CM Littmann[®] Brand

Electronic Stethoscope

MODEL 3100 with Ambient Noise Reduction





Featuring Ambient Noise Reduction $\mathbf{R100}$





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EC REP 3M Health Care D-41453 Neuss, Germany



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GB) English	pp. 1-19
F) Français	pp. 20-37
Œ	Deutsch	pp. 38-54
) Italiano	pp. 55-71
ES) Español	pp. 72-88
\mathbb{N}) Nederlands	pp. 89-105
SE) Svenska	pp. 106-122
ØK) Dansk	pp. 123-139
NO) Norsk	pp. 140-156
F) Suomenkielinen	pp. 157-173
PD) Portugês	pp. 174-190
GR) Ελληνικά	pp. 191-207

3M[™] Littmann® Electronic Stethoscope Model 3100

With Ambient Noise Reduction

Introduction

Congratulations and thank you for choosing the 3M[™] Littmann[®] Electronic Stethoscope Model 3100.

The Model 3100 brings you the very latest thinking in advanced auscultation technology and simplicity in operation.

The Model 3100's combination of Ambient Noise Reduction technology, frictional noise dampening materials, state-of-theart amplification of both bell and diaphragm modes, and an all-new user interface takes you to the next level in acoustic performance and ease of use.

Whether you are auscultating infant, pediatric or adult patients, in quiet or noisy environments, or picking up difficult-to-hear heart and body sounds, you'll appreciate all the technology that's been built into this latest electronic stethoscope from the Littmann® brand.

Hear it. With Confidence.

SAFETY INFORMATION

Please read, understand, and follow all safety information contained in these instructions prior to using this electronic stethoscope. Retain these instructions for future reference.

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 complete chestpiece with diaphragm and binaural.				
i	Attention, see instruction for use.				
IPX4	Protected against splashing liquid (chestpiece only).				
X	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.				
	Both product and packaging do not contain natural rubber latex.				
AP	Indicates Category AP Equipment. Tested for use with flammable anesthetic mixture with air.				

Explanation of Signal Word Consequences				
▲ CAUTION:	Indicates a hazardous situation, which, if not avoided, could result in minor injury and/or property damage.			
NOTICE:	Indicates a hazardous situation, which, if not avoided, may result in property damage.			

\triangle caution

- To reduce the risks associated with infection follow all cleaning and disinfecting instructions included in this manual. Establish and follow a cleaning and disinfecting schedule.
- To reduce the risks associated with very strong electromagnetic fields avoid using the stethoscope near strong radio frequency signals or portable and/or mobile RF devices. If you hear sudden or unexpected sounds, move away from any radio transmitting antennas.
- To reduce the risks associated with sharp edges make sure that the soft sealing earlips are snapped firmly into position as shown in this manual. Use only Littmann replaceable earlips.
- To reduce the risks associated with an incorrect result store and operate this stethoscope only as instructed in this manual. As there is no acoustic (non-amplified) mode available with this stethoscope, replace the alkaline battery within two hours of the battery life icon beginning to flash in the LCD display. Use only type AA batteries. Also, do not immerse the stethoscope in a liquid or subject it to any sterilization processes.
- To reduce the risk associated with an electrical shock do not use the stethoscope on patients without the stethoscope's diaphragm cover in place.

NOTICE

- To reduce the risks associated with environmental contamination follow applicable regulations when disposing of this stethoscope. Properly dispose of, or recycle, spent batteries.
- No modification of this equipment is allowed. Use only authorized 3M service personnel to repair this stethoscope. Read, understand, and follow all the safety information on the battery package.

Intended Use

The 3M Littmann® Electronic Stethoscope Model 3100 is intended for medical diagnostic purposes only. It may be used for the detection and amplification of heart, lungs, arteries, veins and other internal organs with the use of selective frequency ranges. It can be used on any person undergoing a physical assessment.

Operator Profile

The 3M Littmann® Electronic Stethoscope Model 3100 is designed to be used by anyone who wishes to listen to sounds as described in the Intended Use section above. This manual provides complete information on how to operate the Model 3100 so that no additional operating training is required.

Functional Description

The Model 3100 electronic stethoscope picks up sounds, such as heart and lung sounds, from a patient's body. After amplification and filtering, the sounds are sent to the user through a binaural headset. The stethoscope chestpiece is designed for use with adult, pediatric, and infant patients.

The user interface for the stethoscope includes a 5-button keypad and an LCD display. Sound processing is carried out with the aid of a digital signal processor. Stethoscope power is provided by a single AA battery in the chestpiece. A power management system is included to prolong battery life.

