

Nabtesco

Hybrid Knee

Instruction Manual

(NI-C3 Series)

Language: English



Introduction

Thank you for purchasing Nabtesco's Hybrid Knee. Hybrid Knee is a totally new intelligent prosthetic knee joint that integrates hydraulic and pneumatic control with computer control to provide safe and pleasant walking. For safe use, be sure to read this manual and familiarize yourself with the Hybrid Knee. Carefully keep this manual conveniently available for future reference. Also read through the User's Guide and explain the safety information contained therein to the patient before handing the User's Guide to him/her.

Important Information

Intended purpose of Hybrid Knee

Hybrid Knee was designed and is manufactured for use as a prosthetic knee joint by above-knee amputated, knee disarticulated, and hip disarticulated patients. Do not use Hybrid Knee for any other purposes. For hip prostheses, it is recommended to use a torsion adapter to prevent significant torsion from being applied to Hybrid Knee. This device is intended for single patient multiple use.

For the specifications for Hybrid Knee, see 8. Product Overview.



WARNING

-
- Do not use Hybrid Knee outside of the specification range. Do not modify the main body or parts. Doing so can cause injury or damage Hybrid Knee.
-

Cautions for handling Hybrid Knee safely

Nabtesco Corporation (hereinafter referred to as "Nabtesco") cannot foresee all potential residual risks of Hybrid Knee and risks resulting from human errors and the usage environment. Although there are many instructions and prohibitions for handling Hybrid Knee (assembling, adjusting, and maintaining the prosthesis), all these matters cannot be described in this document or on the warning labels on the body of Hybrid Knee.

Therefore, when handling Hybrid Knee, it is necessary not only to observe the precautions stated in this document, but also to take the safety measures necessary for a prosthesis knee joint. Particularly important matters concerning the safe handling of Hybrid Knee are described below. These matters apply to the persons who assemble and adjust Hybrid Knee.

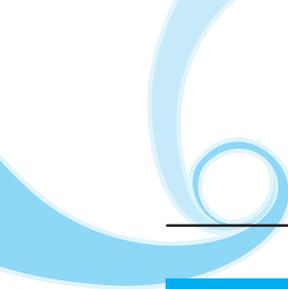
If you have a serious incident related to Hybrid Knee, please report it to the manufacturer (contact information on the back cover) and the competent authority in your country.

Read this document thoroughly

Before handling Hybrid Knee, 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 Hybrid Knee must have attended Hybrid Knee 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 Hybrid Knee license seminars to fit the product for prosthetic users. It covers the following references: NI-C311, NI-C311s, NI-C313, NI-C313s.

Copyright

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If 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 Hybrid Knee without this document can cause accidents.

Information

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

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1 Safety Precautions

1-1 Contraindications

The following users cannot use Hybrid Knee.

- Persons who cannot understand how to use the knee and the precautions for use
- Persons experiencing pain in the amputated limb
- Persons who weigh over 125 kg (or over 100 kg for highly-active users)
- Persons who engage in sports that put a significant burden on the knee

1-2 Definition of Symbols

 WARNING	Indicates a potentially hazardous situation which, if this symbol is not observed, could result in serious injury.
 CAUTION	Indicates a potentially hazardous situation which, if this symbol is not observed, could result in minor or moderate injury or property damage.
 CAUTION	Indicates a general caution to be observed.
 Prohibition	Indicates prohibition of a specific action.
 Mandatory Action	Indicates obligation to perform a specific action.

1-3 Mandatory Precautions



WARNING



Mandatory Action

Be sure to hand the separate **User's Guide** directly to the user and explain precautions for use.

Improper use can cause falling or injury.



Mandatory Action

Upon detecting any abnormal noise, looseness, or drop in hydraulic resistance, discontinue use and contact your local sales representative/dealer.

Continued use despite a detected abnormality may cause damage of parts, leading to falling.



Prohibition

DO NOT use for a person who weighs over 125 kg.

If used for a person who weighs over 125 kg, damage of parts may occur, leading to falling. This, however, does not preclude loading and unloading of baggage, etc. occurring in daily life.

***For K4 individuals, the weight limit is 100 kg.**



Prohibition

DO NOT place the hand behind the knee when flexing the knee. **DO NOT** touch the knee when extending it.

The hand can be caught, causing injury.



Prohibition

Never attempt to disassemble or modify Hybrid Knee.

Failure to observe this warning can cause breakage of parts, leading to falling.



Prohibition

DO NOT attempt to charge, disassemble, heat, or short-circuit the battery, and **DO NOT** dispose of it in a fire.

Failure to observe this warning can cause an explosion or fire.



CAUTION



**Mandatory
Action**

Be sure to attend the operation training course offered by your local sales representative/dealer.

Incorrect adjustment can prevent pleasant walking.



**Mandatory
Action**

Be sure to undergo periodic inspection every two years.

If Hybrid Knee is used without inspection, parts can become worn down more quickly.



Prohibition

A socket should be formed and aligned so that neither the socket nor any other part contacts the pneumatic cylinder at the maximum flexion angle.

It will damage the pneumatic cylinder, impeding normal walking.



Prohibition

DO NOT drop parts such as a screw in the frame.

Continued use after any part is dropped will damage the pneumatic cylinder, impeding normal walking.



Prohibition

DO NOT allow contact with liquids such as water, salt water, chlorinated water, soapy water, gel soap, bodily fluids, and exudations. DO NOT use any detergent or solvent (thinner) for cleaning.

Doing so could result in rusting, discoloration, desiccation of the grease, resulting in a malfunction and abnormal noises.



Prohibition

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

Doing so could result in a malfunction.

1-4 Compatible Medical Devices (Prosthesis Components)

Hybrid Knee reference	NI-C311, NI-C311s	NI-C313, NI-C313s
Proximal connectors	Female pyramidal connectors	M36 screw connectors
Distal connectors	φ34 tube adapter	φ34 tube adapter

2 Certification of International Standard

Structural durability

Hybrid Knee was tested for 3 million walking cycles with a load of 125 kg which corresponds to the average walking distance for 3 years. We will not assume liability for ageing or damage of the product due to long-term usage.

*For products with an extended warranty, the replacement of structural parts during periodic inspections is covered by the warranty.

ISO10328-P6-125kg^{*)}



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

K Level (MOB)

K2 Level (MOB2): User can handle small environmental barriers such as curbs, steps, or uneven 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. This includes children and athletes.

EMC Information

Hybrid Knee belongs to Group 1 and Class A equipment in accordance with IEC/EN60601-1-2. Hybrid Knee 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 are provided or specified by the manufacturer, Nabtesco Corporation.
 - Do not use any chargers, accessories, or peripheral devices except those sold by Nabtesco Corporation.
Doing so may increase the emission of, or decrease the resistance to, electromagnetic waves of Hybrid Knee.
 - Do not use Hybrid Knee near other electronic equipment. Portable and mobile RF communications equipment can affect Hybrid Knee. If you must use Hybrid Knee near such equipment, be sure to ensure safety.
 - Please carefully read this instruction manual to avoid the risk of ignition or electric shock.
-

Declaration of Conformity

Nabtesco Corporation hereby declares that the 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.

3 Basic Construction and Operational Principle

3-1 Basic Construction

Hybrid Knee has accomplished sophisticated integration of the hydraulic rotary damper to control the stance phase, the MRS system, and the microprocessor-controlled pneumatic cylinder for the swing phase.

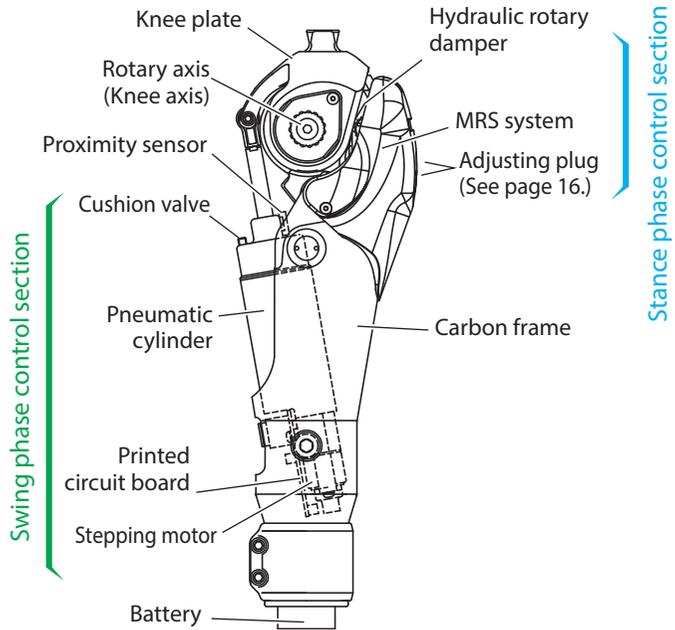


Fig. 1 Main Components

3-2 Operational Principle

The hydraulic rotary damper reliably functions while the prosthesis is in contact with the floor, thus preventing abrupt buckling. When the prosthesis leaves the floor, the microprocessor-controlled pneumatic cylinder functions, providing swing control that responds to cadence.

