ALLUX™

Instruction Manual

For Prosthetists

Product Type：NE-Z41, NE-Z41SH
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Language : English

⚠ CAUTION

- Carefully read the instruction manual prior to use.
- Adjust ALLUX™ 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 a microprocessor 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

Intended purpose of ALLUX™

ALLUX ™ was designed and is manufactured for use as a prosthetic knee joint by above-knee amputated, knee disarticulated, hip disarticulated patients. 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™.

This device is intended for single patient multiple use.

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™.

If you have a serious incident related to ALLUX™, please report it to the manufacturer (contact information on the back cover) and the competent authority in your country.

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 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.
It covers the following references: NE-Z41, NE-Z41SH.

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.

About trademarks

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 About Adjustment App
4. Assembly procedures	Aligning method Use of extension cable Contact with socket at maximum flexion angle
5. Selective Modes by Application Remote Control	Explanation of selective modes by Application Remote Control
6. Precautions on adjustment	Precautions on use of the Adjustment App
7. States of ALLUX™	Explanation of states of ALLUX™ and vibration alert pattern
8. Charging procedures	Procedures for charging ALLUX™ and backup battery pac
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
14. Symbols Used	Explanation about symbols of labels

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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.

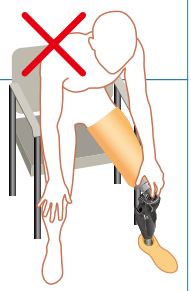
1.2 Warning

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 carry heavy items at all time.
- Do not perform violent operations when carrying a heavy item.
- 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 ALLUX™, do not put your hand behind the knee joint.
- When extending ALLUX™, do not touch the knee.
  This can cause injury from your hand being caught in the knee joint.
- Be careful so that the form cover or stocking gets caught in the four-bar joint section or other parts.
  It may cause an operational malfunction.

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 use the product in a low-pressure area such as a high mountain.
- Be sure to hand over the attached User's Guide to the user and explain the precautions for use.
- 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 battery 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.

- Ensure that no solid particles or foreign objects can penetrate into the product.
  The parts could be damaged or broken, thus resulting in a fall.
- Do not immerse the product in liquids, such as water.
  ALLUX™ is not resistant to penetration from water jets, steam, or submersion.
- If it gets wet, wipe ALLUX™ firmly with a lint-free cloth and let it fully air dry in the shade.
- Do not contact liquids such as salt water, chlorinated water, soapy water, gel soap, body fluids and exudates.
- If ALLUX™ comes in contact with above liquid, wipe it with a lint-free cloth moistened with fresh water.
  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.
- Do not leave the unit unused for an extended period of time.
  Could cause performance problems or failures do to the battery remaining in completely discharged state,the hydraulic fuild or bearing grease deteriorating, and/or the knee axis becoming set in a fixed position.

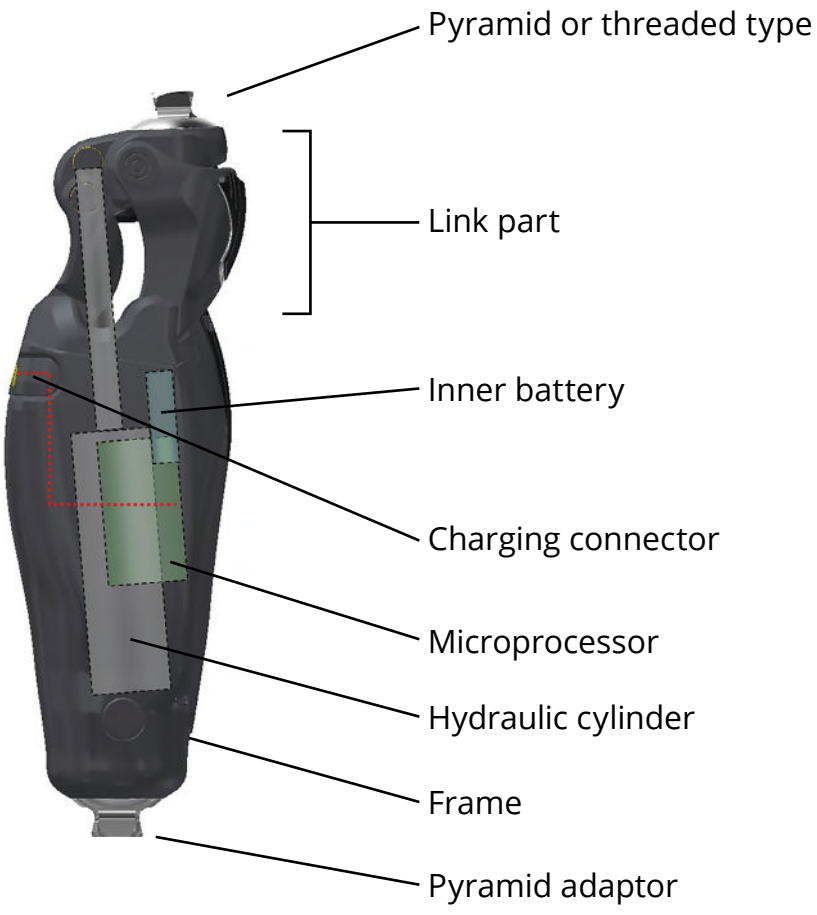
2 Product Overview

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 ALLUX™ 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

●Structural durability

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)

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 ALLUX™.
- Do not use ALLUX™ adjacent to other equipment. Portable and mobile RF communications equipment can affect 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 REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC

2 Product Overview

2.4 Specifications

- Type：NE-Z41 (pyramid), NE-Z41SH (threaded)
- Application range & Weight limit:
  ～K3(MOB3):125kg(275 lb)
  K4(MOB4):100kg(220 lb)
- Weight: 1510g(NE-Z41)/1520g(NE-Z41SH)
- Maximum flexion angle: 180°
- Water resistance: IP44
- Internal power supply:
  Lithium ion battery
- Communication distance: Within 5 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.

NOTICE

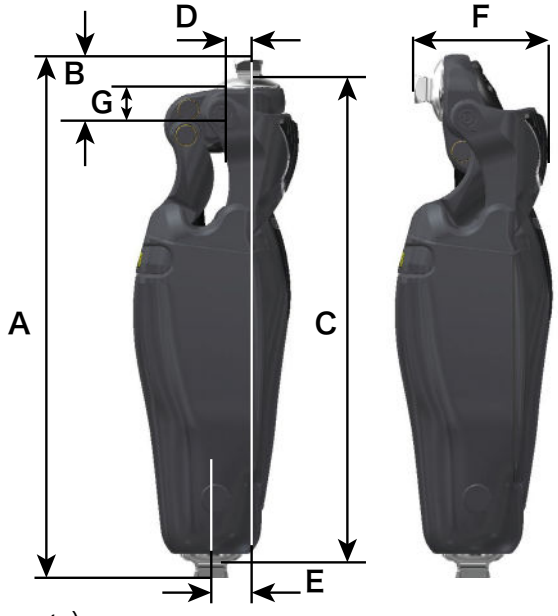
- Do not give the product a strong impact, such as hitting the front cover to the product.
  This could deteriorate its water-proof performance.
- Do not immerse the product in water.
- Do not wash the product with a high temperature or pressure.
  This could allow water invasion and damage the product.
- If the product is wetted, wipe the moisture out.
- Do not allow saltwater such as seawater to attach to the product.
- If liquid other than water attaches, wash the product. Do not use any detergent.
  Such liquid could cause rust or corrosion.

