

FEPSim® USER MANUAL



Model: FEPSim 1000 Horizontal



Model: FEPSim 1000 Vertical

CONTENT

This FEPSim User Manual describes the setup, use, maintenance, and storage of FEPSim 1000 Horizontal and FEPSim 1000 Vertical models.

This FEPSim User Manual describes the setup, use, maintenance, and storage of FEPSim 1000 Horizontal and FEPSim 1000 Vertical models.

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1 About FEPSim®

Designed by therapists for therapists, FEPSim restores the use of the hands, wrists, and upper extremities by focusing on real-world functional problems that patients and clinicians face daily. FEPSim maximizes range of motion, strength, and endurance through targeted, purposeful, and progressive exercise and activity simulation.



FEPSim 1000 Horizontal



FEPSim 1000 Vertical

FEPSim 1000 is available in both Horizontal and Vertical models, allowing for treatment across multiple planes of motion. Together, the Horizontal and Vertical models create a comprehensive hand and upper extremity rehabilitation system incorporating gross motor, fine motor, and task-specific training.

For further information, visit FEPSim.com.

1.1 Intended Purpose

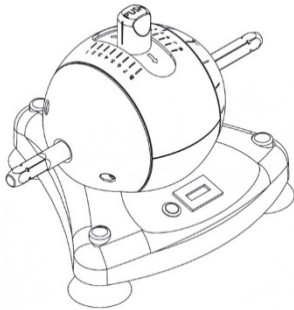
FEPSim 1000 is intended for use only as directed by a qualified clinician. It has been designed to aid in treating many conditions:

- Stroke and other neurological conditions
- Fractures of the elbow, forearm, wrist, and hand
- Weakness and deconditioning of the upper extremity
- Tendon repair
- Tendinopathy of the elbow, forearm, wrist, and hand
- Sprains and strains of the elbow, forearm, wrist, and hand
- Complex Regional Pain Syndrome (CRPS) of the upper extremity

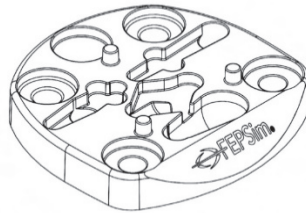
Through their different orientations, progressive resistance options, and interchangeable accessories, the Horizontal and Vertical FEPSim 1000 units complement one another to create varied, practical, and real-world activity simulation. Together, the FEPSim units offer a comprehensive treatment program with a focus on upper extremity strength, flexibility, endurance, and neuromuscular re-education.

2 FEPSim 1000 Horizontal

This section relates to the horizontal model only. For the vertical model, see Section 3.








FEPSim 1000 Horizontal



Horizontal Storage Base

2.1 FEPSim 1000 Horizontal Standard Accessories

The following accessories are included with the Horizontal FEPSim:

 qty 2				
2" Dowel	Doorknob	Lever	Key	T Handle

To order additional or custom accessories, please see Section 9 for Contact Information.

2.2 Using FEPSim 1000 Horizontal

FEPSim can be secured to any smooth, stable surface and used with the patient in a seated or standing position.

2.2.1 Set Up

- 1) Remove FEPSim from the storage base and place it on a clean, smooth, stable, horizontal surface, such as a table.



Never mount FEPSim on a vertical surface like a wall or window. The suction cups may release and FEPSim may fall, injuring nearby persons or damaging the device.

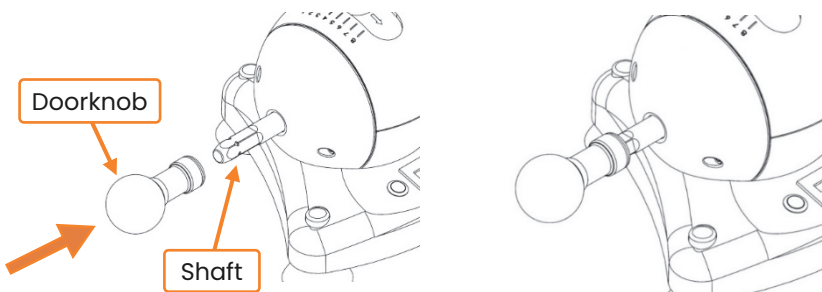
- 2) To secure it, press down on the base so that the three suction feet stick to the surface.