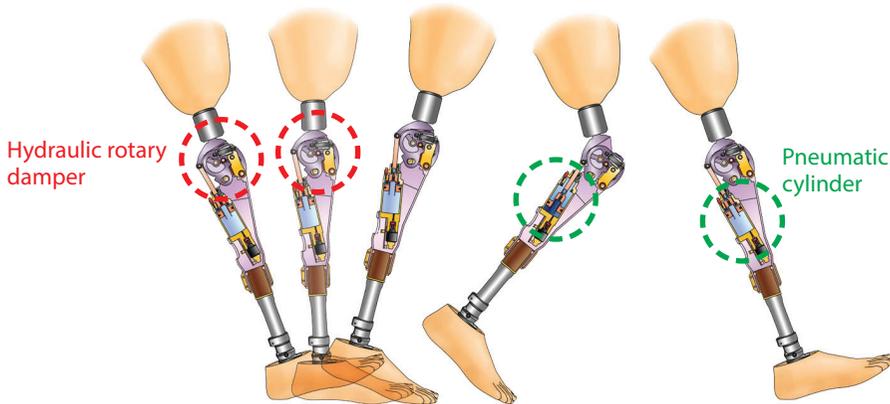


Fig. 2 Level Floor

3-3 Stance Phase Control

When the knee is flexed, the hydraulic rotary damper produces hydraulic resistance, thus preventing abrupt buckling. The **MRS** (Mechanism of Reaction Force Sensing) system mechanically detects floor reaction force and sets hydraulic resistance to ON or OFF. When floor reaction force exists at the heel side from the sensing point, hydraulic resistance is turned on. When it exists at the toe side, the hydraulic resistance is turned off.

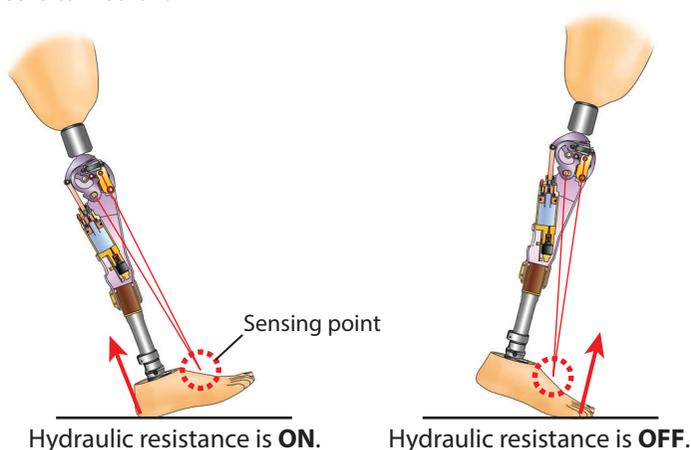


Fig. 3 MRS System

● Yielding function

By having the heel land first, the patient can slowly flex the knee while applying body weight to the knee. After getting familiar with the yielding function, he/she can perform various acts such as descending a slope or stairs.



WARNING

In order to make the yielding function effective, be sure to strike the floor with the heel first.

Striking the floor with the toe first will turn off hydraulic resistance, meaning the body weight cannot be supported.

There is a risk that knee buckling may occur, causing falling-down. For safe use, fully understand the operational principle and proper walking method, and provide the patient with instructions. → See  **POINT 1** (page 18).

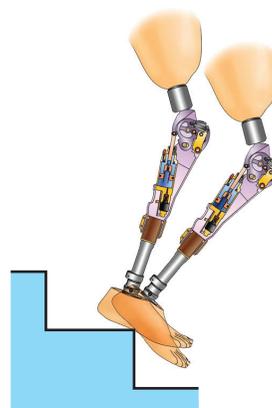


Fig. 4 Stairs

Note: Hybrid Knee is intended to assist the capability of a person who uses a prosthesis. Nobody can descend a steep slope or stairs without proper gait training.

3-4 Swing Phase Control

The microprocessor calculates the time for one walking cycle by using data on knee joint flexion as detected by the proximity sensor. Also, this microprocessor stores a maximum of 10 stages of adjustment data, which consists of the cadence and reaction force of the pneumatic cylinder, for each patient. When cadence changes, the microprocessor commands the stepping motor to activate the needle valve immediately to select a swing speed for the prosthesis.

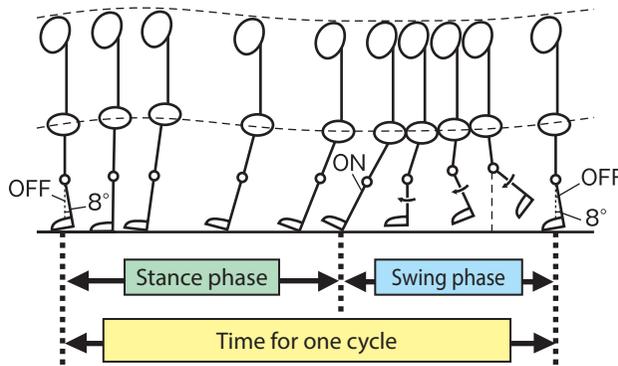


Fig. 5

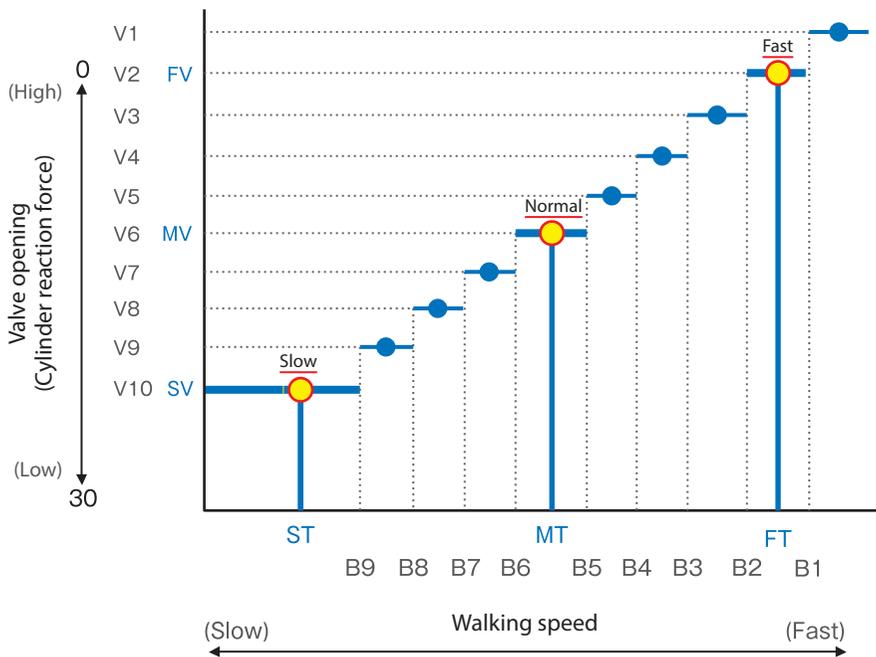
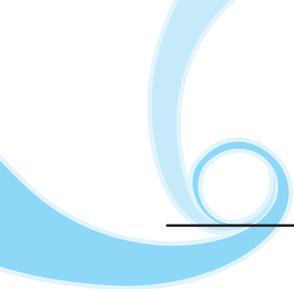


Fig. 6 10-Stage Setting



● **When walking stops**

When the patient stops walking for 8 seconds or more, the needle valve is automatically set to his/her normal cadence.

● **When the battery is running low**

When the remaining battery power is low, the needle valve is automatically set to the normal cadence of the patient. After that, it can not respond to a cadence change but the patient can walk at a constant speed.

● **Data storage**

As adjustment data is stored in the memory, it will not be deleted even if the battery connector is pulled out. In other words, readjustment is not required even when the battery is replaced.

4 Before Use

4-1 Scope of Delivery

Please confirm that the following items are included.

- **Hybrid Knee** 1
- Dedicated lithium battery 1 (already set)
- User's Guide 1
(After explaining the content, hand it directly to the patient.)
- Instruction Manual (this book) ... 1

4-2 Assembly Procedure

4-2-1 Static Alignment

Perform static alignment according to the following procedure.

● Alignment of frontal plane

Complete alignment so that the load line passes through the center of the knee joint and falls in the heel center of the foot section.

● Alignment of sagittal plane

As shown in Fig. 7, complete alignment so that the weight load line passes through the range of 0 to 10 mm in front of the center of the knee axis of the knee joint.



CAUTION

When the device is not aligned as recommended, excess load is imposed on the parts, accelerating wear.
For a hip prosthesis, use of a torsion adapter is recommended.

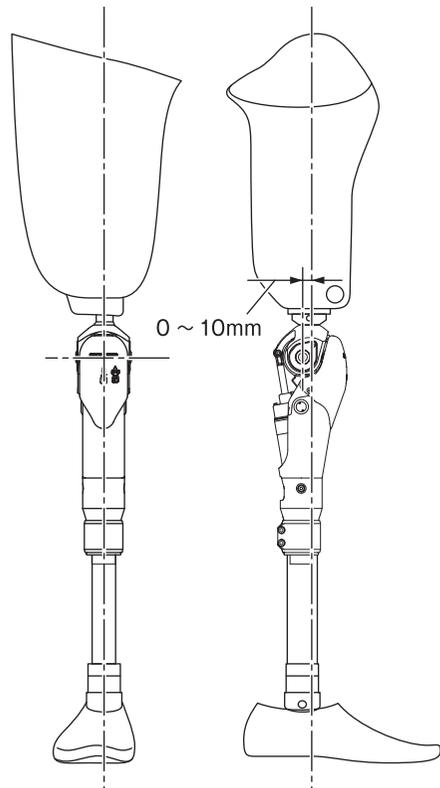


Fig. 7

4-2-2 Assembling the Tube

- 1 Loosen the outer clamp bolts, insert the tube into the inner clamp, and push the tube until it hits the stopper of the inner clamp.
- 2 When assembling the tube, be sure to align the split groove of the outer clamp with that of the inner clamp.
- 3 Tighten the bolts to a torque of 4.5 to 5 N·m.



CAUTION

For safe use, you are recommended to use the tube made by Nabtesco. If you absolutely must use one made by another manufacturer, be sure to use one whose outer dimensional tolerance is within ± 0.05 mm.

