

PLIÉ® 2.0 MPC KNEE, THREADED TOP

INSTRUCTIONS FOR USE

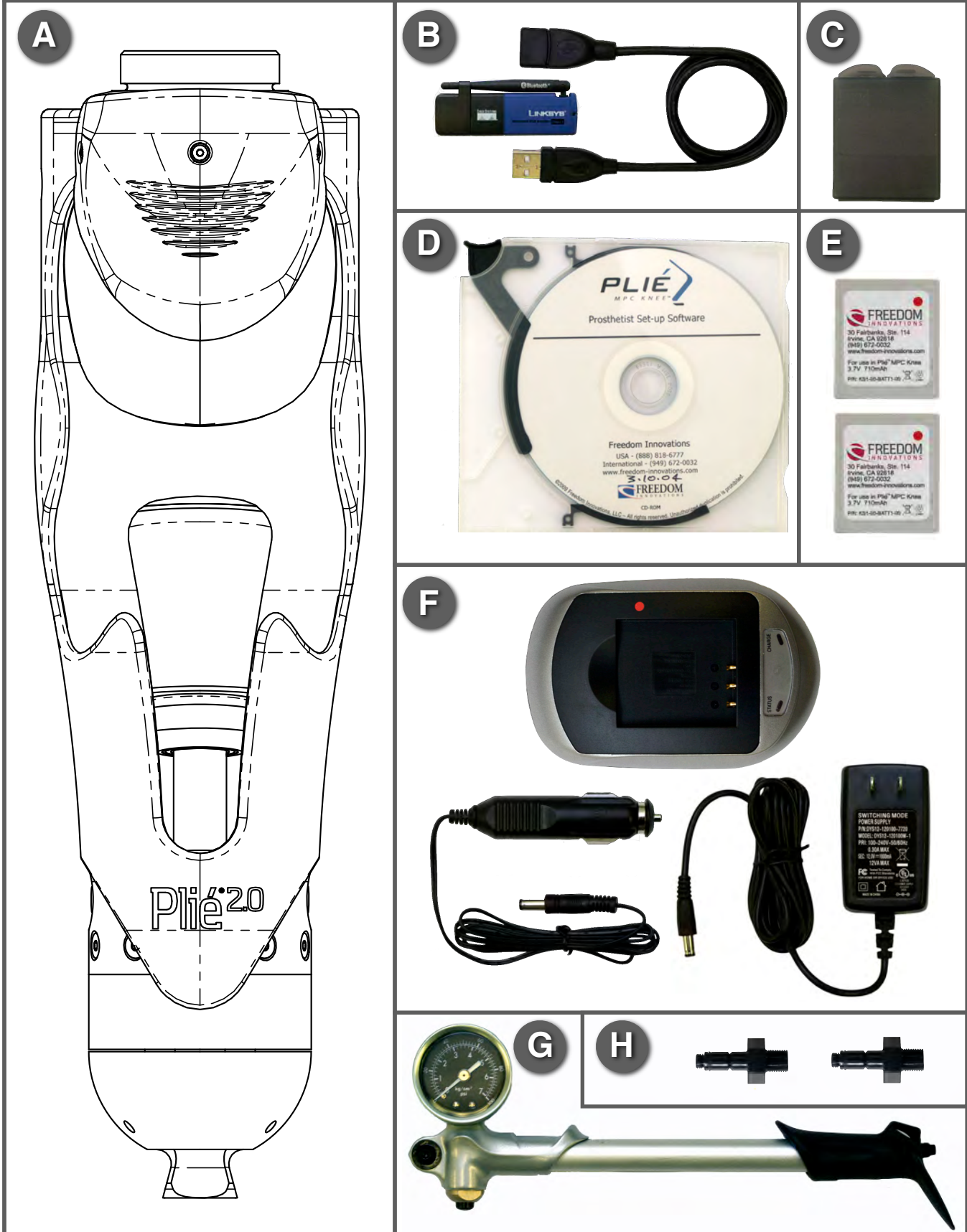
 **FREEDOM**
INNOVATIONS

Table of Contents

Product Number: KD2-00-KNEE2-KT

Appropriate Use	5
Symbols Legend	6
Safety Information	6
Knee Functions	8
Technical Data	8
<i>Installation Instructions</i>	<i>8</i>
<i>Battery and Battery Charger Specifications</i>	<i>8</i>
<i>Environmental Specifications</i>	<i>8</i>
<i>Storage</i>	<i>9</i>
<i>Water Resistance</i>	<i>9</i>
<i>Cleaning</i>	<i>9</i>
<i>Finishing Options</i>	<i>9</i>
Battery and Power Information	9
<i>Battery Charging</i>	<i>9</i>
Software	9
<i>Installation</i>	<i>10</i>
<i>Plié Control</i>	<i>10</i>
<i>Plié Gait Lab</i>	<i>15</i>
Alignment	15
<i>Bench Alignment</i>	<i>16</i>
<i>Static Alignment</i>	<i>16</i>
<i>Dynamic Alignment</i>	<i>16</i>
Set-Up	16
1. <i>Establish Wireless Connection</i>	<i>17</i>
2. <i>Plié Setup Wizard</i>	<i>17</i>
3. <i>Adjust Manual Hydraulic Settings</i>	<i>17</i>
4. <i>Optimize Microprocessor Settings</i>	<i>18</i>
<i>Document</i>	<i>18</i>
Technical Support	19
Warranty	19
Service and Repair	19
Regulatory Compliance, Disclosures, and Classification	19
<i>Wireless Operation</i>	<i>19</i>
<i>IEC/EN 60601 Classification</i>	<i>19</i>
<i>Directive 2002/96/EC on Waste Electronic & Electrical Equipment (WEEE)</i>	<i>19</i>
<i>Conformite Europeenne and Authorized Representative Identification</i>	<i>20</i>

Plié® 2.0 MPC Knee, Threaded Top (images not to scale)





Recommended Foot Components



Pictured	Part Description	Part Number	Included w/knee	Quantity	Available Separately
A	Plié® 2.0 MPC Knee, Threaded Top	KD2-00-KNEE2-00	✓	1	✓
B	Wireless USB Adapter	KS1-00-BLUE1-00	✓	1	✓
C	Battery Case		✓	1	
D	Software CD-ROM	KS2-00-SFTW1-00	✓	1	✓
E	Lithium Ion Battery (w/battery case)	KS1-00-BATT1-00	✓	2	✓
F	Battery Charger with Car Adapter	KS1-00-CHRG1-00	✓	1	✓
G	Air Pump with Hose Adapter	KS1-00-AIRP1-00	✓	1	✓
H	Hose Adapter for Air Pump	KS1-00-VALV1-00	✓	1	✓
I	Stance Bezel Kit, Replacement	KS1-00-BEZL1-KT		1	✓
J	O-rings, set of 5	KS1-00-RING1		5	✓
K	Air Cap, Replacement	KS1-00-PLUG1-00		1	✓
L	EUROPEAN ADAPTER	KS1-00-ADPTE-00	International only	1	✓
	EUROPEAN BATTERY CHARGER	KS1-00-CHRG1-00	International only	1	✓
M	Battery Cap, Replacement	KS1-00-BCAP1-00		1	✓
N	Plié MPC Knee Case	KS1-00-CASE1-00	✓	1	✓
O	Protective Cover, Replacement	KS2-00-PROC1-00		1	✓
	Quick Reference Guide	KS2-00-QREF1-00	✓	1	✓
	Instructions for Use	KS2-00-TMAN1-00	✓	1	✓
	User Guide	KS2-00-UMAN1-00	✓	1	✓
P	Highlander® foot component	FS3			✓
Q	Runway® foot component	RS2 or RS2-K1			✓
R	Renegade® foot component	RS1 or RS6			✓

Appropriate Use

The Plié® 2.0 MPC Knee, Threaded Top should only be used by individuals with lower limb loss including knee disarticulation and transfemoral amputees and/or individuals with congenital anomalies.

