



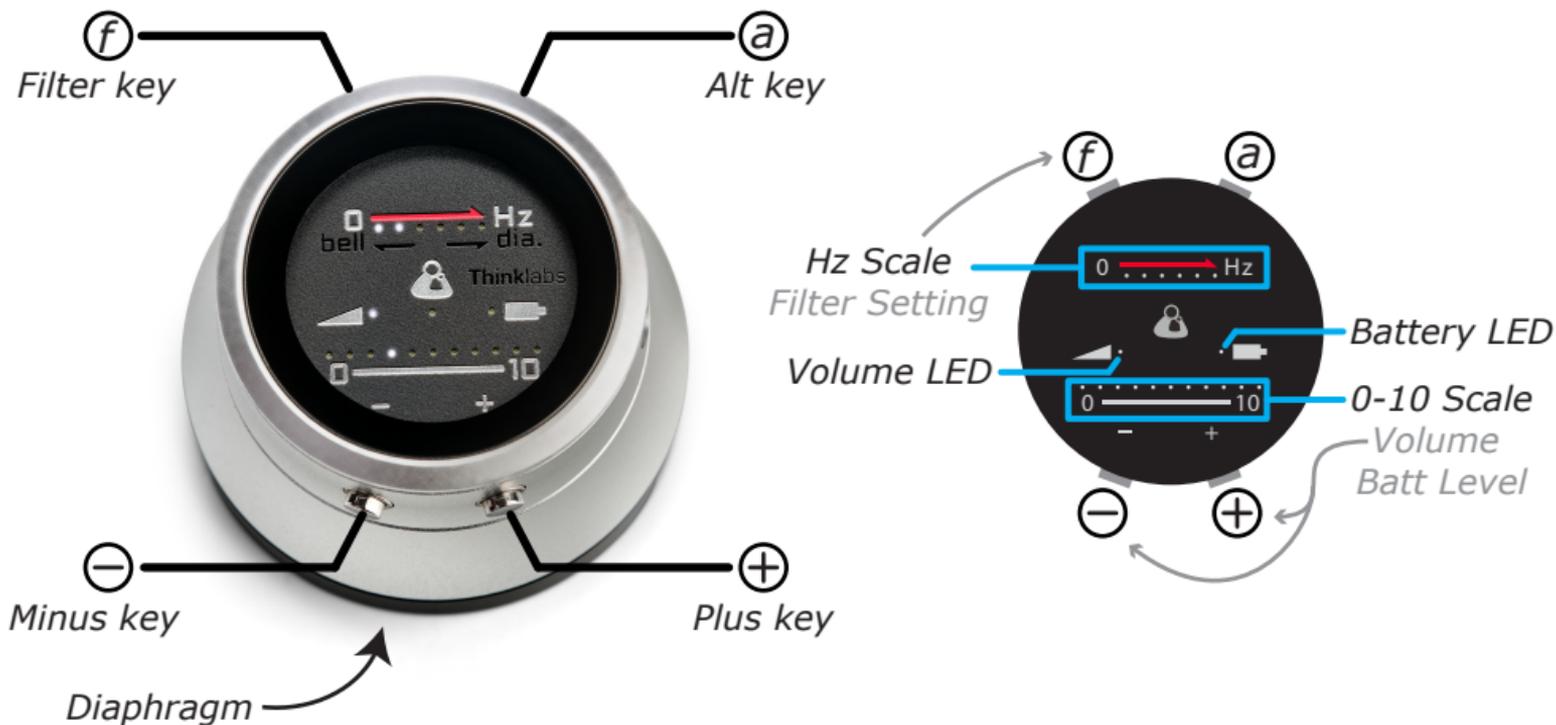
Thinklabs One
Digital Stethoscopes

User Manual

Congratulations. You now own a state-of-the-art auscultation instrument made with advanced technology and fine materials. Thinklabs One is designed for the most discerning users who seek the highest quality.

This manual provides instructions for use of your Thinklabs One. The best designed products are easy to use, with advanced features hidden below the surface and available to those who require them. Use this Manual to familiarize yourself with the functions.

