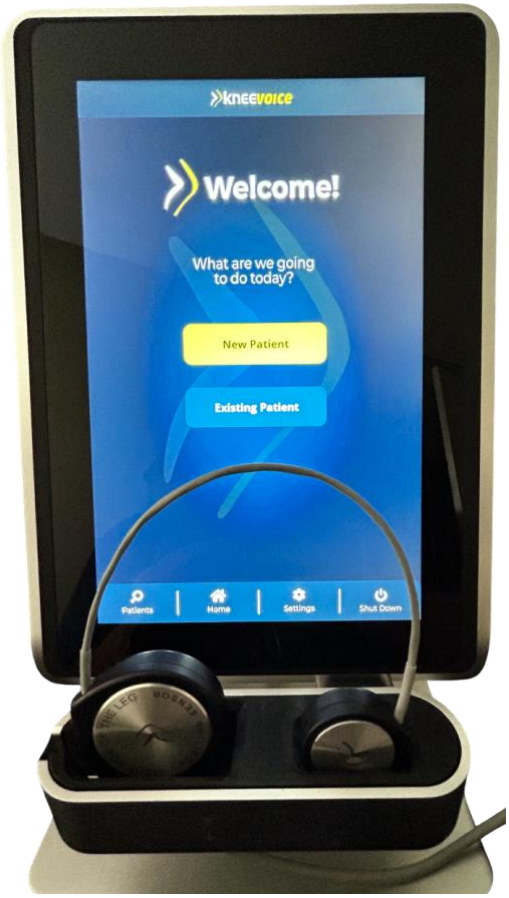
Cartilage Auscultation System

Instructions for Use



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Device Description

The Kneevoice™ Cartilage Auscultation System (CAS) is a system that captures the sounds and vibrations emitted by the articular cartilage during joint motion. It is a non-invasive instrument that reveals the level of cartilage damage based on the characterization of joint sound emissions. The Kneevoice CAS device consists of an audio and position sensor assembly cabled to a digital console. The console consists of an enclosure, power components, a touch screen display, a processor and memory. The console is mounted to a desktop stand. In use, the audio and position sensor assembly is attached to the top of the patient's patella using the disposable self-adhesive patches. The audio sensor listens to the sounds produced by the patellofemoral joint while the patient flexes their knee eight times from a 0 to 90-degree range of motion. The audio and position sensor electronics send the sound and motion data to the console over a cable. The console receives the data stream and performs noise reduction, band-pass filtering and pattern recognition.

Indications for Use

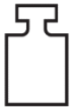
The Kneevoice Cartilage Evaluation System is intended to be used as a part of physical assessment of a patient by healthcare professional for diagnostic decision support in clinical settings. It is intended to be used by a physician as a noninvasive tool to amplify and record distinct sounds (vibrations) within the patellofemoral section of the knee.

Caution: *Federal law restricts this device to sale by or on the order of a physician.*

Contraindications

Contra-indications include knee range of motion less than 30 degrees, clinically evident knee joint swelling, neuromuscular diseases, cognitive impairment, history of dementia, psychiatric disorders and mental disorders.

Symbol Glossary

Symbol	Symbol Title/Description	Symbol	Symbol Title/Description
	Manufacturer		Date of manufacture
	Prescription only (USA)		System mass
	Catalog number		Serial number
	Batch code or lot		Unique device identifier

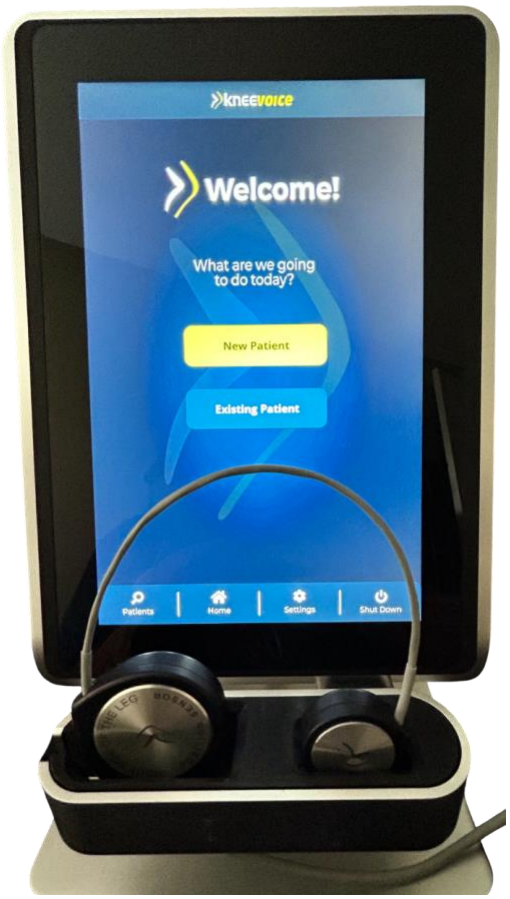
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Symbol	Symbol Title/Description	Symbol	Symbol Title/Description
	Caution or warning to consult accompanying documents to avoid patient or operator hazard		Consult operating instructions for use
	Do not re-use		Dispose of properly
	Type BF Applied Part		Humidity limitation
	Temperature limits		**Warning**
	No pushing		

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Parts List
Kneevoice Cartilage Auscultation System

Part no. 750-3600-001



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Includes:

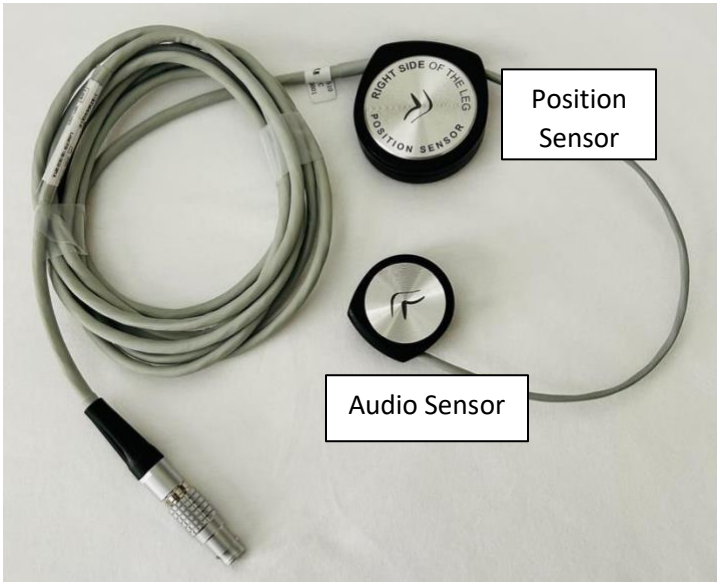
Console

Part no. 700-3601-001



Sensor Cable Assembly

Part no. 700-3602-001



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Console AC Power Supply

Part no. 700-3603-001



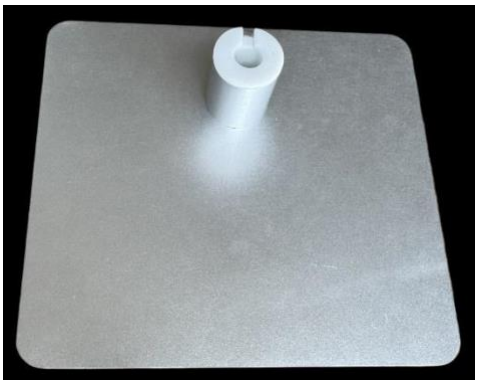
Console Power Cord Cable

Part no. 3906-018-010-HC



Desktop Stand

Part no. 700-3604-001

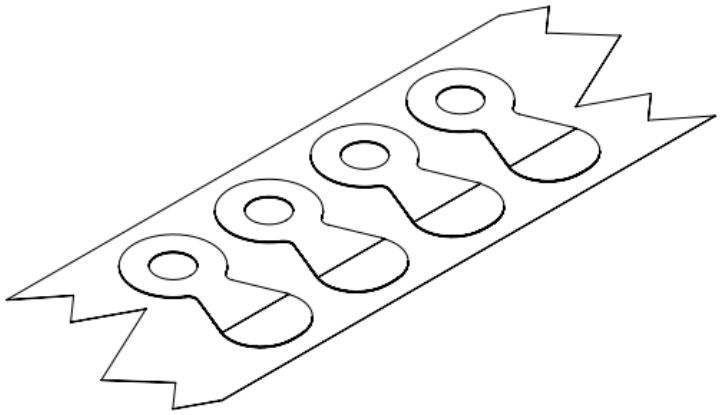


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Adhesive Patches

(Dispenser roll of 200 each)

Part no. 750-3607-001



Assembly Instructions

NOTE: Do not proceed with assembly and use of the device if package and contents are damaged.