The Plié® 2.0 MPC Knee, Threaded Top is appropriate for users with the potential or capability:

- of negotiating obstacles in the community or workplace.
- exerting sufficient hip joint voluntary muscle control.
- who would benefit from microprocessor controlled knee stability.
- of ambulating with variable cadence and/or descending stairs and ramps.

The Plié® 2.0 MPC Knee, Threaded Top is not appropriate for users:

- having inadequate hip joint voluntary muscle control.
- having inadequate cognitive ability to charge the batteries and care for the device.
- desiring stance flexion knee motion on level ground.
- with body weight exceeding: 125 kg (276 lbs.) for moderate activity.
- with body weight exceeding: 100 kg (220 lbs.) for high activity.

Symbols Legend

The following symbols are found on the Plié® 2.0 MPC Knee, Threaded Top:



- Attention, refer to Plié® 2.0 MPC Knee, Threaded Top *Instructions for Use*.



- Type BF applied part.



- Conformité Européene (European conformity).



- Federal Communications Commission (USA conformity).



- Separate collection for electrical and electronic equipment.

The following symbols are found within this *Prosthetist Instructions for Use*:



- Warning! Failure to adhere to this warning may result in user injury, knee damage, or limit the function of the knee.



- Tip! This information will help the prosthetist and/or user understand the knee.

Safety Information

Prior to use, the prosthetist should discuss the following warnings with the user to prevent injury.

- The rotation set screw of a three- or four-prong lamination adapter should be aligned posterior and square to the knee. The proximal threaded top should be disengaged a maximum of 259° from full insertion into a three- or four- prong lamination adapter. Failure to properly insert the threaded top into a three- or four-prong lamination adapter may result in damage, cause user injury, and will void the warranty.
- Without power, the Plié® 2.0 MPC Knee, Threaded Top will not release into swing phase. In this powered-down mode, the knee will default to the *stance flexion resistance* setting. Insert a charged battery to resume normal knee function.
- Use only the batteries and battery charger intended for use with the Plié® 2.0 MPC Knee, Threaded Top.
- Extreme temperatures will affect the performance of the Plié® 2.0 MPC Knee, Threaded Top. Allow sufficient time for the knee to return to temperatures within the specified operating temperature range before use.
- High elevations and cold temperatures will affect the knee internal air pressure. In these conditions, the user may be required to increase the air pressure to resume normal function.
- The Plié® 2.0 MPC Knee, Threaded Top requires air pressure for normal operation. A cylinder air pressure of less than 20 PSI may detrimentally affect the *stance flexion resistance*. The user should be provided with the included air pump and instructed of its proper use. The user will be required to maintain sufficient air pressure by periodically recharging the air reservoir, using the provided air pump. The cylinder air pressure should not exceed 100 PSI.
- The threaded cap for the *swing flexion resistance* should remain threaded in the port except when the user is adjusting the air pressure. The threaded cap functions as a secondary seal and prevents lint and debris from contaminated the air valve seat. The threaded cap should be gently tightened with fingers or a 4mm allen key.
- If the user changes shoe heel height, the alignment may become unstable. An adjustable heel height prosthetic foot is recommended or the user should be provided with heel wedges to accommodate various heel heights.

- If the user changes shoe heel height, the Plié Control Threshold Setting may require adjustment as the knee requires a minimum user toe loading (adjustable *Toe Threshold*) to release into swing phase.
- The Plié® 2.0 MPC Knee, Threaded Top requires calibration of the load and angle sensors. Loss of sensor calibration may prohibit the knee from normal function. Re-calibrate the sensors to resume normal function.
- During repetitive activities without swing phase, such as the use of exercise equipment, the user should turn the *stance flexion resistance* setting counterclockwise to the “Off” position with a 4mm allen key. After the activity, the user should adjust the *stance flexion resistance* to its previous setting.
- The Plié® 2.0 MPC Knee, Threaded Top intended use does not include knee stance flexion gait on level surfaces. Failure to adhere to the alignment recommendations may result in undesirable user gait characteristics on level surfaces. As the *stance extension resistance* is non-adjustable, certain undesirable gait characteristics may only be eliminated via alignment, user physical therapy, and/or user gait training.
- The Plié® 2.0 MPC Knee, Threaded Top *stance flexion resistance* functions as the resistance for stance phase level ground ambulation, sitting down, stumble recovery, and stair/ramp descent. Caution must be exercised when adjusting the *stance flexion resistance* to ensure adequate resistance is present for stumble recovery function.
- The intended use of the Plié® 2.0 MPC Knee, Threaded Top is normal ambulation. If the user intends to run with the Plié MPC Knee, the computer and manual settings may require adjustment for optimal running function.
- The user should avoid stepping backwards as the knee stability may be compromised.
- The user’s socket should not contact the hydraulic cylinder. Failure to comply may result in cylinder damage and will void the warranty.
- The Plié® 2.0 MPC Knee, Threaded Top should not be submerged in water to depths greater than 0.5 m (1.6 ft). The user should not intentionally expose the knee to water during activities such as showering, swimming, fishing, etc. Failure to comply may cause corrosion and/or noise and will void the warranty.
- While the Plié® 2.0 MPC Knee, Threaded Top withstands moist environments, continual use in wet conditions may result in corrosion and/or undesirable operational noise.
- If the hydraulic cylinder shaft seal causes noise during user ambulation, lubricate the shaft with a few drops of 3-in1 oil.
- All purchased, serviced, and repaired Plié® 2.0 MPC Knee, Threaded Tops are sent to customers with the following default hydraulic cylinder manual settings: *swing flexion*=30 psi, *swing extension*=0, *stance flexion*=5. Additionally, the computer settings are sent to customers with default settings. The prosthetist should adjust the manual and computer settings to meet the needs of each Plié® 2.0 MPC Knee, Threaded Top user prior to use.
- The Plié® 2.0 MPC Knee, Threaded Top is not field-serviceable and may only be repaired by Freedom Innovations, LLC. Attempts to disassemble, repair, or modify the Plié® 2.0 MPC Knee, Threaded Top, including changes to the tension on any of the threaded fasteners, could put the user at risk for serious injury and will void the warranty.
- If applying talcum powder when donning the prosthesis, the user should take care to prevent the powder from contacting the hydraulic cylinder shaft. Talcum powder may cause noise and/or acceleration of shaft seal wear.
- A thin film of oil on the hydraulic cylinder is normal. Only return the Plié® 2.0 MPC Knee, Threaded Top for repair if the oil appears to be leaking from the hydraulic cylinder.
- Freedom Innovations, LLC is responsible for radio frequency compliance. Changes to any portion of the wireless system not expressly approved by Freedom Innovations may void the user’s authority to operate the equipment.
- A wireless USB adapter is supplied with the Plié® 2.0 MPC Knee, Threaded Top. While other wireless adapters may be compatible, Freedom Innovations, Inc. only provides technical support for the supplied device.
- During wireless transfer of data files from the knee to the computer, the Plié® 2.0 MPC Knee, Threaded Top will remain in stance phase. Instruct the user to refrain from ambulating by sitting or standing during data file transfers.

- If the Plié® 2.0 MPC Knee, Threaded Top causes harmful interference with other wireless devices, the user may alleviate the interference by: reorienting, relocating, and/or increasing the separation distance between the receiving device and the Plié® 2.0 MPC Knee, Threaded Top. To determine if the Plié® 2.0 MPC Knee, Threaded Top is the cause of interference, remove and reinsert the battery.
- Federal law requires the Plié® 2.0 MPC Knee, Threaded Top only be sold by a prosthetist at the written authorization of the user's physician.

