

EvoKnee

Instructions for Use (IFU)

For certified practitioners (CPO) and users



EvoKnee microprocessor-controlled prosthetic knee

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IMPORTANT Do not fit or use the device without reading this document. Keep this document and hand it over with the device. EvoKnee may only be fitted by practitioners who have completed Protet certification training.

1. General information

These Instructions for Use (IFU) apply to the fitting and daily use of the EvoKnee microprocessor-controlled prosthetic knee. The document addresses two audiences: Sections 4.1 and 6 are specific to certified practitioners (CPO); all other sections address both audiences — the person using the device should read Sections 4.2, 7–11 and 13 in particular. The EvoKnee Quick Guide (EVK-QG) is also published as a quick fitting reference.

A large-print or digital version of this document is available from the manufacturer on request.

When you receive the product, open the package and check for damage or missing parts (scope of delivery: Section 5). If the package is damaged, do not use the product and contact your dealer or Protod.

Field	Information
Document code / version	EVK-IFU-EN · v0.11 (DRAFT) · 2026-09-15
Manufacturer	Protod Protez Ortez A.Ş. — Melih Gökçek Bulvarı No:151/37 Protod Park, İvedik OSB, 06105 Ankara – Türkiye
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The symbols used in this document and on the labels are explained in Annex B.

2. Device description and operating principle

EvoKnee is a single-axis, hydraulically damped, microprocessor-controlled prosthetic knee joint. Sensors continuously detect the gait phase; hydraulic valves are driven by motors to adjust flexion and extension resistances in real time. The device is used as part of a prosthetic system together with a socket, adapters and a prosthetic foot.



EvoKnee — side view

2.1 Safety philosophy

The knee is at SUPPORT resistance by default. Release into swing is granted only when the safe conditions are met together; whenever the system cannot recognize a situation, the outcome is always a "supported knee". This principle underlies all behavior of the device.

- Stumble protection: if unexpected load is detected during swing, the knee returns to support.
- Sitting support: a sitting descent is recognized and supported with controlled resistance.
- Stance lock: leaning on a slightly flexed knee locks flexion; the lock is released only by a genuine extension movement.
- Safe shutdown: if the battery reaches the critical level or the device is switched off, the valves move to the shutdown position — the knee is never left free.

Essential performance: detection of the gait phase, provision of phase-appropriate hydraulic resistance, and maintenance of safe (supported) behavior in fault conditions.

2.2 EvoSave power management

After a period without movement, the device automatically enters a low-power sleep. Waking at the first movement is too fast for the user to notice — sleep is imperceptible. Sleep is always entered in the support position; if the user stands up during sleep, the knee does not collapse.

- The LED is off while the device is asleep.
- While asleep, the power button does not switch the device off — it wakes it first; to switch off, hold the button while the device is awake.
- The device does not sleep while charging or while data exchange with the app is in progress.

3. Intended purpose and clinical framework

3.1 Intended purpose

EvoKnee is used, integrated into a prosthetic system, to prosthetically replace the missing knee joint function in adult individuals with amputation at or above the knee joint (knee disarticulation, transfemoral amputation, hip disarticulation). It is designed exclusively for prosthetic fitting and is used on a single patient.

3.2 Indications

- Knee disarticulation, transfemoral amputation or hip disarticulation.
- Mobility class K2 – K4.
- Maximum user weight 125 kg (body weight).

3.3 User group and use environment

Fitting, alignment, calibration and clinical settings are performed only by practitioners (CPO) who have completed Protod certification training. Daily use is by the person fitted with the device.

Use environment: daily life, indoors and outdoors; -10 ... +40 °C. Showering, swimming and immersion in water are outside the scope of use.

3.4 Contraindication

- Body weight above 125 kg.

NOTE Precautions: If there is doubt about the capacity to learn to use the prosthesis safely, fitting is subject to the practitioner's individual assessment. The same assessment applies in cases of advanced combined hearing and vision loss that prevents perception of the device signals (LED, beep, vibration).