- Dimensions：

	NE-Z41	NE-Z41SH
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.



- Compatible medical devices (prosthesis components):

ALLUX™ reference	NE-Z41	NE-Z41SH
Proximal connectors	Female pyramidal connectors	M36 screw connectors
Distal connectors	Female pyramidal connectors	Female pyramidal connectors

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-Z41		Backup battery holder NE-SC01	
Instruction Manual 81-SS00125	This Document	User's Guide 81-SS00126	
Bluetooth password and unit number 81-SS00133		Information as to Periodic Inspection 81-SS00135	

※ For screw heads, 81-SS00062 Knee Release Adapter Instruction Manual will be added.

【Designated devices】

Charging port cap NE-CC01		Power OFF cap NE-CC02	
Backup battery pac NE-SB01		Extension cable NE-CL02	
Battery charger NE-BC01		AC adapter NE-AD01	
Plug adapter(UL) NE-PAXX		Backup battery charging cable NE-CL01	

※ The shape of the plug depends on the form ordered.
※ Backup battery pac may not be included depending on the form ordered.

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

3 Before Use

3.2 Preparation for adjustment

Install the Adjustment App to the smartphone used for ALLUX™ adjustment.

●ALLUX™ supports the following operating systems (OS):

Android : 7 or later
(There is no guarantee that it will work on every Android device.)
iOS : 13 or later

●The installation and adjustment methods vary depend on the OS. Download the Adjustment App manual corresponding to the OS from the website below and follow the instructions.

Website for downloading the Adjustment App Manual:
https://mobilityassist.nabtesco.com/app_info/

●The Adjustment App cannot be used unless the password is provided so that only licensed prosthetists can adjust the product.

CAUTION

■Do not give the password to other people (including the user). Use of the Adjustment App by an unlicensed person may lead to inappropriate adjustment and cause an accident such as a fall.

Bluetooth®

Precautions on Bluetooth

■Radio waves emitted by a Bluetooth device may affect the operation of electronic devices and other devices.
Turn off Bluetooth devices when near priority seats in trains, in areas where flammable gas is generated such as in airplanes, near automatic doors and fire alarm devices, as it may cause an accident.

■We do not take any responsibility for the leakage of information when using Bluetooth technology.

■This product does not guarantee wireless connection with all Bluetooth devices. The Bluetooth device to be connected must comply with the Bluetooth standard specified by Bluetooth SIG and must have obtained at least a certification. In addition, even if the device to be connected complies with the Bluetooth standard, phenomena such as inability to connect or different display/operation may occur, depending on the characteristics and specifications of the device.

■Do not disassemble or modify this product as the wireless functionality of this product has been certified to meet technical standards.

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 ALLUX™ 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 180°.

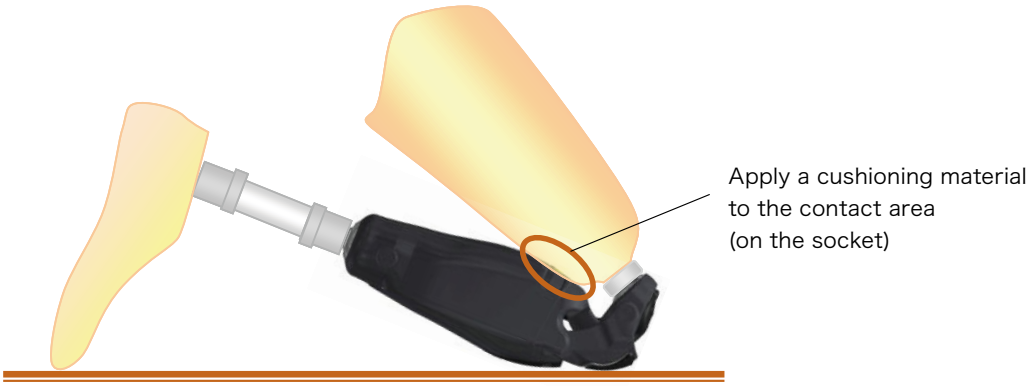
NOTICE

- 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 ALLUX™ then ensure to use some form of cushioning (elastic material such as rubber) in the socket to avoid any direct contact. In case the adaptor of the socket or pipe inevitably contacts with ALLUX™, avoid the contact with the part upper the charging port.

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

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

(2) Do not apply a load heavier than the body weight at bending ALLUX™ 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 ALLUX™ is flexed.
  The battery may short-circuit, could result in a malfunction.

5 Selective Modes by Application Remote Control

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 Application Remote Control to change the operational modes. The optional buttons on the Application Remote Control can be customized as appropriate.

5.2 Application Remote Control

The Application Remote Control allows you to switch to ALLUX™ mode. To change modes, tap the button on the Application Remote Control within 5 minutes of bending and stretching your knee or removing your body weight and then applying it while standing in safe posture.(See 6.1)
Press the '1' button on the Application Remote Control to return to normal mode.

WARNING

- If using a smartphone, be careful to prevent buttons etc from incorrect operation.
  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 incorrect operation of the Application Remote Control has occurred.

NOTICE

- Do not use a smartphone when devices that may emit radio waves are prohibited, such as in an airplane.
- Connecting and putting out the battery charger or power source OFF cap returns ALLUX™ to the normal mode set for button 1 of the Application Remote Control.
  Note that the state can be changed before and after charge.

How to change the operational modes.

- Assume safe posture. (See 6.1. Safe posture)
- Tap buttons 1-5 on the Application Remote Control.
- Then a pop-up will appear. Select "OK".

The vibration will sound continuously for 2 seconds.

- The selected mode is applied.

CAUTION

- After a mode change, move ALLUX™ to check the behavior.
  If the mode has not been changed to the intended one due to a wrong button operation, an accident such as a fall may occur.

5 Selective Modes by Application Remote Control

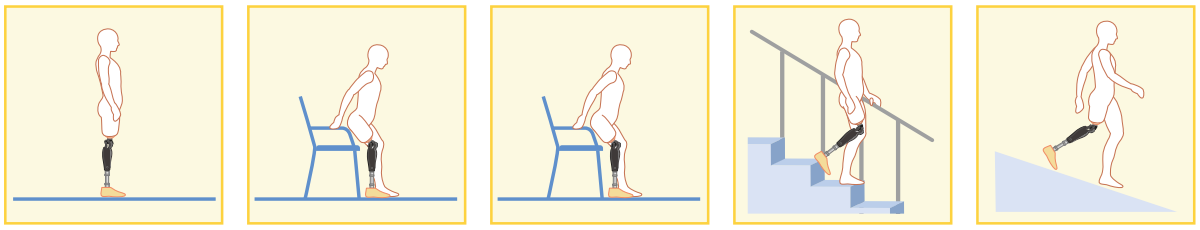
5.3 Normal Mode

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 flexion or extension resistance.

5.3.2 Yield Function

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



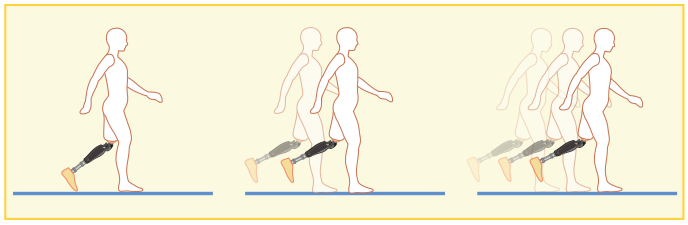
Standing | Sitting down | Standing up | Going down steps | Going downhill

WARNING

■Hold onto the handrail while getting down the stairs.
An intended behavior of the product may cause a fall.

