ICON

microprocessor knee

college park

TECHNOLOGY *for the* HUMAN RACE

technical instructions

FIGURE 1

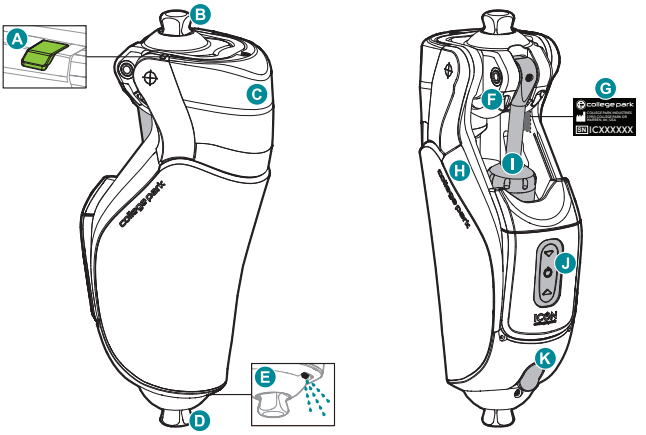
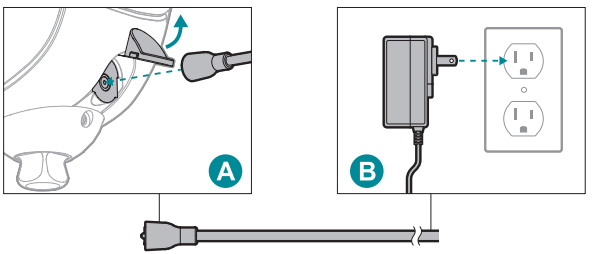


FIGURE 2



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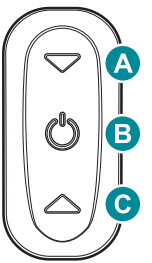

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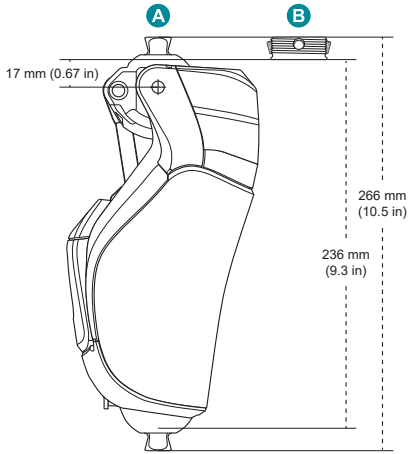

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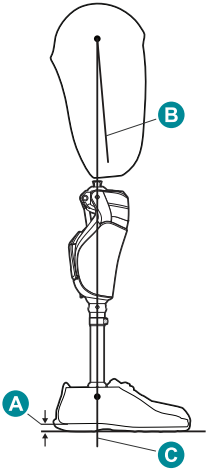


FIGURE 6

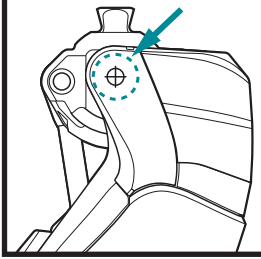


FIGURE 7

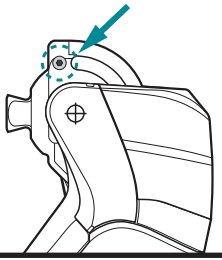


FIGURE 8

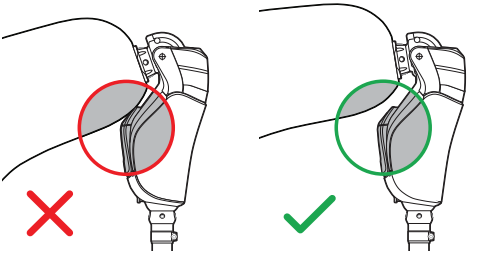
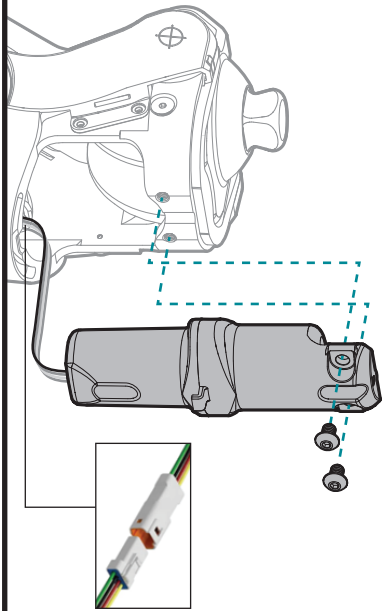


FIGURE 10



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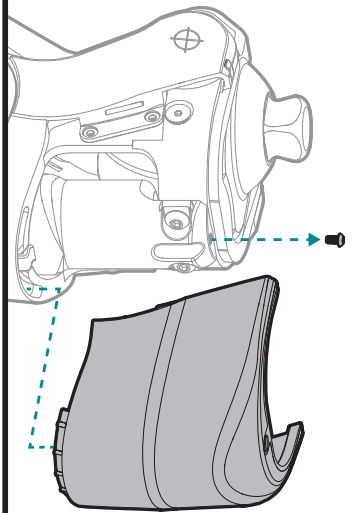

This document is intended for use by certified and licensed prosthetic clinicians only.
For user approved operations, see the Icon Microprocessor Knee User Guide.

