be charged. ALLUX™ and the backup battery cannot be charged simultaneously.

Attach backup battery and the cable carefully so as not to get it caught when the knee joint is flexed.



【Limitations of the battery】

When the battery capacity in ALLUX™ is reduced, the fully charged backup battery in ALLUX™ can be used up to once. When the battery in ALLUX™ has exhausted to a certain level, the backup battery cannot be used.

【Confirming with the aviation regulations】

The backup battery shall be carried on the plane in accordance with aviation regulations.

7 States of ALLUX™

WARNING

- Connect the backup battery in a state where the safe posture can be ensured.
  Flexion/extension resistance may suddenly change, leading to a fall.
- Do not secure the backup battery case on the thigh side (above the knee joint).
  The cable may be caught between knee joint parts or damaged during flexing action, and an excessive load may be applied to the connector, thereby disconnecting the cable.
- Secure the backup battery case on a side of ALLUX™ body(Frame).
  The socket and backup battery may get into contact at the maximum flexion angle, and the backup battery may be damaged.
- Do not insert or remove the backup battery while walking as it may lead to a fall.
  * If the cable is disconnected or the battery is damaged during walking, the user cannot walk normally and may fall.

- Do not use the backup battery for any other devices.
  It may cause damage to the battery or the device.
- Do not use constantly in the normal state.
  When discharged to a certain level, the backup battery cannot be used.
- Do not charge with any charger other than the specified one.
  Risk of fire or explosion.
- Do not exopse to water or fire.
  Rust or deformation could make the auxiliary battery unstable.
- Do not use under the scorching sun, near fire, or in any environment with temperatures exceeding +40˚C/+104˚F.
- Do not leave or store at temperatures of -20˚C/-4˚F or less or +60˚C /140˚F or more.
  Could hasten battery degradation.
- Do not use if significantly scratched or deformed.
  The power supply ceasing due to poor contact etc, the parts Could be damaged or broken, thus resulting in a fall.
- Do not drop from a height. Do not allow strong shock.
  Could result in a malfunction.
- Do not use if liquid leaks or an abnormal odor is exuded.
  Could lead to failure of the main ALLUX™ unit.
- Do not allow babies, children or animals to touch, lick or put in their mouths—may cause explosion of battery.

- Do not disassemble or modify.
- Do not damage it intentionally by sticking a sharp tool or stepping on.
  Risk of fire or explosion.

- Do not expose to any liquid while backup battery terminal is exposed.
- Do not touch with wet hands.
  Could lead to a battery short and the risk of electric shock.

- Do not constantly use the backup battery (NE-SB01).
- After using the backup battery, charge the main body and backup battery.
  Could hasten battery degradation.

7 States of ALLUX™

【Specifications for backup battery】

- Service temperature: 0℃/+32℉ to +40℃/+104℉
- Resistance to ambient temperature: -20℃/-4℉ to +60℃/+140℉
- Resistance to ambient humidity: 10 to 90%RH
- Charger: NE-BC01
- Applicable device: ALLUX™ (NE-Z4 or NE-Z4SH)
- Service life: 1 year

Backup battery NE-SB01	

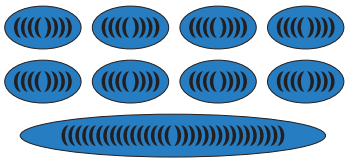
7 States of ALLUX™

7.2.4 Battery exhaustion (zero battery)

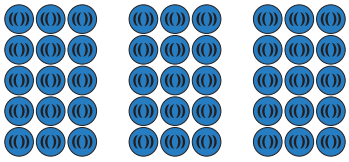
When the internal power supply has exhausted and ALLUX™ cannot be used, the warning about battery exhaustion will be given by vibration. Then, the vibration for request for safe posture will be given. When the user takes the safe posture, the walking control will be stopped, and ALLUX™ will be locked or free(see 6.13). In this case, ALLUX™ can be used continuously for one day by connecting the backup battery (NE-SB01). (For the specifications for the backup battery, see 7.2.3)
ALLUX™ will be recovered from this state by charging.

WARNING

■When the vibration indicating the battery exhaustion or requiring the safe posture sounds, the user must stand in a safe posture immediately.
Even if the user is not in standing in a safe posture after 1 minute of warning vibration, the knee joint will be forcibly locked. or free even if the user is walking. Therefore, the user may fall.



0.75sec8times+ (4sec) : No more walk



0.5 * 3times×15回 : Request for safe posture

⇒The knee will be locked even if the user is not in the safe posture after the completion of vibration for 1 minute.

●The user must take the safe posture.
●The knee will be locked in the flexed state (at a high yielding resistance).
When the 'free' low battery setting (6.13) is selected, the knee flexion becomes free.
●Connect the backup battery to ALLUX™. (For the cautions for use of the backup battery, see 7.2.3.)
* ALLUX™ will enter the normal mode stated in 7.2.1, and the vibration for confirmation of backup battery capacity will sound.
* The backup battery must be charged.

【When the backup battery is not available or the user goes back home】
●Charge ALLUX™. (See 8 “Charging procedures.”)