5.3.3 Walking speed auto-adjust function

ALLUX™ automatically adjusts the flexion and extension resistance according to walking speed.



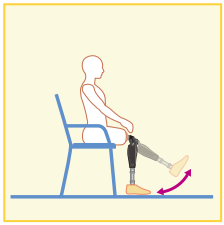
CAUTION

■Check the setting in a safe place, such as in between parallel bars.
An inappropriate adjustment may produce bad timing.

5 Selective Modes by Application Remote Control

5.3.4 Seated position

When in a seated position, ALLUX™ maintains no resistance in flexion or extension.

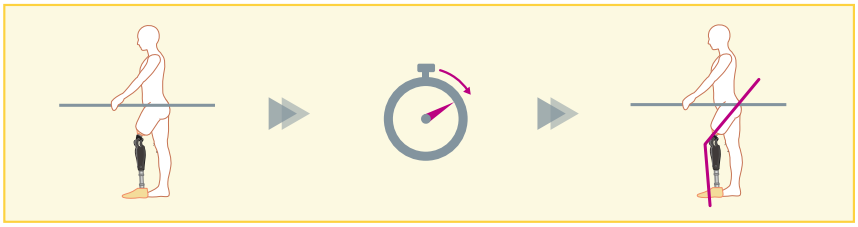


CAUTION

■When standing up from a seated position, put your weight on the side with the prosthesis.
With no load applied, a free state continues, which may cause a knee to bend.

5.3.5 Safety lock

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



CAUTION

■During a safety lock, keep putting weight on ALLUX™. With no load applied, the lock may be released, causing ALLUX™ to bend.

5.3.6 Bicycle

When riding a bicycle with ALLUX™, lower the Stance Resistance value to a low setting to allow it to easily flex.

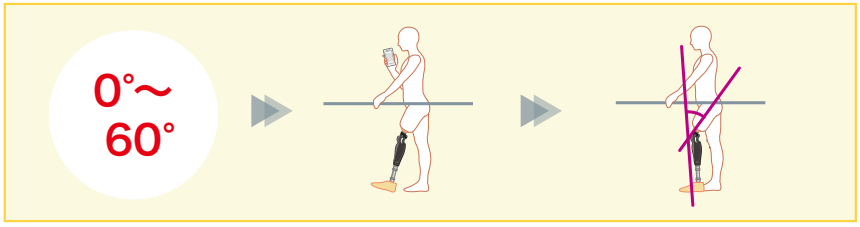
CAUTION

■If riding a bicycle is more comfortable in “Free mode”, make sure the user is able to stand using their sound side while in the riding position. Make sure they are aware that if the prosthesis is used to stand, while stopping, there will be no microprocessor stumble recovery or highresistance to prevent the knee from bucking and the user may fall.

5 Selective Modes by Application Remote Control

5.4 Flexion angle limit mode

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

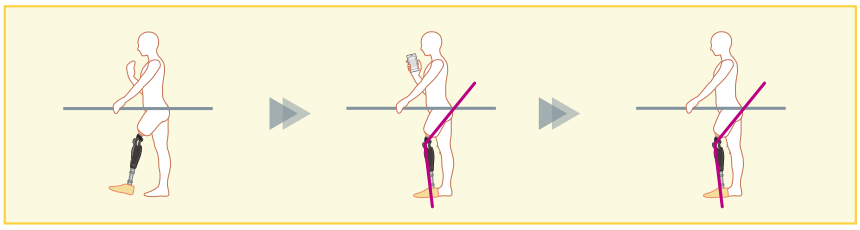


NOTICE

■Bend ALLUX™ to the lock angle swiftly; do not stop in the middle. ALLUX™ may be damaged.

5.5 Variable selective flexion lock mode

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

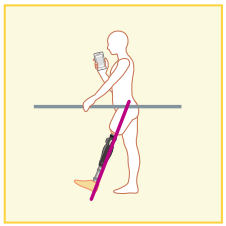


NOTICE

■Bend ALLUX™ to the lock angle swiftly; do not stop in the middle. ALLUX™ may be damaged.

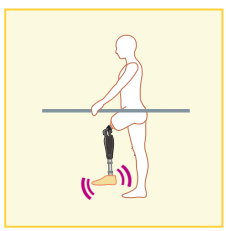
5.6 Full extension lock mode

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



5.7 Free swing mode

In free swing mode, ALLUX™ is kept free.



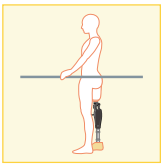
6 Precautions on adjustment

The specific procedures for the adjustment are provided in the Adjustment App Manual. Here, the precautions on adjustment are described.

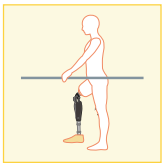
6.1 Safe posture and condition ready for communication

'Safe posture' refers to the posture taken in order to change the mode before using the Application Remote Control or communicating with the Adjustment App. 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 ALLUX™ 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.

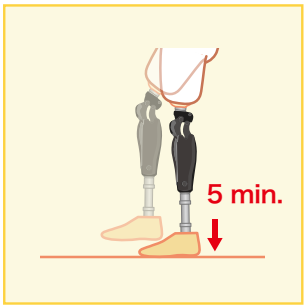
CAUTION

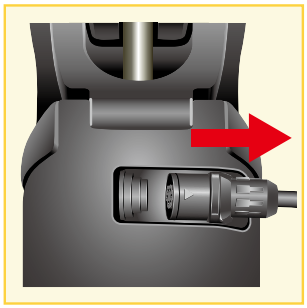
- Explain to the user about the safe posture, and ensure that the user understands it.
- When the user takes the safe posture without applying the body weight to ALLUX™, he/she must hold a handrail or sit down. Flexion/extension resistance may suddenly change, leading to a fall.

6 Precautions on adjustment

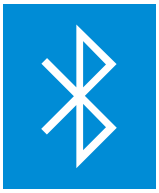
In order to conserve power, ALLUX™ is not always in communication mode.
Communication mode is activated in ALLUX™ 5 minutes after lightly bending and extending, or 5 minutes after applying your body weight and then removing it. Once ALLUX™ communication is established, this state lasts until communication is disconnected.

【Communication mode enabled:】
①For 5 minutes after ALLUX™ is slightly flexed and extended
②For 5 minutes after the user applies his/her body weight to ALLUX™
③For 5 minutes after the battery charger or power OFF cap is disconnected from ALLUX™

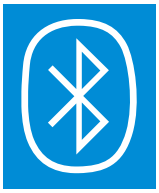




Adjustment App displays the communication state icons as below.

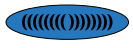


Not connected



Connected

When you board an airplane or other such vehicles and need to turn off the wireless function of ALLUX™, you can use the Application Remote Control to turn it off.
To reactivate the wireless function again after that state, follow the procedure provided below.
①Remove the battery charger or the power source OFF cap from ALLUX™.
②In the case, loads are applied intermittently on the toe or heel four times (this operation can be changed on the smartphone).
A vibration will occur to tell the reactivation of the wireless function when operation ② is performed.