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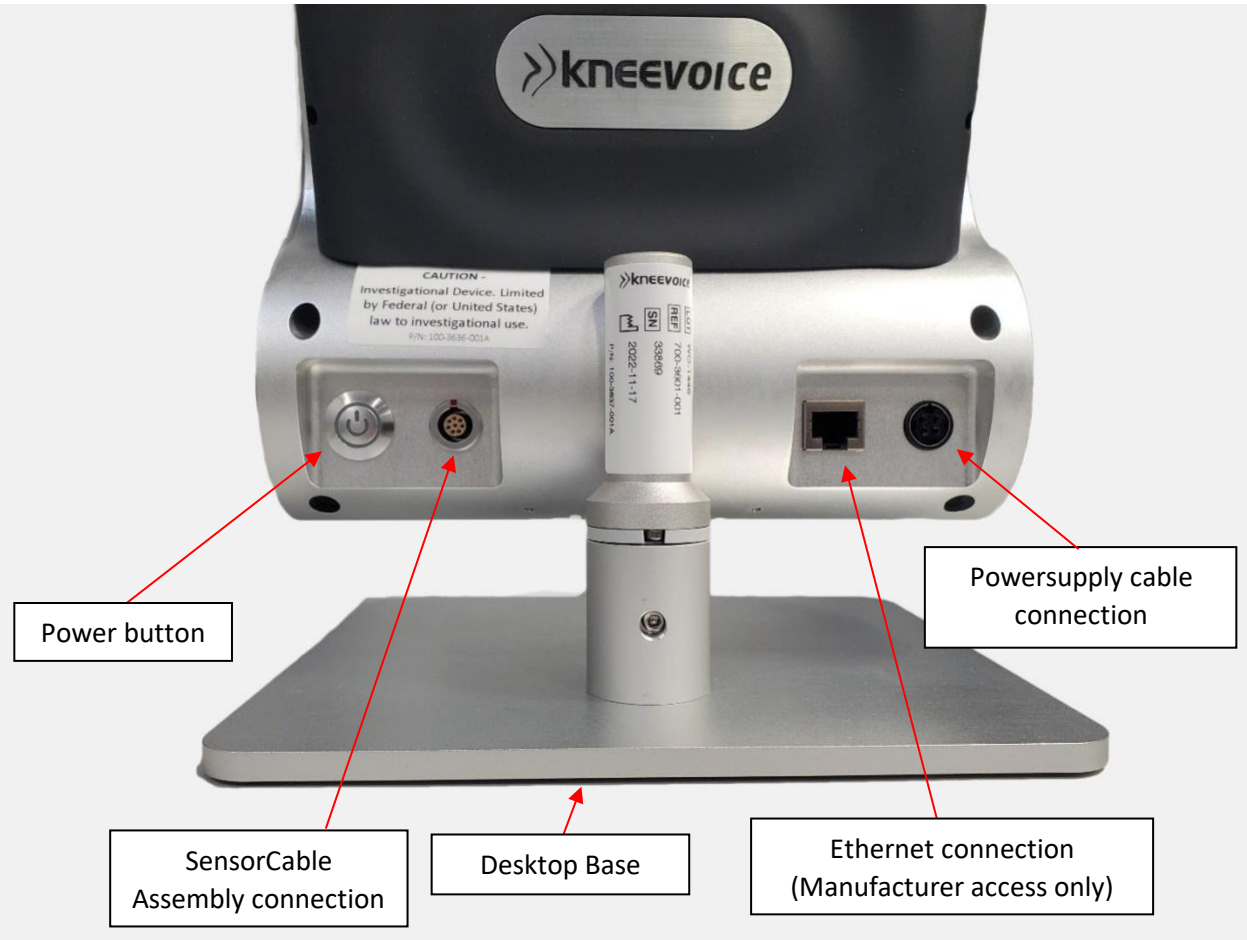


Figure 1

1. Remove console, power supply cable, sensor cable assembly and desktop stand from packaging.

2. Attach console to desktop stand by inserting console mounting post into desktop stand vertical post. See Figure 1

    a. Indexing pin provided to lock console into position.



3. Attach power supply cable to console. (See Figure 1)

4. Attach sensor cable assembly to console. (See Figure 1)

5. Place audio sensor and position sensor into console holding tray.

6. Plug console power supply cable into 110V outlet.

- WARNING: To avoid the risk of electrical shock, this equipment must only be connected to a supplies main (electric supply) with protective earth (grounding).

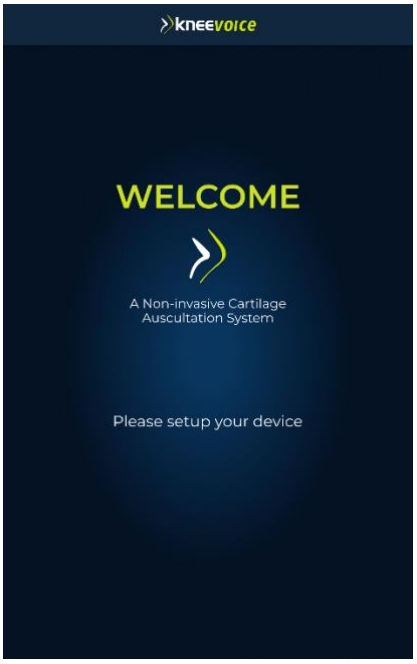
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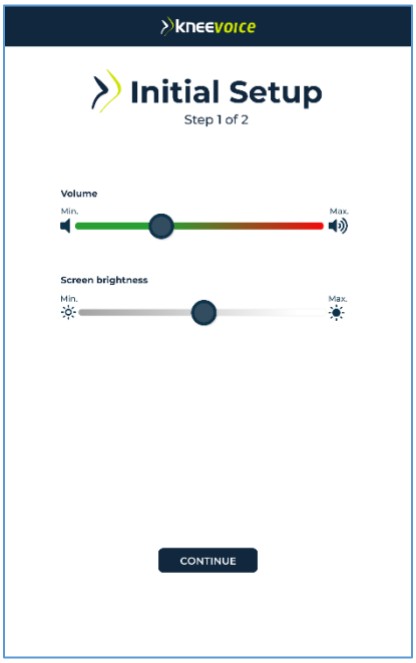
- WARNING: Position equipment where the power cord can be easily disconnected.

Initial Setup Instructions

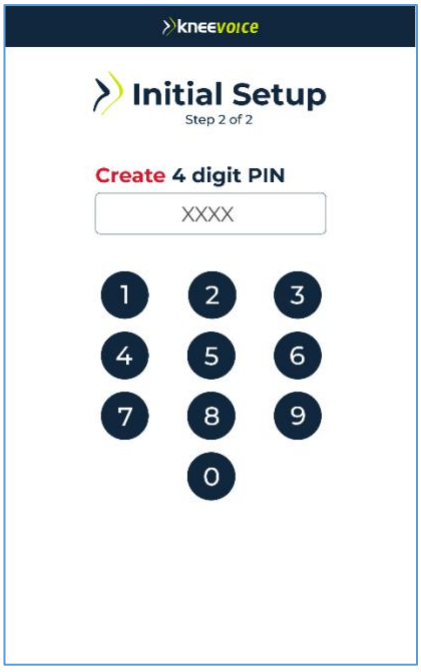
1. Turn on console power.