Federal Law restricts that the Icon Microprocessor Knee is to be purchased, configured, and fit only by a board-certified prosthetist, licensed by the state in which they practice. This device is intended for use in accordance with the information contained in this document. Instruct the patient on proper use of this device before transferring device to patient.

Thank you for purchasing the Icon Microprocessor Knee from College Park Industries. The following pages will cover everything you need to know about this system from setup to operation. If you have any questions, concerns, or comments, please contact our Technical Service team at 800 728 7950 (US/Canada), (+1) 586 294 7950 (International).

In the following document you will find information on everything from initial setup to maintenance and care of the Icon Microprocessor Knee. Read these instructions carefully and educate the end user on all functions of this product before final delivery.

The Icon Microprocessor Knee is fully assembled and undergoes electronic testing verification before it is shipped.

What's in the box?

Hardware

Icon Microprocessor Knee

Battery Charger w/ Adapter

Instruction Manuals

Icon Microprocessor Knee Technical Instructions

Icon Microprocessor Knee Quick Setup Guide

Icon Microprocessor Knee User Manual

Stride Studio App Instructions

These diagrams are to help familiarize you with the unique parts of the Icon Knee. These parts are referenced in the instructions and used when speaking with a technical service representative.

KEY COMPONENTS *(FIGURE 1)*

A. LED Indicator

B. Pyramid (Proximal Attachment)

C. Knee Pad

D. Pyramid (Distal Attachment)

E. Drainage Port

F. Upper Assembly

G. Serial Number

H. Knee Frame

I. Hydraulic Unit

J. Button Pad

K. Charging Receptacle / Dust Cover

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FUNCTION

The Icon Knee is a single-axis, hydraulically dampened microprocessor-controlled knee. A system of integrated sensors is used to determine when to make changes to flexion and extension resistances. Functions include:

FUNCTIONS

- Level ground walking
- Stumble recovery
- Stair and ramp ascent/descent
- Stability during standing
- Walking backwards
- Low/critical battery mode

FEATURES

- Default stance
- Waterproof in fresh water (IP68)
- Temperature accommodation
- Training mode

USER SELECTED MODES

- Normal walking
- Flexion lock / free swing
- Programmable custom modes

PRODUCT DESCRIPTION

The Icon Knee is constructed with an integrated pyramid (proximal) and integrated pyramid (distal).

INTENDED USE

The Icon Knee, intended for transfemoral amputees, is a prosthetic device designed to restore some function of an anatomical knee joint.

⚠ INDICATIONS:

- Transfemoral prosthetic fittings.
- Patients must fulfill the physical and mental requirements for perceiving visual/acoustic signals and/or mechanical vibrations.

⚠ CONTRAINDICATIONS:

- Patients exceeding the 150 kg / 330 lbs weight limit.
- Patients who cannot achieve a full extension moment.
- Unusual activities, including extreme sports.
- Use in corrosive environments, including salt or chlorinated water.

TECHNICAL SPECIFICATIONS

STRUCTURAL SPECIFICATIONS

Frame Material	Aluminum	**Joint Type**	Single-Axis	**Flexion**	130°
Build Height	1.7 cm (0.67 in)	**Assembly Weight**	1,530 g	**Patient Weight Limit**	150 kg (330 lbs)
Warranty	3 years				

DEVICE OPERATION

Battery	Lithium-Ion, 3.6 V, 3450 mAh	**Time to full charge**	approximately 6 hours (time to 50% charge = 2 hours)
Cable	5V, 2.5A DC	**External Power Supply**	Use only provided power supply to charge the Li-ion battery

WIRELESS

Connection	Bluetooth 5.0/Bluetooth Low Energy (BLE)	**Maximum Speed**	24 Mbps
Operating Frequency	2.402 - 2.480 GHz	**Effective Radiated Power**	12.00 dBm

ENVIRONMENTAL USE CONDITIONS

Charging	32F to 113F (0C to +45C)
Operating	14F - 140F (-10C - 60C), Pressure: 70-106 kPa, Humidity: 0%-100% relative humidity
Storage & Transport	-4F to 140F (-20C to +60C) *, Pressure: 70-106 kPa, Humidity: 0%-90% relative humidity

Note: If storing device above or below operating temperature, allow the device to return to within operating temperature range before use. The device must be brought up to the operating temperature, allow the device to sit for 15 minutes.