Serial Number

Each Littmann Electronic Stethoscope Model 3100 comes with a unique serial number for easy identification. Please record your serial number in this manual for future reference: ______

INSTRUCTIONS FOR USE

1. Insert Battery

Insert AA battery (provided in package) into Stethoscope.



2. Position Headset

Eartips should point in a forward direction as you insert them into your ear canals. When ear tips are properly positioned, diaphragm will face towards your body.



Your new Littmann Electronic Stethoscope is designed to give you a very comfortable, acoustically sealed fit. It comes with two sizes of eartips to assure a perfect fit. The large eartips are pre-installed. Smaller eartips are included in package. Please choose the set that is most comfortable for you.

To remove eartips, pull eartips firmly away from eartube. To apply new eartips, push eartip firmly onto eartube to secure.



3. Adjust Headset for Comfort

To <u>reduce</u> spring tension in the headset, hold each eartube at the bend near the eartips and gradually pull apart until fully extended (180 degrees).



Increase Tension

To <u>increase</u> spring tension, grasp the headset with one hand where the metal eartubes enter the plastic tubing, and squeeze until the plastic tubing on one eartube touches the other. Repeat as necessary.

4. Turn On / Off

This stethoscope comes equipped with an advanced power management system.

- Manual Turn On: Depress and release power button. LCD display will activate, indicating stethoscope is on.
- Manual Turn Off: Depress and <u>hold</u> power button for two seconds. LCD display will shut off, indicating stethoscope is off.



- Auto Off with Standby Feature: After manual turn-on, stethoscope will stay on during use, but switch to a powersaving "standby" mode after 20 seconds of inactivity. LCD display will display the Littmann® logo during standby mode. When stethoscope diaphragm or any button is pressed, LCD display settings will reappear and stethoscope will be ready to use. After two hours of non-use, the stethoscope will leave standby mode and fully power off. You may customize on-time and off-time to meet your own personal needs. See Custom Configuration section below.
- LCD Display Backlight: Backlight options are available for use at low ambient light conditions. By default, depressing and releasing the power button at any time will illuminate the LCD display for five seconds.

5. Select Filter

This stethoscope comes equipped with both bell (low frequency) and diaphragm (high frequency) filters. The default setting is the diaphragm filter. Instructions for changing the default filter setting are given in the **Custom Configuration** section below. To select filter: Depress and release filter button (as shown in diagram) until desired filter mode appears on LCD display.



6. Adjust Sound Amplification Level

The Model 3100 sound level can be amplified in 8 increments up to 24X amplification of a non-electronic (cardiology-level) stethoscope. Level 1 is equal to a non-electronic stethoscope. Level 9 is equal to 24X amplification of a non-electronic stethoscope. The greater the amplification, the more bars you will see.

A default start-up amplification level can be set using the instructions provided in the **Custom Configuration** section below. The default setting is marked by the box on the vertical bar shown in the volume icon in the LCD display. The illustration shows a default amplification setting at Level 3.



- Increase Amplification: Press (+) button until desired amplification level is achieved
- Decrease Amplification: Press () button until desired amplification level is achieved

7. Monitor Patient Heart Rate

The Model 3100 detects and displays an acoustic-based heart rate when presented with consistent heart sounds (heart rate variation < 10%). It takes five seconds to compute the initial heart rate and updates are provided every two seconds. Prior to the initial reading, the display shows two dashes (--). For heart rates outside a range of 30-199 bpm, the display will also show two dashes (--).

The acoustic-based heart rate display functions best when the Model 3100 is placed near the apex of the patient's heart and can be monitored while using any filter mode and/or volume level. If the heart rate changes from consistent to inconsistent or if there is excessive ambient noise, patient movement or lung sounds during auscultation, the heart rate display number will display two dashes (--).



8. Monitor Battery Life

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Battery life is indicated by an icon in the LCD display.



The Model 3100 comes with a AA Alkaline battery. This battery will last for approximately 60 hours of continuous use. In a typical clinical setting, this represents about three months.

As the alkaline battery life depletes, the icon will change as follows:



The battery icon begins to blink when only a few hours of battery capacity remains.

 \triangle CAUTION: When the battery is completely depleted the scope becomes inoperable. No sound will be transmitted without a functioning battery.

IMPORTANT! NiMH (rechargeable) and Lithium batteries may also be used in the Model 3100. However, battery type must be specified to ensure a reliable battery life indication (see **Custom Configuration** section below).

9. Custom Configuration

The Model 3100 stethoscope has several operational settings that can be changed using its configuration menu system. Within this menu system, the (+) and (-) buttons are used for scrolling and the (M) button is used for selecting options. The Filter button acts an "escape" key, used for returning to the previous menu or to the operating mode of the stethoscope.

