



NABTESCO™

User's Guide

Product Type: NE-Z4, NE-Z4SH

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CAUTION

- Carefully read the User's Guide prior to use.
- Keep this User's Guide 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 user's guide (hereinafter referred to as this document) was produced by Nabtesco Corporation to ensure safe and comfortable use of the ALLUX™.

This document describes matters concerning typical usage such as fitting and walking, maintenance, trouble shooting and cautionary notes that anyone utilizing the ALLUX™ needs to know.

Important Information

Purpose of ALLUX™

ALLUX™ was designed and is manufactured for use as an artificial knee joint by above-knee, knee disarticulation, and 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.

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

Only the persons who have received ALLUX™ license seminar are allowed to assemble and adjust it. If necessary, inquire your ALLUX™ certified prosthetist.

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

Nabtesco owns the copyright for this document. It is not permitted to duplicate any part of drawings and technical documents including this document by any means (copying or recording on electronic media) without our prior authorization. When you have questions about the copyright of this document for copy or reference, contact Nabtesco.

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
4. Safe posture	Explanation about how to take the safe posture
5. Selective mode by remote controller	Explanation of Selective modes by remote controller
6. Remote controller maintenance	How to change the battery and attach the strap
7. States of ALLUX™	Explanation of states of ALLUX™ and vibration alert patterns
8. Charging Procedure	Charging procedure for ALLUX™ Charging the backup battery
9. Maintenance Parts	Explanation of service parts
10. Troubleshooting	Methods for confirming to improve feeling
11. Disposal	Explanation about method of disposal of ALLUX™
12. Periodic inspection	Explanation about periodic inspection and warranty period
13. Warranty	Explanation about warranty

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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

	<ul style="list-style-type: none"> ■ Please ensure to read the notes on usage. 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.
	<ul style="list-style-type: none"> ■ 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.
	<ul style="list-style-type: none"> ■ 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 for 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 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.