2. Initiate setup.





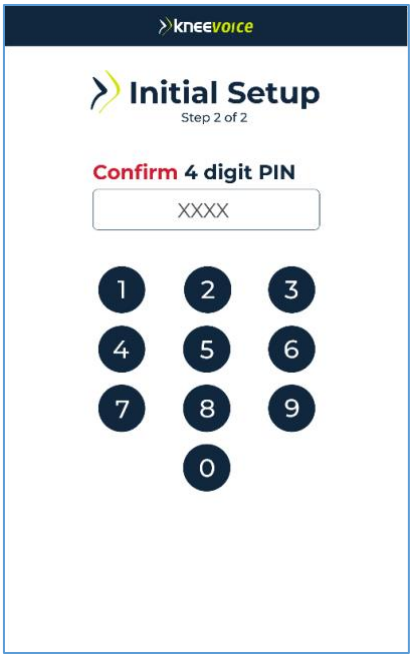
3. Create four-digit PIN.



WARNING: The use of ascending or descending digits (i.e. 1234, 4321) or repeated digits (i.e. 0000) is not allowed.

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4. Confirm four-digit PIN.



Operating Instructions for New Patient

NOTE: The device system is designed for use indoors in a medical clinic examining-room environment with minimal noise exposure, ambient temperature/moisture and standard lighting conditions.

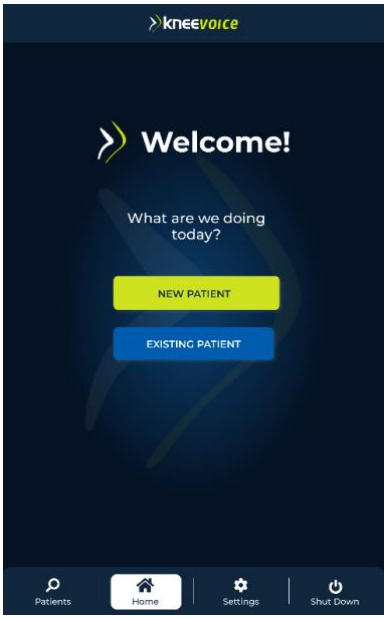
⚠ WARNING: Do not use near MRI.

Avoid electromagnetic disturbances during operation: Do not operate the device in the presence of diathermy, electrocautery, MRI or similar electromagnetic energy-emitting equipment. If such equipment is used in the same environment, temporarily discontinue device use or relocate the device away from the source.

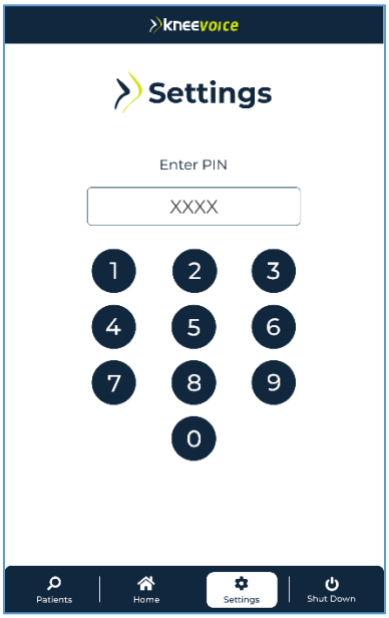
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CAUTION: Do not modify any of the Kneevoice components as this could lead to inaccurate readings.

1. Turn on power to console (See Figure 1) and select “NEW PATIENT”. Default language is English.

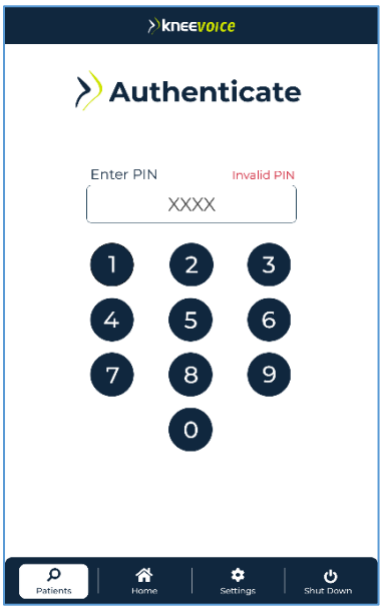


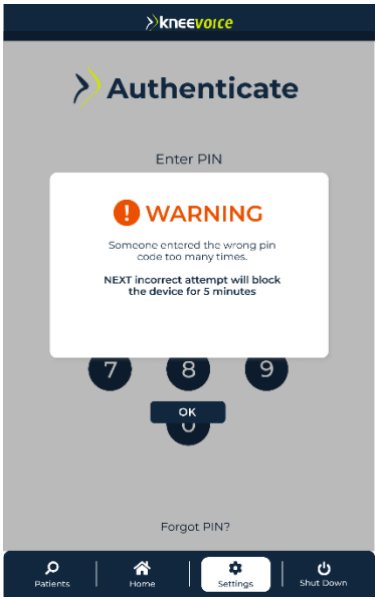
2. Enter four-digit PIN.



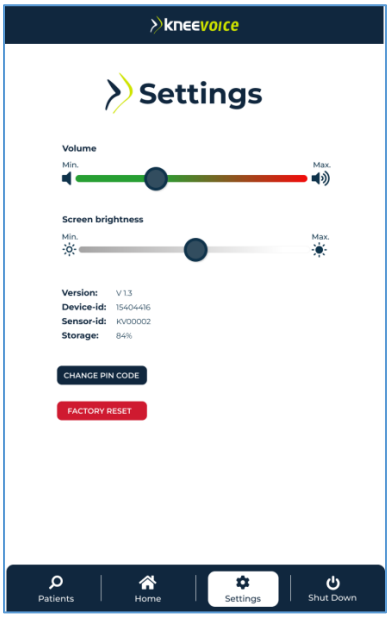
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a. If PIN is entered more than three times, the software will time out for five minutes.





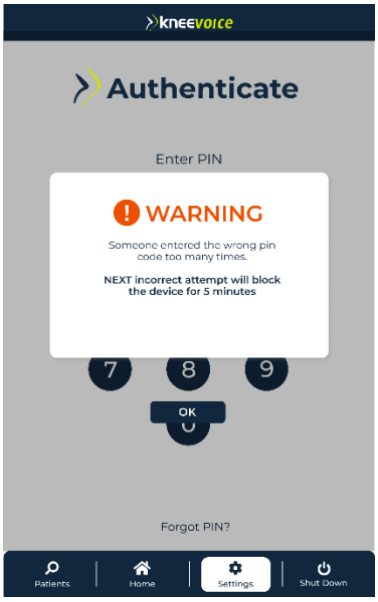
b. PIN can be changed by entering current PIN and selecting Settings.





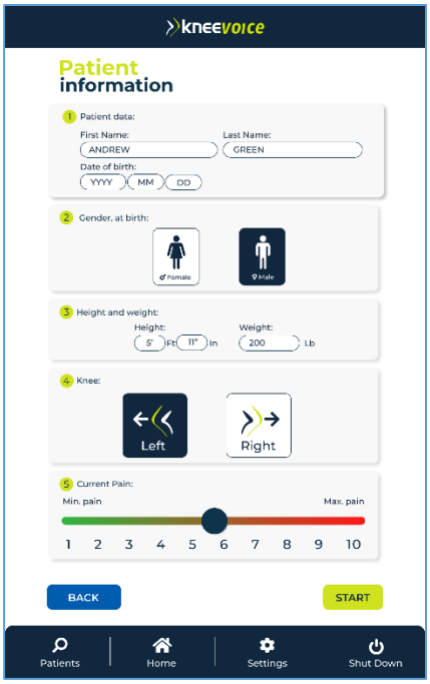
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c. PIN code can be reset by selecting Settings and “Forgot PIN?”.