3.5 Clinical benefit

Supported stance and controlled knee behavior provide safe standing, controlled ramp/stair descent and recovery support after stumbling. By providing controlled support, the device promotes safe mobility and participation in activities of daily living.

4. Safety

WARNING = protects against risk of injury · CAUTION = protects device or therapy function. The numbers (W-xxx) correspond to Protected safety records.

NOTE Residual risks: Despite its protective functions, the device cannot prevent all falls; stumble protection may not prevent a fall in every scenario. During intensive uninterrupted use, hydraulic heating may temporarily change the feel of resistance. The possibility of failure cannot be entirely eliminated in an electronic device — in fault conditions the device pulls itself into supported behavior.

4.1 For the practitioner

WARNING Do not let the patient walk on an uncalibrated device. The device signals this with a RAPIDLY FLASHING yellow LED + a short beep every 10 seconds (steady yellow indicates a medium battery). (W-001)

WARNING The calibration postures must be performed exactly: foot off the ground in the sitting step; knee fully extended and weight balanced on both feet in the standing step. An incorrect posture corrupts the references. (W-002)

WARNING The weight and height entered during calibration must be correct; incorrect data skews load sensing. (W-024)

WARNING An incorrect torque value can lead to loosening of the connection and a fall; use a torque wrench at every fitting. EvoKnee pyramid screws are tightened to 15 Nm. (W-022)

WARNING The socket–housing clearance at full flexion must be at least 4 mm; otherwise the socket strikes the hydraulic unit and damages the device. If the clearance is insufficient, the socket must be revised. (W-023)

WARNING Combine EvoKnee only with components appropriate to the prosthetic system and user weight that meet the relevant standards; do not use unapproved accessories. (W-026)

CAUTION "Reset to factory defaults" only returns the settings to factory values (calibration is retained); the knee feel changes for the patient — inform the patient. (W-016)

CAUTION Teach the patient the functions of the mode button and the mode confirmation signals. (W-017)

4.2 For the user

WARNING In Cycle mode and any other mode that releases the knee, the knee bears no load — do not stand or walk while in these modes. (W-004)

WARNING Do not walk with the device switched off — the knee provides only fixed passive resistance; the gait algorithm does not run. (W-005)

WARNING Showering, swimming and immersion in water are prohibited; avoid contact with salt/chlorinated water. The device is rated IP66 (fully dust-tight, resistant to powerful water jets); intentional water contact is nevertheless prohibited due to seal ageing and the effects of hot/salt/chlorinated water. (W-006)

WARNING At the low-battery warning (red LED + beep), charge as soon as possible. At the critical level, the device performs a safe shutdown and the support function stops. (W-007)

WARNING If you have an active implant (pacemaker, defibrillator, etc.), do not carry or charge the device and its charging equipment close to the implant; consult your physician before use. (W-025)

WARNING Driving with the prosthesis is subject to national regulations and an assessment by the competent authority/physician; it is not recommended before such an assessment. (W-010)

WARNING Despite stumble protection, using a handrail is recommended on steep stair and ramp descents. (W-011)

WARNING Running as a sport, jumping and impact sports are prohibited; unavoidable running of a few steps is tolerated. (W-013)

WARNING Do not expose the device to heat sources (stove, car dashboard, sauna); do not use outside the operating temperature range. (W-014)

CAUTION Intensive uninterrupted supported descent (e.g. a long ramp) may heat the hydraulic unit; the feel of resistance may change temporarily and the housing may warm up. If you feel noticeable heat on touch, take a break. (W-015)

WARNING The device always starts in normal walking mode — a device switched off in a special mode is NOT in that mode after power-on. (W-018)

WARNING Do not walk with the charging cable plugged in; charging while wearing the device is allowed only in a seated position. (W-019)

4.3 For both audiences

WARNING The maximum user weight is 125 kg (body weight). (W-003)

WARNING Do not open or disassemble the device; all service operations, including battery replacement, are performed only by an authorized service center. (W-008)

WARNING The device is classified MR Unsafe: do not take it into an MR environment; keep it away from strong magnetic/electromagnetic fields. (W-009)