Knee Functions

The Plié® 2.0 MPC Knee, Threaded Top is a single axis prosthetic knee joint system providing microprocessor control of both the swing and stance phases of gait. The microprocessor monitors an embedded load sensor and an angle sensor to precisely control the transitions between the stance and swing phases of gait. Three manual settings allow the hydraulic cylinder to provide adjustable resistance for *stance flexion*, *swing flexion*, and *swing extension*. The hydraulic cylinder also provides non-adjustable *stance extension* resistance. The Plié Control software allows the knee function to be optimized for each individual's user's gait, including the stumble recovery parameters. The Gait Lab software provides the prosthetist with access to recorded data files of the microprocessor.

Technical Data

Installation Instructions

The Plié® 2.0 MPC Knee, Threaded Top should be fully threaded into a three- or four-prong lamination adapter, with 0 to 259 deg of disengagement allowed for transverse rotational alignment.



The rotation set screw of a three- or four-prong lamination adapter should be aligned posterior and square to the knee. Placing the rotation set screw anterior will contact the battery cap. Placing the rotation set screw on the medial or lateral sides may cause the knee frame to contact the screw head.

Plié® 2.0 MPC Knee, Threaded Top Specifications

Microprocessor control cycle: 1000 Hz

Actuator speed: 10 milliseconds

Operating voltage: 3.6-4.2 VDC

Maximum user weight (moderate activity): 125 kg (276 lbs.)

Maximum user weight (high activity): 100 kg (220 lbs.)

Build clearance: 236mm (*Figure K*)

Product weight, pyramid top: 1243 g (2.74 lbs.)

Maximum flexion angle, pyramid top: 117°

Frame/cylinder construction: aluminum

Hydraulic cylinder default manual settings: *swing flexion* = 30 psi, *swing extension* = 0, *stance flexion* = 5

Patents: USPO #5,190,126, #6,978,872, and #7,655,050. Other patents pending.

Battery and Battery Charger Specifications

Battery type: lithium-ion

Battery voltage: 3.7 VDC

Battery capacity: 710 mAh

Battery life: 24 hours depending on use

Charger input voltage: 12 VDC

AC power adapter input voltage: 100-240 VAC, 50/60 Hz

Environmental Specifications

Storage temperature range: -20 °C to 80 °C (-4 °F to 176 °F)

Operating temperature range: -5 °C to 45 °C (23 °F to 113 °F)

Storage and operating relative humidity range: 0% to 100%, including condensation

Storage and operating atmospheric pressure range: 500 hPa to 1060 hPa (7.3 psi to 15.4 psi)

Storage

Store the Plié® 2.0 MPC Knee, Threaded Top in a fully extended, unbent position. To conserve battery power during storage, simply remove the battery from the knee.

Water Resistance

The Plié® 2.0 MPC Knee, Threaded Top resists low-pressure water spray and occasional, brief submersion in water up to a depth of 0.5 m (1.6 ft). If the knee is sprayed by or submerged in salt water or chlorinated water, immediately rinse with fresh water and allow to dry. When changing the battery, the user should verify that the battery cap is correctly seated. If water enters the battery compartment, failure of the battery and/or knee electronics may result.

Cleaning

For cleaning, the outside surfaces of the frame and hydraulic cylinder may be wiped down with isopropyl alcohol.

Finishing Options

The Plié® 2.0 MPC Knee, Threaded Top may be finished with a cosmetic/protective cover. However, the choice of cover material may affect normal knee function. A cover should be modified or not used if it detrimentally affects the knee performance. A discontinuous, two-piece cover is recommended as its impact on knee performance is minimal.



Care should be taken during cover fabrication to ensure the user has adequate access to the battery compartment and the posterior manual knee settings of the hydraulic cylinder.

Battery and Power Information

Two lithium-ion batteries and a battery charger are included with the Plié® 2.0 MPC Knee, Threaded Top. A fully charged battery will provide the user with approximately one day of typical use. The battery charger is compatible with both of the included AC and DC charging cords.



During transport, the spare battery should be stored in the provided plastic case to avoid the risk of a battery short circuit and to keep the battery terminals clean.

Battery Charging

It is not possible to overcharge the Plié® 2.0 MPC Knee, Threaded Top batteries using the provided charger:

- Connect the *battery charger* into an appropriate power source. The “Status” indicator LED will illuminate red, indicating the battery charger is powered on.
- Align the red dot on the battery with the red dot on the charger. Insert the battery into the charger so it is completely seated. The “Charge” indicator LED will illuminate red, indicating the battery is charging.
- When the battery is charged to 90% capacity, the “Charge” indicator LED will flash red and green. When the battery is fully charged, the “Charge” indicator LED will illuminate green. Charging of a fully discharged battery takes approximately two hours.



Use only approved batteries and battery charger (battery part# AG-BATT-XX, and battery charger part# AG-CHRG-XX, where XX specifies current revision number). Use of unapproved batteries and/or battery chargers may cause user injury and/or knee damage and will void the warranty.

Software

The Plié® 2.0 MPC Knee, Threaded Top requires software to program the knee via a wireless connection. The provided CD-ROM installs two programs, Plié Control and Plié Gait Lab. Although the default computer settings may function, it is the responsibility of the prosthetist to optimize the computer settings for each user. Prior to software installation, verify the computer meets the following minimum requirements:

- Microsoft Windows XP w/Service Pack 2 or later operating system
- 1.0 Mhz processor

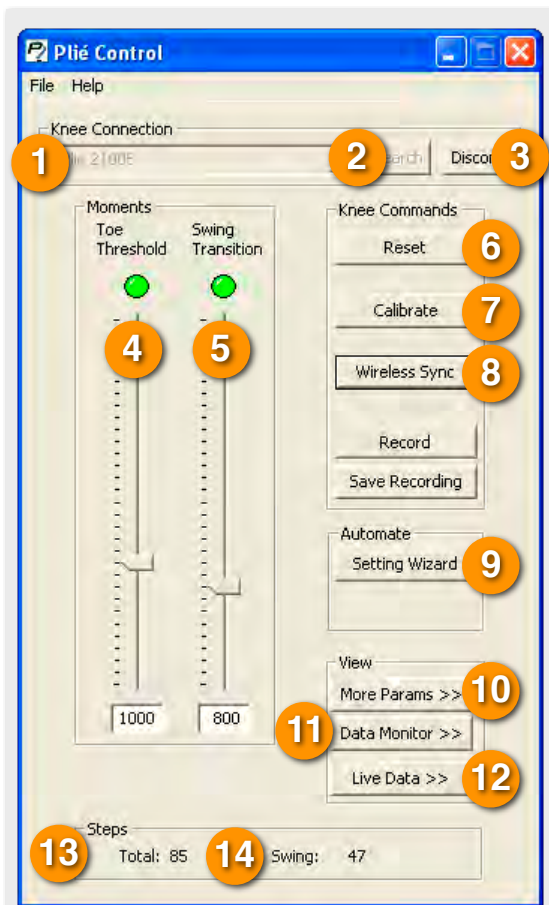


Figure A



Figure B

- 256K Random Access Memory (RAM)
- USB port

Installation

To ensure successful installation of the software, follow these steps:

- Login to the computer as an *administrator*.
- Insert the provided Plié® 2.0 MPC Knee, Threaded Top Prosthetist Set-Up Software CD-ROM.
- Follow the subsequent installation screens, agreeing to the terms of the software License Agreement.
- Access the software programs and an electronic version of this document (Start>All Programs>Plié).

Tip The software may be installed on an Apple Macintosh computer if a Microsoft Windows operating system is installed in a separate partition. Apple Bootcamp or a third party emulation software is required.