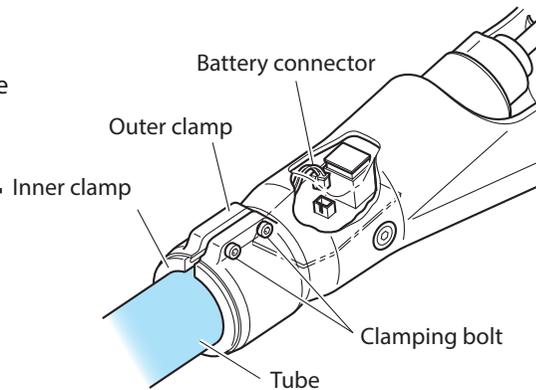


Fig. 8a Assembling the Tube

4-2-3 Inserting the Battery Connector



CAUTION

Before inserting the battery connector, be sure to eliminate static electricity by, for example, touching a desk.

The battery connector has been disconnected for shipment. To use Hybrid Knee, be sure to insert the battery connector into the circuit board connector.

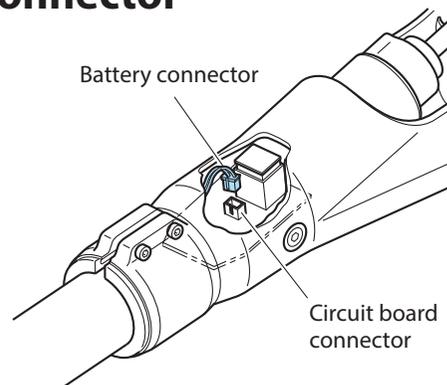


Fig. 8b Inserting the Battery Connector



CAUTION

- Connect the programming unit and then perform a reset.
 - Confirm that the motor sound is normal.
- * When the motor has been running for a long time, perform the reset operation. (There is a risk that battery electricity may be abnormally consumed.)

4-2-4 Precautions on Socket Forming



CAUTION

When making the socket, make sure that neither the socket nor parts touch the pneumatic cylinder when the knee joint is flexed to the fullest extent.

Failure to do so may cause damage to the pneumatic cylinder, adversely affecting the function.

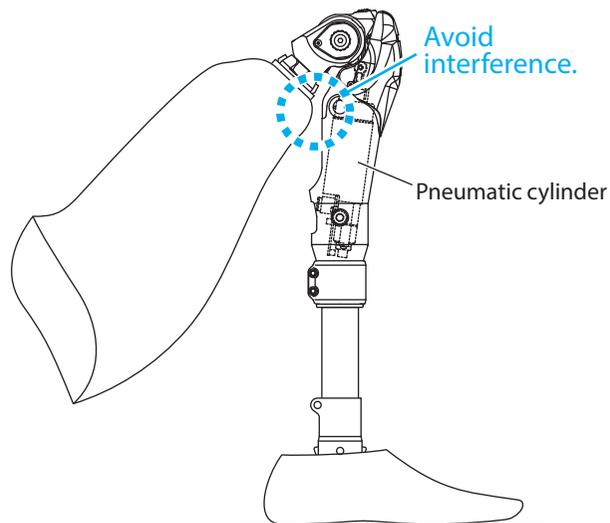


Fig. 9

5 Adjustment

5-1 Adjusting the Stance Phase Control

First, adjust the stance phase control. The hydraulic damper has two kinds of adjusting plugs, which are to be used as shown in Fig. 10 and Table 1.

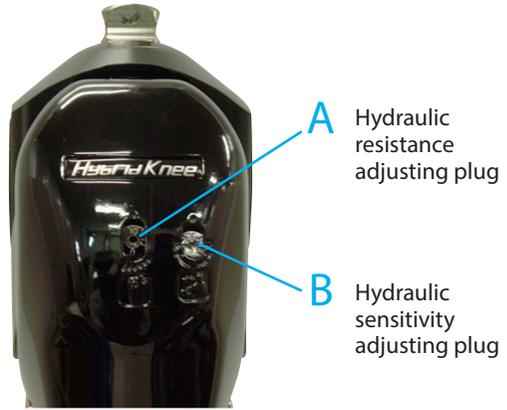
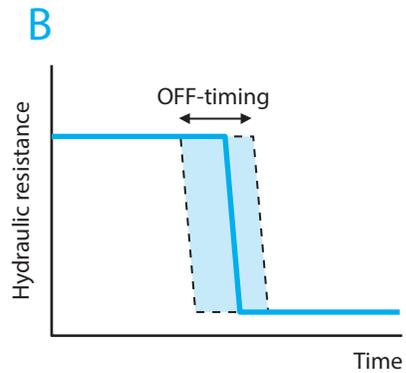
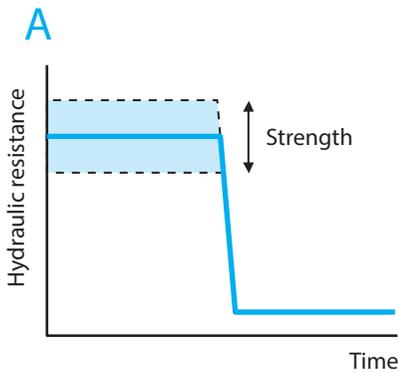


Fig. 10 Location of the Adjusting Plugs

Table 1 How to Select Adjusting Plugs

	Adjusting plug	Effect	When to perform adjustment
A	Resistance	Yielding strength (Hydraulic resistance)	Different body weight and activity level
B	Sensitivity (OFF-timing)	Increasing effectiveness and sustainability (OFF-timing) of the yielding function.	When sticking occurs during swing transition, and when the yield duration is insufficient





IMPORTANT

The adjusting plugs have been set to the positions which are common to most people **in the factory default setting**.

If you can not find suitable positions, turn the plugs to their original position.

A Hydraulic resistance adjusting plug: Set to the scale 10.

B Hydraulic sensitivity adjusting plug: Set to the scale 15.

5-1-1 Adjusting the Hydraulic Resistance

Insert a hex wrench obliquely upward into the hydraulic resistance adjusting plug, and turn to change the hydraulic resistance.

- **Clockwise (Scale readings become smaller.):**
Hydraulic resistance becomes higher at the stance phase.
- **Counterclockwise (Scale readings become larger.):**
Hydraulic resistance becomes lower at the stance phase.

Adjust by using scale readings as a guide. Read the scale at the mark on the window.

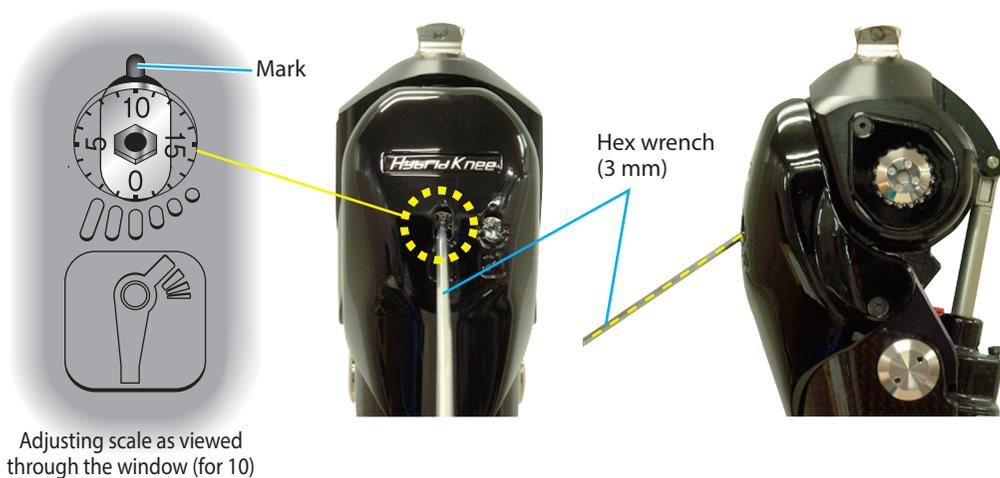


Fig. 11 How to Adjust Hydraulic Resistance

Procedure

- 1 Make sure that the scale reads 10 and then have the patient stand within parallel bars. (Fig. 12)
- 2 Have the patient place his/her weight on the prosthesis and confirm that the yielding function works properly.
→ See  **POINT 1**
- 3 Have the patient feel two different levels of yielding strength by adjusting the scale as follows.
 - (1) **Scale reading 0* (strongest)**
 - (2) **Scale reading 15 (weak)**

* The reading "0" is where the plug is fully closed by turning clockwise.
- 4 Taking the reading 10 as the benchmark, finely adjust the adjusting plug and choose a desirable level of strength.
→ See  **POINT 2**

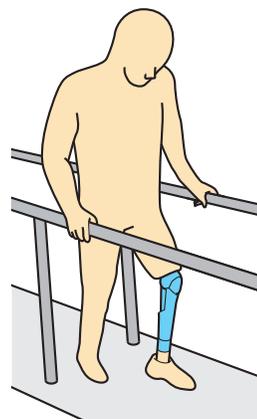


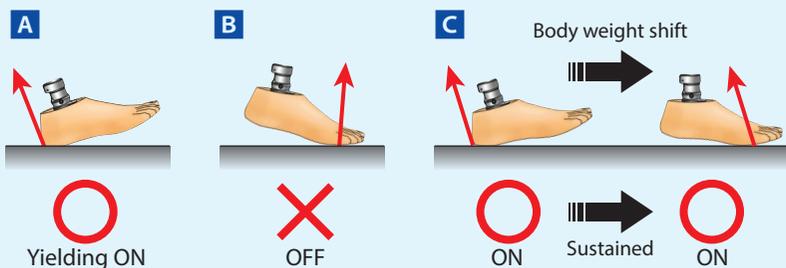
Fig. 12



POINT 1 How to Obtain Yielding

Three methods are available according to application of body weight:

- A** When body weight is applied to the heel, yielding function can work.
- B** When body weight is applied to the toe, yielding can not work.
- C** After sufficiently applying body weight to the heel, when the patient shifts body weight toward the toe while yielding function is retained, hydraulic resistance is sustained.