WARNING Do not use portable RF communication equipment (including radios, powerful transmitters and antenna cables) closer than 30 cm to the device; performance may degrade. (W-029)

WARNING If the motion-sensing fault signature is heard (3 very short beeps, then one beep per minute), walking may continue; contact service as soon as possible. The battery drains faster. (W-012)

WARNING Do not continue using a damaged or impacted device; a service check is required. (W-020)

WARNING Software updates are performed only with the battery at least 40% charged and the device not worn — or with the user seated and motionless. (W-021)

CAUTION Do not insert fingers or clothing into the moving mechanism area (around the knee axis, full-flexion range) — risk of pinching. (W-027)

NOTE For air travel information, see Section 13.

5. Scope of delivery and technical data

Scope of delivery:

Catalog No	Item
PR04.MP.001	EvoKnee knee joint
—	USB-C charging cable
—	Documents (IFU + Quick Guide)

Weight	1550 g
Total height	255 mm (230 mm from bottom pyramid to rotation axis)
Maximum flexion angle	130°
Maximum user weight	125 kg (body weight)
Mobility class	K2 - K4
Protection class	IP66 — fully dust-tight, resistant to powerful water jets
Battery	Built-in Li-ion, 14.8 Wh
Charging	Full charge in ~2.5 h via USB-C
Battery life	~1.5 weeks in typical use
Connectivity	Bluetooth LE → ProtedGO app
Operating temperature	-10 ... +40 °C
Relative humidity	0 - 90%, non-condensing
Storage	15 - 25 °C, dry environment

5.1 Combination and accessories

The connections are pyramid-standard. EvoKnee is combined only with socket adapters and prosthetic feet that meet the user weight class (125 kg) and the relevant standards (e.g. ISO 10328) (W-026). For adjacent components, the respective manufacturer's own instructions for use (including torque) apply.

In hip disarticulation, EvoKnee is combined with a suitable prosthetic hip joint; the hip joint's own instructions for use apply.

Cosmetic cover: an approved cosmetic cover is not currently offered for EvoKnee; the device is designed for use without a cover. If a cosmetic covering is desired, consult the manufacturer — a covering may affect the audibility of signals and heat dissipation.

6. Fitting (summary for practitioners)

This section summarizes the fitting workflow; the full procedure is in the EvoKnee Quick Guide (EVK-QG). Fitting is performed only by practitioners who have completed Protod certification training.

1. Mechanical assembly: pyramid connections 15 Nm; in bench alignment the knee rotation axis is 0–10 mm behind the plumb line (dropped from the socket mark at trochanter level — details: EVK-QG); socket–housing clearance ≥ 4 mm at full flexion.
2. Static alignment: patient standing, weight even on both feet; ± 5 mm tolerance from the bench target, always within the 0–10 mm window.
3. Charging, first power-on and ProtodGO pairing.
4. Calibration (3 steps): sitting $\sim 90^\circ$ with the foot off the ground $\rightarrow$ standing at full extension with balanced load $\rightarrow$ patient data (weight + height).
5. Dynamic observation and fine-tuning of the clinical settings.

NOTE Verify the device serial number (SN) before connecting — this prevents writing settings to the wrong device when several devices are present in the clinic.

6.1 Clinical settings

Each setting has its own value range; the lower end acts toward Locked (full lock), the upper end toward Free (fully free). Values are internal device units; record them as numbers in the patient file. Detailed descriptions and the recommended adjustment order: EVK-QG Section 7.

Setting	Function (short)
Descent Resistance	Support (yielding) resistance of the stance phase — standing, descent, after stumbling
Terminal Extension Damping	Braking as the knee approaches full extension at the end of the step
Swing Flexion Resistance + Angle Limit	Flexion resistance and angle limit in swing
Extension Resistance	Forward-swing resistance in swing
Sitting Resistance	Sitting descent support (the app does not allow a value freer than Descent)
Heel Damping + Angle Limit (opt.)	Heel-strike comfort damper
Power-off Flexion / Extension Resistance	Fixed passive resistances while the device is off

7. Use

7.1 Switching on and off

- Switching on: press the power button. Power-on is confirmed with 1 long beep + vibration. The device always starts in normal walking mode and at support resistance.
- Switching off: hold the power button for ~1.5 seconds; the device switches off with 2 beeps. On shutdown, settings and counters are saved and the valves move to the safe shutdown position.