Plié Control

The Plié Control software is necessary for programming Plié® 2.0 MPC Knee, Threaded Tops (Figure C). The Plié Control consists of a main window and four auxiliary windows. The auxiliary windows may be accessed from the main window. The Plié Control software is compatible with Agility™ MPC Knees, Plié MPC Knees, and Plié® 2.0 MPC Knee, Threaded Tops. To access the Plié Control, select from the All Programs menu (Start>All Programs>Plié>Plié Control).

Tip To achieve a successful user outcome, it is not necessary to understand all the features of the Plié Control software. For instructions specific to setting-up a Plié® 2.0 MPC Knee, Threaded Top, see section titled, "Set-Up."

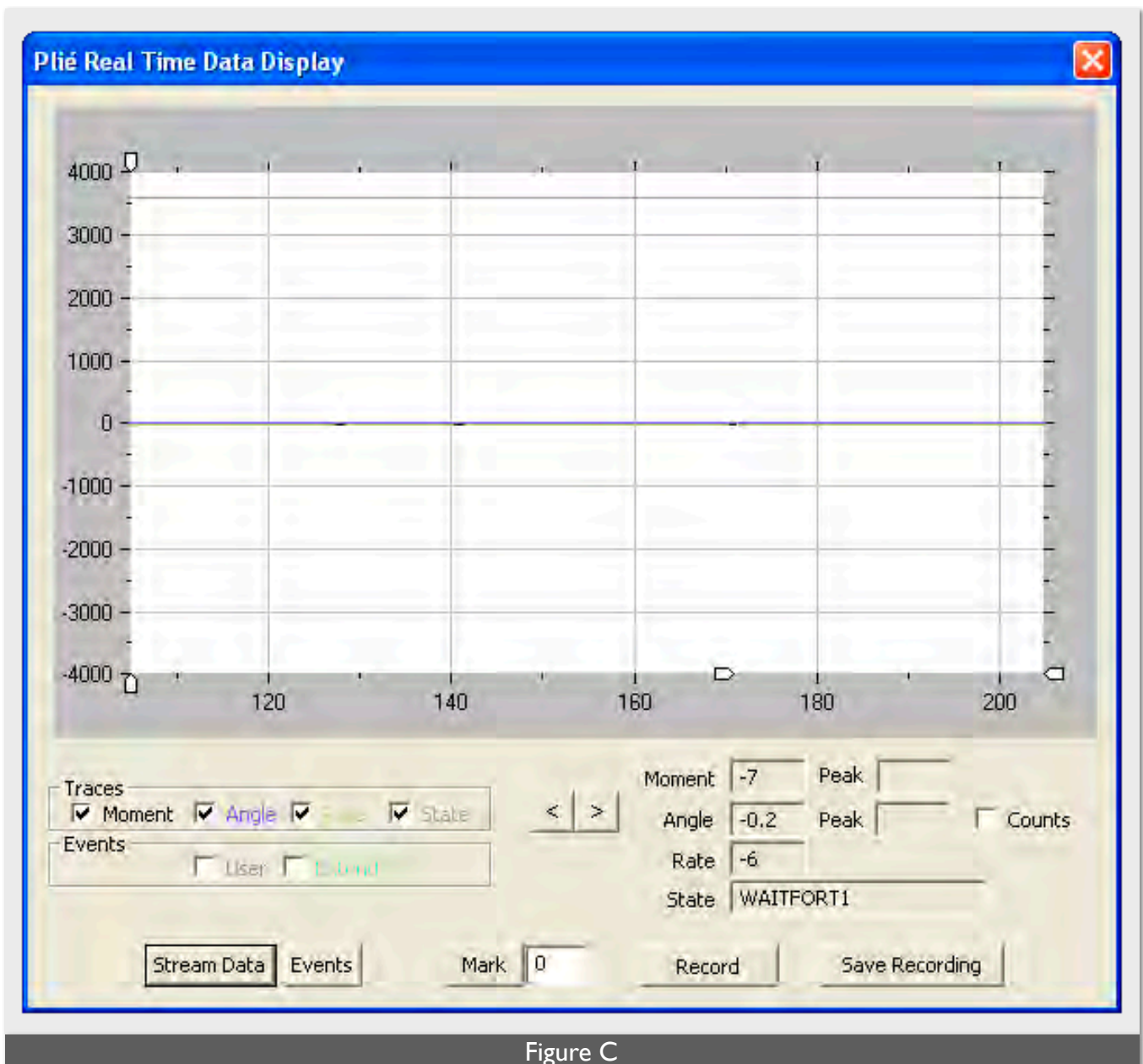


Figure C

Main Window

The numbered items below refer to the corresponding numbers in the Plié Control main window of Figure C.

1. Knee Connection - Active wireless knees are displayed in this drop-down menu.
2. Search - select the **Search** icon to find active wireless knees.
3. Connect/Disconnect - Select the **Connect/Disconnect** to establish or discontinue a wireless connection.
4. Toe Threshold (T1) - The **Toe Threshold** determines how much force the user must load the toe to initiate swing phase during ambulation. A higher value requires more toe loading by the user to initiate swing phase. The **Toe Threshold** may be adjusted by moving the slider or typing a numerical value in the text box and selecting the “Enter” key. A green circle indicates the values shown are the values stored in the knee memory.
5. Swing Transition (T2) - The **Swing Transition** determines when the knee will release into swing phase. A higher value will release into swing earlier as it corresponds to a point earlier on the user’s moment curve. The Swing Transition may be adjusted by moving the slider or typing a numerical value in the text box and selecting the “Enter” key. A green circle indicates the values shown are the values stored in the knee memory.
6. Reset - Select **Reset** to restore a knee to the default computer settings.
7. Calibrate - Select **Calibrate** to establish the reference zero values for the embedded sensors. The knee must be extending fully within five minutes of selecting **Calibrate**.