CAUTION

Provide appropriate alignment, selection of a foot part, and gait training so that the patient can sufficiently apply his/her body weight to the heel. When the heel load is insufficient, the yielding function may not be sustained.



POINT 2 Guide for Intensity of Hydraulic Resistance

- Although hydraulic resistance varies by weight and activity, the standard level is generally between 5 and 15. If you are not sure, set it to 10.
- The patient may feel that hydraulic resistance is weak due to an insufficient heel load. Provide sufficient gait training for  **POINT 1**.

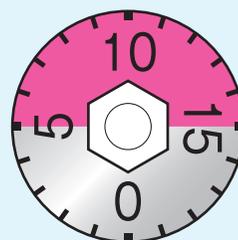


Fig. 13



CAUTION

DO NOT use readings of 19 and above. When the plug is loosened one full turn or more from the fully closed position (reading 0), a risk of oil leakage is created. Hydraulic resistance does not change even if the plug is further loosened.

5-1-2 Walking on a Level Floor

- 1 Have the patient walk within the parallel bars. Provide practice so that the patient fully extends the knee joint in the initial stance phase in normal walking on a level floor.
- 2 Confirm that there is no sticking caused by the yielding function at the time of transition from the stance phase to the swing phase.
- 3 When the patient becomes familiar with walking, perform gait training outside the parallel bars. If sticking occurs, make an adjustment according to the troubleshooting method (see pages 34 and 35).

5-1-3 Adjusting Sensitivity (OFF-timing)

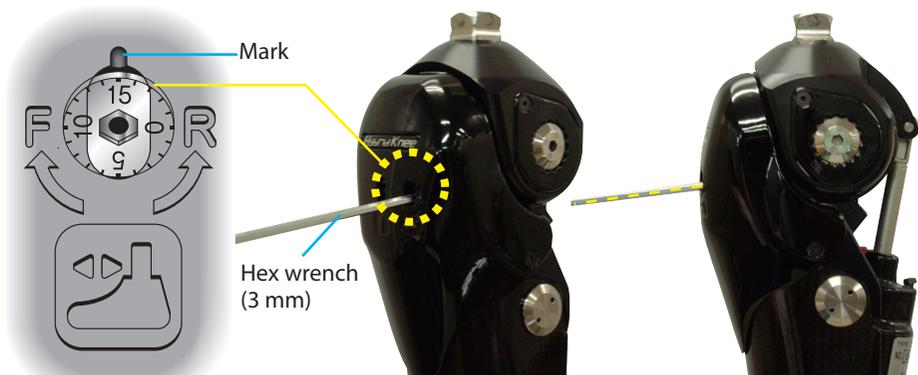
Referring to Table 1 (see page 16), perform sensitivity adjustment.

Sensitivity is set to the standard condition by factory default.
When no problem exists, adjustment is unnecessary.

Referring to the figure below, turn the sensitivity adjusting plug on the right-hand side by using a hex wrench. When the plug is turned, hydraulic resistance will change as follows:

Clockwise (forward) The yielding function becomes more effective and more sustained.

Counterclockwise (rearward) The yielding function becomes less effective and less sustained.



Adjusting scale as viewed through the window (for 15)

Fig. 14 Adjusting Sensitivity



IMPORTANT

The sensitivity adjusting plug can be adjusted up to one loosening turn away from the fully closed position. The factory default is set to the scale 15. If you can not find an appropriate position, it is recommended that you use the factory default setting.



CAUTION

Never loosen the sensitivity adjusting plug more than one turn away from the fully closed position. The plug is designed for anti-dropping. If the plug is loosened more than one turn, the parts may be damaged.

5-2 Adjusting the Swing Phase Control

5-2-1 Adjusting the Hydraulic Resistance

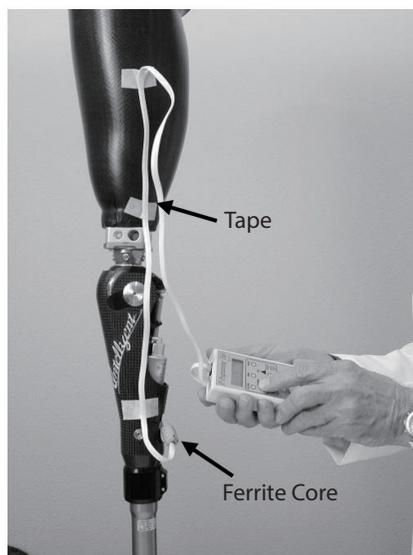
1 PREPARATION

Note The knee unit must be properly aligned and the stance phase adjustment set before the programming.

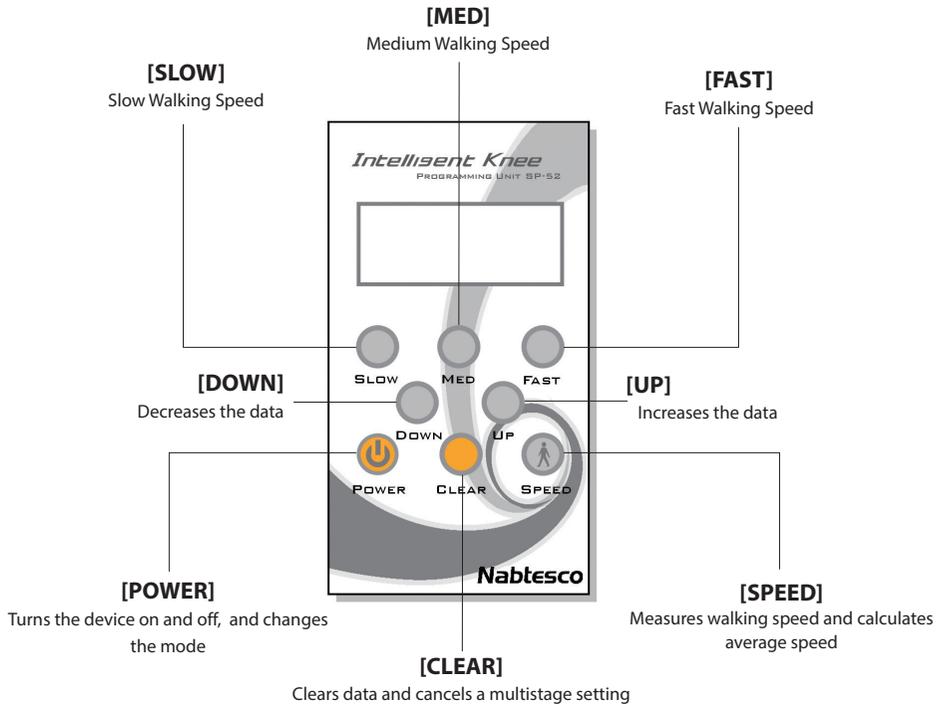
Note Before connecting, eliminate static electricity on your body by touching a table or the like. Failure to do so may damage the knee unit circuit board.

Connect the Programming Unit SP-52 to the knee joint using the included cable. The cable should be set with the connector with a ferrite core connected to the knee unit. Use tape to affix the cable so that the cable will not disturb his/her walking.

Note You must use the specialized cable included with the programming unit. The programming unit must not be used for other devices besides the Nabtesco Intelligent Knee series. An improper connection could cause failures of the products.



2 KEY EXPLANATION



[RESET] (on top-side)
Resets the microprocessor function and the 0 position of the needle valve

* CABLE x 1 (Included) 2 m with a ferrite core

Fig.15 SP-52 Programming Unit

3 ADJUSTING PROCEDURES

a. ADJUSTING MODE

To program the swing phase control of the knee unit, base line data should be collected by having the user walk at the Medium, Slow, and Fast speeds. Normally, programming for a knee unit can be accomplished only using this mode.

Display	Operation Procedure	Operating Key					
		SLOW	MED	FAST	UP/DOWN	POWER	SPEED
	Connect the programming unit to the knee joint, press "POWER," then release it immediately.					○	
HELLO! SP-52 rev.01 WAIT	Wait for approximately two seconds.						
ADJUSTING MODE ↓ ADJ.MODE PRESS MED	Select "MED" for normal walking.		○				
SELECT MV= 10	Perform a trial walk at medium speed. (Initial value: 10) Select the optimum MV value for the knee swing using "UP" and "DOWN."				○		
STEPS = 7 MT=---	Press "SPEED" several times, and select the "STEPS". (5 to 7 steps can be chosen.)						○
GO = 0 MT=120	Have the user walk at medium speed until "GO = 0" is shown, and measure the speed MT.						
V S > 10 > ? T ? > 120 > ?	Check the value of medium speed, and select "SLOW" for slow walking.	○					
SELECT SV= 15	Perform a trial walk at slow speed, and select the optimum SV value for the knee swing using "UP" and "DOWN". (Initial SV = MV value + 5)				○		
STEPS = 7 ST=---	Press "SPEED" several times, and select the "STEPS."						○
GO = 0 ST=160	Have the user walk at slow speed until "GO = 0" is shown, and measure the speed ST.						
V 15 > 10 > F T 160 > 120 > ?	Check the value of slow speed, and select "FAST" for fast walking.			○			
SELECT FV= 05	Perform a trial walk at fast speed, and select the optimum FV value for the knee swing using "UP" and "DOWN". (Initial FV = MV value - 5)				○		
STEPS = 7 FT=---	Press "SPEED" several times, and select the "STEPS."						○
GO = 0 FT= 80	Have the user walk at fast speed until "GO = 0" is shown, and measure the speed FT.						
V 15 > 10 > 05 T160 > 120 > 80 ↑↓ OK:POWER OFF	When this message appears, press "POWER." Data for up to 10 stages is automatically calculated on the basis of the detected data, and is transferred to the circuit board on the knee unit. Then the power automatically turns OFF.					○	
GOOD-BYE	Unplug the cable and walk freely.						

b. CONFIRMATION MODE

This mode allows you to check the programmed data in the knee unit. When the user walks, the current valve position can be displayed.