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3. Input new patient information.



4. Position patient on exam table or high chair in an upright position to be able to fully extend leg.
    a. Note: Patient's foot must not touch the floor in order to unload the joint.

5. Expose patient's leg from the foot up to mid-thigh.

6. Position console for HCP and patient to view touchscreen.

    a. Note: Place console on stable platform and away from patient to prevent injury if console inadvertently pushed off platform.



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7. Prepare audio sensor.
    a. Wipe the audio sensor surface with 70% isopropyl alcohol wipes.
    b. Peel adhesive patch from dispenser strip and attach to the audio sensor as shown.



8. Prepare position sensor.
    a. Wipe all parts of the position sensor back surface with 70% isopropyl alcohol wipes.
    b. Peel adhesive patch from dispenser strip and attach to position sensor as shown.



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9. Attach audio and position sensors.
    a. Wipe patient skin with 70% isopropyl alcohol wipe.
    b. Peel adhesive patch protective liner from the audio sensor and apply to the center of the patella. (See Figure 2)

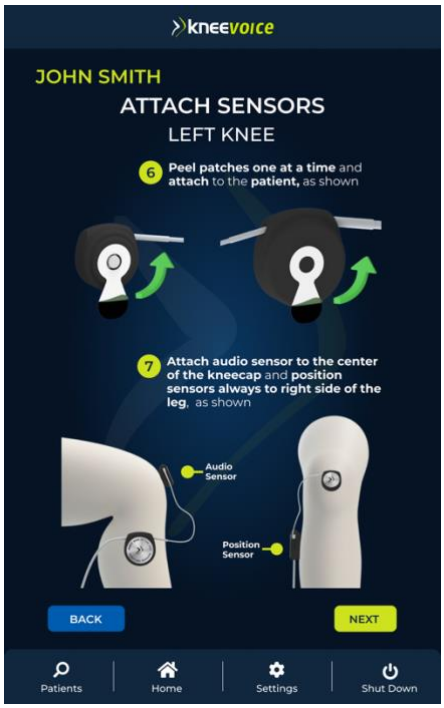
       NOTE: The sensor is sized approximately the same size as the patella and will help center it.

       NOTE: The cable connected to the audio sensor must be on the left side when facing the patient as shown. (See Figure 2)

    c. Peel adhesive patch protective liner from the position sensor and attach to the right side of the patient's tibia below the joint line. (See Figure 2)

       NOTE: The cable between the audio sensor and position sensor should have enough slack to bend the knee at 90 degree flexion and fully extended. (See Figure 2)

       NOTE: The cable leading to the console from the position sensor must be on the left side when facing the patient as shown. (See Figure 2)



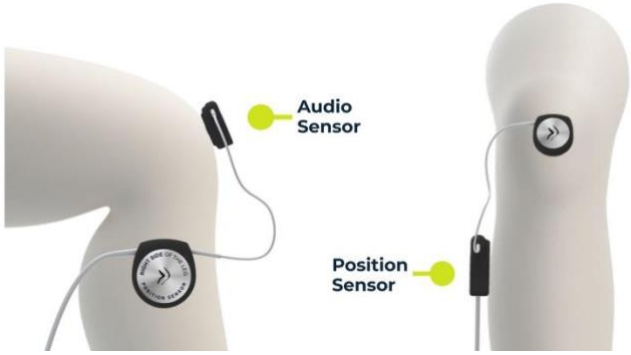


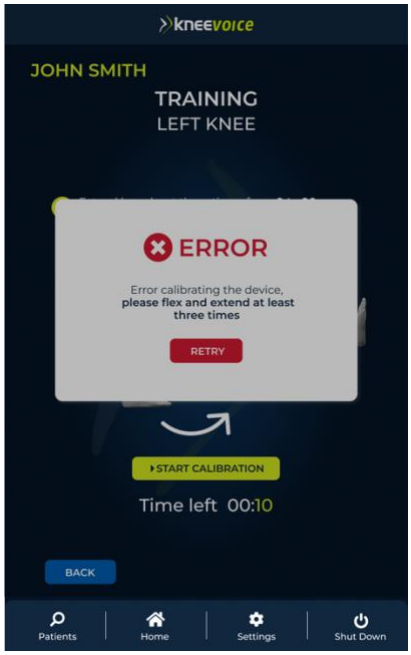
Figure 2

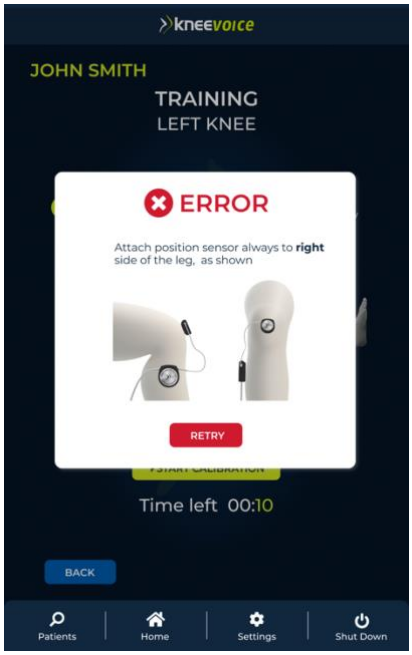
WARNING: The cable from the position sensor to the console should not touch the tibia and not be constrained when connected to the console. This will eliminate any random noise that could be acquired during the recording phase.

⚠ WARNING: To avoid asphyxiation, keep cable away from head and neck area.

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10. Calibrate position sensor by extending leg twice from 0 to 90 degrees within the allotted time.
    a. If calibration not successful, select Retry.







11. Start examination.





Note: Cadence is monitored to help patient complete eight extensions within the allotted time.

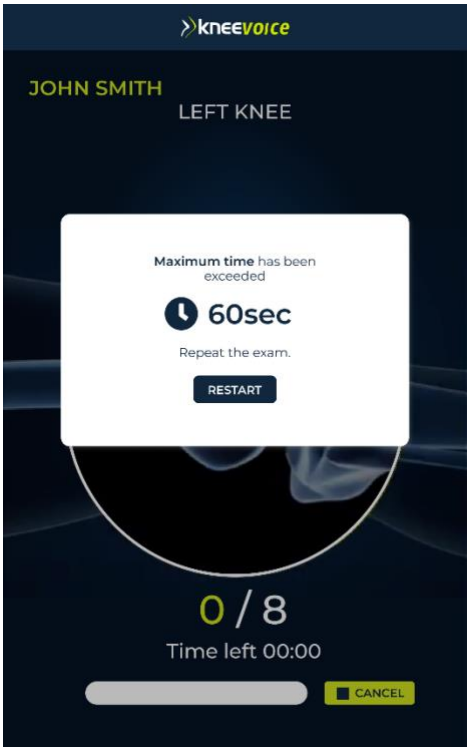
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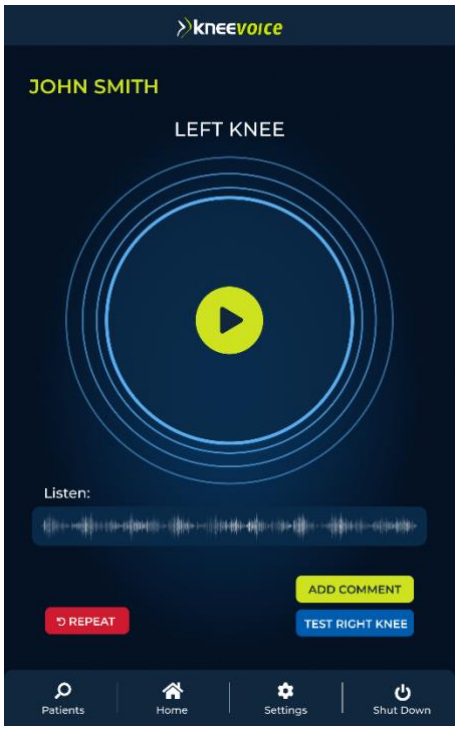
12. If eight leg extensions are not completed within maximum time, exam can be repeated by selecting “RESTART”.