IP RATING

IP68	Dust tight and protected against freshwater at a maximum depth of 2 meters for 1 hour.

SAFETY

Only start up the product in accordance with the information contained in the supplied documents.

Failure to follow these technical instructions or use of this product outside the scope of its Limited Warranty may result in injury to the patient or damage to the product.

EN

LEGEND OF SYMBOLS

Note: Possible technical damage.

Info: Basic information regarding this product.

CAUTION

Caution: Possible risk of accident or injury.

WARNING

Warning: Possible risk of severe accident or injury.

SAFETY INSTRUCTIONS

Info: Use on airplanes

Airlines may not permit the use of this device on their aircraft. Check with the airline before travelling to ensure this device is allowed for use on the plane.

Info: Disposal

These products may not be disposed of with household waste in some jurisdictions. Disposal that is not in accordance with the regulations of your country may have a detrimental impact on health and the environment. Please observe the information provided by the responsible authorities in your country regarding return and collection processes.

CAUTION

Caution: Improper adjustment

Improper handling or adjustment of the device may cause the stance control to malfunction, which can increase the risk of fall.

CAUTION

Caution: Avoid contact with the socket

Avoid any impact to the socket, frame, adapter contact, or the interface panel on the back of the device. Damage to this panel or any of its components may cause the product to malfunction (Figure 8).

CAUTION

Caution: Use on stairs and ramps

For maximum safety use a handrail when descending stairs and ramps. Particular caution is required when carrying children downstairs.

CAUTION

Caution: Risk of pinching where the knee joint bends

Ensure that fingers and other body parts are not in this area when bending the knee joint.

CAUTION

Caution: Unsupervised use

It is not recommended for children to operate this device without the supervision of an adult. Use extreme caution around small children and household pets.

CAUTION

Caution: Risk of accident while operating a vehicle

A lower extremity amputee's ability to drive a vehicle is determined on a case-by-case basis. Factors include the type of fitting (amputation level, unilateral or bilateral, residual limb conditions, design of the prosthesis) and the amputee's abilities. All persons are required to observe their country's national and state driving laws when operating vehicles. For insurance purposes, drivers should have their driving ability examined and approved by an authorized test center.

CAUTION

Caution: Improper use

Any type of excessive strain, overload or improper use may lead to faulty control or malfunction of the Icon Knee, resulting in a risk of injury. The Icon Knee was developed for everyday use and must not be used for unusual activities. These unusual activities include, for example, sports with excessive strain and/or shocks, or extreme sports. Careful handling of the prosthesis and its components not only increases their service life but, above all, ensures your personal safety! Should the prosthesis be subjected to unusual stresses (such as a fall), immediately contact a certified prosthetist and have the prosthesis inspected for any damage.

CAUTION

Caution: Consequences of product deterioration

Wear and tear on system components can lead to malfunction of the Icon Knee, resulting in a risk of injury. Follow the specified service intervals. The service life of this device is 6 years (excluding battery). Patient concerns about the function should be reported to the prosthetist immediately, including but not limited to noise, sudden loss of function, etc.

CAUTION

Caution: Mechanical overloading

External mechanical influences or loads, such as impacts and vibration, can lead to faulty control or malfunction of the Icon Knee and result in a risk of injury. The Icon Knee should not be subjected to mechanical vibrations or impacts.

CAUTION

Caution: Manipulation of system components

Independent changes and/or modifications to system components may lead to faulty control or malfunction of the Icon Knee, resulting in a risk of injury. No modifications of Icon Knee except those described in this information document are authorized. The Icon Knee and damaged components may only be opened or repaired by certified College Park technicians.

CAUTION

Caution: Battery damage

Damage can occur to the battery when dropping, knocking, crushing, vibrating, or puncturing. Avoid damaging lithium batteries and devices. Always inspect for signs of damage, such as hissing, leaking, cracking/ bulging, and smoking before use. If any of these signs are present, immediately place away from flammable materials. Remove the device from service and contact your prosthetist. Do not charge.

CAUTION

Caution: Penetration of dirt and moisture into charge port

The penetration of dirt or moisture into the charge port may lead to faulty control or malfunction of the Icon Knee and result in a risk of injury. Dirt/debris should be removed from the Icon charge port. Ensure it is dry before charging.

CAUTION

Caution: Water and humidity

The knee can be operated in freshwater but cannot be used in extreme situations such as diving or jumping into water. It is protected against freshwater at a maximum depth of 2 meters for 1 hour. The knee is not resistant to corrosion and should not come into contact with corrosive materials, saltwater, chlorinated water, or pH extremes.