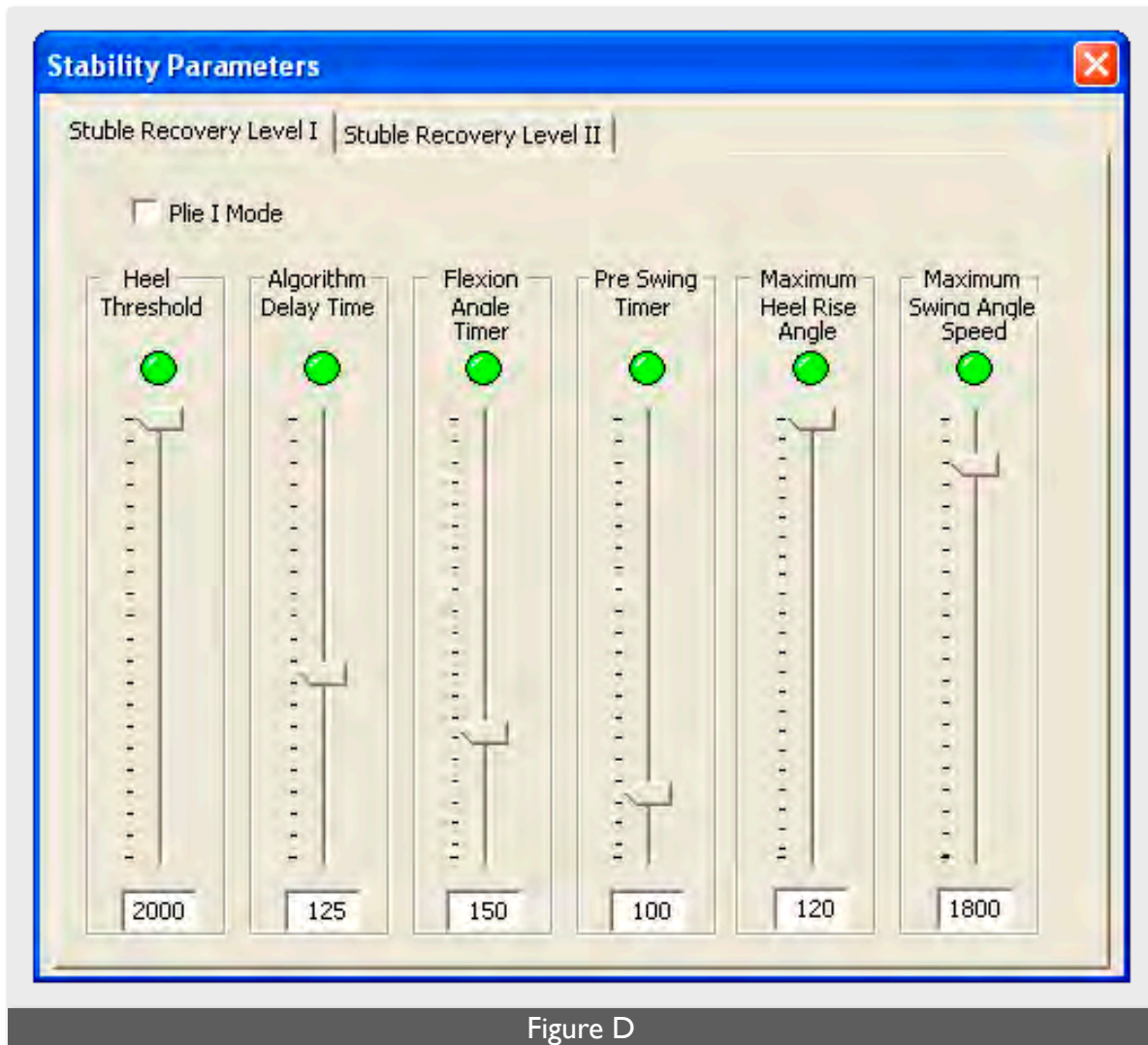
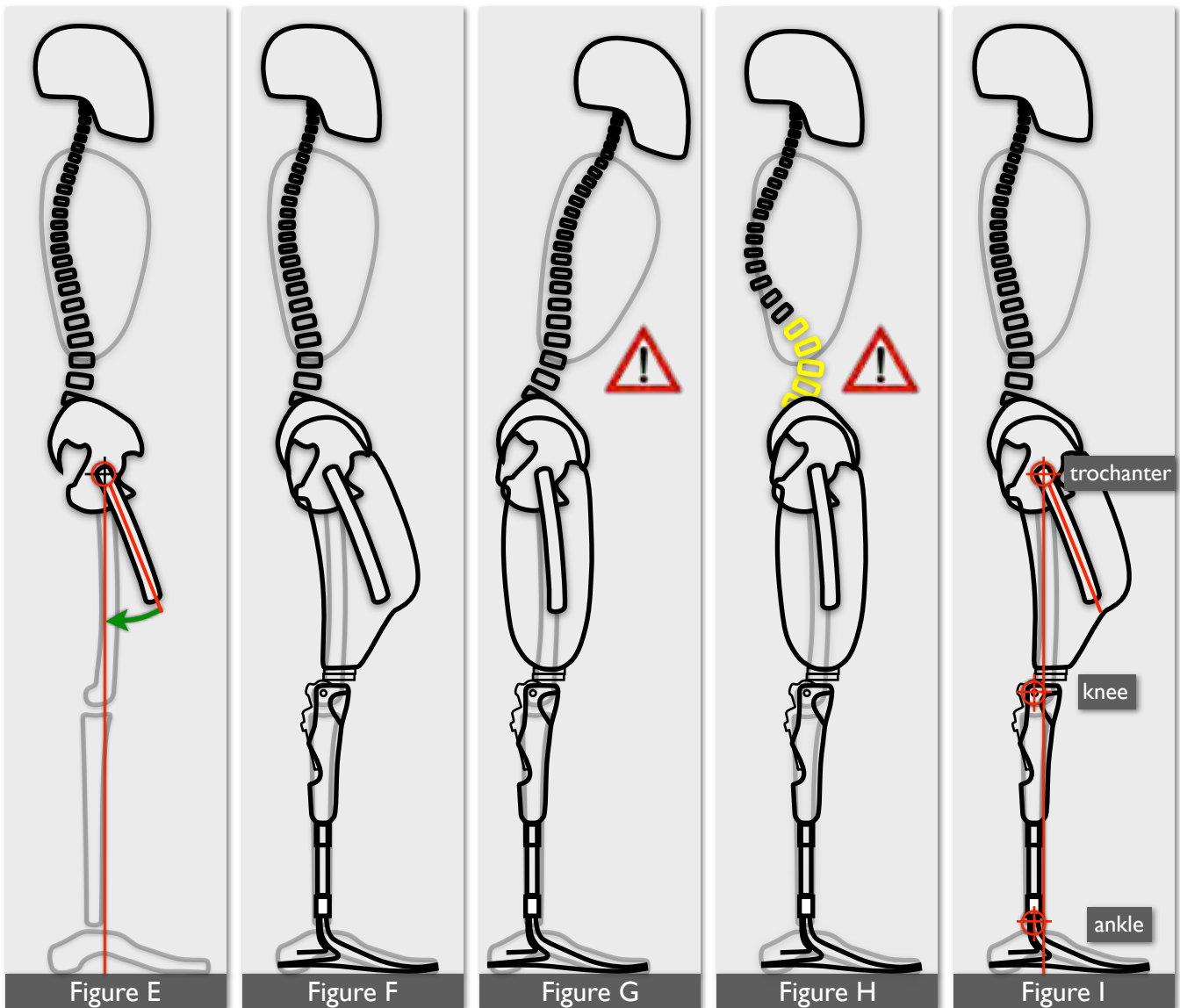


Figure D

8. Wireless Sync - Select **Wireless Sync** if the software and knee fail to sync (circles remain red).
9. Setting Wizard - Select the **Setting Wizard** to open the auxiliary Plié Setup Wizard. The Plié Setup Wizard includes a sophisticated algorithm designed to optimize the Toe Threshold, Swing Transition, and the advanced Stability parameters (Plié Control>More Params). For advanced discussion of the Plié Setup Wizard, see section titled, "Set-Up."
10. More Params - Select **More Params** to open the auxiliary window for the advanced Stability parameters.
11. Data Monitor - Select **Data Monitor** to open an auxiliary window for diagnostic use only.
12. Live Data - Select **Live Data** to view the auxiliary Plié Real Time Data Display for viewing data as the user ambulates.
13. Steps Total - Indicates how many times the prosthetic toe of the user exceeded the Toe Threshold value.
14. Steps Swing - Indicates how many times the knee released into swing phase.

Plié Real Time Data Display

The Plié Real Time Data Display allows the viewing of live data as the user ambulates. The Plié Real Time Data Display provides a data rate of 4 Hz (4 samples per second). Due to the limited data stream bandwidth (knee microprocessor data rate is 1000 Hz), the Plié Real Time Data Display should not be used for setting the user's computer parameters. To access the Plié Real Time Data Display, select the **Live Data** icon in the Plié Control main window. To stream live data, select the **Stream Data** icon. The Plié Real Time Data Display is illustrated in Figure C.



The Plié Real Time Data Display is useful for verifying calibration of the sensors. If the user unweights the knee, the Moment trace should have zero value. If the knee is fully extended, the Angle should have zero value.

Stability Parameters

The Stability Parameters window provides access to advanced stumble recovery settings via two tabs. To optimize the advanced stumble recovery settings, follow the steps provided in the Plié Setup Wizard. To access the Stability Parameters window, select the **More Params** icon in the Plié Control main window. The Stability Parameters window is illustrated in Figure D.



Manually adjusting the Stability Parameters is not recommended. If the Plié I Mode box is checked, the advanced stumble recovery is not active. The knee should only be in Plié I Mode during set-up.