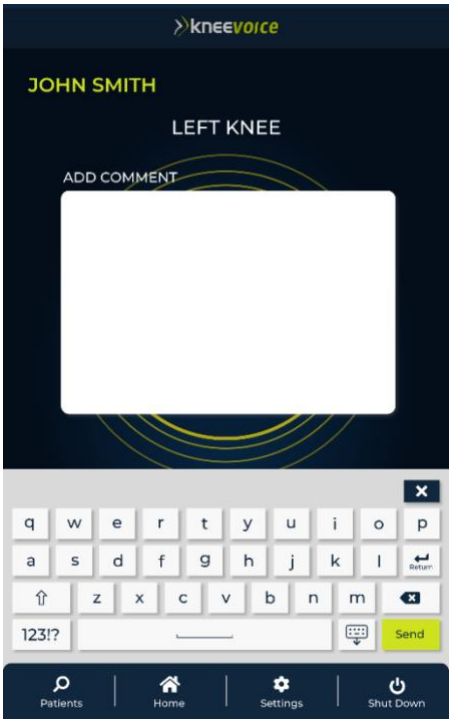
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13. Select recording to review audio results.



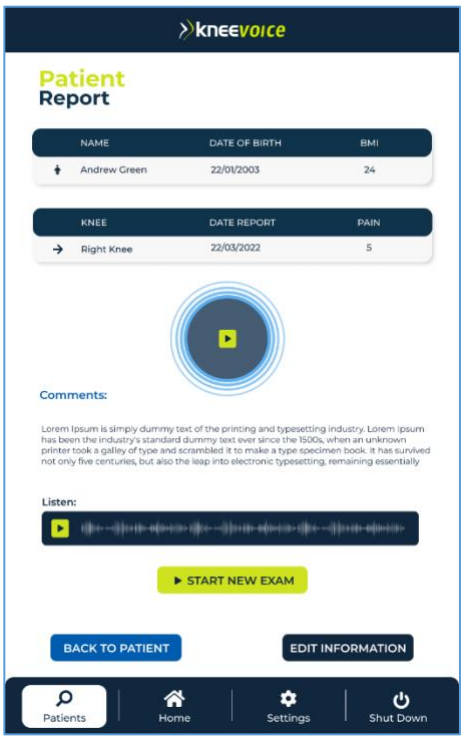


14. Add comments, if desired.

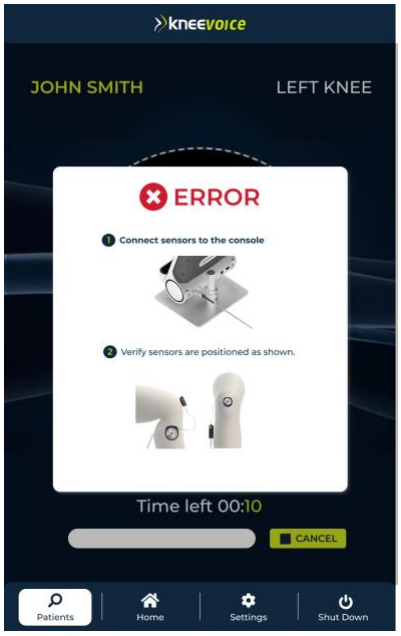


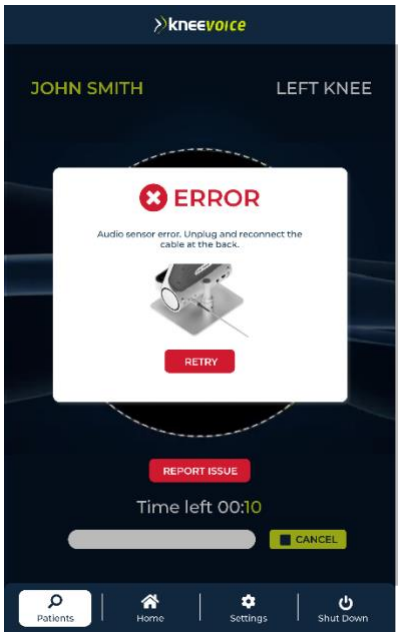
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15. Patient Report can be viewed.



16. If sensors do not function, check connection to the console and verify sensor positions. Select “REPORT ISSUE” if issue not resolved.





17. To conduct exam again, select “REPEAT” and follow step 11.

18. When exam completed, remove each adhesive patch/sensor from patient skin using pull tab.

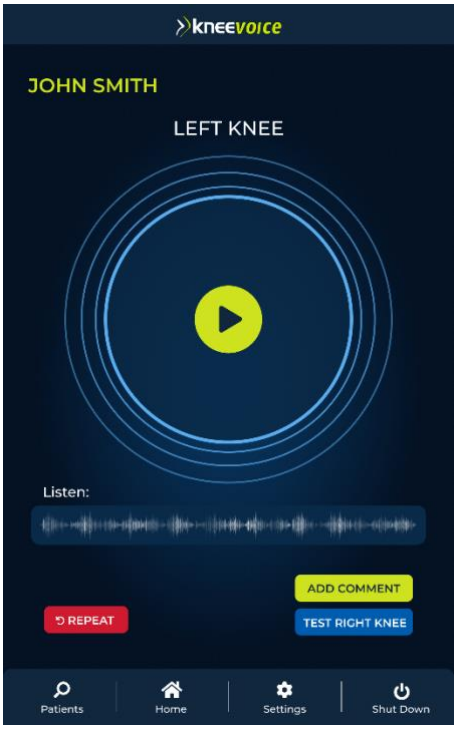
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19. Remove adhesive patch from each sensor using pull tab and dispose as biohazard waste.

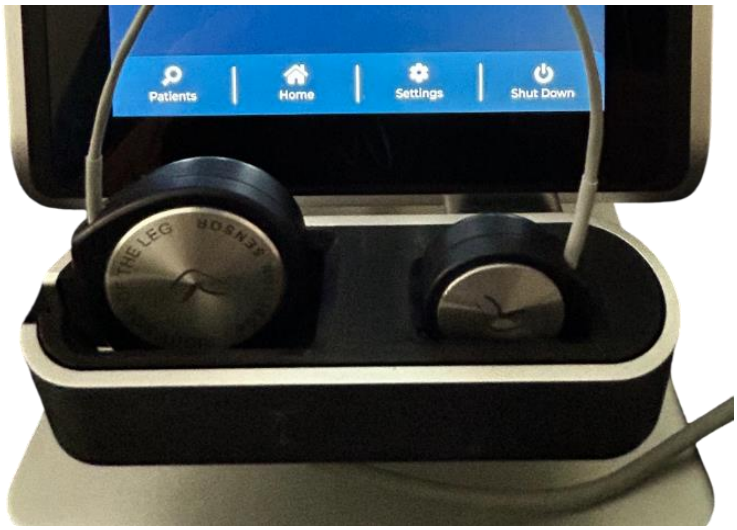
20. Hand wipe sensors, cables and console screen per standard procedures using 70% isopropyl alcohol wipes.

- WARNING: Do not use near liquids or immerse in liquids.