7 States of ALLUX™

7.2.5 In high-temperature state

If the yielding function is continuously used for a long time, ALLUX™ may be heated to a high temperature. When the temperature of ALLUX™ rises, the vibration for warning about increasing temperature will sound at first. In this state, the user can walk. If ALLUX™ is used continuously, the vibration for alerting the user to stop using due to high temperature will be given. When the user takes the safe posture, the knee will be locked (yielding resistance with high flexion resistance). After the temperature drops, ALLUX™ can be used again.

WARNING

- The user must stop walking with the yielding function or take a rest and stay still until the knee joint cools down in accordance with the high-temperature warning vibration
- The user must move to a place where he/she can stop walking safely and take the safe posture within 1 minute in accordance with the vibration for alerting to stop using.
  Flexion/extension resistance may suddenly change, leading to a fall.

* ALLUX™ cannot be unlocked (released from high yielding resistance) until its temperature drops.

- Do not touch any metallic part of the prosthesis knee joint.
  Could result in burns.

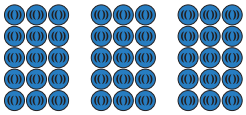
【When the temperature is increasing】

* Stop walking with the yielding function or take a rest and stay still until the knee joint cools down.

【When the temperature has abnormally increased】

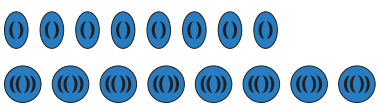
- Take the safe posture.
- The knee will be locked in the flexed state(at a high yielding resistance).

【When the knee joint cools down】



⇒The knee will be restored to the normal state even if the user is not in the safe posture after the completion of vibration for 1 minute.

- The vibration for confirmation of battery capacity will sound.



* When the knee joint is released from the high-temperature state, it has not cooled down completely. Therefore, if the user continues to walk with the yielding function in the same manner, the knee joint will be immediately locked by the high temperature. The user is recommended to take a rest for 10 to 20 minutes until the knee joint sufficiently cools down.

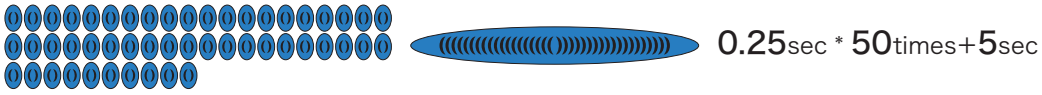
7 States of ALLUX™

7.3 In case of malfunction

If a malfunction occurs in a sensor in the knee joint and it cannot serve as a knee joint, the vibration for warning about malfunction will sound, and the knee will be locked (yielding resistance with high flexion resistance). No vibration may sound, or the knee may not be locked depending on the malfunctioning part.

WARNING

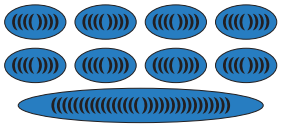
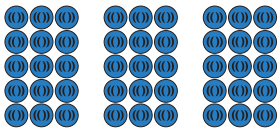
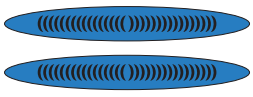
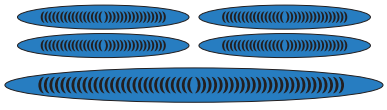
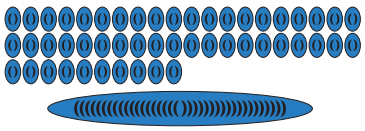
- If the knee joint is defective, the user cannot walk normally.
- If the vibration for warning about malfunction sounds, immediately discontinue the use, and contact the Distributor. Normal walking will not be supported, possibly resulting in a fall.



- The knee will be locked (at a high yielding resistance).