 **2**sec **:reactivates the wireless function.**

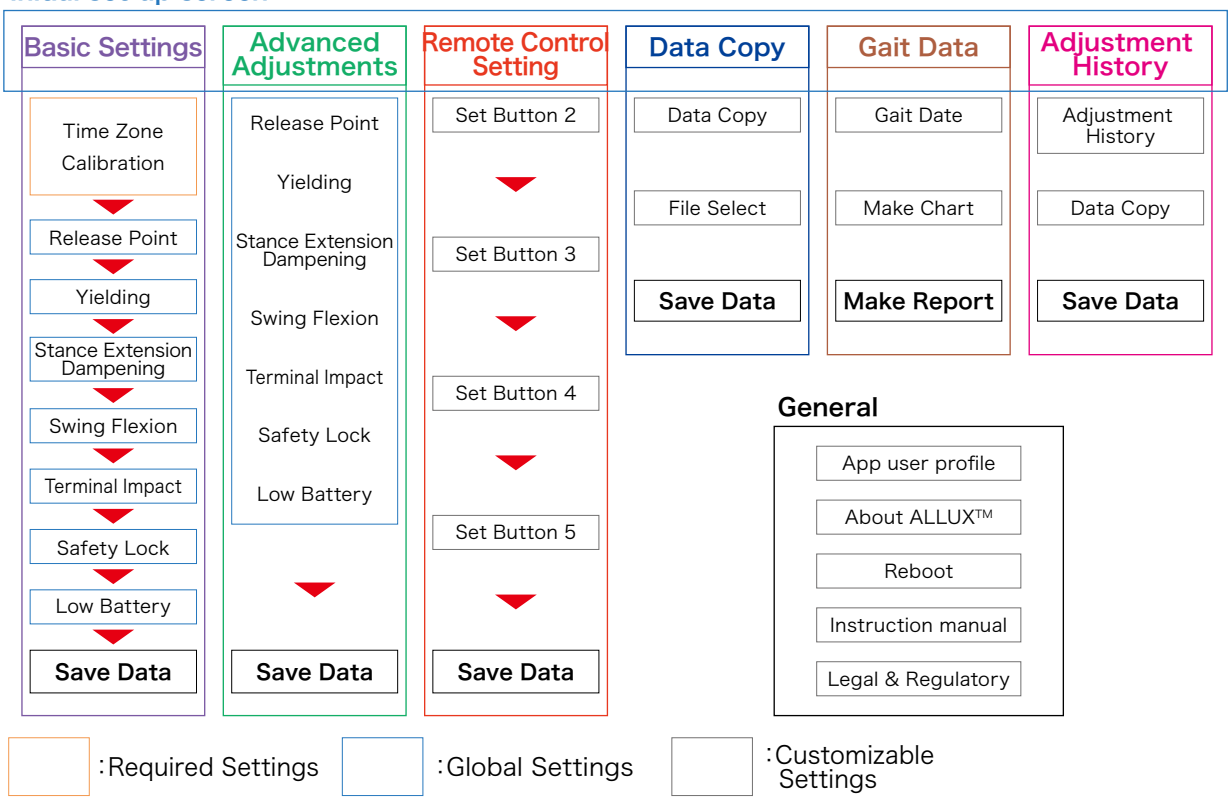
Note that this vibration occurs if operation ② is performed even when the wireless function is active. (Up to firmware version 50.38)

6 Precautions on adjustment

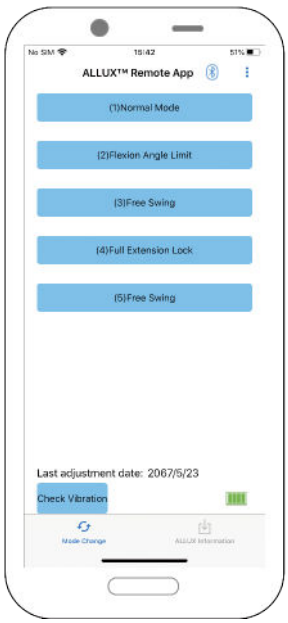
6.2 Adjustment Procedures

Adjustments are undertaken in the following steps.
The details are provided in the Adjustment App Manual.

Initial set-up screen



The initial setting of the Application Remote Controlat the delivery is as follows.



Default Remote control setting:
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

These settings can be changed by the Remote control setteing of Adjustment App.
Adjustment is not necessary when the default setting is used.

6 Precautions on adjustment

6.3 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.
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.

6.4 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 6.6) after calibration.
  The setting value of the optimal release point may change and normal walking may be impossible.

6.5 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 ALLUX™ is locked when he/she tries to walk.

6 Precautions on adjustment

6.6 Adjusting the Toe Release Point

Factory default setting = 80

Set the toe release point for transition to the swing phase. Check the walking condition in parallel bars where the user's safety can be ensured.

CAUTION

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

6.7 Adjusting the Stance Flexion Yielding

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

6 Precautions on adjustment

6.8 Adjusting the Stance　Extension Dampening

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

Normally, set the extension resistance in stance phase to 5, no resistance state. Adjust the resistance only when the user uses the double knee motion. 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 stance extension dampening may be increased. Check the double knee resistance before starting use in a low-temperature environment. Since ALLUX™ 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 ALLUX™ 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.

6.9 Adjusting the Swing Flexion Resistance

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

Adjust the flexion resistance in the swing phase. After the resistance is adjusted based on the normal walking speed, ALLUX™ 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.
If the knee cannnot smoothly shift to swing phase, user may fall.

*If ALLUX™ jams (cannot shift to the swing phase) and the user cannot walk, re-adjust the toe release point as stated in 6.6

6 Precautions on adjustment

6.10 Adjusting the Terminal Impact(Swing Extension)

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

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, ALLUX™ 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, ALLUX™ cannot extend completely, and the user may fall.

6.11 Adjusting the Safety Lock

Factory default setting = Invalid

The safety lock is designed to lock ALLUX™ at a flexed angle in which the user stops for a certain time with ALLUX™ 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 ALLUX™, and his/her knee may be bent.

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

CAUTION

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

6.12 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 Control setting of Adjustment App.
The user may not be able to move to a safe place because of the low battery.

7 States of ALLUX™

7.1 States of ALLUX™

ALLUX™ has some modes, i.e. charging mode, backup battery pac connecting mode, modes selected by the Application Remote Control, 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 6.5.).
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 pac is connected at this time, ALLUX™ can be used for one day. The backup battery pac 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 ALLUX™ cannot be used without charging, the user cannot use ALLUX™ even if the backup battery pac is connected. When the battery is exhausted, a high yielding resistance (flexion resistance value30) or a free state (flexion resistance value0) is applied to the flexion resistance (See 6.12 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 battery 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 ALLUX™ 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 pac is not recommended. Could hasten battery degradation. * After using the backup battery pac, charge the internal power supply and backup battery pac. * The operational duration time may vary due to the temperature, deterioration, or walking conditions.

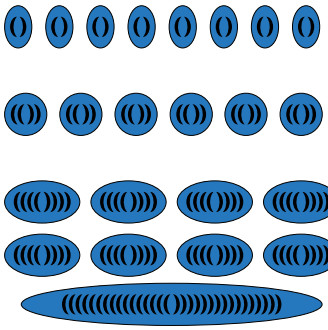
7 States of ALLUX™

7.2 Normal use state

7.2.1 When battery charger or power OFF cap is disconnected

When the battery 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 battery charger and power OFF connector, connect the charging port cap (NE-CC01).