21. To test opposite knee, select “TEST XXXX KNEE” and repeat steps 7 through 21.

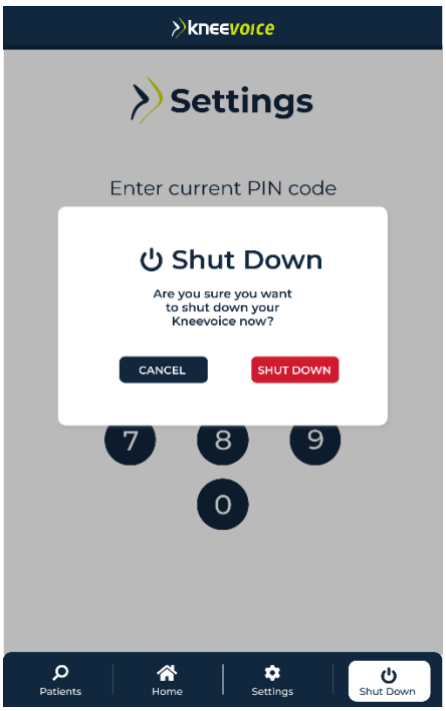


22. After the exam, place the audio sensor and position sensor into the console holding tray.



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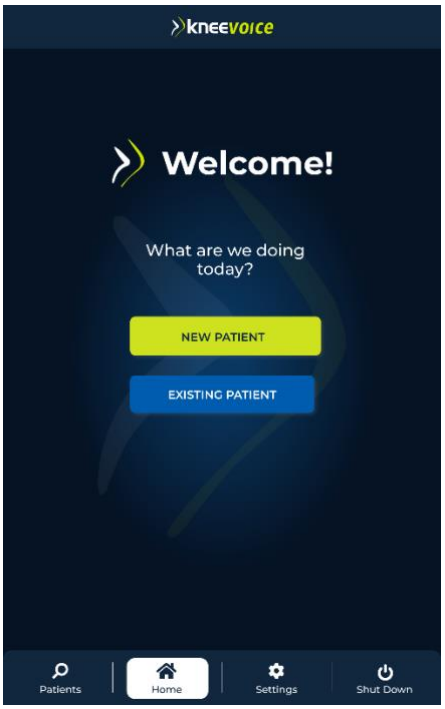
23. Turn off console when not in use. (See Figure 1)





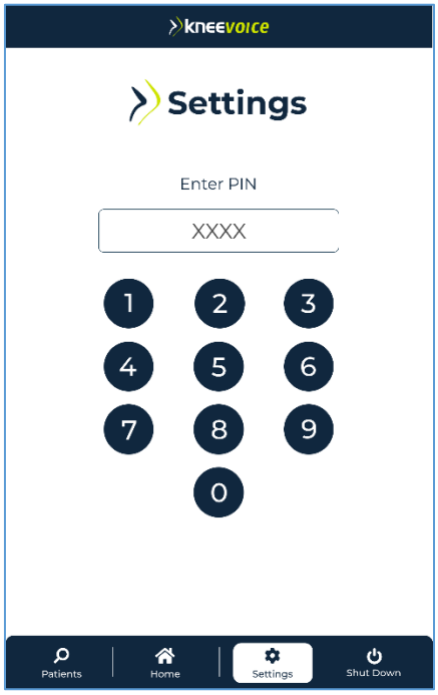
Operating Instructions for Existing Patient

1. Exam can be conducted with existing patient by selecting “EXISTING PATIENT”.

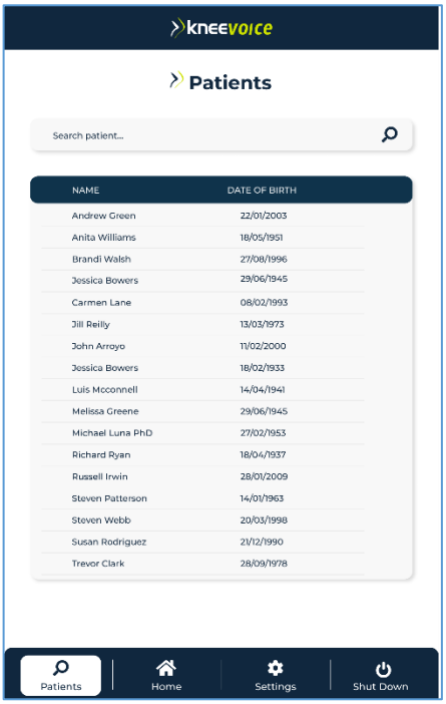


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2. Enter four-digit PIN.



3. Search and select patient name from device listing.



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4. Patient information can be edited before starting exam.



5. Patient History can be reviewed.



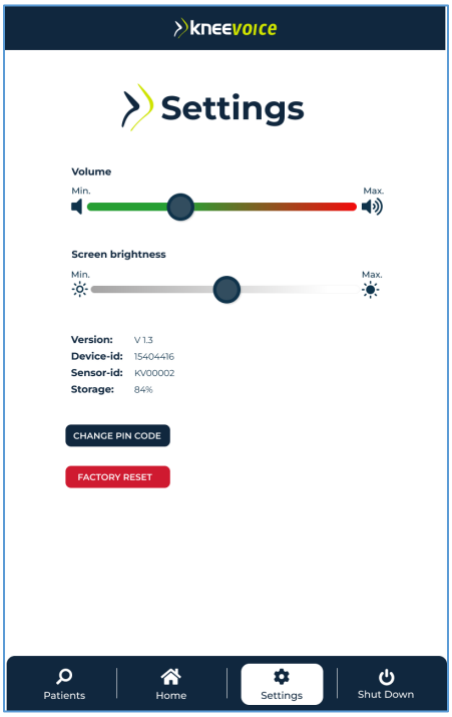
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6. Start exam with existing patient follow steps 4 through 20

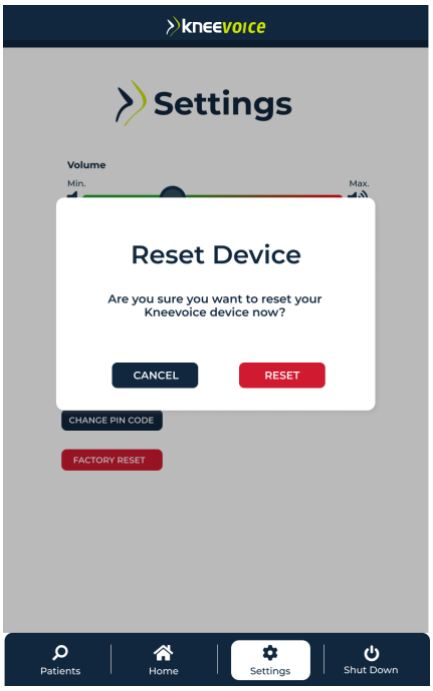
Editing Device Settings

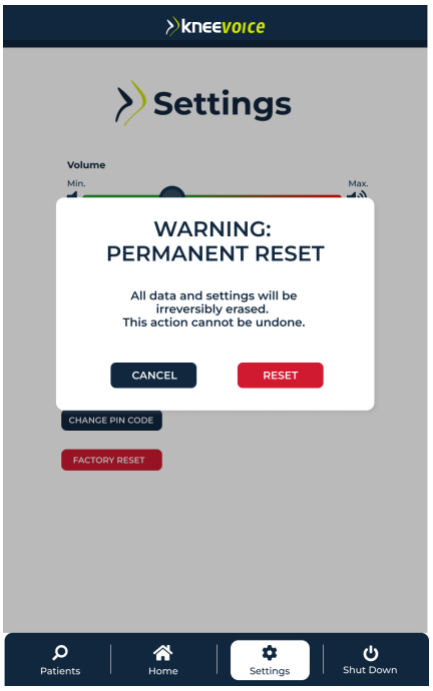
1. Options to edit device settings:

    a. Adjust volume
    b. Adjust brightness
    c. Change PIN CODE



2. Resetting device:





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Cleaning Requirements

Gently wipe sensors, cables and console screen using 70% isopropyl alcohol wipes.