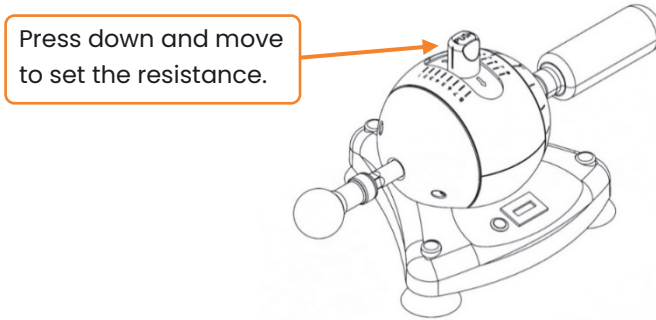
To avoid damage, do not move FEPSim before releasing the feet. To release a foot, press the silver button and gently lift the corner. See Section 5.

- 3) Clean and disinfect all accessories as per your local facility health procedures. See Section 4.
- 4) FEPSim accessories are universal and can be connected to any FEPSim shaft. Add the desired accessory to the shaft on either side of FEPSim by sliding it on until it clicks. If the accessory does not click into place, remove it from the shaft, rotate the shaft, and try installing it again. To remove, firmly pull the accessory off the shaft.

Example: Attach the Doorknob:



- 5) Set the resistance by using the central lever: press down, move forward or backward to the desired resistance, then release. Ensure the lever locks into place once the resistance is set.



Note: The resistance level varies from 1 to 8 (3.9 to 23.5 in-lb or 0.44 to 2.64 N·m). See Section 8 for more detail on how the resistance level correlates to torque.

Note: The resistance level should be determined by a clinician and based on treatment goals, the patient's current ability, the accessory being used, and the number of repetitions desired.

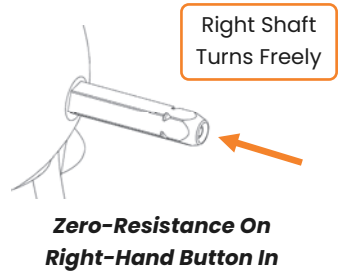
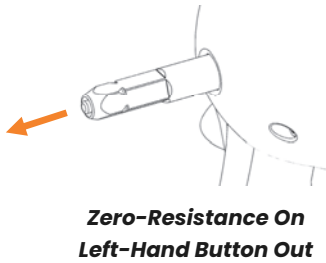
6) Your FEPsim is ready for patient use.

2.2.2 Zero-Resistance Shaft

FEPsim 1000 Horizontal models with serial numbers H0000100 and up can be set so that the right-hand shaft is disconnected from the left-hand shaft and the resistance element. This leaves the right-hand shaft with zero resistance and allows FEPsim to be used by patients with very little hand and wrist strength.

How to enable the zero-resistance option:

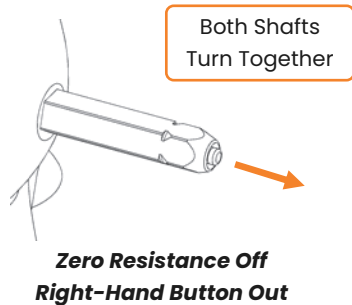
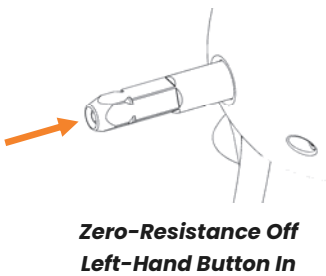
- 1) Remove any accessory from the right-hand shaft.
- 2) Find the button at the centre of the shaft end and press it in. You may need to rotate or wiggle the right-hand shaft slightly until the button can be pushed in.