●Disconnect the battery charger or the power OFF cap. When the vibration does not sound as below, connect the battery 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.

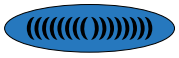
WARNING

■After disconnecting the battery 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 battery charger or power off cap are connected.

●Connect the battery 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 pac

When the battery is exhausted, the control of ALLUX™ will be stopped. Connecting the backup battery pac (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.

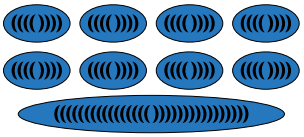
0.5sec×**8**times

- Remove the Charging port cap.
- Fit the backup battery holder (NE-SC01) containing the backup battery pac 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 pac to ALLUX™.

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

0.25sec×**8**times **:3hours or more**

0.5sec×**8**times **:Less than 3hours**



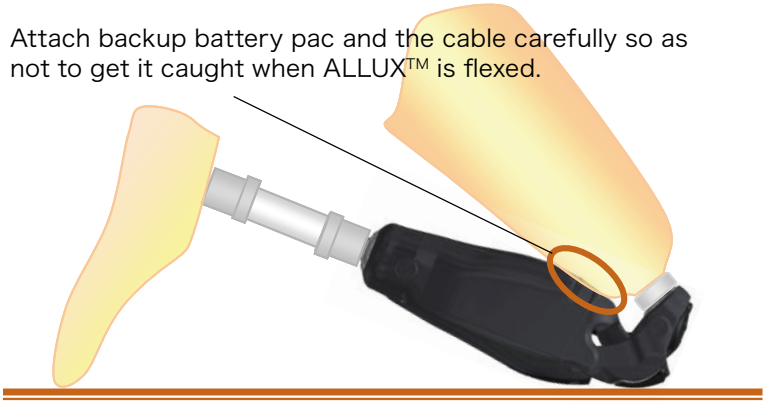
0.75sec**8**times+**(4**sec**):No more walk**

  * The backup battery pac must be charged.

【How to use】

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

Attach backup battery pac and the cable carefully so as not to get it caught when ALLUX™ is flexed.



【Limitations of the battery】

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

【Confirming with the aviation regulations】

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

7 States of ALLUX™

WARNING

- Connect the backup battery pac 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 holder on the thigh side (above ALLUX™).
  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 holder on a side of ALLUX™ body(Frame).
  The socket and backup battery pac may get into contact at the maximum flexion angle, and the backup battery pac may be damaged.
- Do not insert or remove the backup battery pac 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 pac for any other devices.
  It may cause damage to the battery or the device.
- Do not use constantly in the normal state.
  The main battery for internal power supply of ALLUX™ shall not be charged by backup battery.
  When discharged to a certain level, the backup battery pac cannot be used.
- Do not charge with any battery 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 pac terminal is exposed.
- Do not touch with wet hands.
  Could lead to a battery short and the risk of electric shock.

NOTICE

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

7 States of ALLUX™

【Specifications for backup battery pac】

- Service temperature: 0℃/+32℉ to +40℃/+104℉
- Resistance to ambient temperature: -20℃/-4℉ to +60℃/+140℉
- Resistance to ambient humidity: 10 to 90%RH
- Battery charger: NE-BC01
- Applicable device: ALLUX™ (NE-Z41 or NE-Z41SH)
- Service life: 1 year

Backup battery pac **NE-SB01**	

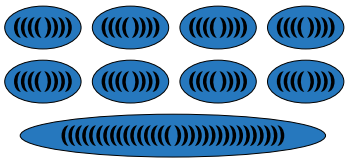
7 States of ALLUX™

7.2.4 Battery exhaustion (zero battery)

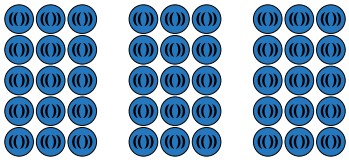
When the internal power supply has exhausted and ALLUX™ cannot be used, the warning about battery exhaustion will be given by vibration. Then, the vibration for request for safe posture will be given. When the user takes the safe posture, the walking control will be stopped, and ALLUX™ will be locked or free(see 6.12). In this case, ALLUX™ can be used continuously for one day by connecting the backup battery pac (NE-SB01). (For the specifications for the backup battery pac, 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, ALLUX™ 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×15times : Request for safe posture

⇒ALLUX™ 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.
●ALLUX™ will be locked in the flexed state (at a high yielding resistance).
When the 'free' low battery setting (6.12) is selected, the knee flexion becomes free.
●Connect the backup battery pac 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 pac capacity will sound.
* The backup battery pac must be charged.

【When the backup battery pac is not available or the user goes back home】
●Charge ALLUX™. (See 8.1.2 “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, ALLUX™ 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 ALLUX™ 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.

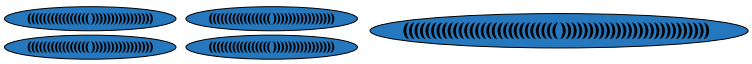
- Do not touch any metallic part of the prosthesis knee joint.
  Could result in burns.

【When the temperature is increasing】

4 sec * **2** times with **30** sec interval

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

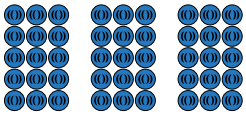
【When the temperature has abnormally increased】



4sec * **4**times+**10**sec

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

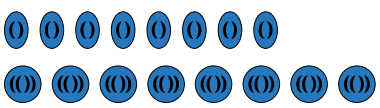
【When ALLUX™ cools down】



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

⇒ALLUX™ 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.



0.25sec×**8**times ：**3hours or more**

0.5sec×**8**times ：**Less than 3hours**

* When ALLUX™ 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, ALLUX™ will be immediately locked by the high temperature. The user is recommended to take a rest for 10 to 20 minutes until ALLUX™ sufficiently cools down.

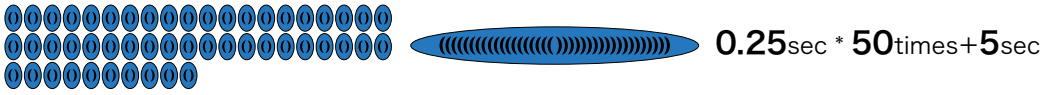
7 States of ALLUX™

7.3 In case of malfunction

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

WARNING

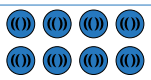
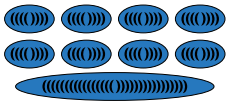
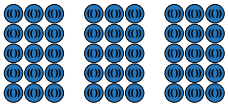
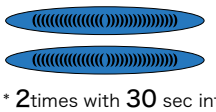
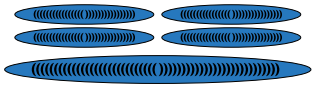
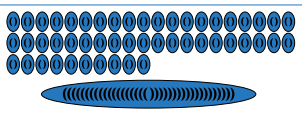
- If ALLUX™ is defective, the user cannot walk normally.
- If the vibration for warning about malfunction sounds, immediately discontinue the use, and contact the Distributor. Normal walking will not be supported, possibly resulting in a fall.



- ALLUX™ will be locked (at a high yielding resistance).