To enter the Setup Menu: Depress and release the (M) button. This will display a menu of setup options. (NOTE: Only 3 options will visible at a time. All options can be viewed in sequence upon scrolling with either the (+) or (-) buttons.)



To select the power setting: Select the "POWER" option in the Setup menu. Use the (-) and (+) buttons to scroll through the list of power settings. Press and release the (M) button to select a setting.



(GB) English

The power settings provide different degrees of power consumption. In general, the longer the stethoscope remains in an active mode, the greater its power consumption. The factory default is the MEDIUM level. (NOTE: The Auto Off power management feature is further described below.)

To select the battery type: Select the BATTERY option in the Setup menu. Use the (-) and (+) buttons to scroll through the list of battery types. The LITHIUM battery is a non-rechargeable cell especially recommended for low-temperature operation of the stethoscope. The NIMH battery is rechargeable (external charger required). Press and release the (M) button to select a setting. The factory default is the ALKALINE battery.

To select the preset (default) volume level: Select the SET VOL option in the Setup menu. Press and release the (M) button to select the current level as default. The factory default is level 3.

To select the preset (default) filter setting: Select the SET FLTR option in the Setup menu. Press and release the (M) button to select the current filter as default. The factory default is the diaphragm filter.

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through the list of options. Press and release the (M) button to select. The factory default is ALWAYS. The ALWAYS option will illuminate the backlight at all times at a reduced level while the stethoscope is powered on and not in standby mode. The ON DMND option will illuminate the backlight for five seconds by depressing and releasing the power button. The DISABLE option disables the backlight at all times and will conserve power.

> SET FLTR BACKLITI AUTO OFF

To select the backlight setting: Select the BACKLITE option in the Setup menu. Use the (-) and (+) buttons to scroll

ON DMND

ALWAYS DISABLE





Two different settings work together to influence the length of time the Model 3100 is on full power: The AUTO OFF setting (ENABLE vs. DISABLE) and the POWER setting (HIGH, MEDIUM, and LOW - HIGH setting uses more battery power, LOW setting uses less battery power). To increase battery life, ENABLE the Auto Off feature and select the LOW power setting.





When the AUT0 OFF feature is enabled, the stethoscope will enter standby mode after a period of time determined by the POWER setting if there is no contact detected on the diaphragm AND the buttons are not activated. When the AUT0 OFF feature is disabled, the stethoscope will enter standby mode after a period of time determined by the POWER setting from the last button activation. In addition, when the AUT0 OFF feature is disabled, there will be an audible alert 10 seconds prior to entering standby mode. After entering standby mode, the Model 3100 will be powered on when contact is detected on the diaphragm or by button activation. Otherwise, the Model 3100 will completely power off after the period of time determined by the POWER setting (see below).

With AUTO OFF feature ENABLED:

SETUP	Options	Detail		
POWER	HIGH	Remains on full power for 30 seconds before entering standby		
		Remains in standby for 5 hours before powering off		
		Backlight remains lit for 5 seconds after pressing the power button		
	MEDIUM	Remains on full power for 20 seconds before entering standby		
		Remains in standby for 2 hours before powering off		
		Backlight remains lit for 5 seconds after pressing the power button		
	LOW	Remains on full power for 10 seconds before entering standby		
		Remains in standby for 30 minutes before powering off		
		Backlight remains lit for 3 seconds after pressing power button		

With AUTO OFF feature DISABLED:

SETUP	Options	Detail	
POWER	HIGH	Remains on full power for 7 minutes before entering standby	
		Remains in standby for 5 hours before powering off	
		Backlight remains lit for 5 seconds after pressing power button	
	MEDIUM	Remains on full power for 5 minutes before entering standby	
		Remains in standby for 2 hours before powering off	
		Backlight remains lit 5 seconds after pressing power button	
	LOW	Remains on full power for 3 minutes before entering standby	
		Remains in standby for 30 minutes before powering off	
		Backlight remains lit 3 seconds after pressing power button	

To obtain model and software version information: Select the "ID" option in the Setup menu. Use the (-) and (+) buttons to scroll through the list of reference numbers. Press (M) to return to the operating mode of the stethoscope.



To leave the Setup menu: Press the Filter button or press the (M) button to select the EXIT option. This will return the stethoscope to its normal operating state.



10. Other Operating Considerations

Operating range is -22° to 104°F (-30° to 40°C), 15 to 93% relative humidity.

Storage and transport range is -40° to 131°F (-40° to 55°C), 15 to 93% relative humidity.

To extend the life of your stethoscope, avoid extreme heat, cold, solvents and oils. Remove the battery whenever the stethoscope will not be used for several months.