7 States of ALLUX™

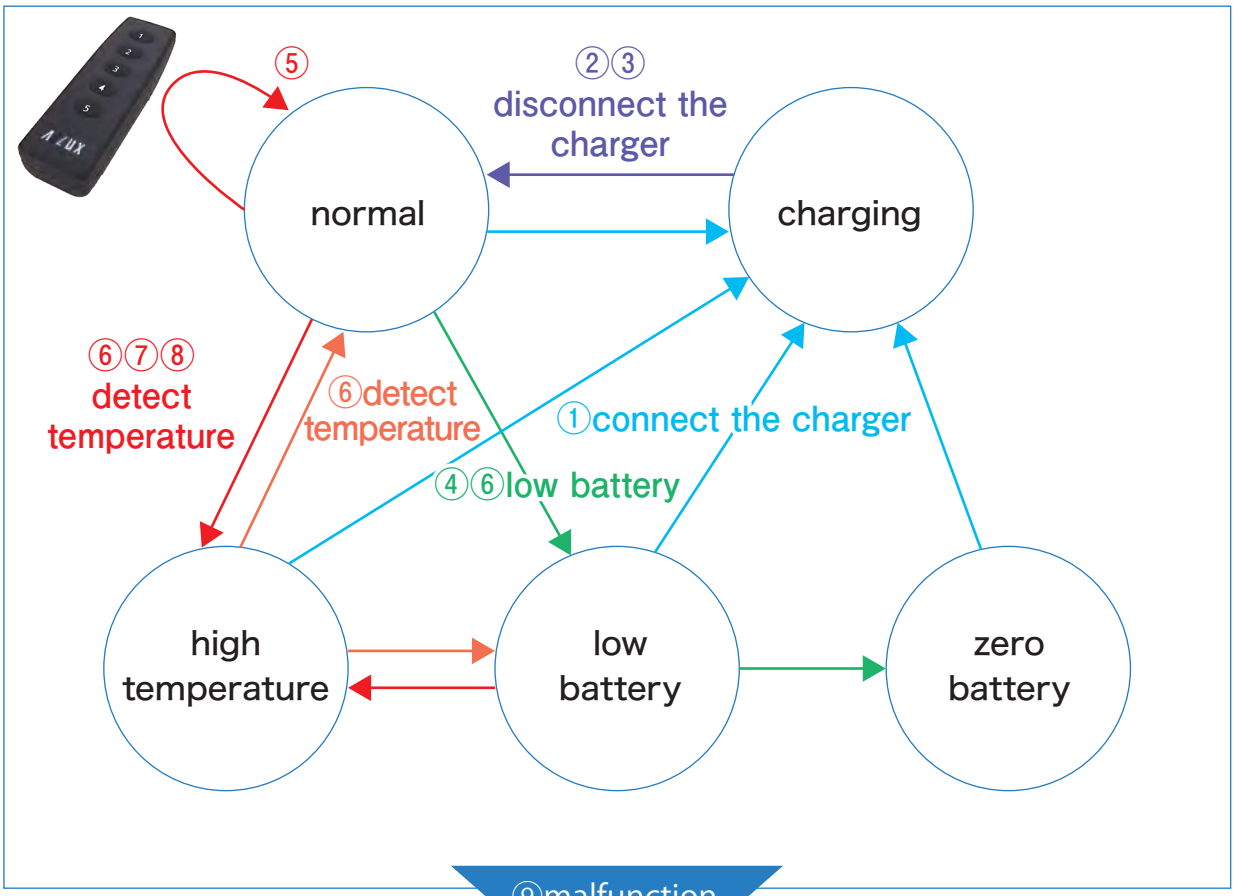
7.4 Vibration alert pattern chart

	Vibration alert	Notification timing	Meaning
①	 2sec	When the charger or Power OFF cap is connected	Control of the ALLUX™ has been stopped.
②	 0.25sec × 8times	When the charger or Power OFF cap are disconnected	The battery level supports at least 3 hours
③	 0.5sec × 8times	When the charger or Power OFF cap are disconnected	The battery level supports less than 3 hours
④	 0.75sec8times+(4sec)	When the charger or Power OFF cap are disconnected	Normal walking is not currently supported due to battery level ※1 being insufficient. Please connect an auxiliary battery or recharge it.
⑤	 2sec	Operational mode changed via remote controller (See 5.2)	The ALLUX™ mode change has been completed using the remote control.
⑥ ⑥ ⑥	 0.5 * 3times × 15times	Low remaining battery High temperature state Recovering from abnormally high temperature	Status requiring a safe posture. If this status continues ensure to contact our company or the distributor as a malfunction may have occurred.
⑦	 4 sec * 2 times with 30 sec interval	When the main ALLUX™ unit is becoming abnormally hot	The main ALLUX ™ unit is becoming abnormally hot. However, normal walking can still continue.
⑧	 4sec * 4times+10sec	When the main ALLUX™ unit has become abnormally hot	Normal walking is not currently supported by the ALLUX™ and will not return until the temperature has dropped. Please wait until normal status has been achieved, as indicated by vibration pattern ⑥.
⑨	 0.25sec * 50times+5sec	When the main ALLUX™ unit has been malfunctioned	The status of the ALLUX ™ is abnormal and normal walking is not supported. The abnormal status could be resolved by inserting/removing the charger or power off cap. If this does not solve the problem then please ensure to contact the Distributor.

*1: Remaining battery refers to the remaining capacity of the ALLUX™ main battery or the backup battery.
Only a guide as it can vary with the usage conditions.
*2: If no vibratory notification occurs when the charger or power supply off connector is removed then an abnormality may have occurred.

7 States of ALLUX™

The figure below provides the different types of ALLUX™ status and the transitionary vibration notification patterns.



※No.1-9 correspond to numbers in the vibration alert pattern chart (7.4).

8 Charging Procedures

8.1 Charging ALLUX™

The internal power supply of ALLUX™ and backup battery shall be charged with the special charger (NE-BC01). When using ALLUX™, it is recommended to charge it every day as a rule.

WARNING

- If the vibration does not sound when the charger is disconnected, discontinue use, and contact the prosthesis manufacturer.
  The vibration may be defective. Cautions and warnings cannot be given.
  Flexion/extension resistance may suddenly change, leading to a fall.
- Remove the prosthesis before charging.

- Do not use for any purpose other than charging ALLUX™.
- Do not connect any adapter other than the supplied AC adapter to the charger.
- Do not use the AC adapter for any other electronic devices.
- Do not charge outdoors.
- Do not drop from a height. Do not give a strong shock.
- Do not leave or store at a temperature of -10˚C/+14˚F or less or +60˚C /+140˚F or more.
- Charge indoors in a temperature range from 0˚C/+32˚F to +40˚C/+104˚F.
- Do not pull the connector cable with a force of 30 N (3 kgf) or more.
- Do not charge from a car (cigar plug cord).
- After charging, do not use without the Charging port cap (NE-CC01).
- Do not put any conductive body, such as metallic parts, to the connector terminal of ALLUX™.

Failing to follow the above could cause the charger to malfunction or result in the risk of fire.