Plié Setup Wizard

The Plié Setup Wizard optimizes all the computer settings for Plié® 2.0 MPC Knee, Threaded Tops only. To access the Plié Setup Wizard, select the **Setting Wizard** icon from the Plié Control main window. The Plié Setup Wizard is illustrated in Figure B.

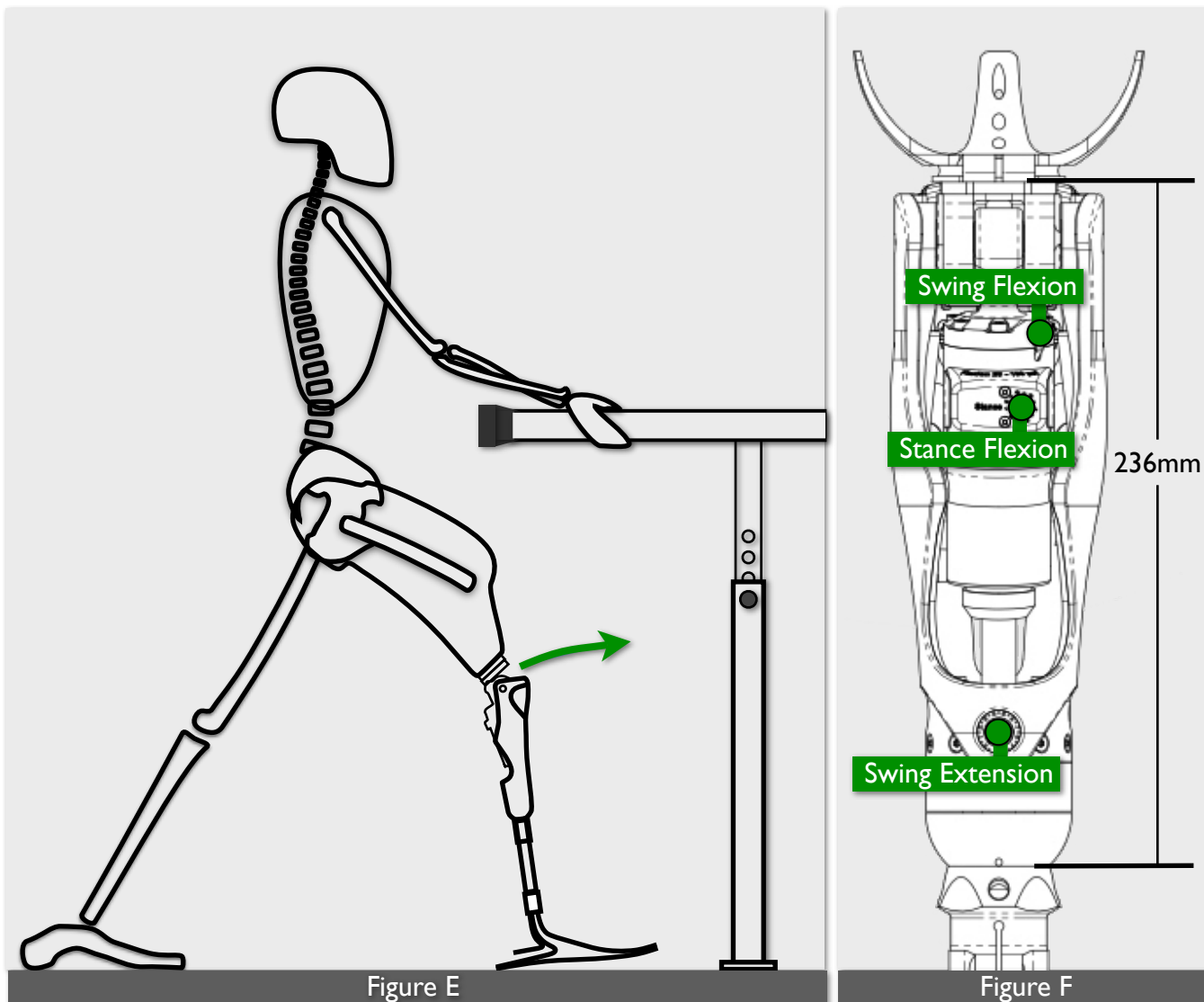


Figure E

Figure F

The Plié Setup Wizard progresses through four steps to optimize the user's computer settings. A dialogue box provides written instruction for each step. Data is recorded as the user ambulates. The Plié Setup Wizard analyzes the recorded data to select the optimal Toe Threshold, Swing Transition, and advanced Stability Parameters.

The Plié Setup Wizard begins with the First Set Up. The First Set Up mode allows alignment adjustments, calibrates the sensors, and recommends optimal Toe Threshold and Swing Transition values. The Toe Threshold is set to two-thirds the value of the user's average peak moment. The Swing Transition is set so the knee releases into swing phase immediately prior to the firing of the user's hip flexors. A minimum of twenty user steps is recommended. The suggested Toe Threshold and Swing transition values can be transferred to the knee. This process should be repeated several times to ensure the optimal values are suggested.

After the First Set Up is complete, the advanced Stability Parameters are enabled. Three data files are captured as the user ambulates at his/her slowest, self-selected, and fastest cadences. The data files are analyzed and values for each Stability Parameter are suggested. The suggested values can be transferred to the knee.

The Stability Parameters permit stumble recovery to be engaged anytime between the stance-swing phase transition and peak swing flexion (heel rise). The microprocessor monitors the ten Stability Parameters via the load sensor and angle sensor. The three data recordings identify the user's normal gait pattern window. If the microprocessor detects deviations outside the user's normal gait pattern window, stumble recovery is engaged. Stumble recovery is available to the user throughout swing phase.