7 States of ALLUX™

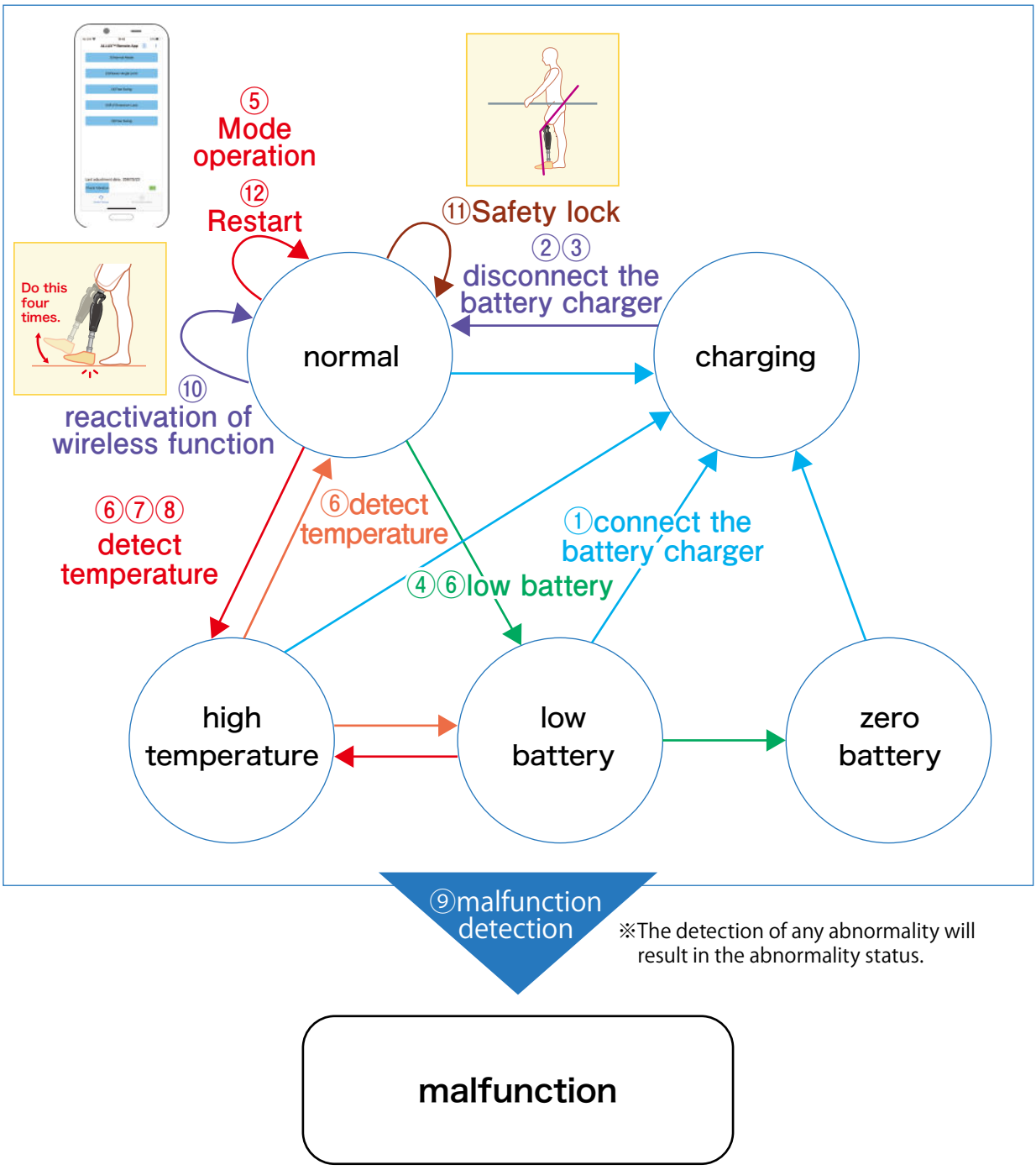
7.4 Vibration alert pattern chart

	Vibration alert	Alert conditions	Meaning
①	 2sec	When the battery charger or Power OFF cap is connected	Control of ALLUX™ has been stopped.
②	 0.25sec × 8times	When the battery charger or Power OFF cap are disconnected	The battery level supports at least 3 hours
③	 0.5sec × 8times	When the battery charger or Power OFF cap are disconnected	The battery level supports less than 3 hours
④	 0.75sec8times+(4sec)	When the battery 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 Application Remote Control (See 5.2)	ALLUX™ mode change has been completed using the Application Remote Control.
⑥ ⑥ ⑥	 0.5sec * 3times × 15times	Low remaining battery High temperature state Recovering from abnormally high temperature When the control of the hydraulic cylinder becomes temporarily unstable	Status requiring a safe posture. If this status continues ensure to contact the distributor as a malfunction may have occurred.
⑦	 4 sec * 2times 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 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 ALLUX™ is abnormal and normal walking is not supported. The abnormal status could be resolved by inserting/removing the battery charger or power off cap. If this does not solve the problem then please ensure to contact the Distributor.
⑩	 2sec	When the load is intermittently applied to the toe or heel four times	The wireless function of ALLUX™ has been reactivated.
⑪	 0.5sec × 1times	Safety lock	The safety lock is being activated.
⑫	 0.25sec × 8times	When you press the restart button of the Adjustment App or the Application Remote Control	Reboot ALLUX™.

*1: Remaining battery refers to the remaining capacity of ALLUX™ main battery or the backup battery pac.
Only a guide as it can vary with the usage conditions.
*2: If no vibratory notification occurs when the battery charger or power supply off connector is removed then an abnormality may have occurred.
*3: If another notification condition is met while the alert is set to vibration mode, the vibration may be switched on.

7 States of ALLUX™

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



※No.1-12 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 pac shall be charged with the special battery charger (NE-BC01). When using ALLUX™, it is recommended to charge it every day as a rule.

- If the vibration does not sound when the battery 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 battery 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 battery 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 battery 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 battery 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-PAXX). 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 battery 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 battery charger connector to the connector terminal of ALLUX™ while sliding along the guide from outside the frame.
* If you try to connect from an angle, the pins of the connector terminal will be bent and charging will not be possible.

The vibration will sound continuously for 2 seconds.

Connector cover

Connector terminal

Battery charger connector

8 Charging Procedures

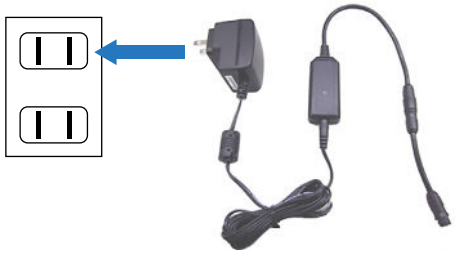
●The LED lamp on the battery charger will light on in orange.
* If the temperature of ALLUX™ is higher than +40˚C/+104˚F just after ALLUX™ is used, the green LED lamp will flash.
●When charging is completed after a certain time, the LED lamp will turn green.
* If ALLUX™ is left for a long time after the completion of charging and the battery capacity becomes lower than a certain level, the battery will be recharged.
●Remove the battery charger connector.
Slide the lever on the charger connector to right to unlock and remove it.
* The charger connector may be damaged if the charger cable is disconnected without unlocking.
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 the distributor.
●Fit the charger port cap.


Remove the AC adapter from the commercial power supply.

8.1.3 Charging the backup battery pac

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

●Connect the backup battery charging cable to the battery 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 pac to the backup battery charging cable.
●The LED lamp on the battery charger will light on in orange.
※ If the temperature of ALLUX™ is higher than +40ºC/+104ºF 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 pac 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.
■Keep children and infants away while the AC adaptor is connected to the commercial power supply.
There is a risk of electric shock.