Mode (M) button



Power button

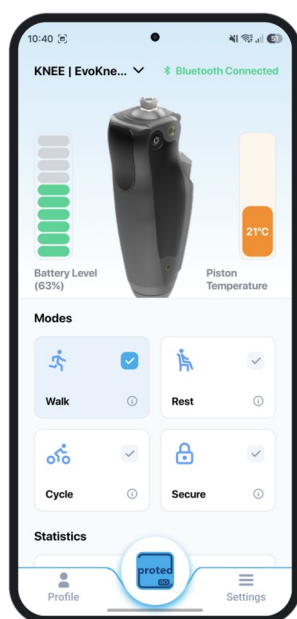
7.2 Daily use

- Level walking: the knee adapts to your walking speed automatically; no special action is needed.
- Standing: the knee is at support resistance; if you lean on a slightly flexed knee, the stance lock engages and is released only by an extension movement.
- Sitting down: the sitting descent is recognized and supported with resistance; you can sit down in a controlled way.
- Ramp and stair descent: the support resistance allows a controlled descent; use a handrail on steep descents (W-011).
- Stumbling: if unexpected load is detected during swing, the knee returns to support; you can recover your balance and continue walking.
- Ramp/stair ascent: lead with the sound leg, using the step-to technique.

7.3 Activity modes

Modes are selected from ProtedGO; some modes can also be entered and exited with the mode button on the device. A mode change is confirmed with a beep + vibration.

Mode	Behavior
Walk — normal mode	Standard walking algorithm — the mode at power-on
Rest	Knee in relaxed support behavior
Cycle	Knee free in both directions; BEARS NO LOAD (W-004)
Secure	Knee locked / fixed high-resistance behavior



Device home screen: battery status and mode selection

WARNING Do not stand or walk in modes that release the knee. The device returns to normal walking mode at every power-on. (W-004, W-018)

7.4 Daily checks

- Before donning, check the device for visible damage, cracks or loosening.
- If you notice unusual noise, vibration or a change in the feel of resistance, stop using the device and contact service (W-020).
- Check the battery status from the LED color (Section 9).
- In case of significant weight gain or loss, contact your practitioner — the patient data in the calibration must be updated (see W-024).
- Walking in the rain is safe; dry a wet device with a dry cloth. Showering, swimming and immersion remain prohibited (W-006).
- If the LED does not light when you move the device, it may be switched off — switch it on with the power button. (A sleeping device wakes by itself on movement and the LED lights.)

8. Signals (LED · beep · vibration)

The device communicates its status with the LED color, beeps and vibration. Power-on, shutdown and mode changes are confirmed with a beep + vibration.

Signal	Meaning	Action
Green LED	Battery good (full/high)	—
Yellow/amber LED	Battery medium	—
Orange LED	Battery getting low	Plan charging
Yellow LED flashing rapidly + beep every 10 s	Not calibrated (distinguished from the battery yellow by flashing)	The practitioner performs calibration
Red LED + beep every ~30 s	Low battery	Charge as soon as possible
Purple LED	Charging	Normal — returns to battery color when complete
LED off	EvoSave sleep or switched off	Move the device or switch it on with the button
1 long beep + vibration	Power-on confirmation	—
2 beeps	Shutdown confirmation	—
Power-on signature + 2 short beeps	The device restarted	Usable; have the log read out at the next service visit
Single short beep (during use)	A valve command could not be executed	If it repeats: service
3 beeps (intermittent)	Internal communication problem	Switch off and on; if it persists: service
3 very short beeps + one beep per minute	Motion sensing disabled — the device continues to operate safely	Walking is possible; service as soon as possible

9. Battery and charging

For charging, use a CE-marked, IEC 62368-1 compliant adapter capable of 5 V $\geq$ 2 A and a good-quality USB-C cable. The port is on the rear-lower area of the device; make sure it is dry and clean before charging. A full charge from empty takes about 2.5 hours; the LED lights purple while charging. Do not charge with a damaged cable or adapter.