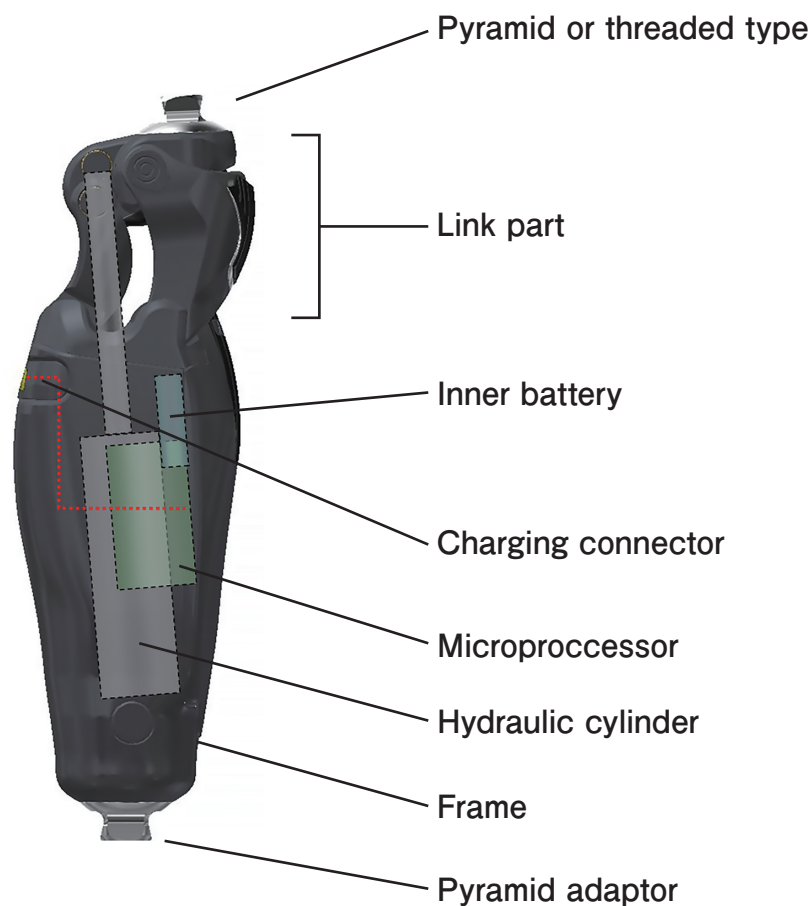
2 Product Overview

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°C/+14°F ~ +40°C/+104°F



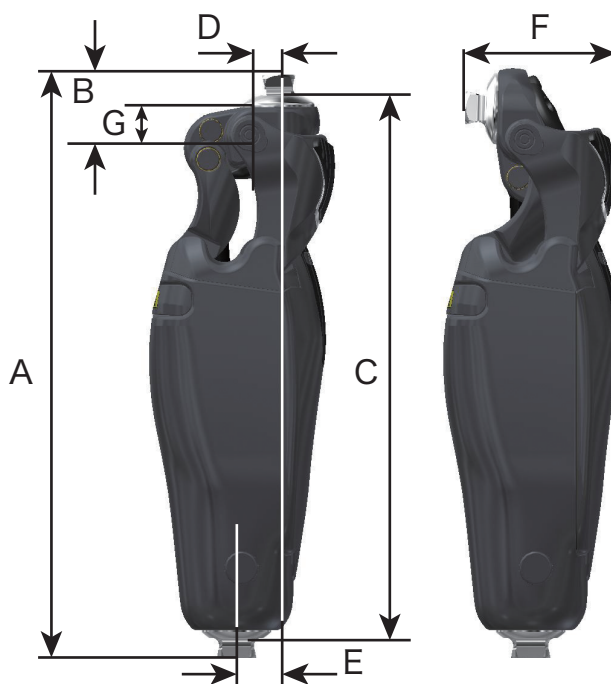
CAUTION

■ 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(for prosthetist)
User's Guide	1 copy	81-SS00099E(this document)
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 battery charging cable NE-CL01	1 pc.	

NOTICE

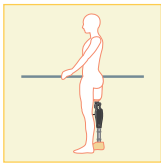
- Do not use non-designated peripheral devices. That might cause a crash of ALLUX™.

4 Safe Posture

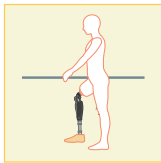
4.1 Safe posture and condition ready for communication

'Safe posture' refers to the posture taken in order to change the mode before using the remote controller or communicating with the ALLUX™ software. Be sure to understand the following safe postures before using ALLUX™.

【Safe posture】



the state you stretch your knee straight with ALLUX™ and may apply your body weight on it.

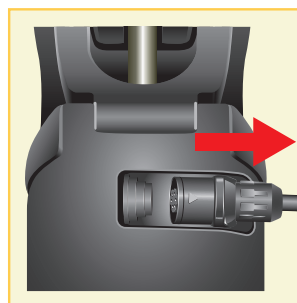
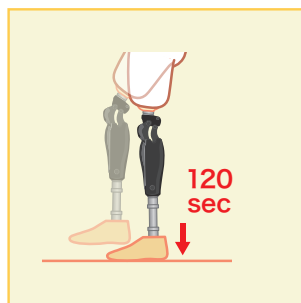
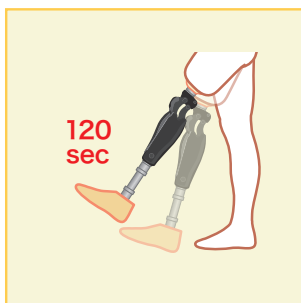


the state you do not apply your body weight on ALLUX™ and may bend your knee.



- Do not take the posture in an unstable state. When taking the safe posture without applying the body weight to ALLUX™, hold a handrail or sit down. You may lose your balance and fall over.

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 removing your body weight and then applying it, or 120 seconds after disconnecting the charger or power OFF cap from ALLUX™.



5 Selective Modes by Remote Controller

5.1 ALLUX™ operational modes

ALLUX™ has five operational modes.

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

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

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 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 remote control to return to normal mode. The remote controller requires two AAA batteries. Please replace the batteries if the remote controller does not work properly, or within 2 years.



WARNING

- Avoid malfunction of the remote controller
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 and power off cap will result in the ALLUX™ returning to the normal mode set using the '1' button on the remote control.
Please exercise caution as the status may differ before and after charging.