Display	Operation Procedure	Operating Key					
		SLOW	MED	FAST	UP/DOWN	POWER	SPEED
	Connect the programming unit to the knee joint. Press and hold "POWER."					○	
HELLO! SP-52 rev.01	Hold "POWER" and wait for approximately one second.					○	
CONFIRM MODE	When this message appears, release "POWER."					○	
WAIT	Wait for approximately two seconds.						
CONFIRM MODE ↓ V1= 5 B1= 120	Press "UP" or "DOWN" to display data stored to the knee joint. After three seconds, the previous message will reappear.				○		
CONFIRM MODE V5= 9	While walking, the value on the second line varies with the walking speed.						
GOOD-BYE	Press "POWER" to turn the programming unit off.					○	

c. MANUAL MODE

Using Manual Mode, the needle valve can be set at a fixed position like a normal pneumatic knee joint. This mode is useful, for instance, when training.

Display	Operation Procedure	Operating Key					
		SLOW	MED	FAST	UP/DOWN	POWER	SPEED
	Connect the programming unit to the knee joint, and press and hold "POWER."					○	
HELLO! SP-52 rev.01	Wait for approximately two seconds.					○	
CONFIRM MODE	While this message is being displayed, keep it pressed.					○	
MANUAL MODE	When this message appears, release "POWER."					○	
WAIT	Wait for approximately two seconds.						
MANUAL MODE V = 15	The value on the second line shows the current fixed valve opening. Press "UP" and "DOWN" to select the optimum valve opening.				○		
GOOD-BYE	The power turns off. The valve opening is fixed. Note: To restore the normal function, go into "ADJUSTING MODE" and then just turn off the power.					○	

d. COPY MODE

Use Copy Mode to transfer stored data from one knee to another such as a loaned unit.

Display	Operation Procedure	Operating Key					
		SLOW	MED	FAST	UP/DOWN	POWER	SPEED
	Connect the programming unit to the knee unit. Press and hold "POWER" and "SPEED" simultaneously.					⊙	⊙
HELLO! SP-52 rev.01	Wait for approximately one second.					⊙	⊙
COPY MODE	When this message appears, release "POWER" and "SPEED".					⊙	⊙
WAIT	Wait for approximately two seconds.						
CHANGE IP! PRESS SPEED	Connect the programming unit to another knee joint and press and "SPEED".						⊙
PRESS SPEED TO WRITE!	Press "SPEED" again for confirmation.						⊙
GOOD-BYE	After the copy is performed, the power is automatically turned off.						

e. BATTERY CHECK MODE

This mode shows the total steps that the user has walked as well as an estimation of the remaining battery life.

If the battery connector is disconnected, the data on the total number of steps will be reset.

Note This function is available for all Hybrid Knee NI-C311 and Intelligent Knee devices produced after December 2005.

Display	Operation Procedure	Operating Key					
		SLOW	MED	FAST	UP/DOWN	POWER	SPEED
	Connect the programming unit to the knee unit. Press and hold "POWER" and "SPEED".					⊙	⊙
HELLO! SP-52 rev.01	Wait for approximately one second.					⊙	⊙
COPY MODE	While this message is being displayed, keep them pressed.					⊙	⊙
EXTENSION MODE	While this message is being displayed, keep them pressed.					⊙	⊙
IP BAT CHK MODE	When this message appears, release "POWER" and "SPEED".					⊙	⊙
WAIT	Wait for approximately two seconds.						
APPROX. 75% ■■■■■■■■	The value shows the approximate residual capacity of the knee's battery.						
STEP 1234567 REST 4345678	By pressing "DOWN", you can display the total number of steps the user has walked, as well as the estimated remaining number of steps that can be taken before the battery is depleted. Note: The message will not be displayed if the value of the total steps is less than 100,000 steps. Press "UP" to go back to the previous indication.				⊙		
GOOD-BYE	Press "POWER" to turn the programming unit off.					⊙	

f. EXTENSION MODE

For fine adjustment of programming, use Extension Mode. In this mode, the roles of the keys are changed as follows; "SLOW" Key → [SELECT], "MED" Key → [ENTER], "FAST" Key → [SAVE]

Display	Operation Procedure	Operating Key					
		SLOW	MED	FAST	UP/DOWN	POWER	SPEED
	Connect the programming unit to the knee unit. Press and hold "POWER" and "SPEED".					⊙	⊙
HELLO! SP-52 V01	Wait for approximately one second.						
COPY MODE	While this message is being displayed, keep it pressed.						
EXTENSION MODE	When this message appears, release "POWER" and "SPEED".					⊙	⊙
WAIT	Wait for approximately two seconds.						
EXT.MODE A= 0 D=120	The second line shows Address (A) and the Input Data (D) at the address.						
EXT.MODE A= 10 D= 5	Using "UP" and "DOWN", go to the address to be changed.					⊙	
SELECT DATA! A= 10 D= 5	Press "SLOW" to select the address.	⊙					
SELECT DATA! A= 10 D= 4	Then, using "UP" and "DOWN", change the value of data.					⊙	
ENTER! A= 10 D= 4	Press "MED" to enter changed data. If other data needs to be changed, repeat the above procedure.		⊙				
SAVE! A= 10 D= 4	After all data is changed, press "FAST" to save the data in the microprocessor.			⊙			
GOOD-BYE	Press "POWER" to turn the programming unit off.					⊙	



CAUTION

Never change any data, except for the data at the addresses mentioned below. Adjustment without knowledge about the programming may cause malfunction of the knee control and trouble with the user's walking. After adjustment, confirm that the data was surely changed as intended.

Table: Address and Data

ADDRESS	DATA (Description)	ADDRESS	DATA (Description)
A=00	B1: Fastest Boundary of Walking Speed	A=10	V1: Fastest Valve Position
A=01	B2: 2nd Boundary	A=11	V2: 2nd Valve Position
A=02	B3: 3rd Boundary	A=12	V3: 3rd Valve Position
A=03	B4: 4th Boundary	A=13	V4: 4th Valve Position
A=04	B5: 5th Boundary	A=14	V5: 5th Valve Position
A=05	B6: 6th Boundary	A=15	V6: 6th Valve Position
A=06	B7: 7th Boundary	A=16	V7: 7th Valve Position
A=07	B8: 8th Boundary	A=17	V8: 8th Valve Position
A=08	B9: 9th Boundary	A=18	V9: 9th Valve Position
A=09	255 (Terminal Data)	A=19	V10: 10th Valve Position
A=22	Valve Position when stopping (Default: MV Value)	A=23	Valve Position when voltage of battery drops (Default: MV Value)

g. COM. MODE: This mode is not available for use, and is only to be used by the manufacturer.

4 ERROR MESSAGES AND TROUBLESHOOTING

● ERROR MESSAGES

Message displayed: KNEE JOINT LOW BATTERY

When	Cause	Solution
Turning on the power.	Depleted battery of the knee joint.	Replace the battery of the knee joint.
<p>Special Note: This message will be displayed when voltage of the battery in the knee joint is low. This message may not appear if the knee unit has been left on for a long period of time.</p>		

Message displayed: PROGRAMMER LOW BATTERY

When	Cause	Solution
When power is turned on or during adjustment.	Depleted battery of the programming unit.	Replace the battery of the programming unit.
<p>Special Note: This message will be displayed when voltage of the battery in the programming unit is low.</p> <p>Note Replace the battery as soon as possible so that the data during programming will not be lost.</p>		

Message displayed: COM. ERROR

When	Cause	Solution
When power is turned on or during adjustment.	<p>A) Depleted battery of the knee joint.</p> <p>B) Communication error between the programming unit and the circuit board of the knee unit.</p> <ol style="list-style-type: none"> 1. Incorrect cable used. 2. Connection error. 3. Cable breakage. 4. Circuit board connected improperly. 5. Programming unit failure. 6. Dust or dirt on contact area. 	<p>A) Replace the battery.</p> <p>B) Take measures depending on the cause.</p> <ol style="list-style-type: none"> 1. Use the proper cable that was supplied. 2. Insert the connector fully. 3. Replace the cable. 4. Press RESET. 5. Replace the programming unit. 6. Clean the contact area and keep the plastic plugs in place.
<p>Special Note: If the error message disappears, resume normal use. If "COM.ERROR" continues to be displayed and the power is shut off automatically, you need to press RESET once and turn the power on.</p>		

Message displayed: ST<MT ERROR!

When	Cause	Solution
After measuring ST data in Adjusting Mode.	SLOW is faster than MED.	Re-measure the SLOW data. Press SPEED and walk slowly.
<p>Special Note: If the problem cannot be solved by the solution, the walking data of MED may be too large (slow). Press CLEAR twice in succession to erase the MED data, then re-measure the MED data.</p>		

Message displayed: MT<FT ERROR!

When	Cause	Solution
After measuring FT data in adjusting mode.	FAST is slower than MED.	Re-measure the FAST data. Press SPEED and walk quickly.
<p>Special Note: If the problem cannot be solved by the solution, the walking data of MED may be too small (fast). Press CLEAR twice in succession to erase the MED data, then re-measure the MED data.</p>		

● TROUBLESHOOTING

Use the following information if there is any trouble during any phase of use.