- Do not disassemble or modify.
  Could result in a malfunction.

- Do not pour any liquid, such as water.
- Do not touch with wet hands.
  Could lead to a battery short and the risk of electric shock.

8.1.1 Specifications for charger and AC adapter

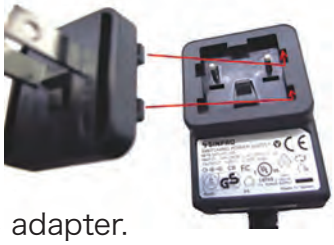
- Service temperature: 0˚C/+32˚F to +40˚C/+104˚F
- Resistance to ambient temperature: -10˚C/+14˚F to +60˚C/+140˚F
- Resistance to ambient humidity: 10 to 90%RH (non condensing)
- Input voltage: 12 V
- Input current: Max. 1 A
- AC adapter: NE-AD01 (Input voltage: 100 V to 240 V)

8 Charging Procedures

8.1.2 Charging procedures

Connect the charger (NE-BC01) and AC adapter (NE-AD01) indoors, and charge the battery through a commercial power supply. Although the charging time depends on the residual battery capacity, the battery will be fully charged after about 3 hours. Four types of plug adapters are available for the AC adapter. In Japan, use the type A (NE-PA01). The type C (NE-PA02), type BF (NE-PA03) and type O (NE-PA04) can be supplied to each contries in accordance with the proper configulation.

●Fit the plug adapter (type A) to the AC adapter as shown in the following figure.
* When they are fitted normally, a snap will be heard.
* To remove the adapter, slide it while pressing the center pawls.



●Connect the charger and AC adapter.
●Insert the plug adapter of the AC adapter to a commercial power supply.
* For connection to a supply not in the U.S.A., use an attachment plug adaptor of the proper configuration for the power outlet, if needed.

NOTICE
■Do not charge if the plug adapter is not fitted correctly.
■Do not use any adapter other than the supplied plug adapter. Could result in a malfunction.

●Remove the Charging port cap (NE-CC01) of ALLUX™.
* Remove it sliding the Charging port cap lever in the arrow direction.
●Connect the charger connector to the connector terminal of ALLUX™.

The vibration will sound continuously for 2 seconds.

Connector cover

Connector terminal

Charger connector

8 Charging Procedures

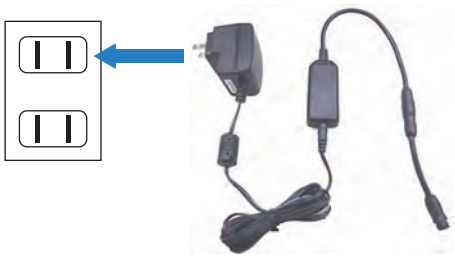
●The LED lamp on the charger will light on in orange.
* If the temperature of ALLUX™ is higher than +40℃/+104℉ just after ALLUX™ is used, the green LED lamp will flash.
●When charging is completed after a certain time, the LED lamp will turn green.
* If ALLUX™ is left for a long time after the completion of charging and the battery capacity becomes lower than a certain level, the battery will be recharged.
●Remove the charger connector. The vibration described on 7.2.1 sounds.
* If the vibration for insufficient battery capacity sounds although the battery has been fully charged, the lithium ion battery may have deteriorated. Contact Our company.
●Fit the charger port cap.


Remove the AC adapter from the commercial power supply.

8.1.3 Charging the backup battery

Charge the backup battery in the same manner as when charging the main body of ALLUX™. Connect the charging cable for backup battery (NE-CL01) to the charger connector, and connect to the backup battery.

●Connect the backup battery charging cable to the charger and AC adapter stated in 8.1.2.
●Insert the plug adapter of the AC adapter to a commercial power supply.



●Connect the backup battery to the backup battery charging cable.
●The LED lamp on the charger will light on in orange.
※ If the temperature of ALLUX™ is higher than 40℃ just after ALLUX™ is used, it will enter the charge standby state. The battery will be automatically charged when it cools down.
●When charging is completed after a certain time, the LED lamp will turn green.
※ If ALLUX™ is left for a long time after the completion of charging and the battery capacity becomes lower than a certain level, the battery will be recharged.
●Remove the backup battery from the backup battery charging cable.


Remove the AC adapter from the commercial power supply.

NOTICE

■Do not leave the AC adapter plugged into the commercial power supply when it is not used for charging.
The AC adaptor may overheat or catch fire.

8 Charging Procedures

8.1.4 Indication by LED lamp on charger

The LED lamp on the charger has four modes. When it does not light up, recheck the connection referring to 8.1.2. If the LED lamp still does not light up, the charger or the AC adapter may be defective. Contact the Distributor.

ON:During charging	The charger is normally working.
Flashing:Charging error	The charger cannot charge owing to a failure.
ON:Completion of charging	The battery has been charged fully.
Flashing:Waiting until charging	Waiting until the heated battery cools down.