- Assume safe posture. (See 4. Safe posture)
- Push an optional button (1-5) on the remote controller for over 1.5 seconds,
- vibration will sound for 2 seconds.
- The selected mode is applied.



Operational Modes

- ① Normal mode: normal walking --- button 1 or optional button
- ② Flexion angle limit mode: lock the knee at a designated angle --- optional button
- ③ Variable selective flexion lock mode: lock the knee at the angle designated by the remote controller --- optional button
- ④ Full extension lock mode: lock the knee at the fully extended position --- optional button
- ⑤ Free swing mode: maintain the least resistance against bending and stretching --- optional button

5 Selective Modes by Remote Controller

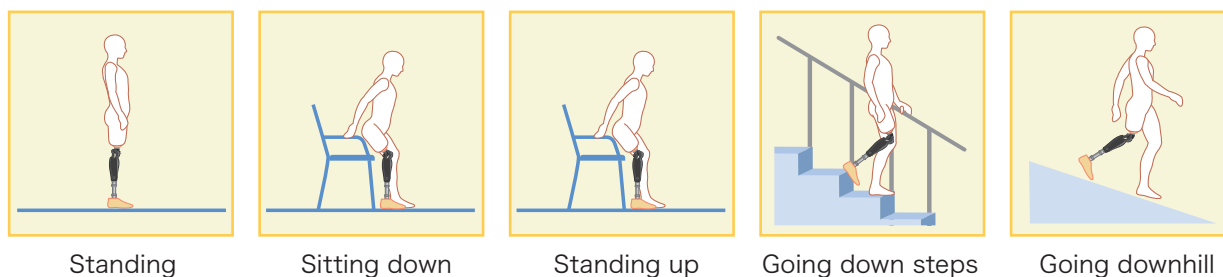
5.3 Normal Mode

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.

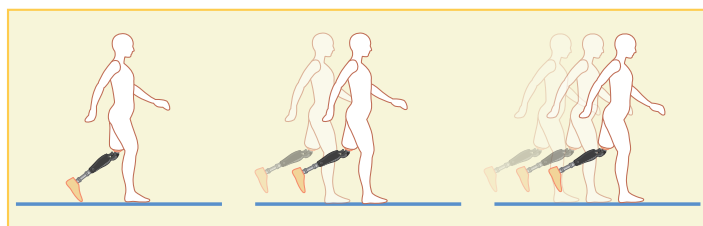
5.3.2 Yield Function

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



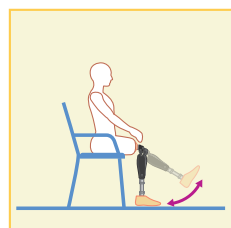
5.3.3 Walking speed auto-adjust function

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



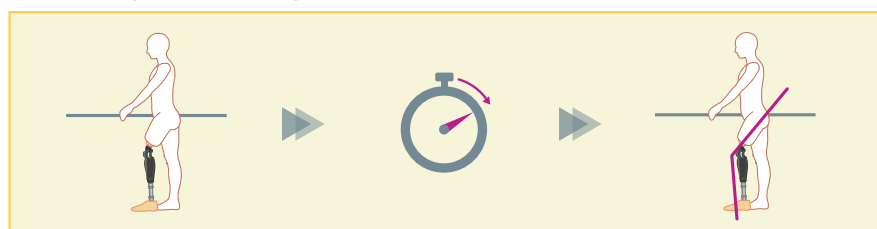
5.3.4 Seated position

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



5.3.5 Safety lock

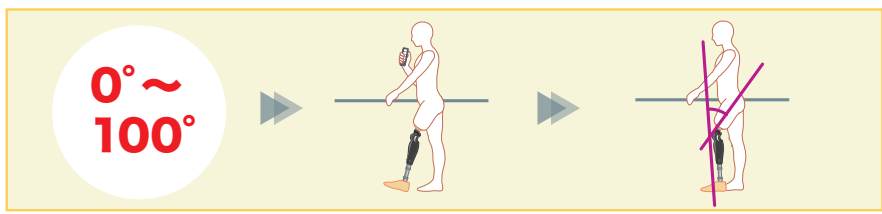
When under a burden and knees are bent continually for a few seconds, ALLUX™ locks the bending resistance at a certain angle. (This function can be turned off or the sensitivity can be adjusted.)