8 Charging Procedures

8.1.4 Indication by LED lamp on battery charger

The LED lamp on the battery 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 battery charger or the AC adapter may be defective. Contact the Distributor.

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

LED lamp on battery charger

Backup battery charging cable

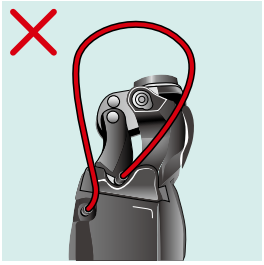
8.1.5 Use of extension cable

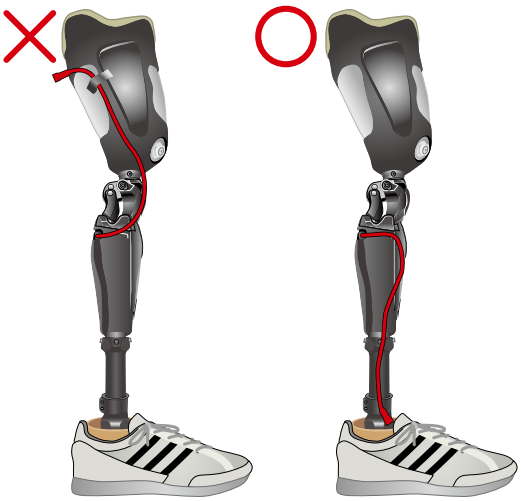
Use an extension cable when ALLUX™ charging connector is covered with form cover, etc.

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 ALLUX™ bends.
- Make sure the cable does not get caught in the socket when using ALLUX™ 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

The lifetime of the device is 6 years, depending on the activity level of the patient. The actual useful life is ultimately determined by the prosthetist upon request of the device's owner.
While the device is in use and after the end of the period of use, its functionality and operating condition should be assessed by the prosthetist periodically with a minimum frequency of 2 years.

9.1 List of maintenance parts

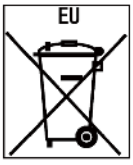
During periodic inspection, the following maintenance parts are used.
When you want to purchase replacement parts for maintenance or have to questions about maintenance of ALLUX™,contact the Distributor.

【Replacement of battery】

Main body of ALLUX™ NE-Z41		If the battery life is coming to an end, receive the main body of ALLUX™, and return it to the distributor.
Backup battery pac NE-SB01		When the life of the backup battery pac is coming to an end, purchase a new one from the distributor, and replace it.

NOTICE

■The backup battery pac 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 cover, pad, and stopper】

Consult your prosthetist for replacement.
The following parts can be purchased from us.
Replace the extension rubber stopper following the procedure shown in 9.2.

Extension rubber stopper N-G012	

The following parts can be replaced by us. Send it back to us.

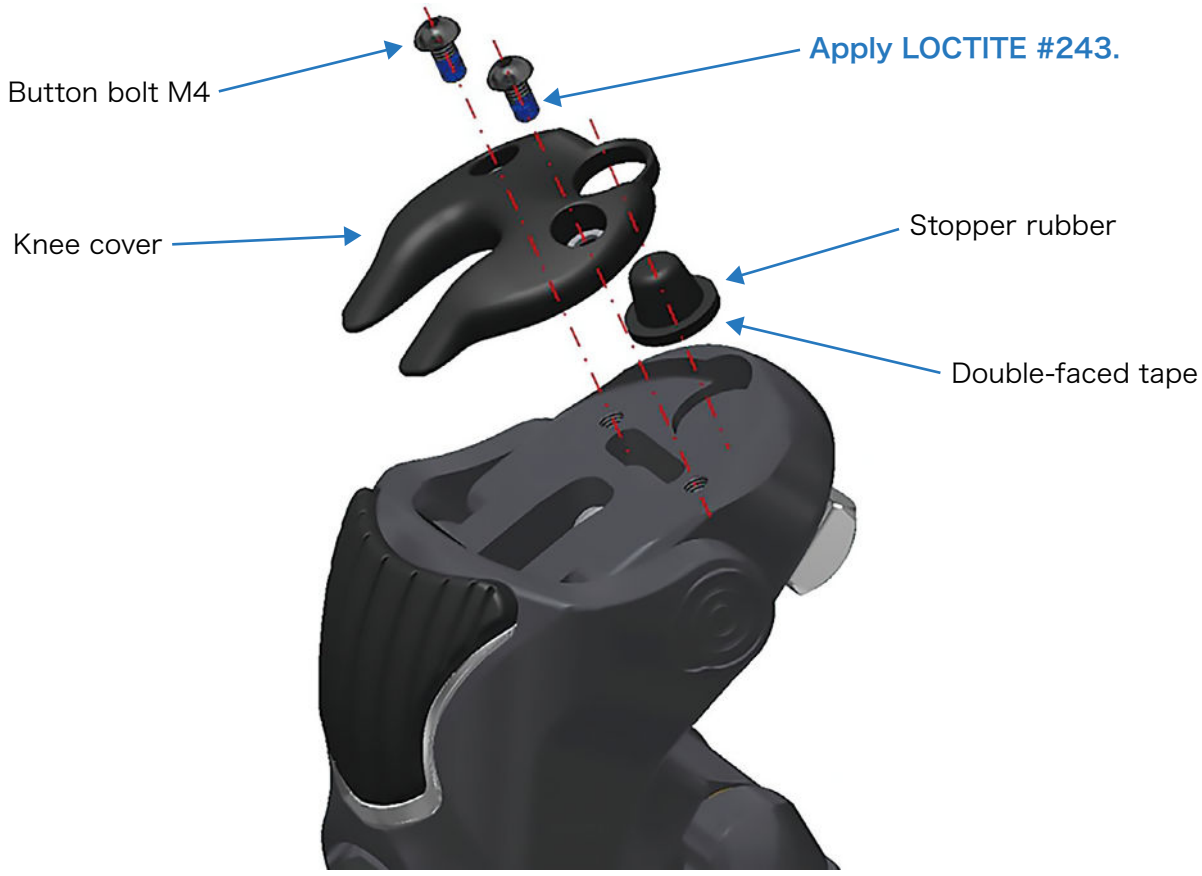
Front link pad NE-FC01		**Front cover pad NE-FC02**	
Front link ST pad NE-FC03			

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).



NOTICE

■Do not apply a commonly-sold lubricant.
Such lubricant may impede a smooth bending of ALLUX™.

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 with smartphone

See the section for troubleshooting in the Adjustment App Manual.

10.1.2 During adjustment with ALLUX™

Problem	Check item	Remedy
ALLUX™ 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 6.6)
	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 ALLUX™ 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 ALLUX™ is not flexed at the late stage of stance phase.	Lower and adjust the stance phase extension damper setting, so that ALLUX™ 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 ALLUX™ 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 6.8)
	Check that the alignment is appropriate.	Adjust the alignment so that ALLUX™ completely extends at the initial stage of the stance phase. (See 4.1)

10 Troubleshooting

Problem	Check item	Remedy
Hydraulic resistance is applied unintentionally (ALLUX™ 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 6.6)
	Check that the alignment is appropriate.	Adjust the alignment so that load can be easily applied to the toe. (See 4.1)
	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 6.6)
	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 6.11)
	Check that the user holds ALLUX™ in a slightly flexed state and applies the weight sufficiently to ALLUX™. (When the weight is not applied or ALLUX™ is flexing or extending even slowly, the lock does not function.)	Train the user to hold ALLUX™ in a slightly loaded state.
	Check that the calibration has been performed.	Redo the calibration. (See 6.11)
	In cases other than above	Contact the distributor.