- 3) Verify that the right-hand shaft can be turned freely.
- 4) Attach the desired accessory onto the right-hand shaft.

How to disable the zero-resistance option:

- 1) Remove any accessory from the left-hand shaft.
- 2) Find the button at the centre of the shaft end and press it in. You may need to rotate the right-hand shaft as much as a full turn until the button can be pushed in.



- 3) Verify that both ends of the shaft rotate together.
- 4) Attach the desired accessory onto the left-hand shaft.

FEPSim 1000 Horizontal models with serial numbers of H0000099 or less can be upgraded to include the zero-resistance feature. Please contact your sales representative or KARMED for more information. Contact information is in Section 9 of this manual.

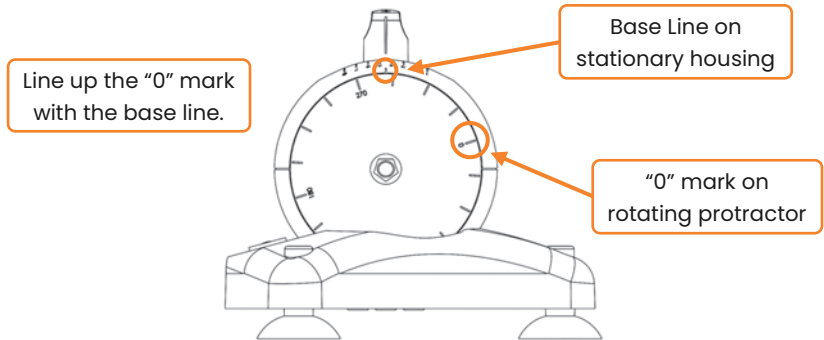
2.2.3 Use

Now that the device is ready to use:

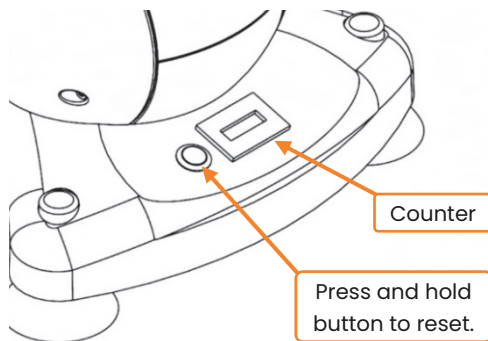
- 1) Verify that FEPSim is firmly secured to the workspace and that the desired resistance level is set.

Note: FEPSim can be positioned so that the shaft is either parallel to the user or at some angle to the user. Rotating the unit allows for different exercises and activity simulation.

- 2) Ensure that the “0” on the protractor is aligned with the base line just above the protractor. Rotating the accessory as far as possible in both directions will determine the patient’s range of motion.



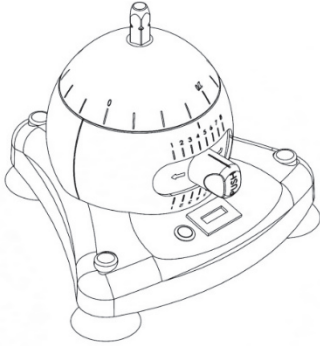
Note: The counter will go up by one each time the “0” passes the base line at the top of the protractor, in both directions. To reset the counter, press and hold the reset button for at least 3 seconds.



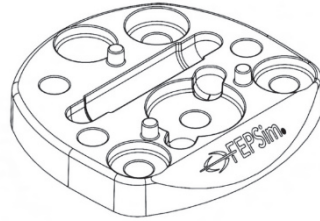
- 3) Exercise as directed.
- 4) Clean and store FEPSim as described in Sections 4 and 5.

3 FEPSim 1000 Vertical

This section relates to the vertical model only. For information on the horizontal model, see Section 2.