LED lamp on charger

Backup battery charging cable

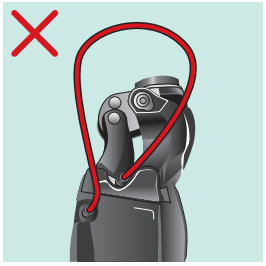
8.1.5 Use of extension cable

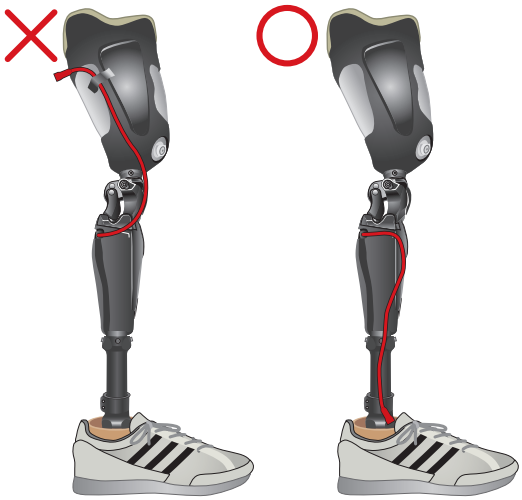
Use an extension cable when the ALLUX™ charging connector is covered with form cover, etc.

NOTICE

- Make sure the extension is used on the ankle side. Using it on the socket side may lead to the cable getting caught when the knee bends.
- Make sure the cable does not get caught in the socket when using the knee at maximum flex.
- Cover the connector of the extension cable when it is not in use. ALLUX™ may become defective when the terminals are contacted or get wet.

Extension cable





9 Maintenance Parts

9.1 List of maintenance parts

During periodic inspection, the following maintenance parts are used.
When you want to purchase replacement parts for maintenance or have to questions about maintenance of ALLUX™,contact the Distributor.

【Replacement of battery】

Main body of ALLUX™ NE-Z4		If the battery life is coming to an end, receive the main body of ALLUX™, and return it to our company.
Backup battery NE-SB01		When the life of the backup battery is coming to an end, purchase a new one from our company, and replace it.
Remote controller NE-RC02		Purchase a new one and replace to it. AAA x2 ,approximatery every year.

NOTICE

■The backup battery is a Lithium ion battery. Do not discard the battery with general household garbage.
If thrown away the battery could short-circuit and cause it to ignite or release harmful fumes.

【Replacement of rubber and pads】

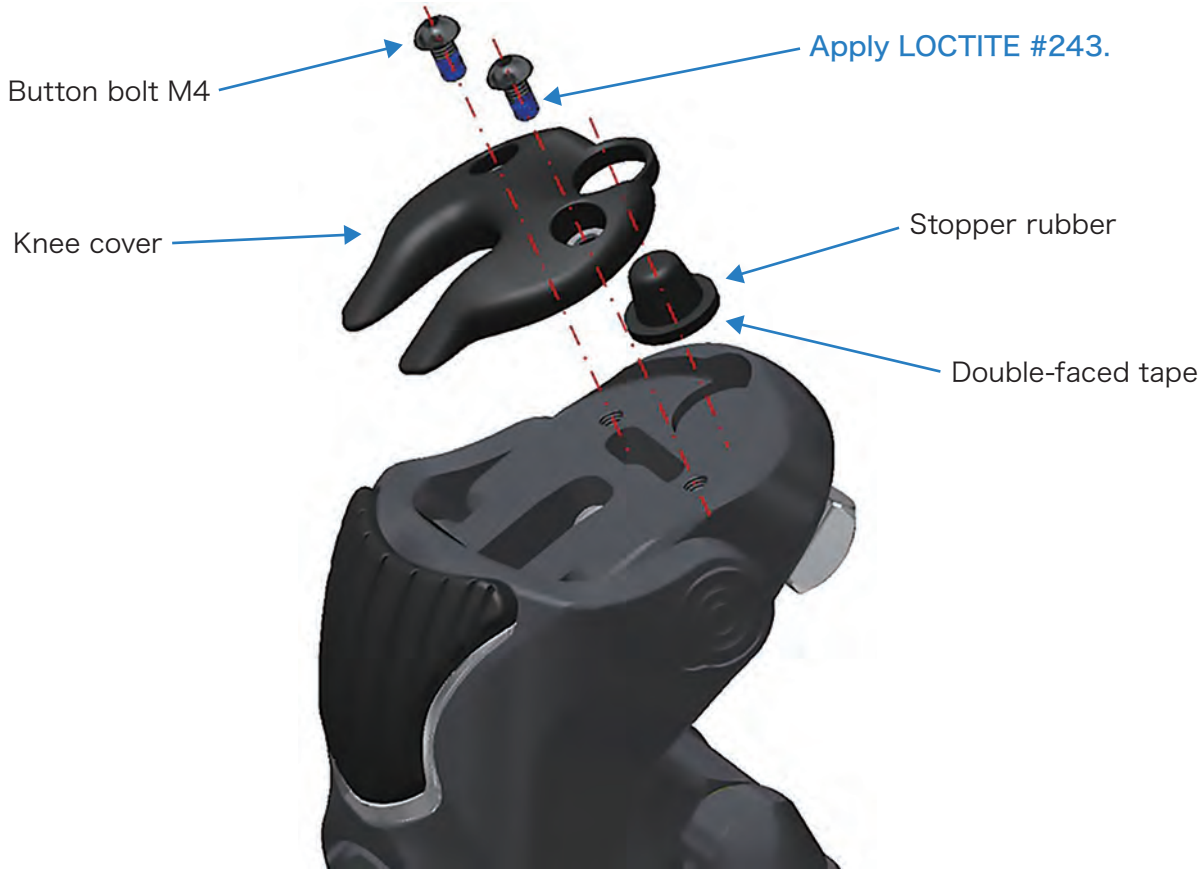
Rubber stopper N-G012		Purchase a new one from the Distributor and replace as outlined in 9.2.
Front link pad NE-FC01		Please contact the Distributor to replace it.
Front cover pad NE-FC02		Please contact the Distributor to replace it.
Front link ST pad NE-FC03		Please contact the Distributor to replace it.