10 Troubleshooting

Problem	Check item	Remedy
ALLUX™ is locked and jams when the user sits down.	Check that the user does not stop flexing ALLUX™ 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 6.11)
	Check that load is not applied to the toe to flex ALLUX™ 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 6.11)
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 6.10)
	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 ALLUX™. (See 6.10)
ALLUX™ 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 6.10)
ALLUX™ 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 6.8)
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 6.9)
	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 6.9)
	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.

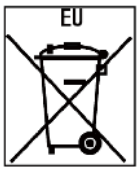
10 Troubleshooting

10.1.3 While in use

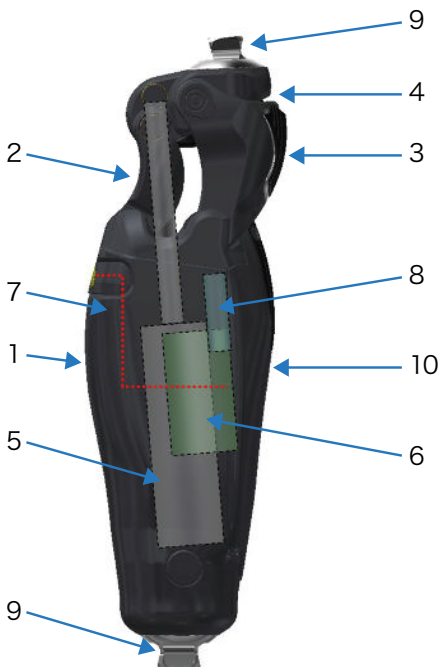
Problem	Check item	Remedy
ALLUX™ cannot be charged	Check that the battery charger connector and AC adapter are surely connected.	Check the connection. (See 8.1.2)
	Check that the vibration sounds when the battery charger connector is connected.	If the vibration does not sound, ALLUX™ may be defective. Discontinue use, and contact the Distributor.
	Check that ALLUX™ 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 Application Remote Control.	Check that the button is pressed within 5 minites after ALLUX™ is flexed and extended or removing the body weight and then applying it.	Flex and extend ALLUX™ or removing the body weight and then applying it, take the safe posture, and operate the Application Remote Control. (See 6.1)
	Check that the user takes the safe posture when operating the Application Remote Control.	
ALLUX™ becomes locked or free.	Check that the vibration did not sounded just before.	If ALLUX™ 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 pac, 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 ALLUX™ section?	Please remove any foreign matter and ensure that normal movement takes place.
	Check that the connections of ALLUX™ 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 ALLUX™ knee unit in each component. When disposing of ALLUX™, 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	Electronic component	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 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.

12.2 How to care

If necessary, wipe the surface with a soft cloth moistened with fresh water.

CAUTION

■Make sure that no moisture or lint from the cloth remains after wiping. Rust and lint caught in the knee may cause abnormalities in the rotating part and affect the bending and streching of the knee.

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 ALLUX™, accessories, Adjustment App, or the password of the Adjustment App are permitted.

13 Warranty

13.2 Warranty periods of designated devices

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

Charging port cap NE-CC01	1 year	
Power OFF cap NE-CC02	1 year	
Backup battery pac NE-SB01	1 year	
Extension cable NE-CL02	1 year	

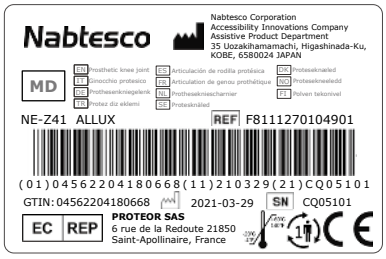
Battery charger NE-BC01	1 year	
AC adapter NE-AD01	1 year	
Plug adapter(UL) NE-PAXX	1 year	
Backup battery charging cable NE-CL01	1 year	
Backup battery holder NE-SC01	1 year	

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 ALLUX™ must be repaired after the warranty period has expired, the warranty period only for the repaired part will be extended for 6 months.
4) ALLUX™ which has been used for 6 years after purchase may be unrepairable.

14 Symbols Used

14.1 UDI label (Packing box)



Legal manufacturer

Made date

MD Medical Device

REF Item number

SN Serial number

GTIN Global Trade Item Number

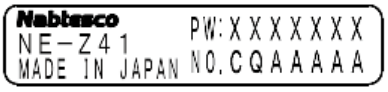
EC REP Authorized representative for EU countries

The maximum and minimum temperatures for storing, transporting,and using the product.

CE Declaration of conformity according to the applicable European directives

Single patient multiple use

14.2 Serial number label (Charging port)



PW: Password for Smartphone

NO. Serial number

14.3 Certification mark label

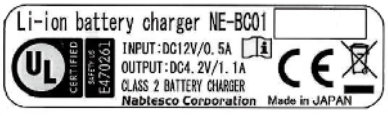
CE Declaration of conformity according to the applicable European directives

The EU requires recycling without landfill. When disposing of it, follow the rules of the local government.

MAX. WEIGHT
~K3 (MOB3) 125kg
K4 (MOB4) 100kg

Body mass limit not to be exceeded. See page 4

14.4 Battery charger label (Battery charger)



Indicates the need for the user to consult the instructions for use.

CE Declaration of conformity according to the applicable European directives

The EU requires recycling without landfill. When disposing of it, follow the rules of the local government.

It certifies that this product complies with UL safety standards.

14 Symbols Used

14.5 AC adapter label (AC adapter)

It certifies that this product complies with UL safety standards.

Compliance with the requirements according to FCC

Charge it indoors.

Energy efficiency level 5

CB mark (Safety tests based on IEC standards)

RCM mark (Safety standards for Oceania)

TüV Rheinland has PSE mark (Safety standards for Japan)

Double insulation

Compliant with LPS standard

DC center plus

TüV Rheinland has certified GS mark (Safety standards for Germany)

Based on RoHS Directive, certain hazardous substances are below the standard value

Declaration of conformity according to the applicable European directives

The EU requires recycling without landfill. When disposing of it, follow the rules of the local government.

INPUT:100-240V~ 47-63Hz 0.4A
OUTPUT:12V ⎓ 1.25A max.

The input is an AC power supply of 47 to 63Hz at 100 to 240V up to 0.4A.The output is a DC power suppy with a maximum of 1.25A at 12V.

14 Symbols Used

14.6 Backup battery label (Backup battery pac)

It certifies that this product complies with UL safety standards.

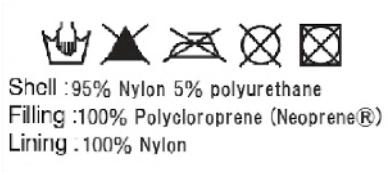
Declaration of conformity according to the applicable European directives

The EU requires recycling without landfill. When disposing of it, follow the rules of the local government.

Indicates the need for the user to consult the instructions for use.

Lithium ion battery

14.7 Backup battery holder label (Backup battery holder)



Wash by hand

chlorine and oxygen bleach is prohibited

Ironing is prohibited

Dry cleaning is prohibited

Tumble drying is prohibited

ALLUX™

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Manufacture

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