5 Selective Modes by Remote Controller

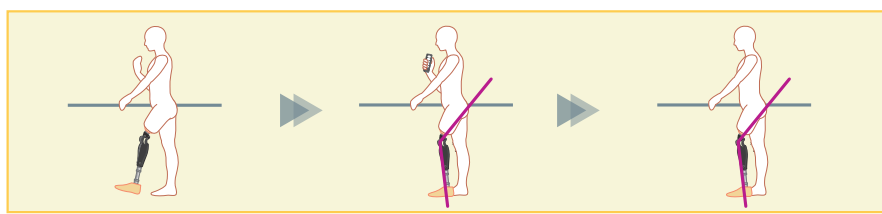
5.4 Flexion angle limit mode

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



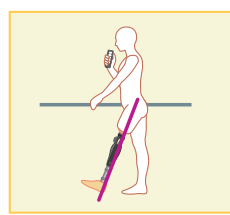
5.5 Variable selective flexion lock mode

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.



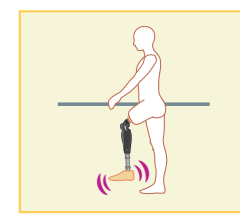
5.6 Full extension lock mode

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.



5.8 Not in use mode (battery level confirmation)

If the remote controller button is set to not in use and the button is pressed then the ALLUX™ mode will not change and the remaining power level will be indicated by vibration patterns instead.

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

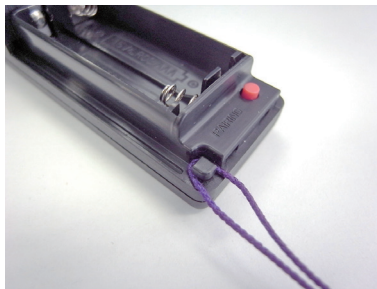
6.1 How to change batteries

When the battery power is depleted, exchange the AAA batteries as below. Please make sure to change the batteries at least once a year.



6.2 How to attach strap

You can attach a strap to carry the remote controller with you. To attach a strap to the remote controller, please follow the steps below.



7 States of ALLUX™

7.1 States of ALLUX™

ALLUX™ has charging mode, backup battery connecting mode, high-temperature mode, battery empty mode. When the mode is changed, the vibration will notice the user about the mode change and you can test the vibration patterns while adjusting the mode.

The internal power supply of ALLUX™ was designed to last for 4 days 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 depending 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. In the mode in which the battery is exhausted, there will be a high yielding resistance or a free resistance to the flexion motion based on choice during adjustment. Please consult your prosthetist.



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 your prosthetist. 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 be available, 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. 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 you 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 (NE-CC02) connected. Walking control ceases and thus if you attempt to use the unit while connected it could impair the walking process and result in a fall.






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

7 States of ALLUX™

7.2.3 Use of backup battery

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

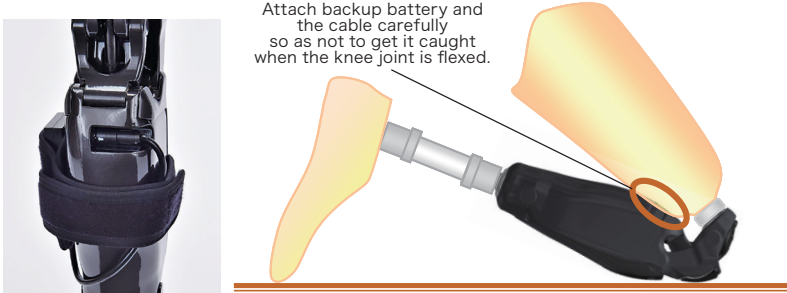
- 0.5sec×8times
 - Remove the Charging port cap.
 - Fit the backup battery case (NE-SC01) containing the backup battery on the body of ALLUX™ or the lower leg side of the armoring, such as the foam cover, and secure it with the Velcro tape.
 - Connect the backup battery to ALLUX™.
- * ALLUX™ will enter the normal mode stated in 7.2.1, and the vibration for confirmation of backup battery capacity will sound.