Controls and Display



Functional Description

The Thinklabs One digital stethoscope provides amplification of heart, lung, and other body sounds. Housed in a chassis the size of the chestpiece of a conventional stethoscope, the One is used in the same way, and for the same purpose, as a conventional stethoscope - for listening to body sounds. The device provides amplification, which can be adjusted by a volume control; and multiple filters are provided for listening to lower- or higher-frequency sounds. Controls are pushbuttons on the circumference of the device. A display shows the volume and filter settings. The user listens to sound via external headphones, which connect via a standard 3.5mm audio jack on the device. Power is provided by an internal rechargeable Lithium Ion button cell.

Service and Warranty

For any problems with this product, please contact Thinklabs directly, regardless of where you purchased the product. We can provide personal, expert support to ensure complete satisfaction with your stethoscope, answer any questions, and resolve any problems you might encounter.

This product is warrantied against manufacturing or materials defects for a period of one year from the invoice date. If a material or manufacturing defect occurs within the warranty period, repairs will be performed free of charge upon returning the device to Thinklabs. The warranty does not cover abuse, excessive or inappropriate use conditions, or accidental damage to the product. The warranty is transferable at Thinklabs' discretion only. Thinklabs may, at its sole discretion, extend the warranty.

Indications for Use - The Thinklabs One Digital Stethoscope is intended for use as an aid in patient diagnosis. It can be used for the amplification of heart, lung, and other body sounds with selective frequency filtering. This product is not designed, sold, or intended for any use except as indicated.

User Profile - The Thinklabs One is designed to be used by medical and allied professionals, by students enrolled in professional training programs, or by patients*. Operation of the device requires no special training beyond the user following the instructions for use. Accurate diagnosis with a stethoscope requires the skills of a medical professional. Patients must consult with a medical professional for medical diagnosis.

* **USA Only** - United States law restricts this device to sale or use by, or on the order of, a physician.

EMC Compliance - USA, Europe and other applicable territories - This equipment complies with EMC requirements of the IEC 60601-1-2.



Caution - this is important to read!

NOTICE - Thinklabs One is intended as an adjunct in patient assessment. It must be used in conjunction with multiple clinical signs and symptoms. If sound clarity is compromised for any reason, refer to maintenance instructions and cease using device until problem is addressed.

Diagnosis The diagnosis of stethoscope sounds is a professional skill. Do not attempt to perform diagnosis without professional training or without the advice and consultation of a medical professional.

Read Instructions To reduce the risk of incorrect use, follow directions for use. Misuse of this product could result in damage to the product, malfunction of the product, or compromise performance.

Battery Safety - Heat To avoid the risk of battery explosion due to high temperature exposure, do not, ever, expose the device to temperatures above 100°C. Do not leave in a hot vehicle in summer!

Battery Charging • To reduce the risk of power loss during of use of the device, charge the battery. The One will not function if battery voltage is depleted. • To reduce the risk of electric shock to a patient, do not charge the device while it is in contact with patients. • Do not use in multiple socket outlets.

Repair & Battery Replacement • To reduce the risk of equipment malfunction, do not attempt to modify or repair this device yourself. If you experience problems, send this device to Thinklabs for repair. • Battery is not user-replaceable. Return to Thinklabs for battery replacement.

Battery Safety - Charger To reduce the risk of electrical faults or battery overheating/fire/explosion, use only the Charger provided. The One has been tested for safety with the provided charger. There is a small but finite probability that other chargers could damage the battery or cause heat, fire or explosion.

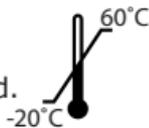


Caution - continued!

Cleaning and Sterilization • To reduce the risk of infection being carried by the stethoscope, clean the stethoscope between patients. Clean using alcohol swabs or non-abrasive cloth dampened with alcohol or water. • To reduce the risk of damage to the product, do not sterilize this device or immerse it in liquids. • Do not service or clean the device while in use.



Storage Conditions To reduce risk of compromise to device performance, avoid use/storage in high temperature or dusty conditions. • Leaving device in excessively hot/cold vehicles is not recommended.