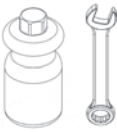
FEPSim 1000 Vertical






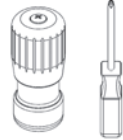

Vertical Storage base

3.1 FEPSim 1000 Vertical Standard Accessories

The following accessories are included with the Vertical FEPSim serial numbers V0000001 through V0000099:

					
1/2" Dowel	Large Lid	Faucet Knob	Small Cap	Screwdriver and Screw	Wrench and Bolt

The following accessories are included with the Vertical FEPSim serial numbers V0000100 and higher:

				
1/2" Dowel	Large Lid	Faucet Knob	Cap and Screw with Screwdriver	Bolt and Screw with Wrench and Screwdriver

To order additional or custom accessories, please see Section 9 for Contact Information.

3.2 Using FEPSim 1000 Vertical

FEPSim can be secured to any smooth, stable surface and used with the patient in a seated or standing position.

3.2.1 Set Up

- 1) Remove FEPSim from the storage base and place it on a clean, smooth, stable, horizontal surface.



Never mount FEPSim on a vertical surface like a wall or window. The suction cups may release and FEPSim may fall, injuring nearby persons or damaging the device.

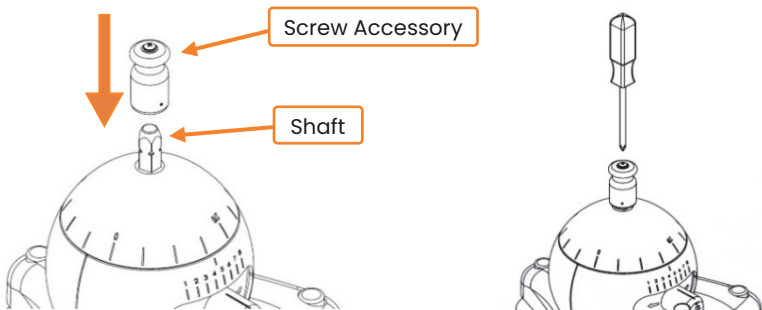
- 2) To secure it, press down on the base so that the three suction feet stick to the surface.



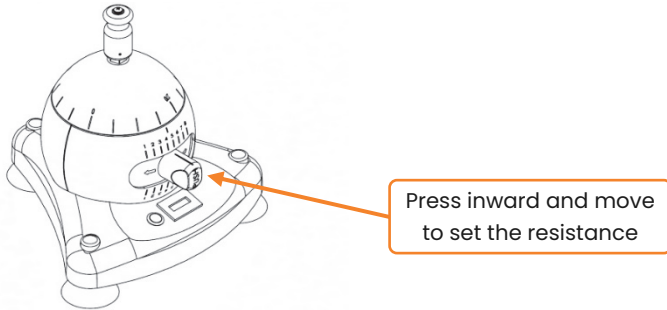
To avoid damage, do not move FEPSim before releasing the feet. To release a foot, press the silver button and lift the corner. See Section 5.

- 3) Clean and disinfect all accessories as per your local facility health procedures. See Section 4.
- 4) FEPSim accessories are universal and can be connected to any FEPSim shaft. Add the desired accessory to the FEPSim shaft by sliding it on until it clicks. If the accessory does not click into place, remove it from the shaft, rotate the shaft, and try installing it again. To remove, firmly pull the accessory off the shaft.

Example: attach a screw accessory to use with the screwdriver:



- 5) Set the resistance by using the central lever: press inward, move left or right to the desired resistance, then release. Ensure the lever locks into place once the resistance is set.



Note: The resistance level varies from 1 to 8 (3.9 to 23.5 in-lb or 0.44 to 2.64 N·m). See Section 0 for more detail on how the resistance level correlates to torque.

Note: The resistance level should be determined by a clinician and based on treatment goals, the patient's current ability, the accessory being used, and the number of repetitions desired.