LED color	Battery status
Green	Good (full/high)
Yellow/amber	Medium
Orange	Getting low — plan charging
Red	Low — charge (accompanied by a beep every ~30 s)
Purple	Charging

- Low battery: the LED turns red and a beep sounds every ~30 seconds; the device keeps working normally — charge as soon as possible.
- Critical level: the device performs a safe shutdown; the valves move to the shutdown position and the knee is not left free. A switched-off device behaves with the Power-off resistances — do not walk with the device off (W-005, W-007).

Usage profile	Daily steps	Approx. charge interval
Less active	~2,500	~19 days
Average	~5,000	~11 days
Active	~10,000	~7 days
Very active	~15,000	~5 days

WARNING Never walk with the charging cable plugged in; charging while wearing the device is allowed only in a seated position. (W-019)

10. ProtedGO (user side)

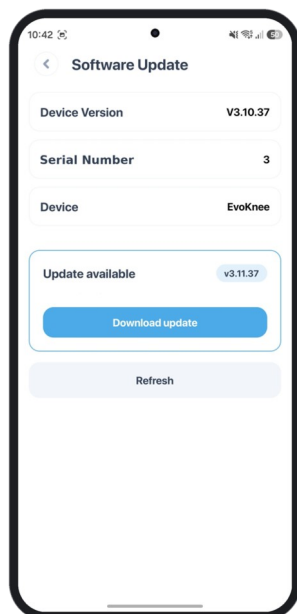
With the ProtedGO app you can view the device status (battery, mode), change the activity mode, follow your step counter and start software updates.

Clinical settings (resistances, angle limits) can be changed only with an approved practitioner account; they cannot be changed from the user app.

NOTE While data exchange with the app is in progress, the device does not go to sleep; the connection will not drop.

11. Software update (OTA)

Updates are performed via ProtedGO; the user or the practitioner can start them. The device accepts only Proted-signed software updates. Conditions: battery at least 40% charged; device not worn — or the user seated and motionless.



Software Update screen

WARNING Do not stand or walk during the update. (W-021)

WARNING If an update fails, the device is not damaged; however, the device will not operate until the update is retried and COMPLETED. Therefore, perform updates while seated, with the charger connected and with your phone online. Restart an interrupted update immediately; if the problem persists, contact service. (W-028)

12. Cleaning, maintenance and service

- The product is non-sterile and does not require sterilization.
- Cleaning: wipe with a slightly damp cloth. Do not use solvents, detergents or pressurized water; do not immerse the device.
- There is no user-serviceable maintenance; all service operations are performed at an authorized service center (W-008).
- Within 30 days of the initial fitting, the practitioner must check the connection torques, alignment and general function.
- At service visits, the device's event logs are read out via the app; these logs speed up fault diagnosis.
- When sending the device to service, state its serial number (SN) — the SN is laser-marked on the device body.
- Contact Proted before shipping the device: due to the built-in lithium-ion battery, shipment is subject to lithium-battery device rules (UN 38.3). For damaged or impacted devices, always obtain shipping instructions from service.
- The device must undergo a periodic safety check at an authorized service center every year.
- The expected service life is 6 years (excluding the battery; the battery is replaced only at an authorized service center).

13. Transport, storage and travel

- Store the device at 15 – 25 °C in a dry environment; protect it from impacts.
- If the device will not be used for a long period: FULLY charge the battery and switch the device off. The battery management system automatically brings the charge level to a cell-safe range during storage; no further action is needed.
- Air travel: the device's Bluetooth cannot be switched off (there is no flight mode). The built-in battery is 14.8 Wh; lithium-ion batteries under 100 Wh are in the standard cabin class. Informing your airline before travel is recommended.
- If the airline requires wireless transmitters to be switched off: switch the device off while seated. Always switch the device on before standing up — power-on completes within seconds. Do not walk with the device off (W-005).
- Airport security: the device may trigger metal detectors; inform the security officer about your prosthesis in advance. X-ray scanning does not harm the device.