Use Environment - Electrical Interference To reduce the risk of audible or functional electrical interference, use the device within the electrical environmental conditions specified in this document. The Thinklabs One has been tested to be resistant to electromagnetic interference (EMI & ESD). However, it may be susceptible to stray electromagnetic fields. If unexpected sounds are heard, change location, or move away from possible sources of interference, such as cellular telephones or wireless devices. Use of cables and accessories not provided herein may result in increased emissions or reduced immunity.

Use Environment - Medical Equipment Systems • To meet IEC 60601-1, connect to equipment that is IEC 60601-1 compliant in the patient environment. • Do not ever connect to equipment that does not comply with IEC 60950-1.

Use Environment - Oxygen Device is not intended for use in an oxygen-rich environment.

Mechanical Damage To reduce the risk of mechanical damage to the device, do not drop the device on a concrete floor.



Disposal To reduce the risk of environmental contamination, dispose or recycle in accordance with local regulations at the conclusion of this device's useful life.

Symbols - See last pages of these instructions for explanation of symbols.

Tips for Optimal Use

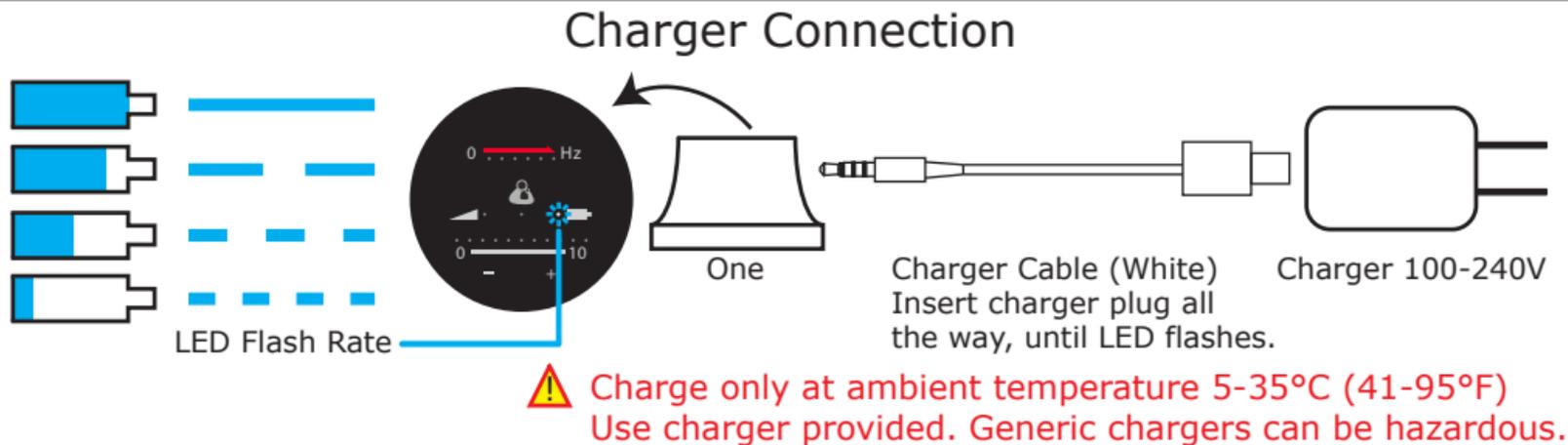
Sound Levels - Protect your hearing! Do not set your stethoscope volume louder than necessary. Adjust volume so that heart and lung sounds are clear and comfortable to hear.

Diaphragm Pressure and Skin Contact - Making skin contact will provide you with the best sound quality. If you do listen through clothing, avoid listening through thick garments.

Headphones - Use Thinklabs headphones or brands/models with powerful bass.

Headphone Fit - Make sure your headphones make a good seal against outside noise to enhance your listening. If other brand headphone plugs are too wide to fit, use the Headphone Adapter. Always insert plug all the way to ensure proper connection.

Cleaning - Use alcohol/other clinical cleaning agents but do not allow liquids inside **One**.