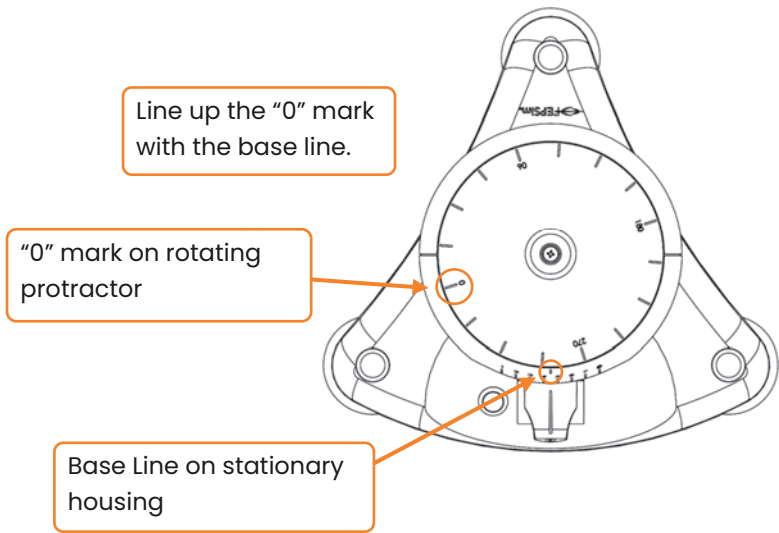
- 6) Your FEPsim is ready for patient use.

Note: the FEPsim Vertical does not have a zero-resistance option.

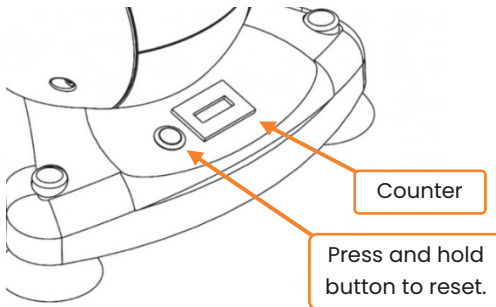
3.2.2 Use

Now that the device is ready to use:

- 1) Verify that FEPsim is firmly secured to the workspace and that the desired resistance level is set.
- 2) Ensure that the "0" on the protractor is aligned with the base line at the front. Rotating the accessory as far as possible from this position in both directions will determine the patient's range of motion.



Note: The counter will go up by one each time the "0" passes the base line at the top of the protractor. To reset the counter, press and hold the reset button for at least 3 seconds.



- 3) Exercise as directed.
- 4) Clean and store FEPSim as described in Sections 4 and 5.

4 Cleaning and Disinfecting

After each use, clean and disinfect FEPSim and all the accessories.

All components may be surface cleaned and disinfected. The following disinfectants may be safely used with FEPSim:

- Hydrogen peroxide up to 10% concentration
- Sodium hypochlorite (bleach) up to 10% concentration
- Isopropyl alcohol up to 100% concentration



FEPSim and its accessories have not been designed to be sterilized. Sterilization by any process, including autoclave, steam, ethylene oxide, electron beam, or ionizing radiation, may destroy the device or its components.



Do not immerse FEPSim in any liquid.

Note: the standard FEPSim accessories shown in Sections 2 and 3 may be immersed in the disinfectants listed above as part of a disinfection procedure.

5 Storage and Transportation

FEPSim is designed to be stored on the supplied FEPSim storage base. The base supplied with each model will house the respective accessories.

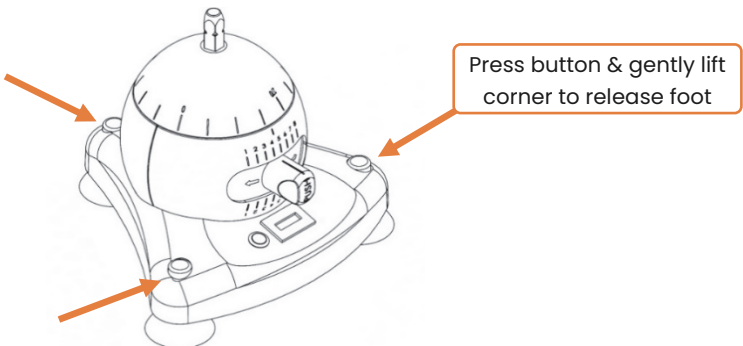


If FEPSim is not stored on the storage base when not in use, the suction cups on the feet may permanently deform and become less effective.