	0.25sec×8times	: 3hours or more
	0.5sec×8times	: Less than 3hours
	0.75sec8times+(4sec)	: No more walk
		
		

* The backup battery must be charged.



- 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.

7 States of ALLUX™



- 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 expose 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.

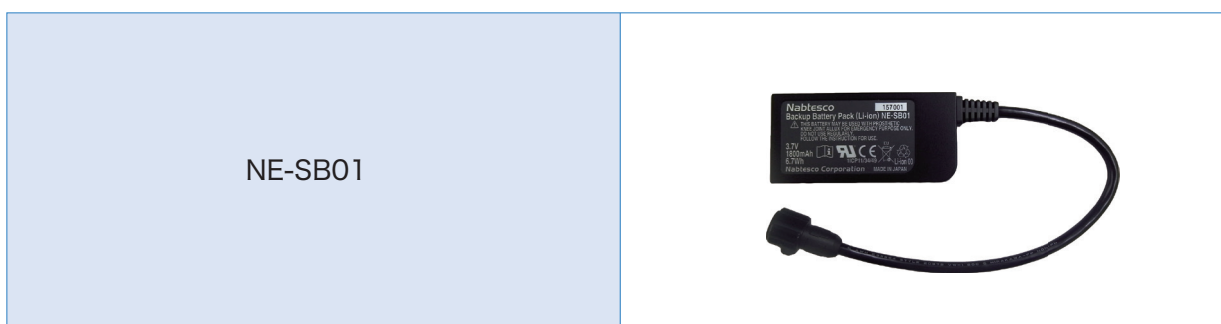
NOTICE

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



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 (yielding resistance with high flexion resistance) or free based on choice during adjustment. 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)

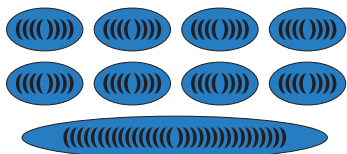
ALLUX™ will be recovered from this state by charging.



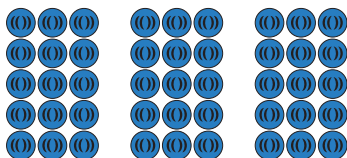
- When the vibration indicating the battery exhaustion or requiring the safe posture sounds, the user must stand in a safe posture immediately.

Even if the user is not in safe posture after 1 minute of warning vibration, the knee joint will be forcibly locked or free even while the user is walking and may result in a fall.

7 States of ALLUX™



0.75_{sec} 8_{times} + (4_{sec}) : No more walk



0.5 * 3_{times} × 15_{times} : 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 is selected, the knee flexion becomes free.
Please ask your prosthesisist.
- 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.”)

7.2.5 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.



- 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.

7 States of ALLUX™

【When the temperature is increasing】



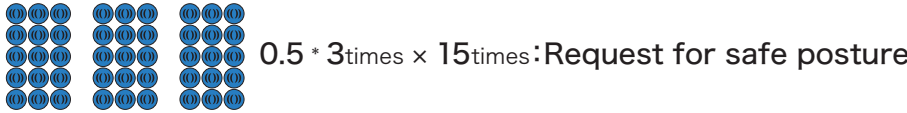
* Stop walking with the yielding function or take a rest and stay still until the knee joint cools down.

【When the temperature has abnormally increased】



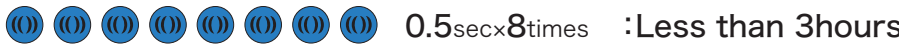
- Take the safe posture.
- The knee will be locked in the flexed state(at a high yielding resistance).

【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.