1. Power On / Off



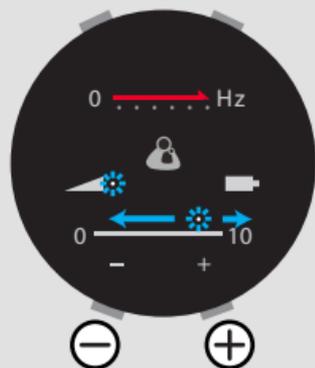
Power On - Hold ANY key until power turns on.

Power Off - Push and Hold (a) and ⊖ simultaneously for two seconds, then release.

Auto Shutoff - Your **One** will shut off automatically after preset auto shutoff time.
(To change shutoff time, see step 5. Factory default = 2 min.)

Battery Level flashes during Power Off. 0=low, 9-10 full.

2. Volume Control & Display

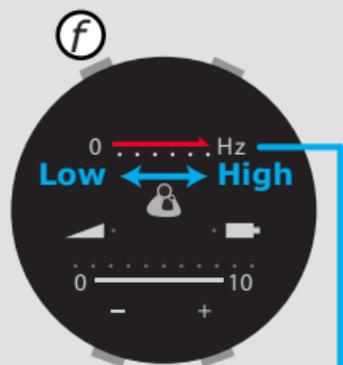


Click ⊖ or ⊕ to adjust Volume Level.
Hold keys to step quickly up or down.

⚠ Protect your hearing! To reduce risk of tinnitus or hearing loss, listen at moderate volume levels.

3. Filter Selection and Display

i See "About the Audio Filters in your One" later in these instructions, for an explanation of filters.

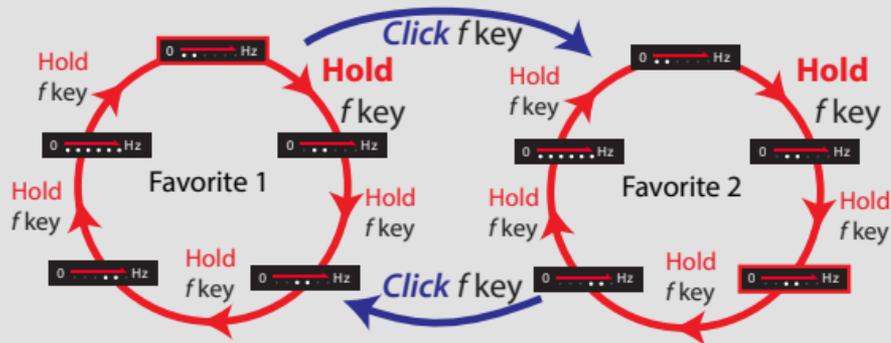


*Hz Scale
shows pitch range
of filter selection*

- Select Filter** - a. **Hold** **f** key for ~2 seconds.
b. Release key when LEDs change.
c. Repeat to cycle through filter choices.

Set two "Favorite Filters" - set two favorite filters, then alternate easily between the two selections:

1. Select 1st Favorite - steps a through c above.
2. **Click** (do not hold) **f** key.
3. Select 2nd Favorite - steps a through c again.
4. Click (do not hold) **f** key to alternate between Favorites.
5. To use any other filter, simply do steps a through c anytime and the Favorite you're currently using will be changed.



NOTE: The filters on your One might be different from the diagram shown here.

4. Checking Battery Level



To check Battery Level:

1. Push any key to Power On.
2. Push and Hold (a) and (-) simultaneously for two seconds.
3. Battery Level flashes across 0-10 Scale before **One** powers off.
The further to the right the LEDs light up, the higher the charge.

(i) Typical battery life in use ~ 240 minutes active listening.
Standby/Power Off time > 4 weeks.

5. Setting Auto Shutoff Time

Start with **One** in the Power Off condition.

1. Turn Power On by firmly clicking any key.
2. Click (a) key once for each minute of the desired auto shutoff time.
For example, click (a) key 3 times for a 3 minute shutoff time.
3. Push and HOLD (a) key until One shuts off (~15 seconds).

- (i) • Factory Default = 2 minute auto shutoff time.
• Allowable range is one to ten minutes (1 - 10 clicks).
• To DISABLE Auto Shutoff (unit stays on), do 12 Clicks in step 2 above.