Problem	Cause	Solution
No display appears when power supply is turned on.	A) Battery of the programming unit not connected to unit properly. B) Battery of the programming unit depleted.	A) Connect the battery correctly. B) Replace the battery.
A) The display blinks. B) Abnormal marks appear. C) Display becomes weaker or disappears.	Depleted battery of the programming unit.	Replace the battery of the programming unit.
A) Display blackens and is difficult to read. B) Display is faint and difficult to read.	A) The unit has been subjected to high or low temperatures for a long period of time. B) There is an adjustment error of the unit.	A) Place in room with temperature between 10° to 30°C for 1 hour. Replace the battery if unit does not recover in that time period. B) Replace programming unit.
Display appears only while the power key is being pressed, and disappears when released.	A) The battery in the knee joint is not connected. B) The battery in the knee joint is depleted.	A) Connect the battery in the knee joint. B) Replace the battery in the knee joint.
If display reads "LOW BATTERY" or "COM.ERROR".	Depleted battery of the programming unit.	Refer to the section for ERROR MESSAGES.
Problems during "MANUAL MODE" and / or "ADJUSTING MODE"		
Swing speed of the prosthesis does not change when data is changed.	A) The battery is not connected to the knee joint. B) "0" position error of needle valve. C) The battery in the knee joint is depleted. D) The cylinder module circuit board, motor, or needle valve has been damaged.	A) Connect the battery to the knee joint. B) Press RESET. Press the again key again if the first time is not effective. C) Replace the battery in knee unit. D) Contact the supplier.
The remaining step indicator does not count down when walking speeds are measured.	A) Proximity sensor not connected. B) Damage to proximity sensor, connection, or magnet.	A) Contact the supplier. B) Contact the supplier.
If the display reads "ST<MT ERROR!" or "MT<FT ERROR!".		Refer to the section for ERROR MESSAGES.
Problems during CONFIRMATION MODE		
Terminal impact is too hard.	Terminal impact adjustment is too weak.	Turn the terminal impact adjustment screw clockwise to increase the dampening within the range where the knee reaches full extension.
The prosthetic knee cannot reach full extension.	Terminal impact adjustment is too strong.	Turn the terminal impact adjustment screw counterclockwise to obtain full extension.
The swing of the prosthesis does not coordinate with a speed change.	A) The connection to the battery, motor, or proximity sensor is loose B) The battery in knee unit is depleted. C) Damage to proximity sensor or magnet. D) Pneumatic cylinder faulty.	A) Insert the connector fully. B) Replace the battery of the knee unit. C) Contact the supplier. D) Contact the supplier.

5-2-2 Adjusting the Terminal Impact

When undesirable terminal impact occurs, adjust the cushion valve located above the pneumatic cylinder using the following procedure:

- 1 As shown in Fig. 16, turn the cushion valve with a hex wrench (2 mm).

Clockwise: Cushion effect is enhanced and impact is reduced.

Counterclockwise: Cushion effect is weakened and impact is increased.



Fig. 16 Tightening Procedure of the Cushion Valve

- 2 Have the patient walk slowly, using parallel bars to ensure safety, and confirm that the knee fully extends.
If the knee does not fully extend, turn the cushion valve to the left to weaken the cushion effect.
- 3 Have the patient gradually increase his/her cadence. Select an appropriate valve level by listening to the loudness of terminal impact.



CAUTION

Never use the prosthesis with an excessively strong cushion effect. Failure to observe this caution can cause falling as the knee does not extend fully. Also, it may cause the yielding function to operate unintentionally, resulting in sticking.



POINT 3 Guide to Cushion Adjustment

- Cushion adjustment should be made in consideration of the swing strength of each patient. As a general rule, however, set a value within the marked range.
- The factory default setting is 1 turn to the left from the fully closed position.

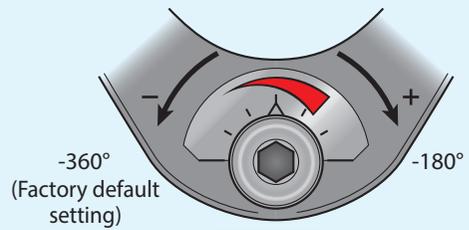


Fig. 17

5-3 Adjusting Yielding for Descending a Slope or Stairs

Before descending a slope or stairs, perform fine adjustments of hydraulic resistance and sensitivity.



**Mandatory
Action**

Before using the prosthesis for walking on a slope or stairs, perform gait training. If appropriate use of yielding is deemed difficult after gait training, use of the yielding function should be prohibited. Failure to observe this instruction may cause a serious accident such as falling-down.



WARNING

If walking on a slope or stairs, the patient must be instructed to secure safety by holding a handrail. Due to the unfavorable floor conditions, there is a risk that the patient may lose balance, resulting in falling-down.

In order to make the yielding function effective, be sure to touch the floor with the heel first. If the toe touches the floor first, there is a risk that the knee might buckle, resulting in falling-down.

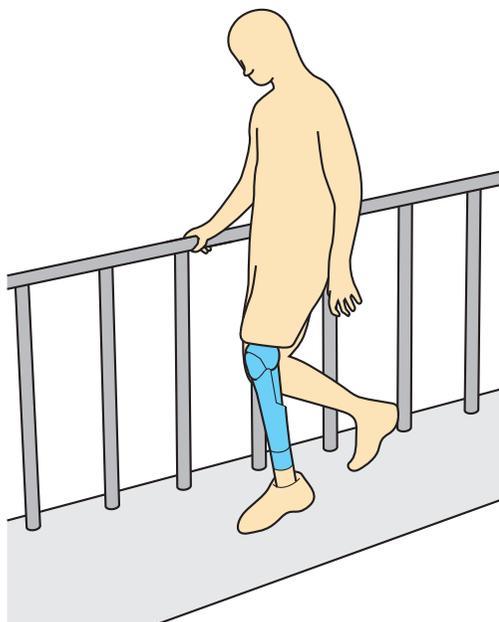


Fig. 18a Descending a Slope

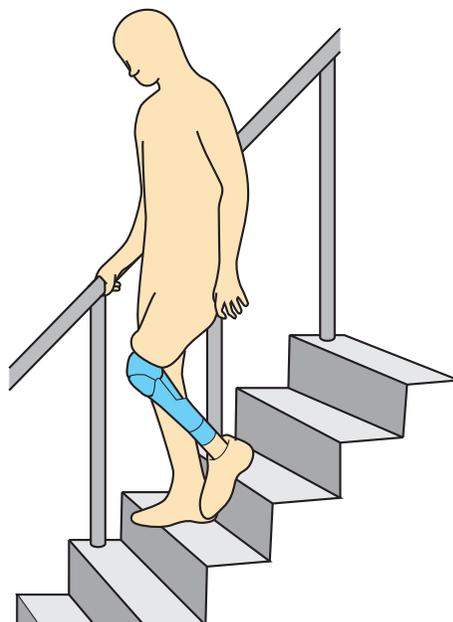


Fig. 18b Descending Stairs

Procedure

● Adjustment for descending a slope

- **Adjustment of hydraulic resistance**

Select an appropriate strength of hydraulic resistance suitable for the angle of the declining slopes where the patient walks in his/her daily life.

→ See **5-1-1** (page 17).

- **Adjustment of the sensitivity adjusting screw**

If sticking occurs at the toe-off when descending a slope or if the yielding function is not sustained, make fine adjustment of the sensitivity adjusting screw.

→ See **5-1-3** (page 20).

● Adjustment for descending stairs (if applicable)

- **Adjustment of hydraulic resistance**

Select an appropriate strength of hydraulic resistance suitable for the stairs where the patient walks in his/her daily life.

→ See **5-1-1** (page 17).

- **Fine adjustment of sensitivity**

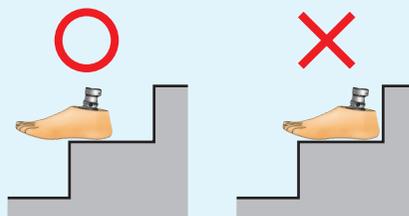
Make fine adjustment of the sensitivity adjusting screw as needed.

→ See **5-1-3** (page 20).



POINT 4 How to Land on the Prosthesis When Descending Stairs

Instruct the patient to put the mid-foot on the edge of the stairs.



5-4 Precautions When Sitting in and Standing up from a Chair



WARNING

- When sitting in a chair, never place the hand behind the knee. The hand can be caught in the swaying part of the pneumatic cylinder, causing serious injury.
- When standing up from a chair, never place the hand on the knee. Fingers can be caught between the knee plate and the hydraulic unit, causing serious injury. If the patient needs assistance in standing up from a chair, we recommend placing hands on the armrests or on the seat*.

* In addition to the above, placing a hand on the socket or placing both hands on the sound leg can also help the patient stand up from a chair. Provide instructions on the safe method according to the patient's circumstances.