- The knee should be switched into lock mode when using it in or near water.
- Use caution when walking on wet surfaces.
- After contact with water, ensure that the water has drained out of the system and that the drainage port has not become blocked (Figure 1-H).
- After the knee encounters moisture, wipe it dry using a lint-free cloth.
- Make sure that the charge port is clean and dry before charging.
- If the knee encounters salt or chlorinated water, it should be rinsed immediately and dried off.
- If the device malfunctions after exposure to water, contact College Park.

CAUTION

Caution: Thermal overloading

Extreme temperature conditions can lead to faulty control or malfunction of the Icon Knee and result in a risk of injury. Avoid areas outside the specified operating temperature range. The operating temperature range must be between **-10 °C and 60 °C (14 °F and 140 °F)**.

CAUTION

Caution: Device external temperature when operating or charging the product

There is a risk of high temperatures (> 41°C) to the external accessible components of the device during operation or charging. Elevated temperatures are normal during use and/or charging of the device. Only use the wall adapter and charging cable provided with the device. Ensure that the wall adapter is connected to a power supply that can provide 5V.

- Discontinue product use, including the charger and wall adapter if the device is hot to the touch and contact College Park.
- Discontinue product use if the device indicates that the cylinder temperature is hot until it cools down and the alert clears. If the alert does not clear, contact College Park.

CAUTION

Caution: Overheating of the hydraulic unit due to uninterrupted, increased activity (i.e., extended walking downhill)

There is a risk of falling due to unexpected behavior when switching into overheating mode. There is also a burn risk due to touching overheated components.

- The risk of overheating alert will be issued via sound and vibration.
- When the alert begins, reduce activity level immediately so the hydraulic unit can cool down. Activities may resume once the alert stops.
- Failure to reduce the activity level can lead to hydraulic overheating and damage to the product.

CAUTION

Caution: Critically low battery status or loss of power

The knee will go into safety mode when in a critically low state. Safety mode means that the stance flexion resistance will enter its pre-set resistance and swing flexion will not be possible. This keeps the knee in high resistance, for safety, until it is charged again.

Make sure that the user can recognize the auditory and/or vibratory signal for power loss.

CAUTION

Caution: Magnetic interference

The Icon Knee and connected components can malfunction when near high-tension power lines, transmitters, transformers, or other sources of strong electromagnetic radiation (such as security systems for goods in department stores). This can result in a risk of injury.

CAUTION

Caution: Too close to HF communication devices (e.g. mobile phones, Bluetooth devices, WIFI devices)

The device may be susceptible to electromagnetic interference from portable and mobile RF communications devices such as mobile (cellular) telephones or other equipment, even if that other equipment complies with CISPR EMISSION requirements. Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Icon Knee, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

The Icon Knee is suitable for use in any environment except where immersion in fluids other than freshwater is possible, or where exposure to highly electrical and/or magnetic fields can occur (e.g. electrical transformers, high power radio/TV transmitters, RF surgical equipment, CT and MRI scanners).

CAUTION

Caution: EM disturbances

Do not use the Icon Knee near active HF SURGICAL EQUIPMENT and the RF shielded room of an EM SYSTEM for magnetic resonance imaging, where the intensity of EM DISTURBANCES is high. High levels of Electro Magnetic disturbances may cause system to stop functioning properly, either not responding to input signal(s) or no movement of the joints.

CAUTION

Caution: Operating the product near active implanted systems

When operating the product, there is a risk of temporary influences of active implantable systems (e.g. pacemakers, defibrillators etc.) because of electromagnetic interference of the product.

- When operating the product in the immediate vicinity of active implantable systems, ensure that the minimum distances stipulated by the manufacturer of the implant are observed.
- Make sure to observe any operating conditions and safety instructions stipulated by the manufacturer of the implant.

WARNING

Warning: Using with other equipment

Ensure that fingers and other body parts are not in this area when bending the knee joint.

WARNING

Warning: Use only specified equipment

Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

WARNING

Warning: Operation of equipment in hospitals

The Icon Knee was designed for use in residential environments (home, restaurants, etc.) not hospitals or industrial areas. If device is used in environments such as hospitals or industrial areas, user might have to relocate to operate device appropriate so that is away from other HF radio devices.

WARNING

Warning: Use in an oxygen rich environment

The device is not designed for use in presence of flammable gases or oxygen rich environments.

WARNING

Warning: Replacement of lithium-ion battery

Use only the College Park Industries manufactured Icon knee battery pack and the provided battery charger with the Icon knee system. Incorrect replacement of the lithium-ion battery can result in unacceptable risk. Always follow the manufacturer's instructions for proper removal of and replacement of battery pack.