About the Audio Filters in your **One**

Filters selectively amplify low, medium or high-pitched sounds, to select for low-pitched heart sounds, mid-range murmurs or high-pitched lung sounds. **One** has multiple filters for greater control over sound than stethoscopes that limit the choice to Bell or Diaphragm.

Pitch (i.e. frequency) is measured in Hertz (Hz) and displayed graphically on a low-to-high Hz Scale, which shows relative frequency range - filters that amplify low-pitched sounds show LEDs towards the left, filters for higher pitched sounds show LEDs toward the right.

The following filters are provided in your Thinklabs One. Factory default favorites are set to Filter 1 and Filter 3. *(Note that the filters on your One might be different from the list provided here.)*



1. 30Hz - 500Hz. Produces strong low frequencies for heart sounds, especially S3. Bass may be challenging for some third-party headphones and other external devices. An intense version of a Bell mode.



2. 60Hz - 500Hz. Good for heart sounds, especially if Filter 1 bass is too intense for your tastes. Similar to Bell mode.



3. 80Hz - 500Hz. Good for lung sounds, heart valve clicks, S2 splits. Removes lower heart sound frequencies. Similar to Diaphragm mode.



4. 100Hz - 1000Hz. Good for lung sounds. Filters out lower frequencies and vibrations. Provides more high frequencies for lung sounds than Filter 3, but this will also increase ambient sound slightly.



5. 20Hz - 2000Hz +/-3dB. Wideband mode, very sensitive. Intended for capturing professional research/academic recordings. Also great for listening if you can handle the sensitivity or you tend to listen at lower volumes.



Maintenance - Diaphragm Cleaning and Replacement

It is important to keep your One stethoscope clean and dust-free - good practice for health reasons anyway. Read below, and see [Cleaning Inside your Stethoscope](#) on the next page.

Cleaning Outside - Wipe any external part of your Thinklabs One Digital Stethoscope with alcohol wipes. The diaphragm can be cleaned with other cleaning agents, but avoid allowing liquids to leak into the stethoscope.

Removing and Cleaning - You can also unscrew the diaphragm ring to clean inside the stethoscope. Turn power off before removing the diaphragm ring. Unscrew the diaphragm ring (counter-clockwise when looking at the diaphragm). You can clean both sides of the diaphragm with alcohol. Make sure that no oil or other residue remain inside of the diaphragm. It's important that the inside surface be clean and free of any surface grease or other chemicals to operate well.

Attaching the Diaphragm - **VERY IMPORTANT** - When you replace the diaphragm and screw on the diaphragm ring (clockwise), make absolutely sure that the ring is straight. It's a good idea to turn it **COUNTER**-clockwise until you feel it align, and then **GENTLY** screw it clockwise. If it feels like it's not screwing on cleanly, start again. The reason is that the thread is intentionally quite soft to keep the ring on, and can be easily damaged. Once the ring is aligned, screw until the diaphragm is in place and doesn't rotate freely, but **DO NOT OVERTIGHTEN** - firm, not tight!

Maintenance - Cleaning Inside Your Stethoscope

There is generally no reason to open your Thinklabs One Digital Stethoscope. However, if the situation arises that you'd like to clean inside, this is how you do it. You might also want to perform these steps if your One stethoscope is producing strange noises, which may be caused by lint or dirt inside your stethoscope.

1. Turn off your Thinklabs One stethoscope (Push and hold "-" and ALT keys together for a few seconds, then release).
2. Unscrew the Diaphragm and clean both the ring and the diaphragm (see previous page).
3. Using a dry air spray, available from office supply stores and hardware stores, spray around the blue circuit that you see when you've removed the diaphragm. Use the straw that's supplied with the spray can. Do it well, but don't overdo it.
4. Allow the open stethoscope to dry out for a couple of minutes or more if you're in a humid environment.
5. Replace the diaphragm (see instructions previous page). READ THEM - they're important!
6. Turn on your stethoscope and check the sound quality. If you're hearing strange sounds, give it a few minutes to dry out more, especially in humid environments, then try again.
7. If repeated cleaning does not correct any noise problems, contact us. If your One stethoscope sounds good, you've probably cleaned your stethoscope successfully.