14. Disposal

The device contains electronic components and a lithium-ion battery; it must not be disposed of with household waste. At the end of its service life, return the device to Proted or to an authorized electronic waste collection point.

15. Troubleshooting

Situation	Possible cause	Action
Yellow LED + periodic beep	Not calibrated	Contact your practitioner (calibration)
Red LED + beep	Low battery	Charge the device
Device does not switch on	Battery fully depleted	Plug in the charger, try again after a few minutes; if not: service
Update failed, device not operating	Interrupted update	Restart the update from ProtedGO and wait for completion; if the problem persists: service
3 very short beeps + one beep per minute	Motion sensing disabled — the device continues to operate safely	Walking may continue; service as soon as possible — battery drains quickly
Single short beep repeating	A valve command cannot be executed	Service
3 beeps (intermittent)	Internal communication problem	Switch off and on; if it persists: service
Bluetooth not connecting	BLE off / distance / device asleep	Enable Bluetooth on the phone, wake the device by moving it, move closer
Feel of resistance changed (on a long descent)	Hydraulic heating (W-015)	Take a break; if the feel does not recover: service
Unusual noise/vibration	Mechanical problem	Stop using; service (W-020)

NOTE For unresolved situations, Proted authorized service: (+90) 312 394 7575 · proted@proted.com.tr

16. Legal information

16.1 Liability

The manufacturer cannot be held liable for damage resulting from fitting or use contrary to the instructions in this document, unauthorized service/part replacement, or use outside the intended purpose.

16.2 Warranty

The warranty period for the product is 2 years. The warranty is valid provided the device is used in accordance with the instructions in this document.

16.3 Serious incident reporting

Any serious incident that occurs in relation to the device must be reported to the manufacturer and to the competent authority of the country in which the user/patient is established. In Türkiye, the competent authority is the Turkish Medicines and Medical Devices Agency (TİTCK). Reporting to the manufacturer: proted@proted.com.tr · (+90) 312 394 7575.

16.4 CE conformity

This product meets the requirements of EU Medical Device Regulation 2017/745. Under the active-device rules of Annex VIII (Rule 13), the product is classified as Class I. Conformity is accordingly the manufacturer's own responsibility. CE marking is applied in accordance with Annex V.

Annex A — Full technical data

Weight	1550 g
Total height / axis distance	255 mm / 230 mm from bottom pyramid to rotation axis
Maximum flexion angle	130°
Maximum user weight	125 kg (body weight)
Mobility class	K2 – K4
Protection class	IP66 — fully dust-tight, resistant to powerful water jets
Battery	Built-in Li-ion 2S (7.4 V nominal), 2000 mAh = 14.8 Wh — replaced only by authorized service
Charging	USB-C, 5 V $\geq$ 2 A · ~2.5 h from empty to full
Battery life	Typically ~1.5 weeks · ~5 days in heavy use
Connectivity	Bluetooth Low Energy (BLE) → ProtedGO (iOS 15+ / Android 10+)
Proximal / distal connection	Pyramid adapter (threaded top connection on special order)
Operating temperature	-10 ... +40 °C
Relative humidity	0 – 90%, non-condensing
Storage	15 – 25 °C, dry environment

Annex B — Symbols

Symbols used on the product label, packaging and in the documents:

	Caution		Consult instructions for use		Do not use if the package is damaged
	Unique Device Identifier (UDI)		Medical device		CE marking in accordance with MDR 2017/745
	Manufacturer		Date of manufacture		Country of manufacture
	Serial number		Catalogue number		Keep away from sunlight
	Keep dry		Fragile, handle with care		Do not dispose of with household waste
	Non-sterile				