THE BATTERY

The Icon Knee contains an internal lithium-ion battery. This battery supplies 3.6 V, 3450 mAh. It is advised to charge the battery daily. For most users, the battery will last up to 16 hours of continuous use, depending on the condition of the battery and the frequency of use.

The battery is shipped with a partial-charge (up to 30%). We recommend charging the battery to 100% before use.

LED INDICATOR

The Icon Knee is equipped with a state-of-charge indicator. This indicator tells the user how much life is left in their current battery. The Icon Knee must be powered on to use this feature.

Press the power button for 1-second to activate the LED indicator light on the side of the knee (Figure 1-B). The number of blinks indicates the state of the charge. Charge level can also be checked via the Stride Studio app.

FEATURE	Description
POWER BUTTON	Press and hold for 1 second to indicate the battery status.

KNEE LED INDICATIONS – BATTERY

COLOR	INDICATOR	BATTERY STATUS
Solid Green		Fully charged, 91-100%
Green Blinking		20 - 90%
Red Blinking		Low Battery, < 20%
Solid Red		Critical Battery, <5% Activates safety mode

CRITICALLY LOW BATTERY STATUS

The knee will go into safety mode when in a critically low state. Safety mode means that the stance flexion resistance will enter its pre-set resistance and swing flexion will not be possible. This keeps the knee in high resistance, for safety, until it is charged again.

BATTERY CHARGER

Icon Knees are supplied with a magnetic charger for the lithium-ion battery. The charger is recommended for daily use and will assure that the battery will receive a full charge and provide maximum running time. There are three power adapter options (US, UK, or European) to match the needs of different regions. Use only the provided power supply to charge the Li-ion battery.

CHARGING THE ICON KNEE BATTERY

1. Only charge the knee on a flat, level surface and in a cool, dry location away from sources of heat and moisture. Only charge the knee on a flat, level surface and in a cool, dry location away from sources of heat and moisture. Plug the wall adapter into the main AC supply (Figure 2-B) and connect the wall adapter to the main AC supply (Figure 2-C).
2. To connect the magnetic connector to the back of the knee, open the dust cover and insert the magnetic connector. (Figure 2-A)
3. The LED (Figure 1-A) will indicate the state of the charge and the knee will automatically begin charging.

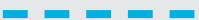
Recharge time from empty is approximately 6 hours.

POWER BUTTON

The power button is in the center position of the button pad on the back of the knee (Figure 3-B). To turn the device on or off, press and hold the power button for 3 seconds. When the device is powered on or off, a multi-colored light on the LED indicator will flash for 1 second.

FEATURE	Description
 POWER BUTTON	Turns knee on/off, initiates Bluetooth pairing.

KNEE LED INDICATIONS – POWER

COLOR	INDICATOR	STATUS
Multi-Color Blink		Power ON or OFF
Blue Blinking		Prompt to pair with Bluetooth.Flashes until pairing is complete.

POWER BUTTON

ON/OFF Press and hold the power button for 3 seconds.

PAIRING ICON KNEE TO MOBILE DEVICE

BLUETOOTH PAIRING The knee must be paired to the Stride Studio app when it is used for the first time. Locate the serial number of the knee in the app and select it. The app will prompt you to press the pairing (power) button on the back of the knee. At this time, the LED turns blue. Press the power button for 1 second and the app will request to be paired with your device.

LOCK/FREE SWING BUTTON

The lock/free swing button is in the top position of the button pad on the back of the knee (Figure 3-A). It is shaped like a caret to match the slider bar in the Stride Studio app.

FEATURE	Description
 LOCK/FREE SWING BUTTON	Switches between normal, lock, and free swing modes.

KNEE LED INDICATION - MODE

COLOR	INDICATOR	STATUS
Solid Purple		Knee in lock mode
Solid Yellow		Knee in free swing mode

LOCK MODE

Activate	Press and hold the mode button for 3 seconds. Once in lock mode, solid state purple LED for duration of lock mode.
Deactivate	Press and hold the mode button for 3 seconds returns to normal mode.
Sound/Vibration Alert	Mode will be indicated with audible and vibratory alert. Both the prosthetist and user can turn the audible alert off using the app.

FREE SWING MODE

Activate	Press and hold the mode button for 6 seconds. Once in free swing mode, solid state yellow LED for duration of free swing mode. *Requirements for free swing to activate:* ▪ Knee must be mostly extended (0-10 degrees) OR ▪ If the knee is flexed more than 10 degrees, the knee must extend a few degrees before activating free swing mode. This will prevent accidental switching when the user is kneeling. This only applies when using the buttons, not the app.
Deactivate	Press and hold the mode button for **3 seconds** returns to normal mode.
Sound/Vibration Alert	Mode will be indicated with audible and vibratory alert. Both the prosthetist and user can turn the audible alert off using the app.