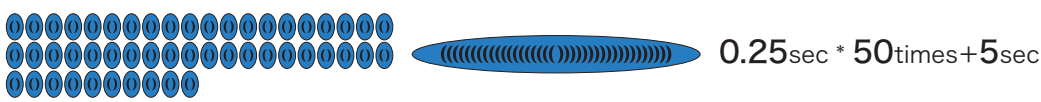
7.3 In case of malfunction

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




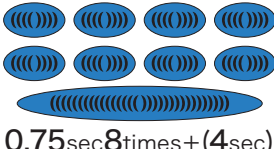



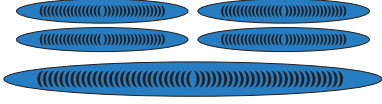
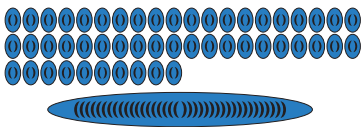
- If the knee joint is defective, the user cannot walk normally.
- If the vibration for warning about malfunction sounds, immediately discontinue the use, and contact your prosthetist. Normal walking will not be supported, possibly resulting in a fall.



- 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	 0.75sec 8times + (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 your prosthesist.

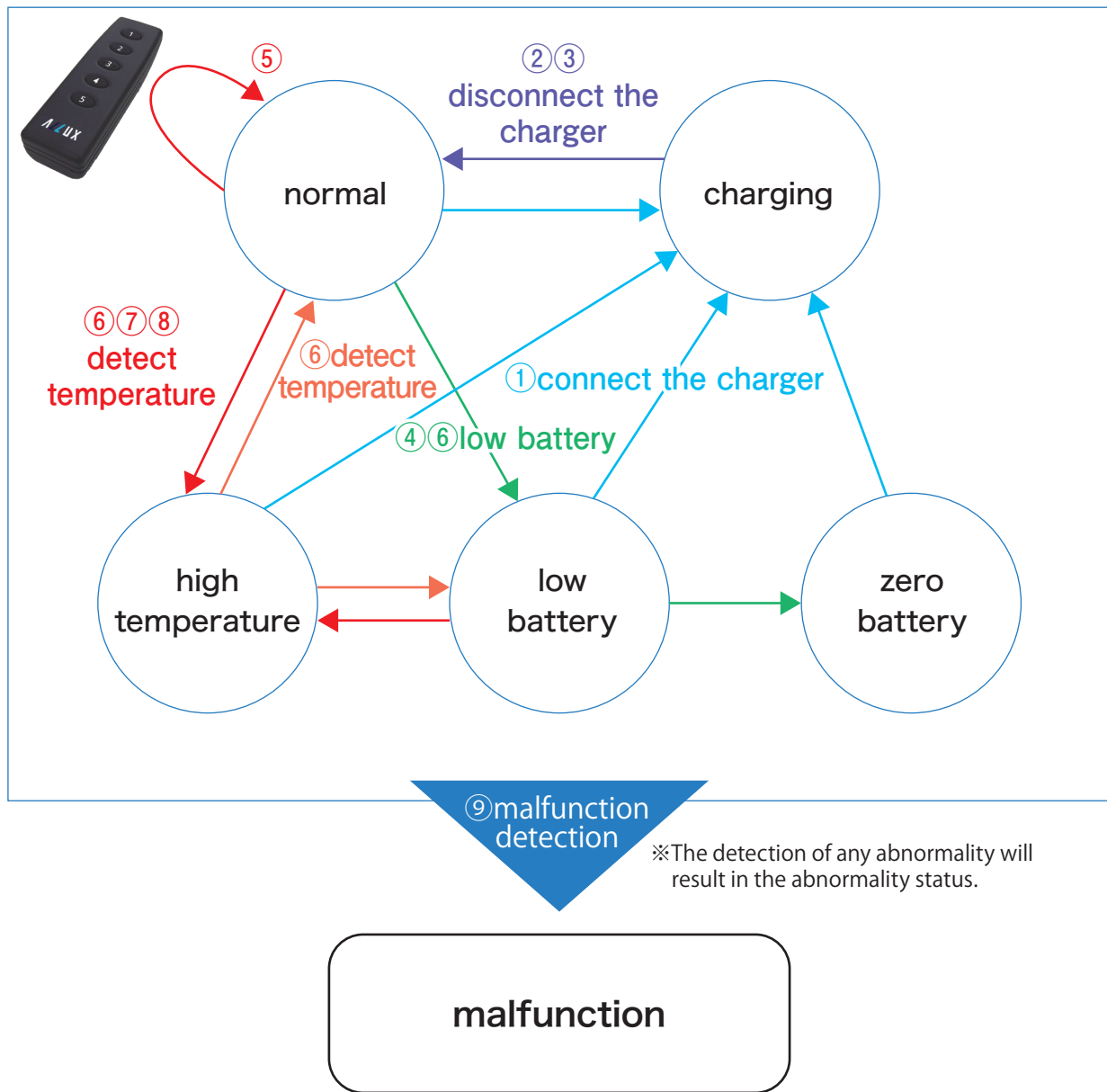
*1: Remaining battery refers to the remaining capacity of the ALLUX™ main battery or the backup battery.