9 Maintenance Parts

9.2 Replacing the extension rubber stopper

If the extension rubber stopper of ALLUX™ has deteriorated, replace it in accordance with the following procedures.

- Remove the two button bolts M4 from the knee cover with a 2.5-mm hexagon wrench.
- Remove the knee cover.
- Remove the extension rubber stopper.
  ※It is applied with double-faced tape. Peel off the tape.
- Fit the new extension rubber stopper.
  ※Apply the extension rubber stopper with the double-faced tape attached to its rear side.
- Fit the knee cover.
- Apply an appropriate amount of a thread locking agent, LOCTITE #243 (or its equivalent), to the button bolts M4.
- Tighten the two button bolts M4 to a tightening torque of 1.4 Nm with a torque wrench (2.5 mm).



10 Troubleshooting

10.1 Troubleshooting list

If any problem occurs during adjustment or assembly of ALLUX™, see the following list. If an appropriate item is not shown in the list, contact the Distributor.

10.1.1 During preparation for connection

Problem	Check item	Remedy
The driver of the wireless dongle cannot be installed.	Check that the hard disk of the PC has a required free space.	Increase the free space on the hard disk of the PC.
ALLUX™ software cannot be installed.		
The PC does not recognize the wireless dongle.	Check that the COM port number is correct.	Check that the dongle is recognized by the device manager. (See 3.2.3)
ALLUX™ software does not start.	Check that the software has been installed correctly.	Uninstall, and reinstall.
	Check that Windows version is appropriate.	Change to an operating system compatible with Microsoft Windows 7 or later. (See 3.2.1)
ALLUX™ cannot be connected.	Check that the COM port number is correct.	Check in the device manager. (See 3.2.3)
	Check that the wireless ID is correct.	Check the number shown on the main body of ALLUX™.
	Check that the power OFF cap is disconnected.	Remove the power OFF cap, and fit the Charging port cap.

10 Troubleshooting

Problem	Check item	Remedy
ALLUX™ cannot be connected.	Check that ALLUX™ has not been left without operation for 120 seconds or more.	Flex and extend the knee to establish communication, and connect communication within 120 seconds. (See 3.2.6)
	Check that ALLUX™ has been charged.	Charge ALLUX™. (See 8.1)
	Check that the wireless dongle has been inserted into the PC.	Insert the wireless dongle into the PC, and check that the green LED lamp lights up.
A COM port error occurs.	Check that the wireless dongle driver has been normally installed.	Uninstall, and reinstall.
	Check that the wireless dongle has been inserted into the PC.	Insert the wireless dongle into the PC, and check that the green LED lamp lights up.
Communication is frequently disconnected.	Check that there is not a strong radio wave source near ALLUX™.	Connect ALLUX™ at a distance of within 2 m from the wireless dongle. (See 3.2.7)
	Check that the wireless dongle is not apart from the knee joint or a metallic object which shields the radio waves is not placed near it.	Connect ALLUX™ at a distance of within 2 m from the wireless dongle. (See 3.2.7)

10 Troubleshooting

10.1.2 During adjustment with ALLUX™ software

Problem	Check item	Remedy
The knee joint cannot smoothly shift from the stance phase to the swing phase.	Check that the release point setting is not too large.	Readjust the release point. (See 6.7)
	Check that the alignment is not too stable.	Readjust the alignment. (See 4.1)
	Check that the foot is not too soft.	Select a foot which can apply a sufficient weight to the toe.
	Check that the knee joint is not unloaded at the late stage of stance phase. Check that the user surely pushes off the ground.	Adjust the foot alignment for plantar flexion, or teach the user how to load during toe-off when walking.
	Check that the knee is not flexed at the late stage of stance phase.	Lower and adjust the stance phase extension damper setting, so that the knee joint completely extends.
The yielding resistance cannot be increased by increasing the flexion resistance in the stance phase.	Check that the alignment is appropriate.	Adjust so that a sufficient weight can be applied to the heel.
	Check that the foot is appropriate.	Select a foot which can apply a sufficient weight to the heel.
	In cases other than above	Contact the Distributor.
Minute flexion movements occur in the knee joint in the stance phase during level walking.	Check that the extension resistance in stance phase is appropriate.	Increase the extension resistance in the stance phase. (See 6.9)
	Check that the alignment is appropriate.	Adjust the alignment so that the knee joint completely extends at the initial stage of the stance phase. (See 4.1)
Hydraulic resistance is applied unintentionally (the knee joint jams in the period of transition to the swing phase).	Check that the release point setting is not too large.	Readjust the release point. (See 6.7)
	Check that the alignment is appropriate.	Adjust the alignment so that load can be easily applied to the toe. (See 4.1)