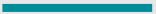
Note: You cannot directly switch to free swing from lock mode or vice versa.

Note: If the knee is in normal mode and the user holds the mode button down for 8 seconds or more, the knee will stay in normal mode

CUSTOM MODE BUTTON

FEATURE	Description
 CUSTOM MODE BUTTON	Custom modes are programmed and enabled using the Stride Studio App. When a custom mode is enabled, it can be activated or deactivated using the button.

KNEE LED INDICATION – CUSTOM MODES

COLOR	INDICATOR	STATUS
Solid Teal		Knee in custom mode

CUSTOM MODE BUTTON

ACTIVATE	Press and hold the mode button for 3 seconds. Once in custom mode, solid state teal LED for duration of custom mode.
DEACTIVATE	Press and hold the mode button for 3 seconds returns to normal mode. Or, if a timer is implemented, it will automatically exit to normal mode.
SOUND/ VIBRATION ALERT	Mode will be indicated with audible and vibratory alert. Both the prosthetist and user can turn the audible alert off using the app.

RECOMMENDED ALIGNMENT

BUILD HEIGHT *(FIGURE 4)*

The proximal knee attachment is a pyramid (Figure 4-A). An additional low profile threaded connector is available to purchase (Figure 4-B).

BENCH ALIGNMENT (TKA) *(FIGURE 3)*

A. Determine the heel height

B. Determine the socket flexion

C. The alignment reference line bisects through the knee center

KNEE CENTER REFERENCE *(FIGURE 6)*

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STATIC ALIGNMENT

With the alignment reference line through the knee center, plantarflex or dorsiflex the foot until the load line is balanced between 1/3 heel and 2/3 toe lever.

KNEE ALIGNMENT

More Stable = slide the knee posterior **More Dynamic =** slide the knee anterior

Note: If the load line is too far anterior to knee center, it may become too difficult to initiate knee flexion. If the load line is too far posterior to knee center, it may cause premature knee flexion.

STANCE TRIGGER RESISTANCE *(FIGURE 7)*

Factory setting = screw is at minimum resistance (easiest to trigger stance flexion) *(Figure 10)*

This sets the amount of toe load required to trigger release into flexion. If the knee goes into flexion too easily at higher walking speeds, this adjustment may need to be increased.

SYMPTOM	DESIRED RESULT	SCREW ADJUSTMENT	
Swing flexion triggered prematurely	Increase Trigger Resistance	Turn **T** clockwise	+
Swing Flexion difficult to trigger	Decrease Trigger Resistance	Turn **T** counterclockwise	−

SOCKET/ FRAME CONTACT POINTS

Care should be taken when configuring the socket / frame and adapters, so they DO NOT contact the knee. Damage to the interface panel or any of its components may cause the product to malfunction (Figure 8).

APP OVERVIEW

Info: For information on use with mobile devices, refer to the **Stride Studio App Instructions**.

DOWNLOAD STRIDE STUDIO APP

Download on the App Store GET IT ON Google Play

College Park's Stride Studio App is available for both iOS & Android devices. Download Stride Studio from Apple App Store or Google Play Store.

MINIMUM OPERATING SYSTEMS:

- Apple iOS 15
- Android Version 8 (Oreo)

Select Stride Studio icon on the device to launch the app.

DASHBOARD SCREEN

SYMBOL	NAME	DESCRIPTION
	Setup	Alignment recommendations.
	Adjustments	Adjustments to Icon Knee resistance and mode selection.
	Custom	Allows prosthetist and user to set custom modes.
	Activity	Activity log: download and print reports.

SYMBOL	NAME	DESCRIPTION
	Information	Technical instructions and online learning resources.
	Battery Status	Indicates battery charge level of Icon Knee.
	Device Warnings	List of error codes. TBD
	Alerts Settings	Turn non-critical alert sounds on/ off. Enables/disables Training mode.

KNEE PAD AND BATTERY REPLACEMENT

KNEE PAD REPLACEMENT

1. Remove fastener on the top of the knee pad (Figure 9).
2. To reinstall, replace the knee pad and reinsert fastener(finger-tighten).

BATTERY REPLACEMENT

The battery can be replaced by the clinician if it no longer holds a charge (Figure 10).

1. Remove knee pad.
2. Use separation tool to separate the waterproof connector.
3. Remove two fasteners holding battery in place, then remove the battery.
4. To reinstall, replace battery and reinsert fasteners (finger-tighten).
5. Reconnect the waterproof connector.
6. Replace knee pad and reinsert fastener (finger-tighten).

TROUBLESHOOTING

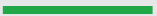
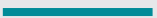
CAUTION

Caution: The Icon Knee should never be serviced while connected to the end user. Ensure that the device is disconnected and powered off before any service or maintenance is performed. This device should never be serviced while in use. Never let children use this handle this device unsupervised. Take caution when using this device around pets that may cause damage to the device.