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 transitionalary 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

- Remove the prosthesis before charging.
- 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.



- 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

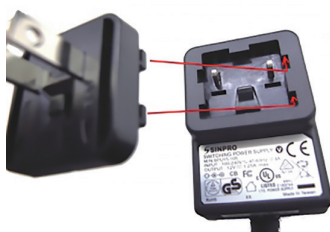
8.1.2 Charging procedure

Connect the charger (NE-BC01) and AC adapter (NE-AD01) to charge from an indoor household power supply outlet. 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 countries in accordance with the proper configuration.

- 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.



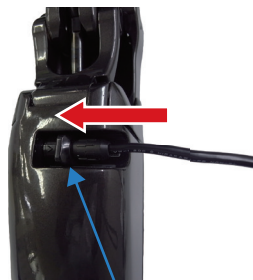
- Remove the Charging port cap (NE-CC01) of ALLUX™.
- Remove it sliding the connector cover lever in the arrow direction.
- Connect the charger connector to the connector terminal of ALLUX™.
- 🔊 The vibration will sound continuously for 2 seconds.



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°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 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 your prosthesisist.
- Fit the charging port cap.



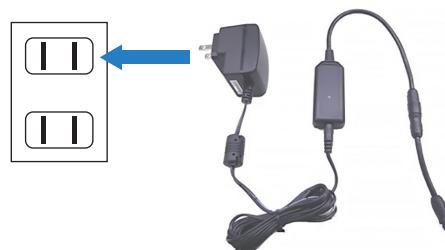
Remove the AC adapter from the commercial power supply.

NOTICE

- Make sure that the vibration sounds when the charging connector is disconnected.
- Contact us if the vibration does not sound. The vibration notification will not be available, flexion/extension resistance may suddenly change, leading to a fall.

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°C 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.

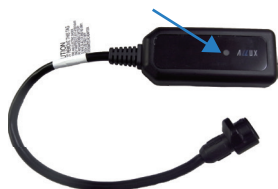
8 Charging Procedures

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 us.

- 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

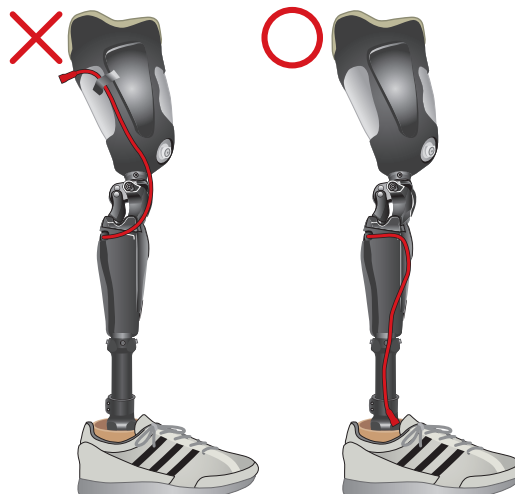
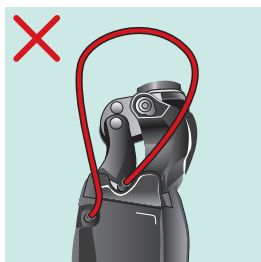
Use an extension cable when the ALLUX™ charging connector is covered with a form cover, etc.

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.

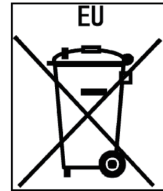
When you want to purchase replacement parts for maintenance or have to questions about maintenance of ALLUX™, contact your prosthesisist.