10 Troubleshooting

Problem	Check item	Remedy
Hydraulic resistance is applied unintentionally (the knee joint jams in the period of transition to the swing phase).	Check that the user can walk shifting his/her weight from the heel to the toe.	Teach the user how to walk leaving the weight to the toe of the prosthesis and applying a sufficient load to the toe during toe-off.
	In cases other than above	Contact the Distributor.
The yielding resistance is not retained when the user descends a slope.	Check that the release point setting is not too low.	Readjust the release point. (See 6.7)
	Check that the alignment is appropriate.	Adjust so that a sufficient weight can be applied to the heel. (See 4.1)
	Check that a foot with a too soft heel is not used.	It is recommended to replace the foot with a foot with an appropriately hard heel or adjust the hardness.
	In cases other than above	Contact the Distributor.
The safety lock cannot be applied.	Check that the safety lock is set to ON.	Check that the lock is set to ON. (See 6.12)
	Check that the user holds the knee in a slightly flexed state and applies the weight sufficiently to the knee. (When the weight is not applied or the knee is flexing or extending even slowly, the lock does not function.)	Train the user to hold the knee in a slightly loaded state.
	Check that the calibration has been performed.	Redo the calibration. (See 6.5)
	In cases other than above	Contact our company.
The knee is locked and jams when the user sits down.	Check that the user does not stop flexing the knee halfway.	Since the safety lock is effective, it is necessary to sit down without stopping.
	Check that setting for safety lock is too sensitive	Adjust the sensitivity (see 6.12)
	Check that load is not applied to the toe to flex the knee after transition to the swing phase.	Since the stumbling lock is effective, it is necessary to sit down without applying load or sit down with the yielding function.
	When the problem cannot be solved by the above measures	Set the safety lock to OFF, and prohibit the use. (See 6.12)

10 Troubleshooting

Problem	Check item	Remedy
A terminal impact sound is caused.	Check that the extension resistance in the swing phase is not low.	Gradually increase the extension resistance in the swing phase. (See 6.11)
	Check that the extension resistance in the swing phase is not too high.	Reduce the extension resistance in the swing phase, and change the setting to completely extend the knee. (See 6.11)
The knee does not completely extend in the swing phase.	Check that the extension resistance in the stance phase is not too high.	Reduce the extension resistance in the swing phase. (See 6.11)
The knee does not completely extend at the late stage of stance phase.	Check that the extension resistance in the stance phase is not too high.	Reduce the extension resistance in the stance phase. (See 6.9)
The heel rise is large.	Check that the flexion resistance in the swing phase is not too low.	Increase the flexion resistance in the swing phase. (See 6.10)
	Check that the user does not significantly flexes his/her hip joint in the middle of transition to the swing phase while walking.	Teach the user not to flex the hip joint deeply.
The toe rubs on the ground in the middle of swing phase.	Check that the flexion resistance in the swing phase is not too high.	Reduce the flexion resistance in the swing phase. (See 6.10)
	Check that the prosthesis is not too long.	Adjust the prosthesis length.
	Check that the foot is not too plantarflexed.	Align the foot in a state of dorsiflexion.

10 Troubleshooting

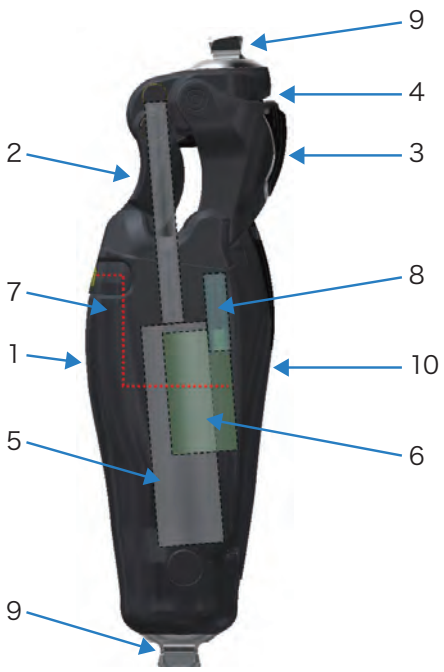
10.1.3 While in use

Problem	Check item	Remedy
ALLUX™ cannot be charged	Check that the charger connector and AC adapter are surely connected.	Check the connection. (See 8.1.2)
	Check that the vibration sounds when the charger connector is connected.	If the vibration does not sound, ALLUX™ may be defective. Discontinue use, and contact the Distributor.
	Check that the knee joint is not at a high temperature.	Leave it until it cools down, and recharge it. (See 8.1)
	In cases other than above	Contact the Distributor.
The mode cannot be changed by the remote controller.	Check that the button is pressed within 120 seconds after the knee is flexed and extended or removing the body weight and then applying it.	Flex and extend the knee or removing the body weight and then applying it, take the safe posture, and operate the remote controller. (See 6.1)
	Check that the user takes the safe posture when operating the remote controller.	
	Check that the batteries of the remote controller have not run out.	Replace the two AAA batteries with new ones.
	Check that the button is held down for a long time.	Hold down the button for 1.5 seconds or more.
The knee becomes locked or free.	Check that the vibration did not sounded just before.	If the knee joint is at a high temperature, wait until it cools down. (See 7.2.5)
	Check that the battery capacity is sufficient.	Connect the backup battery, or charge. (See 7.2.4)
	In cases other than above	Contact the Distributor.
Abnormal noise or backlash occurs.	Check for foreign substances. Are any screws etc. interfering with the knee joint section?	Please remove any foreign matter and ensure that normal movement takes place.
	Check that the connections of the knee joint and foot are not loose.	Check the alignment screw.
	In cases other than above	Contact the Distributor.