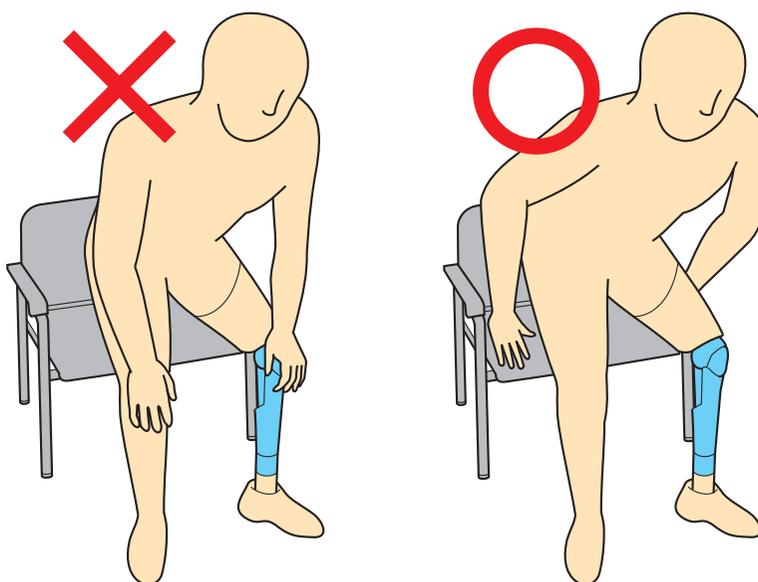


Fig. 19 Recommended Posture When Standing up from a Chair

6 Troubleshooting

Status	Items to be checked	Countermeasures
Even if hydraulic resistance is adjusted to a higher level, yielding strength is not increased.	Check if body weight is being applied properly.	Practice how to sufficiently apply body weight to the heel. → See  POINT 1 (page 18).
	Check if alignment is proper.	Make adjustments so that body weight can be sufficiently applied to the heel.
	Check if the foot is appropriate.	Select a foot with which body weight can be sufficiently applied to the heel.
	The above measures can not resolve the problem.	Contact your local sales representative/dealer.
In the stance phase when walking on a level floor, minor wobbling motions occur on the knee joint.	Check if alignment is proper.	Adjust alignment to the stable side.
	Check if the knee joint is flexed when the heel makes floor contact.	Practice how to walk with the knee fully extended in the stance phase.
	Check if the pneumatic cylinder cushion is adjusted too strongly.	Loosen the cushion valve.
Hydraulic resistance becomes effective when it is not supposed to. (Sticking occurs during transition from stance to swing phase.)	Check if hydraulic sensitivity is adjusted too strongly.	Loosen the sensitivity adjusting plug. (DO NOT make 3 turns or more from the fully closed position.) → See 5-1-3 (page 20).
	Check if the pneumatic cylinder cushion is adjusted too strongly.	Loosen the cushion valve.
	Check if smooth heel-to-toe weight shifting is achieved while walking.	Provide gait training so that body weight is sufficiently applied to the toe of the prosthetic foot at time of toeing off.
	The above measures can not resolve the problem.	It is possible that the load on the toes at the time of push-off is insufficient. Proper alignment, foot selection, adjustment, and gait training are essential to take full advantage of this knee joint.
The yielding function is not sustained when the patient descends a slope.	Check if body weight is being applied properly.	Practice how to sufficiently apply body weight to the heel. → See  POINT 1 (page 18). *
	Check if alignment is proper.	Make adjustments so that body weight can be sufficiently applied to the heel.
	Check if the prosthetic foot has adequate heel stiffness (not too soft).	Select a prosthetic foot with medium heel stiffness.
	The above measures can not resolve the problem.	Contact your local sales representative/dealer.

Status	Items to be checked	Countermeasures
When the patient descends stairs, yielding does not function.	Check if the floor contact position of the foot is appropriate.	Put the mid-foot on the edge of the stairs. → See  POINT 4 (page 32). *
	Check if the toe touches the floor first due to insufficient knee extension.	Swing the prosthesis to fully extend the knee joint. Be sure to put the mid-foot on the edge of the stairs. *
	Even if the knee is fully extended, it is flexed due to its own weight before the foot contacts the floor.	Repeat gait training of how to shift the body weight forward and to obtain the best timing of swing and landing. *
	Even after gait training, the patient cannot fully extend the knee joint.	Select a pneumatic cylinder with a strong spring to assist extension. During its use, however, the patient may feel heaviness during swing motion in the swing phase.
	The above measures can not resolve the problem.	Use of yielding for stairs should be prohibited.

*



WARNING

Make sure that the patient always holds a handrail during gait training. There is a risk that the patient might lose balance and fall down.

→ See 5-3 (page 31).

7 Maintenance

7-2 Replacing the Extension Stopper Rubber

- 1 While flexing the knee joint approximately 90°, remove the extension stopper rubber. As double-sided tape is attached on the back of the extension stopper rubber, it is recommended to use a sharp-pointed stick to remove the rubber.
- 2 Remove dirt and dust from the inside of the groove. Completely remove the double-sided tape without any residual piece. Finally, remove any oil and grease using aerosol.



CAUTION

- Be sure to remove oil and grease. If they are not fully removed, the double-sided tape may not be properly attached and the extension stopper rubber may peel off.
- DO NOT use thinner or acetone to remove oil or grease. These degreasing agents may dissolve paint. Contact with the hydraulic seal may cause damage to the rubber, resulting in oil leakage.

- 3 First, remove the protective cover of a new double-sided tape for the extension stopper rubber. Then, turning the surface with projections upward and placing the thicker side forward, insert it into the groove. After that, press it with sufficient force.

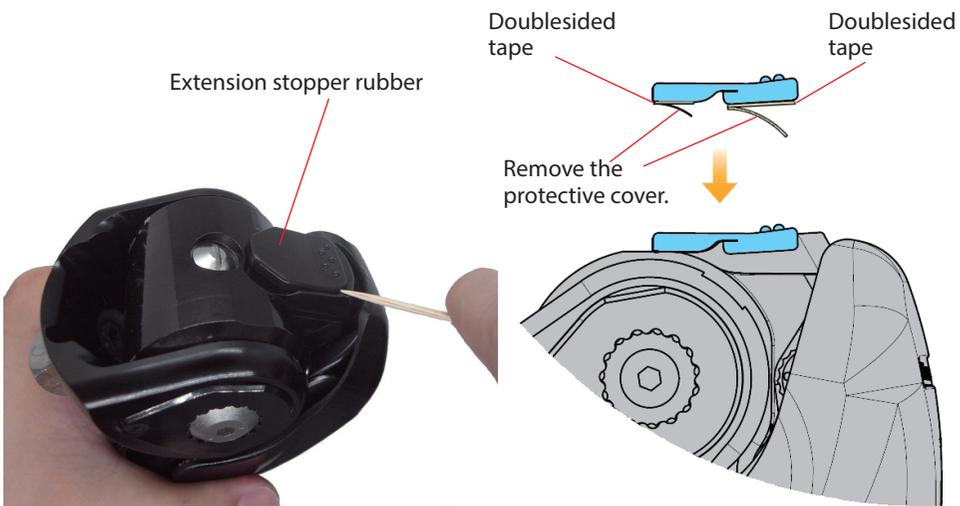


Fig. 20a

Fig. 20b

7-2 Replacing the Battery

- Replace the battery using the following procedure:



Be sure to eliminate static electricity by, for example, touching a desk before starting this work.

- 1 Remove the battery connector from the circuit board (Fig. 21).

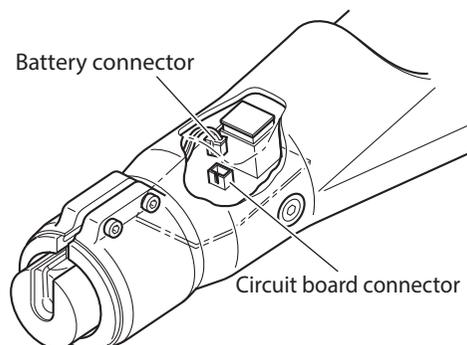


Fig. 21 Removing the Battery Connector

- 2 Loosen the outer clamp bolts and then pull out the tube.
- 3 Remove the outer clamp from the frame, remove the retaining screw, and pull out the inner clamp together with the battery case (Fig. 22).

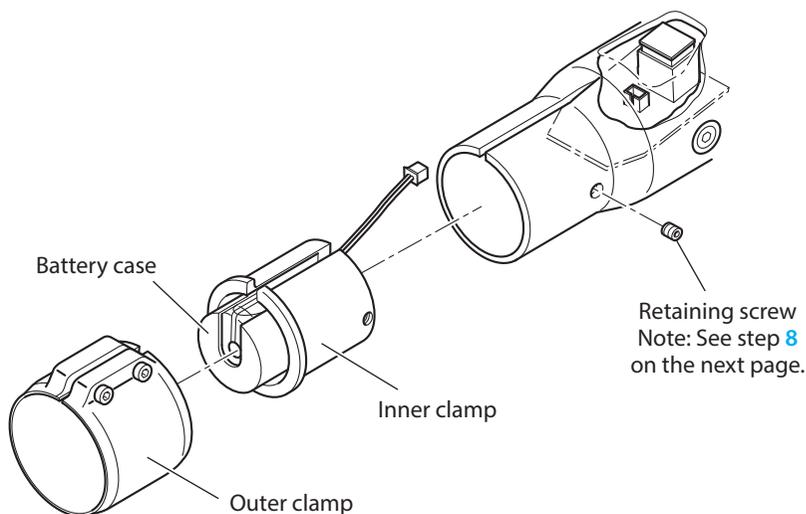


Fig. 22 Removing the Clamps

-
- 4 Turn the cap on the battery case using a coin, and remove the battery. (Figs. 23 and 24).

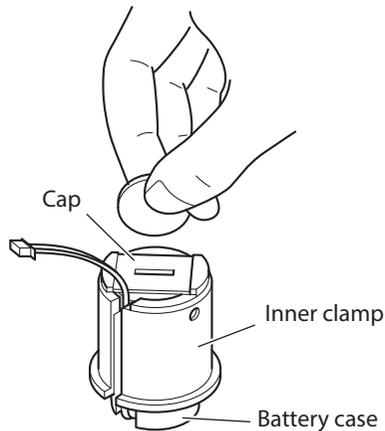


Fig. 23 Removing the Battery Cap

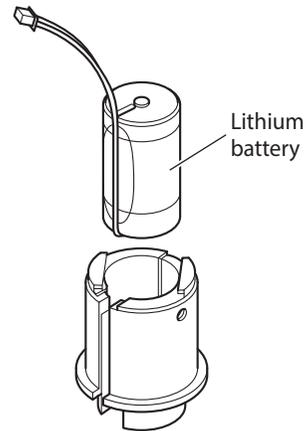


Fig. 24 Removing the Battery

- 5 Insert a new battery into the battery case.

Note: When inserting a battery, align the battery wire with the slit of an inner clamp. [If the battery is placed facing the reverse side, the battery can not be inserted fully (Fig. 24).]