- 1) Remove any accessories from FEPSim by firmly pulling them off the shaft. Return them to their positions in the storage base.

<p>Horizontal model accessories on storage base</p>	<p>Vertical model accessories on storage base (s/n up to V000099)</p>	<p>Vertical model accessories on storage base (s/n V0000100 and up)</p>

- 2) Release the suction feet from the table by pressing the silver button above the foot and gently lifting the corner at the same time.





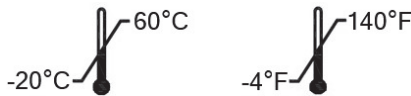
To avoid damage, do not move FEPSim before releasing the feet.

3) Place FEPSim on the storage base.

<p>Horizontal model on storage base</p>	<p>Vertical model on storage base (up to s/n V000099)</p>	<p>Vertical model on storage base (s/n V0000100 and up)</p>

4) Store FEPSim in a cool, dry area out of direct sunlight. FEPSim may be stored in the supplied tote.

Storage temperature range:



5) The entire FEPSim unit, with base and accessories, may be placed in the FEPSim tote for transport.

6 Safety Information

6.1 Precautions & Contraindications

Clinical reasoning and judgement should always guide the use of FEPSim in patient care.

Precautions for use of FEPSim include, but are not limited to, muscle soreness, impaired sensation, cardiovascular disease, cognitive impairment that limits ability to safely participate in exercise, and physical disability that precludes safe exercise.

Contraindications for use of FEPSim include, but are not limited to, severe pain, severe open wounds, suspected deep vein thrombosis, and unstable bone, joint, or soft tissue healing.

6.2 Warnings & Cautions



FEPSim should only be used under the guidance of a qualified clinician such as a Medical Doctor, Occupational Therapist, or Physiotherapist.



Improper use of FEPSim may cause injury.

6.3 Sample Exercises

Exercise prescription using FEPSim should be dictated by trained clinicians after careful review of patient status, needs, and goals. To view a library of FEPSim exercises for treatment ideas and home exercise program assignment, please visit FEPSim.com.



Exercises should be set at an appropriate level for each patient by a qualified clinician.



Therapists are encouraged to trial all accessories and experience the various resistance levels prior to prescribing to patients.

7 FEPSim Technical Support

7.1 Unique Device Identifier (UDI)

Each FEPSim has a unique serial number found on the bottom label of the FEPSim unit.

7.2 Maintenance

FEPSim is intended to provide safe and reliable operation when operated in accordance with the instructions provided by KARMED. If there is any sign of wear or concern with device function, contact KARMED Technical Support. See Section 9 for Contact Information.

7.3 Warranty

This Limited Warranty applies to FEPSim products and accessories purchased from KARMED and covers any defects in material or workmanship under normal use during the Warranty Period of two (2) years from date of purchase.

During the Warranty Period, KARMED will repair or replace, at no charge, products or parts of the FEPSim product or accessories that prove defective because of improper material or workmanship under normal use and maintenance. KARMED will repair the product at no charge, using new or refurbished replacement parts. This Limited Warranty does not cover any problem that is caused by user error, conditions, malfunctions, or damage not resulting from defects in material or workmanship.

To obtain warranty service, please contact FEPSim technical support at tech@FEPSim.com so that we may assess the problem and determine the most appropriate solution for you.

7.4 Return, Cancellation, Exchange Policy

At KARMED, we are committed to excellence before, during, and after you receive your FEPSim and want your device to be a valued part of your clinic. However, should there be a reason to cancel, return, or exchange orders, we will be pleased to assist you.

Items returned within 14 days of shipping from KARMED may be eligible for a full refund, excluding relevant shipping and restocking fees, provided the return requirements are followed.

Before returning your FEPSim, please contact us to obtain a Return Merchandise Authorization number. You can obtain this by contacting your FEPSim sales rep, or by contacting KARMED directly at tech@FEPSim.com. See Section 9 for additional contact information. Returned products must be complete and in full operating condition. Please return your FEPSim with the order information, and in the original packaging if possible. Returned products that do not satisfy these requirements may not qualify for a refund.