[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. The battery replacement cycle is normally 2 years. (Periodic inspection period)
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 ,approximaterly every year.

NOTICE

- The backup battery is a Lithium ion battery. Do not discard the battery with general household garbage. Thrown away short-circuits of the battery may cause ignition and release of fume.



[Replacement of rubber and pads]

Stopper rubber N-G012		Please contact your prosthesisist. Purchase a new one from Local sales representative or Distributor.
Front link pad NE-FC01		Please contact Local sales representative or Distributor to replace it.
Front cover pad NE-FC02		Please contact Local sales representative or Distributor to replace it.
Front link ST pad NE-FC03		Please contact Local sales representative or Distributor to replace it.

10 Troubleshooting

10.1 Troubleshooting list

Should you encounter any issues in the use of your ALLUX™, please check the following list. If you are encountering an issue not listed in the below list, please contact your prosthesisist..

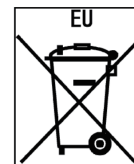
Issue	Check item	Solution
Your ALLUX™ wont charge.	Is the charger connector/AC adapter securely connected?	Check the connection. (See 8.1.2)
	Does vibration sound when connected to the charger?	If the vibration does not sound, it may be defective. Discontinue use, and contact the prosthesis your prosthesisist.
	Is the knee joint hot?	Let your unit cool and then recharge it. (See 8.1)
	Any issue not outlined above	Contact your prosthesisist.
Unable to change modes with the remote.	Are you pressing the button within 120 seconds of flexing and extending the knee or removing your body weight and then applying it?	Flex and extend the knee or removing your body weight and then applying it? , assume safe posture, and use the remote control. (See 6.1)
	Are you in safe posture when operating via the remote control?	
	Are the batteries in the remote control too low?	Replace the two AAA batteries with new ones.
	Are you holding the button long enough?	Hold the button for 1.5 seconds or more.
Knee locks, or is in a free state.	Did the vibration sound just before the knee locked or went into a free state?	If the unit is hot, please wait until it cools. (See 7.2.5)
	Check that setting for safety lock adjustment is too sensitive	Contact your prosthesisist.
	Is the battery capacity is sufficient?	Please charge your unit or connect the backup battery. (See 7.2.4)
	Any issue not outlined above	Contact your prosthesisist.

10 Troubleshooting

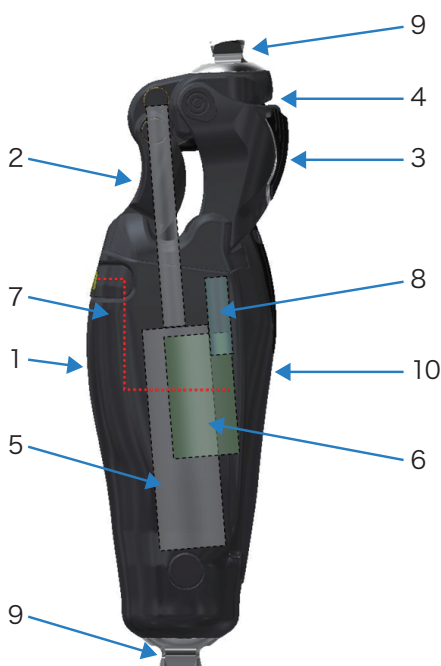
Issue	Check item	Solution
Abnormal noise or weakness in joints.	Check for foreign substances. Are any screws etc. interfering with the knee joint section?	Please remove any foreign matter and ensure that normal movement takes place.
	Does vibration sound when connected to the charger?	Please contact your prosthetist.
	Any issue not outlined above	Please contact your prosthetist.
The safety lock cannot be applied.	Check that you holds the knee in a slightly flexed state and apply 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.)	Hold the knee in a sufficiently loaded state.
	In cases other than above	Please contact your prosthetist.
The knee is locked and jams when you sit down.	Check that you do not stop flexing the knee halfway.	Since the safety lock is effective,it is necessary to sit down without stopping.
	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.
	In cases other than above	Please contact your prosthetist.

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.	Stopper rubber	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 your prosthesisist.

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

13 Warranty

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.



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