- WARNING: Do not use near liquids or immerse in liquids.
- WARNING: To avoid the risk of electrical shock always unplug this device from mains power before cleaning it.

Service Information

There are no user serviceable parts within the CARTILAGE AUSCULTATION DEVICE. Maintenance is limited to cleaning of the external surfaces of the sensor and console.

- WARNING: No modification or alteration of the KNEEVOICE CARTILAGE AUSCULTATION DEVIC is allowed.
- WARNING: Do not interconnect this equipment with other equipment not listed in this Instructions for Use.
- WARNING: Do not use accessories, detachable parts or material not listed in this Instructions for Use.
- WARNING: Any unauthorized changes to the Cartilage Auscultation Device may result in harm to patients, users, or other persons.

Specifications

Environmental Specifications

Parameter	Specification
Electrical Input	100 to 240 VAC, 50/60Hz
Operating Temperature	10 to 30 °C (50 to 86°F)
Storage/Transportation Temperature	0 to 40 °C (32 to 104°F)
Operating Humidity	Up to 95% RH, non-condensing
Storage Humidity	Up to 95% RH, non-condensing
Operating Altitude	Sea level to 6600 Ft
Storage Altitude	Sea level to 14,000 Ft
Shock/Vibration	Passes ISTA 3A

- WARNING: Condensation may cause electrical damage to the KNEEVOICE CARTILAGE AUSCULTATION DEVICE. Do not use the system immediately after it has been brought indoors from extreme outside temperatures. Allow the system to stabilize at room temperature before use.

Disposal

The adhesive patches can be disposed of in ordinary waste. The remaining components may be classified as waste electrical or electronic equipment.

NOTE: This device contains items which may be classified as waste electrical or electronic equipment. Please dispose of the equipment according to local requirements.

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This symbol indicates that the product must be disposed of separately and safely. Therefore, it is your responsibility to dispose of this waste equipment by handing it over to a designated collection point or organization that specializes in recycle of waste electrical or electronic equipment. For more information about where waste equipment can be dropped off for recycling, please contact your local recycling office or electronic waste hauler.

Equipment Classifications

Parameter	Specification
Type of Protection Against Electrical Shock	Class I
Degree of Protection Against Electrical Shock	Type BF
Degree of Protection Against Water Ingress	Ordinary
Mode of Operation	Continuous
Electromagnetic Compatibility	Class A

Physical Specifications

Parameter	Specification
Height	13.5”
Width	7.8”
Depth	7”
Approximate Weight	5.6 kg

Technical Specifications

Parameter	Specification
Display Size	Console touchscreen 10.1 inch
Pixels	1280 x 800
Brightness	400 cd/m²
Hardware	Console: Proprietary processing platform, case data storage capacity - >48 GB; Sensor Cable: Proprietary audio sensor and accelerometer.

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Electronic Compatibility (EMC) User Information

- WARNING: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

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

- WARNING: Portable radio-frequency communications equipment (including peripherals such as antenna cables and external antennas) should be used at least 1 m (39 inches) away from any part of the Kneevoice Cartilage Auscultation System (CAS) including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

- WARNING: The emissions characteristics of the equipment make is suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required), this equipment might not offer adequate protection to radiofrequency communications services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

NOTE: The EMC tables and other guidelines that are included in the Instructions for Use manual provide information that is essential in determining the suitability of the equipment or system for the electromagnetic environment of use. It also provides information in managing the electromagnetic environment of use to permit the equipment or system to perform its intended use without disturbing other equipment and systems or non-medical electrical equipment.

Table 1. Guidance - Electromagnetic Emissions

<table>
<tr><th colspan="3">Guidance and manufacturer's declaration - Electromagnetic Emissions</th></tr>
<tr><td colspan="3">Kneevoice CAS is intended for use in the electromagnetic environment specified below. The user of Kneevoice CAS should assure that it is used in such an environment.</td></tr>
<tr><th>Emissions Test</th><th>Compliance</th><td rowspan="3">Kneevoice CAS must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.</td></tr>
<tr><td>Conducted RF emissions – CISPR 11</td><td>Group 1, Class A</td></tr>
<tr><td>Radiated RF emissions – CISPR 11</td><td>Group 1, Class A</td></tr>
<tr><td colspan="3">Kneevoice CAS is suitable for use in commercial medical establishments including those directly connected to the public low-voltage power supply networks, but not near active HF Surgical Equipment or Magnetic Resonance Equipment.</td></tr>
</table>

Table 2. Guidance - Electromagnetic Immunity

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Guidance and manufacturer's declaration - Electromagnetic Immunity			
Kneevoice CAS is intended for use in the electromagnetic environment specified below. The user of the Kneevoice CAS should assure that it is used in such an environment.			
Immunity Test	**IEC 60601-1-2 Test Level**	**Compliance Level**	**Electromagnetic Environment Guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2, ±4, ±8, ±15 kV air	±8 kV contact ±2, ±4, ±8, ±15 kV air	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 @ 100kHz	±2 kV @ 100kHz	Suitable for use in all establishments including those directly connected to the public low-voltage power supply networks.
Surge IEC 61000-4-5	±0.5, 1.0, 2.0 kV common mode high/low to ground ±0.5, 1.0 kV common mode high to low	±0.5, 1.0, 2.0 kV common mode high/low to ground ±0.5, 1.0 kV common mode high to low	Suitable for use in all establishments including those directly connected to the public low-voltage power supply networks.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% U_T (100% dip in U_T) for 0.5 cycle 0% U_T (100% dip in U_T) for 1 cycle 30% U_T (70% dip in U_T) for 25 cycles 0% U_T (100% dip in U_T) for 250 cycles	0% U_T (100% dip in U_T) for 0.5 cycle 0% U_T (100% dip in U_T) for 1 cycle 30% U_T (70% dip in U_T) for 25 cycles 0% U_T (100% dip in U_T) for 250 cycles	Suitable for use in all establishments including those directly connected to the public low-voltage power supply networks. While not necessary to maintain essential performance, if the user of the Kneevoice CAS requires continued operation during power mains interruptions; it is recommended that Kneevoice CAS be powered from an uninterruptible power supply.
(50 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical domestic establishment.
NOTE U_T is the AC mains voltage prior to application of the test level.			
Essential Performance: None other than that related to basic safety.			
Kneevoice CAS is intended for use in the electromagnetic environment specified below. The user of Kneevoice CAS should assure that it is used in such an environment.			
Immunity Test	**IEC 60601-1-2 Test Level**	**Compliance Level**	**Electromagnetic Environment**

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			Guidance
Conducted RF IEC 61000-4-6	3 Vrms 0.15 to 80 MHz 6 Vrms 0.15 to 80 MHz 6 Vrms ISM and Amateur Radio bands 150 kHz to 80 MHz	3 Vrms 0.15 to 80 MHz 6 Vrms 0.15 to 80 MHz 6 Vrms ISM and Amateur Radio bands 150 kHz to 80 MHz	Portable and mobile RF communications equipment should be used no closer to any part of Kneevoice CAS, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2,7 GHz 80% AM 1kHz	10 V/m 80 MHz to 2,7 GHz 80% AM 1kHz	**Recommended separation distance** d = [3.5/V1]√P d = [3.5/E1]√P 80 MHz to 800 MHz d = [7/E1]√P 800 MHz to 2.7 GHz 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 meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range.[b]
Proximity Fields from RF Wireless Communications Equipment (Table 9 per IEC 60601-1-2)	27 V/m (385MHz) 28 V/m (450MHz) 9 V/m (710MHz, 745MHz, 780MHz) 28 V/m (810MHz, 870MHz, 930MHz) 28 V/m (1720MHz, 1845MHz, 1970MHz) 28 V/m (2450MHz)	27 V/m (385MHz) 28 V/m (450MHz) 9 V/m (710MHz, 745MHz, 780MHz) 28 V/m (810MHz, 870MHz, 930MHz) 28 V/m (1720MHz, 1845MHz, 1970MHz) 28 V/m (2450MHz)	