The Icon Knee features a single, multi colored LED Indicator located on the top right-hand side of the knee. This LED is used to display things like mode detection, battery life, and system errors. The LED will change colors and stay illuminated if in lock mode or free swing/ unlock mode.

The chart below outlines what each of the different LED patterns means. When the device is turned on the LED will blink briefly. Once the device is on, battery life can be checked by pressing the power button for 1 second.

ICON KNEE ALL LED INDICATIONS

COLOR	INDICATOR	STATUS
Solid Green		Fully charged, 91-100%
Green Blinking		20 - 90%
Red Blinking		Low Battery, < 20%
Solid Red		Critical Battery, <5%, Activates safety mode
Blue Blinking		Prompt to pair with Bluetooth. Flashes until pairing complete
Solid Purple		Knee in lock mode
Solid Yellow		Knee in free swing mode
Solid Teal		Knee in custom mode color TBD
Multi-Color Blink		Power ON or OFF

If the Icon Knee is not functioning as expected, try the following

- *Turn the system off, wait several seconds and power back on.*
- *Make sure the battery has sufficient charge. If the battery is too low, charge the battery.*

WARRANTY INSPECTION AND MAINTENANCE INFORMATION

College Park recommends that you schedule your patients for check-ups per the warranty inspection schedule below.

High patient weight or activity level may require more frequent inspections. We recommend you visually inspect the following applicable parts for excessive wear and fatigue at each warranty inspection.

- Knee Assembly, Knee Pad

WARRANTY INSPECTION SCHEDULE FOR THE ICON: SIX MONTHS, THEN ANNUALLY.

TECHNICAL ASSISTANCE / EMERGENCY SERVICE 24-7-365

College Park's regular office hours are Monday through Friday, 8:30 am – 5:30 pm (EST). After hours, an emergency Technical Service number is available to contact a College Park representative.

LIABILITY

The manufacturer is not liable for damage caused by component combinations that were not authorized by the manufacturer

⚠ CAUTION

College Park products and components are designed and tested according to the applicable official standards or an in-house defined standard when no official standard applies. Compatibility and compliance with these standards are achieved only when College Park products are used with other recommended College Park components. This product has been designed and tested based on single patient usage. This device should NOT be used by multiple patients.

⚠ CAUTION

If any problems occur with the use of this product, immediately contact your medical professional. The prosthetist and/or patient should report any serious incident* that has occurred in relation to the device to College Park Industries, Inc. and the competent authority of the Member State in which the prosthetist and/or patient is established.

*"Serious incident' is defined as any incident that directly or indirectly led, may have led, or might lead to any of the following; (a) the death of a patient, user, or other person, (b) the temporary or permanent serious deterioration of a patient's, user's, or other person's state of health, (c) a serious public health threat.

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COMPLIANCE

This device has been tested according to ISO 10328 standard to three million load cycles. The expected life duration under normal usage is 6 million steps. Depending on the amputee's activity this corresponds to a duration of use of four to six years.

ISO 10328 - LABEL

WEIGHT LIMIT (KG)	LABEL TEXT
150	ISO 10328-P7-150 kg

ISO 10328 - "P" - "m"kg*) ⚠

⚠ ***) Body mass limit not to be exceeded!***

For specific conditions and limitations of use, see intended use section of manufacturer's written instructions.

SYMBOLS

FEATURE	DESCRIPTION
⎓	Direct current
⚠	Caution
	See operating instructions/consult instructions for use
	Type B Applied Part

FEATURE	DESCRIPTION
	Refer to instruction manual/booklet
IP68	Dust tight and protected against freshwater at a maximum depth of 2 meters for 1 hour.
	Keep away from water/keep dry
	Temperature limitation

FEATURE	DESCRIPTION
	Medical device manufacturer
	Lot number
	Serial number
	Humidity Rating
	Pressure Rating
FCC ID: 2AS9402	FCC ID of BT Module
IC: 25021-02	IC ID of BT Module
	FCC Mark 21 CFR Part 15
	Non-ionizing radiation
	CE Mark
	Device contains electronic components and/ or batteries that should not be disposed of in regular waste

FEATURE	DESCRIPTION
	On/Off
	Mode Selector
	Custom Modes
	Recyclable Lithium Ion Battery
	Medical Device
	Complies with Australia Radio communications requirements
	Note: Possible technical damage
	Info: Basic information regarding this product
	Caution: Possible risk of accident or injury
	Warning: Possible risk of severe accident or injury