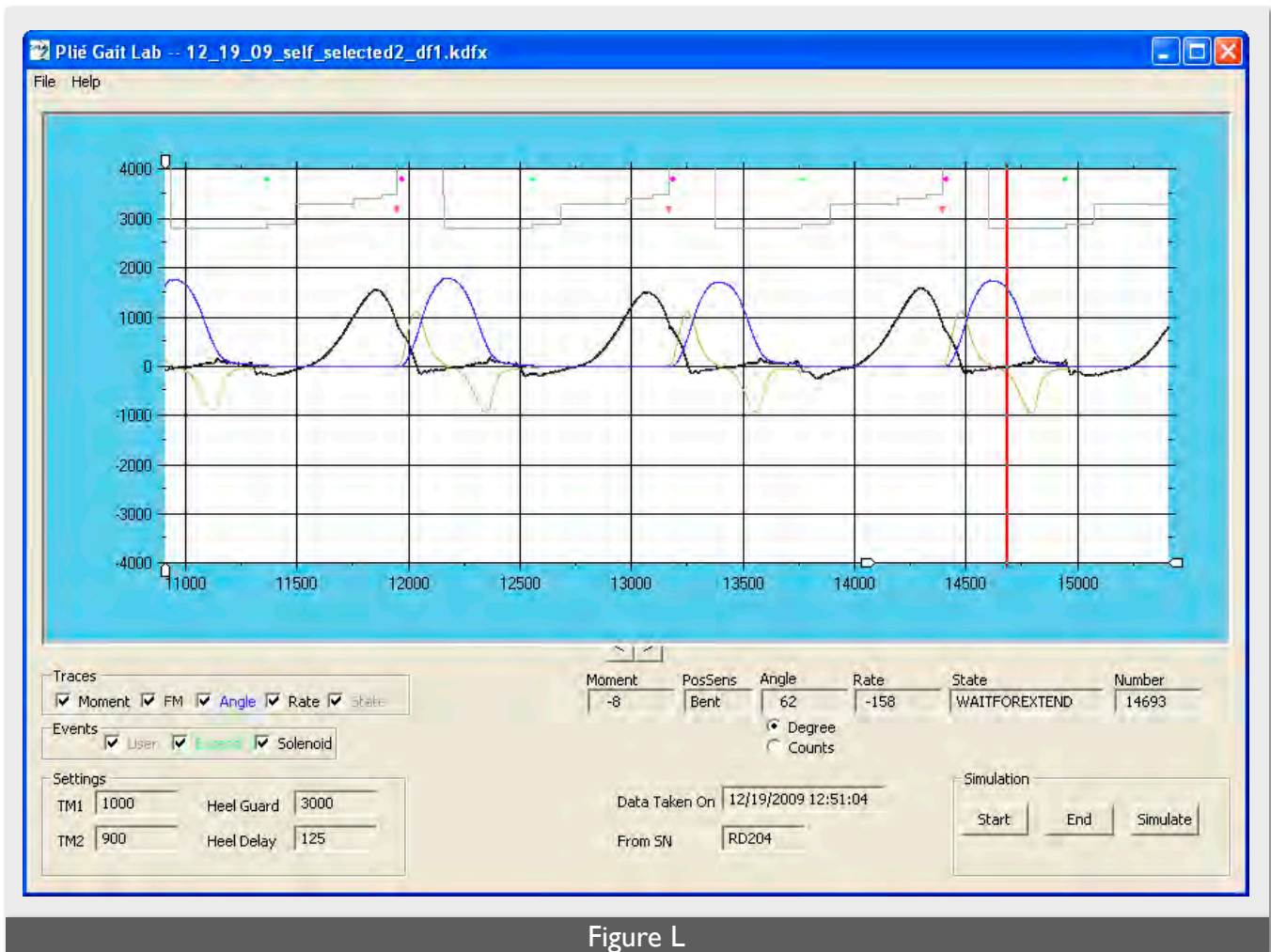


Figure L

Plié Gait Lab

The Plié Gait Lab software allows the prosthetist access to the user's gait data as viewed by the microprocessor. The Plié Gait Lab may be used as a tool for comparing the performance of various prosthetic feet, identifying gait anomalies, simulating the microprocessor algorithm, ensuring proper Plié MPC Knee function, and documenting the progress of the user. The Plié Gait Lab is optional and not necessary for the successful fitting of the Plié MPC Knee. To access the Plié Gait Lab, select from the Programs menu (Start>All Programs>Plié>Plié Gait Lab). The Plié Gait Lab software is illustrated in Figure L.



The white tabs on the bottom and left frames of the data window allow the data view to be modified. To scroll the data, simultaneously place the cursor between the white tabs, hold the left mouse button, and drag the mouse. To collapse or expand the data, simultaneously place the cursor on a white tab, hold the left mouse button, and drag the mouse.

Alignment

Careful attention to the alignment of the socket, Plié® 2.0 MPC Knee, Threaded Top, and the prosthetic foot is essential to a successful user outcome. The prosthesis alignment should account for the range of motion (ROM), voluntary control, and balance of individual users. Proper alignment and user voluntary control are essential to knee stability during stance phase.

Prior to assembly of the prosthesis, the prosthetist should measure the user's hip joint range of motion (ROM) on the prosthetic side to determine if the user has a hip flexion contracture (*Figure E*). If present, the user's hip flexion contracture should be accommodated by attaching the socket to the prosthesis with an appropriate amount of flexion (*Figure F*). Failure to sufficiently accommodate a hip flexion contracture may compromise the user's function during standing and ambulation.



During standing, an unaccommodated hip flexion contracture may prevent the user from standing straight, compromising the user's balance (Figure G). Additionally, an unaccommodated hip flexion contracture may cause excessive lumbar lordosis, compromising the structural integrity of the user's spinal column (Figure H).



During ambulation, an unaccommodated hip flexion contracture may cause an excessively asymmetrical gait pattern.

Bench Alignment

The Plié® 2.0 MPC Knee, Threaded Top was designed to be in a fully extended position during stance phase for level ground ambulation. Consequently, an inherently stable trochanter-knee-ankle (TKA) alignment is essential to a successful user outcome with the Plié MPC Knee. The referenced trochanter on the lateral socket should be placed on or up to 5mm anterior to an imaginary vertical line falling through the knee joint axis (Figure I). Due to the unique characteristics of each user, the optimal alignment may not fall within the recommended guidelines.



An inherently unstable trochanter-knee-ankle (TKA) alignment may cause a rapid extension moment at the knee joint after midstance. The non-adjustable stance extension resistance may be insufficient to dampen the extension moment if the user does not exert sufficient voluntary control and/or if the alignment recommendations are not implemented.



The recommended inherently stable alignment of the Plié® 2.0 MPC Knee, Threaded Top may differ from other knee joints. Consequently, if a new socket is not fabricated for use with a Plié® 2.0 MPC Knee, Threaded Top, the socket attachment component may require re-lamination to the socket to achieve the recommended alignment.

Static Alignment

Prior to ambulation, observe the overall alignment with the prosthesis donned on the user:

- a. Instruct the user to stand between parallel bars.
- b. With equal weight on each limb, adjust the height of the prosthesis as necessary.
- c. Ensure the trochanter-knee-ankle (TKA) alignment follows the recommendations of inherent stability.
- d. Ensure the transverse rotation of the knee and foot is appropriate.
- e. Instruct the user sit in a chair. Adjust the height of the knee joint axis to match the contralateral limb as closely as possible.



To prevent risk of injury to the user, perform the static alignment, dynamic alignment, and set-up between parallel bars.

Dynamic Alignment

Prior to Set-Up, allow the user to adjust to the prosthesis:

- a. Instruct the user to take a lunge step with the prosthesis (Figure J). The lunge motion will allow the user to feel the *stance flexion resistance* and develop confidence. Repeat as necessary.
- b. Instruct the user to carefully ambulate. Teach the user to flex the ipsilateral hip extensor muscles at initial contact to stabilize the knee joint.
- c. Train the user to load the prosthetic toe to initiate the swing phase transition.
- d. Train the user to take steps of equal length.
- e. Adjust the alignment in the transverse, coronal, and sagittal planes as necessary.
- f. Train the user to sit in a chair using the *stance flexion resistance*.

Set-Up

While the Plié® 2.0 MPC Knee, Threaded Top may function adequately at the default settings, both the computer and manual hydraulic settings should be optimized for each user. Follow the five steps below to set-up the Plié® 2.0 MPC Knee, Threaded Top.

1. Establish Wireless Connection

To optimize the microprocessor, communication must first be established between the programming computer and the user's Plié® 2.0 MPC Knee, Threaded Top:

- Open the Plié Control software (Start>All Programs>Plié>Plié Control).
- Insert the provided USB wireless adapter in any available USB port.
- Remove and re-insert the battery. Battery insertion activates the knee wireless module for five minutes.
- Select the **Search** icon.
- After the knee is found, select the **Connect** icon to establish a wireless connection. If the **Connect** icon changes to a **Disconnect** icon, the wireless connection is verified.



*If the software and knee do not appear to be communicating, select the **Wireless Sync** icon to re-establish the wireless connection.*



The green LED inside the knee frame only remains illuminated when the a wireless connection has been established with a computer.

2. Plié Setup Wizard

Open the Plié Setup Wizard (Plié Control>Setting Wizard). Follow the steps provided in the Plié Setup Wizard, always beginning with **First Set Up**.

- Select **First Set Up**. Then select **Next**.
- In the *Basic Set Up Mode* window, select **Set Up Mode**.



The First Set Up mode should only be enabled when setting up a knee. The advanced Stability Parameters are not active and the stumble recovery function is limited in the First Set Up mode.

- As the user unweights the prosthesis, select **Calibrate** icon to calibrate the load sensor. Instruct the user to ambulate or weight the prosthesis in a hyperextended position to calibrate the angle sensor. The angle sensor calibration must be completed within two minutes of selecting the **Calibrate** icon.
- Instruct user to ambulate. If the knee does not release into swing, lower the **Toe Threshold** setting in the Plié Control window until the knee releases.