NOTE:

- A. DO NOT use liquids to clean inside the One stethoscope.
- B. If liquids/dirt entered other areas of your stethoscope, such as via the headphone jack, contact us before dismantling!!! <http://support.thinklabs.com>

Guidance and manufacturer's declaration – electromagnetic immunity

The One is intended for use in the electromagnetic environment specified below. The customer or the user of the One should assure that it is used in such an electromagnetic environment.

IMMUNITY test	IEC 60601 TEST LEVEL	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the One, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d = 1,2\sqrt{P}$ $d = 1,2\sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$ $d = 2,3\sqrt{P} \quad 800 \text{ MHz to } 2,5 \text{ GHz}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	

where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey (Note a), should be less than the compliance level in each frequency range. (Note b). Interference may occur in the vicinity of equipment marked with the following symbol:



NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Note a) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which One is used exceeds the applicable RF compliance level above, the One should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary such as re-orienting or relocating the One.

Note b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Separation Distances

Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the Thinklabs One

The Thinklabs One is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the One can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) the One as recommended below, according to the maximum output power of the communications equipment.

Rated Maximum output power of transmitter, P [W]	Separation distance according to frequency of transmitters, d [m]		
	150KHz to 80 MHz $d = 1.2 \cdot \sqrt{P}$	80 MHz to 800 MHz $d = 1.2 \cdot \sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3 \cdot \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Guidance and manufacturer's declaration - electromagnetic immunity

The One is intended for use in the electromagnetic environment specified below. The customer or the user of the One should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance	
			Electromagnetic environment - guidance	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	+/- 6 kV contact +/- 8 kV air	+/- 6 kV contact +/- 8 kV air	Floors should be wood, concrete or Ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.	Floors should be wood, concrete or Ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	2 kV for power supply lines, 1 kV for input/output lines.	2 kV for power supply lines, 1 kV for input/output lines.	Mains power quality should be that of a typical commercial or hospital environment.	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	1 kV line(s) to line(s) 2 kV line(s) to earth	1 kV line(s) to line(s) 2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.	Mains power quality should be that of a typical commercial or hospital environment.
Interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % UT (>95 % dip in UT) for 0.5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 5 sec	<5 % UT (>95 % dip in UT) for 0.5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the monitor requires continued operation during power mains interruptions, it is recommended that the monitor be powered from an uninterruptible power supply or a battery.	Mains power quality should be that of a typical commercial or hospital environment. If the user of the monitor requires continued operation during power mains interruptions, it is recommended that the monitor be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Mains power electromagnetic compatibility applies to charger, which meets applicable IEC 61000 requirements.

Explanation of Safety Related Labels and Symbols

 Indicates Type B Equipment: The equipment provides protection against electrical shock and electrical current leakage. Applied parts are considered to be the diaphragm and surrounding diaphragm ring.

 This product contains electrical and electronic components and must not be disposed of using standard refuse collection. Please consult local directives for disposal of electrical and electronic equipment.

 Consult instructions for use.

IP2X Protected against solid foreign objects 12.5mm or greater, not protected from ingress of water.

 Indicates a hazardous situation which could result in minor injury and/or property damage.

 Temperature limits.

 Keep dry.

 Fragile, handle with care.

Electromagnetic Emissions

Guidance and manufacturer's declaration – electromagnetic emissions

The One is intended for use in the electromagnetic environment specified below. The customer or the user of the One should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The One 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.
RF emissions CISPR 11	Class B	The One is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

For further Information, Support & Warranty

Support <http://support.thinklabs.com>
support@thinklabs.com

Warranty 1 Year Limited Warranty
<http://thinklabs.com/warranty>



Thinklabs Medical LLC
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support@thinklabs.com

Package Contents:

Thinklabs One Digital Stethoscope
Thinklabs In Ear studio quality headphones
Spare Eartips (Small, Medium, Large pairs provided)
USB Style Battery Charger (100-240V worldwide use)
Charger Cable (white)
Carrying Case
User Manual (this document)



Attention - read these
instructions for use

Thinklabs One assembled in Colorado by Thinklabs.

REF TL1