PLEASE NOTE that the KARMED Return Policy only covers items the customer chooses to return within 14 days of shipping from KARMED, and does not apply to damaged products. If your FEPSim arrives to you damaged or with a defect in material or workmanship, the Warranty Policy applies. In this case, please contact FEPSim technical support at tech@FEPSim.com so that we may assess the problem and determine the most appropriate solution for you.

8 Specifications

8.1 FEPSim General Specifications

Standard Accessories:

Horizontal model

(all serial numbers):

- 2-inch Dowel Grips (quantity 2)
- Doorknob
- Lever
- T-handle
- Key
- Storage Base

Vertical model

(s/n up to V0000099):

- Large Lid
- Faucet Knob
- Small Cap
- Screwdriver and Screw
- Wrench and Bolt
- 1½-inch Dowel Grip
- Storage Base

Vertical model

(s/n V0000100 & up):

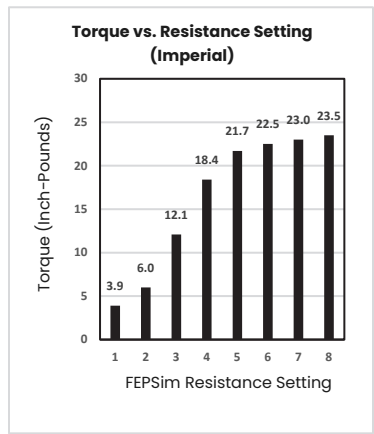
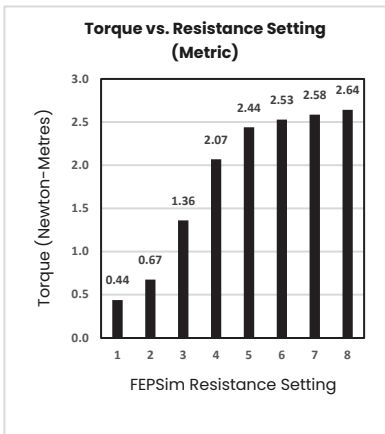
- Large Lid
- Faucet Knob
- Cap and Screw with Screwdriver
- Bolt and Screw with Wrench and Screwdriver
- 1½-inch Dowel Grip
- Storage Base

Weight:

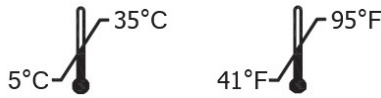
FEPSim weighs approximately 4.5 kg (10 lbs) with standard accessories.

Torque Range:

- 0.44 – 2.64 Newton-Metres (3.9 – 23.5 Inch-Pounds)
- Adjustable in 8 discrete resistance settings.
- Each FEPSim is tested at the factory and includes a certificate of calibration specific to that unit. Typical values are shown below:



Operating Temperature Range:



Counter Battery Life:

The battery for the counter is expected to last 5 to 8 years. If the numbers on the counter screen no longer display, a new battery is needed. The battery cannot be replaced by the user. Contact technical support as described in Section 9.

8.2 List of Symbols (ISO 15223-1 Symbols)

The following symbols are used in this manual, on the product packaging, and the labels to help you recognise important information quickly.

	Manufacturer	Name and address given next to symbol.
	Model Number	If support asks you for the model number, look for it next to this symbol on the bottom of the FEPSim.
	Serial Number	If support asks you for the device serial number, look for it next to this symbol on the bottom of the FEPSim.
	Fragile, Handle with Care	FEPSim is not designed to withstand being dropped or hit with solid objects.
	Keep Dry	Do not immerse FEPSim in any liquid, and surface clean only.
	Temperature Limit	Lower and upper temperature limits written on either side of this symbol.
	Consult Instructions for Use	Refer to instructions for important information before use.
	Caution	Follow this advice to avoid injury and/or damage to equipment.

NOTES

USER MANUAL

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