3. Adjust Manual Hydraulic Settings

Adjust the default manual hydraulic settings in the following order to ensure the knee motion is smooth and symmetrical for the user (*Figure K*). Higher numerical values provide increased resistance for each hydraulic resistance setting.

- Using the pneumatic pump, adjust *swing flexion resistance* (heel rise).



*The pressure on the air pump's pressure gauge indicates the air pressure inside the knee. **Air pressure in the knee drops when the air pump is inserted in the knee, not when is removed.** When the air pump is removed from the knee, a sound of air leaking may be heard. This sound is the expelling of air from the air pump hose to the atmosphere. Approximately ½ the pressure in the knee is lost when the air pump is inserted.*

- Adjust *swing extension resistance* with a 4mm allen key (terminal impact).



The extension control valve used to modify the swing extension resistance is a cam and rotates 360° without damaging the knee. A line indicates the value of the current setting (0-9).

- Adjust *stance flexion resistance* with a 4mm allen key (stair/ramp descent resistance). Optimize performance for stair/ramp descent.



The stance flexion resistance also doubles as the resistance provided for stumble recovery. Caution must be exercised when adjusting the stance flexion resistance to ensure adequate resistance is present for stumble recovery.

4. Optimize Microprocessor Settings

Return to the Plié Setup Wizard (Plié Control>Setting Wizard).

- a. Select the **Suggest T1/T2** icon. Instruct the user to ambulate with variable cadences, including fastest and slowest walking speeds until 20 steps are shown in the **Steps** box.
- b. Select the **Set T1/T2** icon. The suggested values will be set in the knee.
- c. Repeat steps a & b until the suggested T1 and T2 values exhibit minimal variance.



As the data is collected for the T1 and T2 values, instruct user to finish ambulating with his/her slowest walking speed to ensure T1 is set appropriately.

- d. Select the **Next** icon to return to the main *Plié Setup Wizard* window.
- e. Select the **Self Selected Speed** icon and select the **Next** icon.
- f. In the *Self Selected Walking Analysis* window, select the **Start Recording** icon. Instruct the user to take twenty steps at his/her self-selected walking speed. Once complete, select the **Stop Recording** icon.



The dialog box, “Notify user download is about to start,” functions as a reminder to instruct the user to sit or stand as the knee will not release into swing during data file transfers.

- g. Select the **Save Data** icon. The self-selected walking recorded data file will be transferred wirelessly to the computer.
- h. Select the **Next** icon to return to the main *Plié Setup Wizard* window.
- i. Select the **Fast Walking Analysis** icon and select the **Next** icon.
- j. In the *Fast Walking Analysis* window, select the **Start Recording** icon. Instruct the user to take twenty steps at his/her fastest walking speed. Once complete, select the **Stop Recording** icon.
- k. Select the **Save Data** icon. The fastest walking recorded data file will be transferred wirelessly to the computer.
- l. Select the **Next** icon to return to the main *Plié Setup Wizard* window.
- m. Select the **Slow Walking Analysis** icon and select the **Next** icon.
- n. In the *Slow Walking Analysis* window, select the **Start Recording** icon. Instruct the user to take twenty steps at his/her slowest walking speed. Once complete, select the **Stop Recording** icon.
- o. Select the **Save Data** icon. The fastest walking recorded data file will be transferred wirelessly to the computer.
- p. After the three data files have been recorded, select the **Send Values to Knee** icon. The Plié Setup Wizard will transfer the optimal Stability Parameters to the knee.



When recording the three data files, capture the best data possible to ensure the advanced Stability Parameters are optimal. Instruct the user to ambulate outside the parallel bars if stability is not a concern.

5. Document

After completing the knee set-up, provide documentation in the user's records.

- a. Record the knee *Serial Number* in the user's chart. To maintain user confidentiality, the *Serial Number* is referenced when technical support, warranty repairs, or warranty service is required.



The Serial Number can be found on the sticker inside the knee frame or in the main Plié Control window when a wireless connection is established with the knee.

- b. Record the three manual hydraulic settings in the user's chart: swing flexion, swing extension, stance flexion.
- c. Save the user's computer settings on a secure computer. To save, select “Save Settings” for the “File” menu (Plié Control>File>Save Settings).



The user's saved settings can be transferred to a loaner knee. However, due to continuous design improvements, the settings may not be optimal. If problems are experienced with a loaner knee, simply follow the steps provided in this “Set-Up” section.

Technical Support

For Technical Support, please contact Freedom Innovations toll-free at 1-888-818-6777.

Warranty

The Plié® 2.0 MPC Knee, Threaded Top purchase includes a 36 month warranty covering all manufacturer defects. The warranty remains in place only when the product is used as intended, without modifications, following all manufacturer's recommendations. Additionally, the Plié MPC Knee must be returned for service at the specified intervals for the warranty to remain in effect.

The batteries, battery charger, and accessories are provided with a 12 month warranty.

Service and Repair

For the warranty to remain in effect, the knee must be serviced 12 and 24 months after purchase. A loaner knee is provided at the time of knee service.

For knee repairs, please contact Freedom Innovations toll-free at 1-888-818-6777. A loaner knee will be provided upon request. For service and/or repair, please ship the knee in the provided shipping case.

Regulatory Compliance, Disclosures, and Classification

Wireless Operation

Plié® 2.0 MPC Knee, Threaded Top Bluetooth Certification QPLN Ref. No.: Q31606_WT11_SGS

The Plié® 2.0 MPC Knee, Threaded Top complies with the following:

- FCC ID AMPCK001 or FCC ID QQQWT11. 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, and (2) this device must accept any interference received, including interference that may cause undesired operation.
- The Plié® 2.0 MPC Knee, Threaded Top has been tested and found to comply with the EMC limits for the Medical Device Directive 93/42/EEC (EN 55011 Class B and EN 60601-1-2). These limits are designed to provide reasonable protection against harmful interference in a typical medical installation. The Plié® 2.0 MPC Knee, Threaded Top generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with these instructions, may cause harmful interference to other devices in the vicinity.
- IC Certificate 5123A-BGTWT11E
- EU Certificate EC/2006.20013C
- Radio Equipment Japan No: 07215089/AA/00 and 07215089/AA/01
- STSI EN 300-328 under R&TTE Directive 1999/5/EC

IEC/EN 60601 Classification

- Internally powered
- Type BF applied part
- Mode of operation: continuous
- Not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.

Directive 2002/96/EC on Waste Electronic & Electrical Equipment (WEEE)

- We have marked the Plié® 2.0 MPC Knee, Threaded Top with the "crossed out wheeled bin" as instructed by Article 10.3 of WEEE, per Annex IV
- We include the following instruction required by Article 10 of WEEE for the Prosthetist to convey to the End User:
- We instruct Users of the Plié® 2.0 MPC Knee, Threaded Top in private households in the European Union not to dispose of this device as unsorted municipal waste. Instead, contact the European distributor that imported this device and follow their instructions concerning:
 - a. the return and collection systems available to you.

- b. your role in contributing to the reuse, recycling and recovery of Waste Electronic and Electrical Equipment and
- c. the potential effects on the environment and human health that result from the presence of hazardous substances in electrical and electronic equipment.

Conformite Europeenne and Authorized Representative Identification

- We have marked the Plié® 2.0 MPC Knee, Threaded Top with the CE Marking of Conformity required by Article 17 of Directive 93/42/EEC concerning Medical Devices (Medical Device Directive), per Annex XII.
- Below, we mark this Instruction for Use with the required CE Marking of Conformity and identify our Authorized Representative to the European Union.



30 Fairbanks, Suite 114
 Irvine, California 92618
 Toll Free (888) 818-6777
 FAX (949) 672-0084