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Immunity to proximity magnetic fields (Table 11 per IEC 60601-1-2)	9 V/m (5240MHz, 5500MHz, 5785MHz) 8 A/m (30KHz), 65 A/m (134.2KHz), 7.5 A/m (13.56MHz)	9 V/m (5240MHz, 5500MHz, 5785MHz) 8 A/m (30KHz), 65 A/m (134.2KHz), 7.5 A/m (13.56MHz)	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.			
[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 Kneevoice CAS is used exceeds the applicable RF compliance level above, Kneevoice CAS should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating Kneevoice CAS. [b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

Table 3. Recommended Separation from Communications Equipment

Recommended separation distances between portable and mobile RF communications equipment and Kneevoice CAS			
Kneevoice CAS is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The user of Kneevoice CAS helps prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Kneevoice CAS as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter (W)	**Separation distance according to frequency of transmitter** (m)		
	150 kHz to 80 MHz d = [3.5/V1]√P	80 MHz to 800 MHz d = [3.5/E1]√P	800 MHz to 2.5 GHz d = [7/E1]√P
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.69	3.69	7.39
100	11.67	11.67	23.33

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For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (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 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.

Cybersecurity

Security: PIN code
To help protect patient data and restrict device access to authorized users only, the Kneevoice CAS requires the user to create and enter a 4-digit Personal Identification Number (PIN) prior to use. The following requirements apply:

- The PIN must be a four-digit numeric code.
- Default PINs are not assigned. The user must create a PIN at initial setup.
- The use of ascending (1234), descending (4321), or repeated digits (0000) is not allowed.
- The user is responsible for safeguarding the PIN and limiting access to authorized individuals only.
- The user must enter the correct PIN prior to accessing the diagnostic function or patient data.
- After three consecutive incorrect PIN entry attempts, the device will enter a locked state for five minutes and display a screen stating the device is locked for five minutes due to entering an incorrect PIN.
- Users may change their PIN via the Settings menu, which requires successful entry of the current PIN.

Security: Access and Configuration
The Kneevoice CAS is a standalone device that does not connect to networks or other devices. It is not capable of accessing any network or the internet, either wired or wireless.

Security: Software Components and SBOM Availability
The Kneevoice™ Cartilage Auscultation System incorporates third-party software components to support system operation, security, and data processing. Major components include, but are not limited to:

- Embedded Linux Operating System (Kernel 5.x series)
- GNU C Library (glibc 2.x series)
- OpenSSL Cryptographic Library (3.x series, FIPS-validated configuration)
- SQLite Database Engine (3.x series)
- Proprietary Kneevoice Application Software

A complete Software Bill of Materials (SBOM), provided in a machine-readable format in accordance with industry standards, is maintained by Kneevoice, Inc. and includes detailed information regarding third-party and open-source software components.

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Authorized users may obtain the current SBOM by submitting a request to:

SBOMRequests@Kneevoice.com

Requests are processed in accordance with Kneevoice's cybersecurity disclosure and information-sharing procedures. The SBOM is reviewed and updated on a regular basis and following relevant software modifications.

Security: Interfaces
The Kneevoice CAS has an Ethernet port that is not intended for use by the user. The Ethernet port is disabled and ignores inputs when powered on in the medical facility environment. The Ethernet port is inactive and not meant to connect, exchange, or use data with or from other medical devices, products, technologies, or systems.

Security: Maintenance of Cybersecurity Level
The Kneevoice CAS is designed to notify users when malfunctions are detected. In the event of a malfunction, the device no longer performs, enters maintenance required mode, and a maintenance screen appears on the LCD screen. Please contact the service department if this message appears.

The Kneevoice CAS is designed with a method for retention and recovery of trusted default device configuration by authenticated, authorized Kneevoice personnel. The user does not have access to the device configuration. Please contact the service department if any problems with the device occur. Kneevoice will provide all necessary services, including software updates, to maintain functionality, performance, cybersecurity level, and conformity of the device throughout the life and service of the Kneevoice CAS. This includes the assessment of potential security risks and, if required, delivery of information and software updates on a regular basis. Where relevant, Kneevoice will inform users of the vulnerability details and appropriate countermeasures, as applicable, through customer service. Software updates will be deployed by authorized Kneevoice personnel at Kneevoice facility to maintain the cybersecurity level and resolve any unacceptable vulnerabilities.

Security: Product End-of-Life/End-of-Service
Kneevoice will perform regular cybersecurity risk assessments and will provide updates or maintenance support for the Kneevoice CAS. Kneevoice will not send out the Kneevoice CAS to users following the end of support.

Security: Decommissioning
Prior to device retirement, return, refurbishment, or disposal, the user shall remove all personally identifiable information (PII) and protected health information (PHI) from the device using the data-erasure function (refer to **Editing Device** section). Do not dispose of devices containing PHI/PII. If erasure cannot be completed (i.e. device will not power on), contact Kneevoice for decommissioning support.

Troubleshooting

The information contained herein is proprietary and confidential and shall not be used or disclosed, in whole or part, without first obtaining the written permission of Kneevoice, Inc. or assignee(s).

Symptom	Solution
1. Console will not turn on after pressing power button	• Check if power supply is plugged into 110V outlet • Unplug power supply, plug in power supply to restart console
2. Audio sensor will not send audio signal to console software	• Check if cable is plugged into console • Remove and reposition sensor • Check if probe tip is touching the skin
3. Position sensor will not send position data to console software	• Check if cable plugged into console • Remove and reposition sensor
4. Console will not turn off after pressing power button.	• Unplug power cord from outlet and call customer service representative
5. Touchscreen does not function	• Call customer service representative
6. Console becomes excessively hot during use	• Turn off console and call customer service representative
7. Console releases smoke during use	• Turn off console and call customer service representative

Have a backup device (or an approved alternative assessment method) readily available so use can continue without interruption if the primary device malfunctions or stops working. If the device fails, stop use and follow the troubleshooting steps. If unable to effectively troubleshoot the device, make use of your backup device or method and contact the Kneevoice for further assistance.

If you are experiencing any problems or need repair, contact our customer service representative at (310) 309-0745.

Kneevoice, Inc.
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Patents US 10,448,919, K6917EU

Revision History

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Kneevoice™ Cartilage Auscultation System
Instructions for Use

Revision	Date	Description
A	02/28/23	Initial Release EO-2200 (HDA Technology)
B	04/03/23	Added warning in Section 9; EO-2206 (HDA Technology)
C	07/05/23	Updated cleaning instructions, Removed 0-100 scale; EO-2225 (HDA Technology)
D	08/30/23	Updated wiping instructions to use 70% isopropyl alcohol and added trouble shooting section; EO-2235 (HDA Technology)
E	02/26/24	Updated Indications for Use sectionEO-2269 (HDA Technology)
01	05/27/25	Initial Release for KV; updated sensor assembly description and removed ICRS score. Added EMC warnings. Changed part number from 820-10188 (HDA part number) to IFU-0001; DCO 25-16
02	06/19/25	Updated sensor assembly description and screen shots. Changed labels from 200 to 300 each; DCO 25-42
03	07/16/25	Clarified alcohol wipe process; DCO 25-58
04	10/30/25	Updated from three audio sensor tabs to single audio sensor updated EMC information and added cybersecurity section; DCO 25-65
05	07/21/26	Added SBOM Software Security Information; DCO 26-09

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