- 6 Put back the cap on the battery case and secure it tightly.

- 7 Install the inner clamp on the frame.

Note: When installing the inner clamp, place the battery connector on the upper surface of the circuit board as shown in Fig. 22.

- 8 Set the retaining screw.



CAUTION

Tighten the screw until its head reaches slightly below the frame surface and insert the outer clamp. Overtightening may press the battery case and damage the battery.

-
- 9 Insert the battery connector into the circuit board connector (Fig. 21).



CAUTION

- Connect the programming unit and then perform a reset.
- Confirm that the reset has been performed properly by listening for the motor operating sound. With a proper reset, the motor will soon stop.

Note: If the motor does not stop, perform reset again. (There is a risk that battery electricity may be abnormally consumed.)

Disposal of Batteries

Dispose of used batteries strictly in accordance with regulations of the local government concerned. (This product uses a lithium battery.)

7-3 Replacing the Cylinder Module

● Removing the cylinder module

- 1 Pull out the battery connector from the circuit board.
- 2 Remove the clevis bolt and the trunnion pin (Fig. 25).
- 3 Retract the cylinder rod and create space by flexing the knee, and then slowly pull out the cylinder module from the frame. (Pull it out until the circuit board comes above the frame.)
- 4 Remove the proximity sensor connector which is fitted behind the circuit board.

● Installing the cylinder module

- 1 Insert the proximity sensor connector which is fitted behind the circuit board.
- 2 Retract the cylinder rod and create space by flexing the knee, and then slowly insert the cylinder module into the frame.
- 3 Attach the trunnion pin and the clevis bolt (Fig. 25).

Note 1: In order to prevent the clevis bolt from getting loose, apply an appropriate amount of adhesive (equivalent to Loctite 243) to the threads.

Note 2: Apply an appropriate amount of grease to the O-ring of the trunnion.

- 4 Flex and extend the knee to confirm that no abnormality is detected.

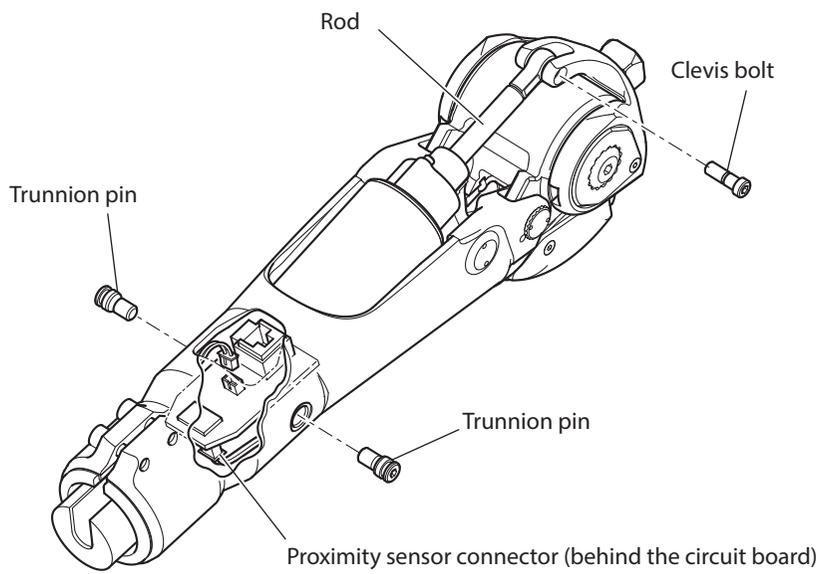


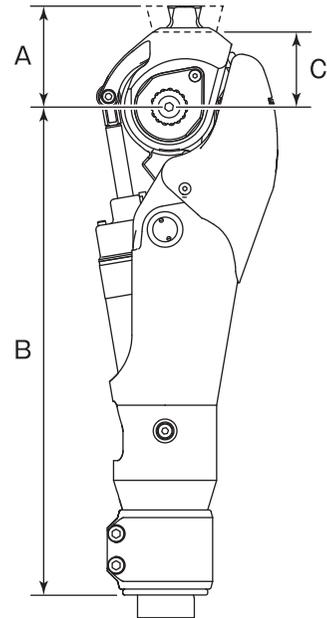
Fig. 25 Removing/Installing the Cylinder Module

8 Outline of the Product

● Specifications

Type		NI-C311/NI-C311s	NI-C313/NI-C313s
Dimensions	Overall length	296 mm	292 mm
	A	51 mm	45 mm
	B	247 mm	247 mm
	C	38 mm	38 mm
Weight		1,375 g	1,385 g
Knee flexion angle		Max. 140°	
Patient's body weight limit		125 kg (100 kg for highly-active users) Compliant with ISO 10328 P6 (A-125 kg)	
Battery life time		Approx. 2 years	

* These specifications are subject to changes without prior notice.



● Lifetime: 6 years

● Features

1 Excellent stance phase stability and yielding function

The hydraulic rotary damper and the unique MRS system serve to accurately create hydraulic resistance and to avoid knee buckling. In addition, the yielding function helps achieve safe descending on a slope and stairs.

Note: Hybrid Knee is intended to assist the capability of an patient who uses a prosthesis. Please note that no one can easily descend a steep slope or stairs without gait training.

2 Wide range of speed follow-up performance and tireless walking

The microprocessor-controlled intelligent mechanism enables walking in a wide range of cadence. In addition, air pressure control can provide easy prosthesis swinging and can reduce fatigue.

3 User friendliness

Stance phase control can be easily adjusted with a hex wrench. The adjustment method for the stance phase control is the same as that for the conventional intelligent knee joint. Battery life time is approximately 2 years*.

Note: Battery life time varies according to the walking pattern of each patient. The battery life time of 2 years is based on a general walking pattern.

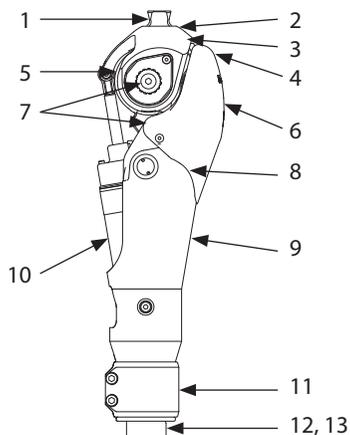
9 Disposal

The table below shows the materials of the Hybrid 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 notifying us, we will dispose of it for you.



Do not discard the lithium battery with general household garbage. If thrown away, the battery could short-circuit and ignite or release harmful fumes.

	Part name	Classification of material	Remarks
1	Joint parts	Metal	Titanium alloy
2	Knee plate	Metal	Aluminum alloy
3	Extension stopper	Rubber	Nitrile rubber
4	Front link	Metal	Aluminum alloy
5	Hydraulic unit	Metal	Body: Aluminum alloy Shaft: Iron alloy O-ring: Rubber
6	Knee cover	Plastic	Nylon 6
7	Fastening / supporting	Metal	Iron alloy
8	Base bracket	Metal	Aluminum alloy
9	CFRP frame	Plastic	Carbon fiber reinforced composite material
10	Pneumatic cylinder	Metal	Body: Aluminum alloy Fastening: Iron alloy O-ring: Rubber
11	Clamp	Metal	Aluminum alloy
12	Battery	Lithium battery	Primary battery
13	Battery holder and cap	Plastic	POM



10 Periodic Inspection and Warranty

● Periodic inspection

- Undergo a periodic inspection every 2 years.
Inspections for the 2nd year are free of charge, and inspections for the 3rd year and following years are offered on a charged basis.
 - Consumable parts (extension stopper rubber, battery) are available for purchase.
-



CAUTION

Be sure to undergo a periodic inspection every 2 years.

Failure to undergo a periodic inspection can nullify the warranty period.

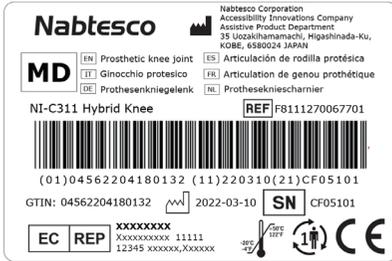
Should the Hybrid Knee be used without a periodic inspection, parts can become worn down more quickly.

● Warranty

For the warranty, please refer to the separate warranty document.

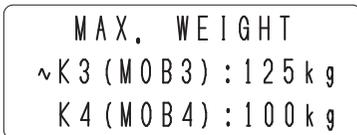
11 Symbols Used

11-1 UDI Label (Packing Box)



-  Legal manufacturer
-  Date of manufacture
-  Medical Device
-  Item number
-  Serial number
-  Global Trade Item Number
-  Authorized representative for EU countries
-  The maximum and minimum temperatures for storing, transporting, and using the product.
-  Declaration of conformity according to the European Regulation 2017/745
-  Single patient multiple use

11-2 Body Mass Limit Label (Knee Joint Body)



Body mass limit not to be exceeded. See page 7.

11-3 Product Type Label (Knee Joint Body)



-  Serial number
-  Declaration of conformity according to the European Regulation 2017/745

11-4 Tightening Torque Label (Knee Joint Body)

4.5 ~ 5 Nm

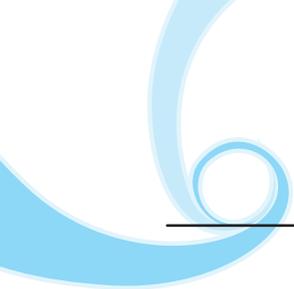
Tighten the clamp within this torque range.

11-5 Lithium Battery Label (Battery)



 It certifies that this product complies with UL safety standards.

 The EU requires recycling without disposal in a landfill. When disposing of this product, follow the rules of the local government.



MEMO

A large, empty rectangular box with rounded corners, intended for writing a memo.

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Nabtesco Corporation

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