11 Disposal

The table below shows the materials of the ALLUX™ knee unit in each component. When disposing of the knee joint, comply with the rules stipulated in the local community. If you return it to Nabtesco after giving such a notification,we will dispose of it for you.

	Part name	Classification of material	Remarks
1.	Frame	Plastic	Carbon fiber reinforced composite material. Aluminum structural parts are inserted in it.
2.	Knee links	Metal	Aluminum alloy
3.	Knee pad	Rubber	
4.	Rubber stopper	Rubber	
5.	Hydraulic cylinder	Metal	Body: aluminum alloy, piston rod: titanium alloy, o-ring: rubber,
6.	Microprocessor control board	Plastic	Electronic substrates and component chips comply with the RoHS directive.
7.	Lead wire	Electric wire	
8.	Battery	Li-ion battery	See 8.1
9.	Joint parts	Metal	Titanium alloy
10.	Other plastic parts	Plastic	Refer to each material symbol on each.



12 Periodic Inspection

12.1 Periodic Inspection

In ensuring safe use please make sure the ALLUX™ has a periodic inspection after 2 years of use. The periodic inspection will be performed free of charge within the warranty period. After the warranty period has expired, the periodic inspection will be performed at the user's expense.
The worn parts (extension stopper rubber and rubber pads) attached to ALLUX™ will be replaced free of charge if they have deteriorated during the periodic inspection within the warranty period.
When you want to ask us about a periodic inspection ,contact the Distributors.

NOTICE	■Ensure that ALLUX™ undergoes periodic inspection after 2 years. If it is used without periodic inspection, wear and deterioration may be accelerated, and the warranty may not cover issues or damages.

13 Warranty

13.1 Warranty

1) The main ALLUX ™ unit is guaranteed for a period of 3 years from the date of purchase (basic contract) and the designated devices described on page 6 a period of 1 year. If failure or damage is caused by inadequacies of design or manufacture of the equipment supplied by us during the warranty period under normal usage, we will repair or replace the relevant part(s).
2) The external parts (extension stopper rubber, rubber pads, etc.) supplied with ALLUX™ are not covered by the warranty.
3) The warranty covers only defective items. We will not compensate for various expenses caused by the product failure or other damages.
4) In the following cases, the repair will be at the customer's expense even within the warranty period.
   - ■When failure or damage is caused by handling not conforming to the precautions stated in this document, dropping during use or giving impact not in the normal state of use.
   - ■When failure or damage is caused by incorrect use or improper modification or repair.
   - ■When failure or damage is caused by fire, earthquake, wind, flood, seawater, lightning or any other extraordinary natural phenomenon.
   - ■When failure or damage is caused by use of a device other than those designated by Nabtesco.
   - ■When failure or damage occurs after the warranty period has expired.
   - ■When failure or damage is caused by adjustment by a party other than those certified by Nabtesco or the Distributor.
   - ■When failure or damage is caused by use without periodic inspection.
5) Liability

   The manufacture will only assume liability if the product is used in accordance with the descriptions and instructions provided in this document. The manufacturer will not assume liability for damage caused by disregards of this document due to improper use or unauthorized modification, or for accident caused by the amputee's (user's) condition, especially due to the change of physical condition.
6) Resale and transfer of ALLUX™

   In thereby ensuring safe after-sales servicing and periodic inspections, and thus overall safety, no reselling or assigning of the ALLUX™, accessories, ALLUX™ software, or wireless dongles are permitted.

13 Warranty

13.2 Warranty periods of designated devices

The warranty periods of the designated devices used for ALLUX™, such as the charger, are shown in the following table.

Remote controller NE-RC02	1 year		Charger NE-BC01	1 year	
Charging port cap NE-CC01	1 year		AC adapter NE-AD01	1 year	
Power OFF cap NE-CC02	1 year		Plug adapter (UL) NE-PA01	1 year	
Backup battery NE-SB01	1 year		Backup battery charging cable NE-CL01	1 year	
Extension cable NE-CL02	1 year		Backup battery holder NE-SC01	1 year	

13.3 Repair

1) If the cause of defect is unclear, the measures will be determined through consultation between the customer and the Distributor.
2) Repair of external painting will be performed at the user's expense. Ask the Distributor for estimation.
3) If the knee joint must be repaired after the warranty period has expired, the warranty period only for the repaired part will be extended for 1 year.
4) ALLUX™ which has been used for 8 years after purchase may be unrepairable.

ALLUX™

Nabtesco Corporation

Manufacture

Nabtesco Corporation
Accessibility Innovations Company
Assistive Products Department
35,Uozakihama-machi,Higashinada-ku
KOBE,658-0024,JAPAN
Phone: +81-78-413-2724
Fax: +81-78-413-2725
http://welfare.nabtesco.com/

Authorized representative for EU contries

ORTHO-REHA Neuhof GmbH
Gundelfinger Straße 6
90451 Nürnberg, GERMANY
TEL: +49 911 643 3940
FAX: +49 911 660 4124

Contact

Please contact us if you find any page missing or disordered.

Nabtesco

Nabtesco Corporation