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COMPLIANCE

STANDARD	EDITION	DESCRIPTION
ISO 10328	Structural testing of lower-limb prostheses-requirements and test methods	*2016*
ANSI/AAMI 60601-1	Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance	*AAMI ES60601-1: 2005 & A1:2012 & A2:2021*
IEC 60601-1-2	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests	*2014 Ed.4+A1*
IEC 60601-1-6	Medical Electrical Equipment – Part 1-6: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Usability	*2010 Ed. 3+A1;A2*
IEC 62366-1	Medical Devices - Part 1: Application of Usability Engineering to Medical Devices	*IEC 62366-1 ED. 1.1 B:2020*
IEC 60601-1-11	Medical Electrical Equipment – Part 1-11: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Requirements for Medical Electrical Equipment and Medical Electrical Systems Used in the Home Healthcare Environment	*2015 Ed.2+A1*
IEC 62304	Medical Device Software - Software Life Cycle Processes	*IEC 62304 ED. 1.1 B:2015*
FCC Part 15	Radio Frequency	
IEC 62133	Secondary Cells And Batteries Containing Alkaline Or Other Non-Acid Electrolytes - Safety Requirements For Portable Sealed Secondary Lithium Cells, And For Batteries Made From Them, For Use In Portable Applications - Part 2: Lithium Systems	*IEC 62133-2 ED. 1.1 B:2021*
IEC 60529	Degrees of Protection Provided by Enclosures (IP Code)	*2013 Ed.2.2*

EMC COMPLIANCE – SPECIFIC MITIGATIONS

The Icon Knee was tested to the listed standards at the appropriate levels for Home Health Care Equipment below to ensure safety of the product regarding immunity and emissions. All devices maintained their performance during and after the tests were completed.

This device complies with part 15 of the FCC rules. Operation is subject to the following two conditions. (1) This device may not cause harmful interference. (2) This device must accept any interference received, including interference that may cause undesired operation.

This device complies with Industry Canada license-exempt RSS standard(s). Operation is subject to the following two conditions: (1) this device may not cause interference, and (2) this device must accept any interference, including interference that may cause undesired operation of the device.

Le présent appareil est conforme aux CNR d'Industrie Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes: (1) l'appareil ne doit pas produire de brouillage, et (2) l'utilisateur de l'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le onctionnement.

PHENOMENON & STANDARD	TEST LEVEL	REMARKS
Radiated Emissions **CISPR11 ed5.0 (with A1:2010), CISPR 11 ed6.1 (2015 +A1:2016)**	Group 1, Class B	*The Icon Knee uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.*
Electro-Static Discharge Immunity Test **IEC 61000-4-2 ed2.0 (2008-12)**	Contact ± 8 kV Air ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV	*The Icon Knee is attached to the patients socket which is design by a certified prosthetist.*
Radiated, Radio-Frequency, Electromagnetic Immunity **IEC 61000-4-3 ed3.0 (with A1:2007+A2:2010)**	10 V/m 80 MHz – 2,7 GHz 80% AM at 1 kHz	*Portable and mobile RF communications equipment should be used no closer to any part of the Icon Knee, including cables, than the recommended in the technical manual. Device does not need to be operated in a shielded environment.*
Power Frequency Magnetic Field Immunity Test **IEC 61000-4-8 ed2.0 (2009-09)**	30 A/m, 50 Hz or 60 Hz	*The Icon Knee should not be operated closer than 15 cm of sources of power frequency magnetic field.*

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TEST SPECIFICATIONS FOR ENCLOSURE PORT IMMUNITY TO RF WIRELESS COMMUNICATIONS EQUIPMENT

TEST FREQUENCY (MHZ)	BAND (MHZ)	SERVICE	MODULATION	MAXIMUM POWER (W)	DISTANCE (M)	IMMUNITY TEST LEVEL (V/M)
385	380-390	TETRA 400	Pulse modulation 18 Hz	1,8	0,3	27
450	430-470	GMRS 460, FRS 460	FM ± 5 kHz deviation 1 kHz sine	2	0,3	28
710 **745** **780**	704-787	LTE Band 13, 17	Pulse modulation 217 Hz	0,2	0,3	9
810 **870** **930**	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	2	0,3	28
1720 **1845** **1970**	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1. 3. 4, 25; UMTS	Pulse modulation 217 Hz	2	0,3	28
2450	2400-2570	Bluetooth WLAN, 802.11 b/g/n, RFIO 2450, LTE Band 7	Pulse modulation 217 Hz	2	0,3	28
5240 **5500** **5785**	5100-5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	0,2	0,3	9

TEST SPECIFICATIONS FOR ENCLOSURE PORT IMMUNITY TO PROXIMITY MAGNETIC FIELDS

TEST FREQUENCY	MODULATION	IMMUNITY TEST LEVEL (A/M)
30 kHz	CW	8
134,2 kHz	Pulse modulation 2,1 kHz	65
13,56 MHz	Pulse modulation 50 kHz	7, 5

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