If you plan to use the stethoscope below 0°F (-18°C) you should use a lithium battery to insure proper function.

Failure to follow care and maintenance recommendations could result in damage to the internal components of the Littmann Electronic Stethoscope. Internal damage could cause malfunction of the product, ranging from a slight decrease in auditory response to complete failure of the product.

If you experience any problems with the electronic stethoscope, do not attempt to repair it yourself. Please notify our 3M Health Care Service Center for directions on shipping and receiving.

MAINTENANCE & WARRANTY

Cleaning

English

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Cleaning of stethoscope should be done between each patient use.

Cleaning the Chestpiece

Under normal conditions, it is unnecessary to remove the diaphragm for cleaning. The diaphragm can easily be cleaned by using an alcohol wipe. If however, it is necessary to remove the diaphragm, carefully follow the instructions below:

- Diaphragm Removal: With power off and diaphragm side up, using a thumbnail, lift the underside portion of the diaphragm out of its designated groove, and peel it off of the chestpiece. The groove that holds the diaphragm in place can be cleaned by sliding the edge of an alcohol swab around the groove. All parts of the chestpiece can be wiped down with alcohol. IMPORTANT: The stethoscope should not be immersed in any solution. Excess liquid used in the cleaning process may result in moisture getting into the internal components.
- Diaphragm Reassembly: Once the diaphragm is completely dry, insert the diaphragm into the groove of the rim, starting at one point, and run your finger around the diaphragm until it is seated back in the groove.

Cleaning Other Parts of the Stethoscope

Eartips, eartubes, plastic tubing and chestpiece can be wiped clean with alcohol. Eartips may be removed for a more thorough cleaning.

NOTICE : Do not immerse the stethoscope in any liquid or subject it to any sterilization process!

Service & Warranty Program

Your Littmann Electronic Stethoscope comes with the finest service and warranty policy in the industry. The Littmann Electronic Stethoscope Model 3100 is warranted against any defects in material and manufacture for a period of two years. If a material or manufacturing defect is discovered during the warranty period, repairs or replacement will be made without charge upon the return of the instrument to 3M, except in cases of obvious abuse or accidental damage.

For Maintenance or Repair Services

Please include your name, physical address, e-mail address, and phone number inside with your stethoscope.

In the U.S.A., send your stethoscope directly to:

3M Health Care Service Center 3M Bldg 502-1W-01 3350 Granada Ave N Suite 200 Oakdale, MN 55128 1-800-292-6298

In Canada, send your stethoscope directly to:

3M Health Care Service Centre 3M Canada, Inc. 80 Enterprise Drive South London, Ontario Canada, N6N1C2 1-800-563-2921

Outside of the U.S.A. and Canada, contact your local 3M subsidiary for maintenance and repair information.

APPENDIX

GB) English

Declaration – Electromagnetic Emissions

The 3M Littmanr® Electronic Stethoscope, Model 3100, is intended for use in the electromagnetic environment specified below. The customer or the user of the Model 3100 should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment –guidance	
г. т.		Model 3100 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	Model 3100 is suitable for use in all establishments, including	
Harmonic emissions IEC 61000-3-2	Not applicable	domestic establishments and those directly connected to the public low-voltage power supply network that supplies	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Not applicable	buildings used for domestic purposes.	

Declaration – electromagnetic immunity

The 3M Littmann® Electronic Stethoscope, Model 3100, is intended for use in the electromagnetic environment specified below. The customer or the user of Model 3100 should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	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%.
Electrical fast transient/ burst IEC 61000-4-4	± 2 kV for supply lines ± 1 kV for input/output lines	Not applicable	
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	Not applicable	
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 magnetic field or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply lines IEC 61000-4-11	< 5 % UT (>95% dip in UT) for 0.5 cycle 40 % UT (60% dip in UT) for 5 cycle 70 % UT (30% dip in UT) for 25 cycle < 5% UT (>95% dip in UT) for 5 sec	Not applicable	

GB English

The 3M Littmann® Electronic Stethoscope, Model 3100, is intended for use in the electromagnetic environment specified below. The customer or the user of Model 3100 should assure that it is used in such an environment.				
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment –guidance	
			Portable and mobile RF communications equipment should be used no closer to any part of the Model 3100, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance:	
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	Not applicable	d = 1,2 ✓ P	
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m 80 MHz to 2.5 GHz	$ d = 1, 2 \checkmark P 80 \text{ MHz to } 800 \text{ MHz} \\ d = 2, 3 \checkmark P 800 \text{ MHz to } 2, 5 \text{ 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 Interference may occur in the vicinity of equipment marked with the following symbol: $	

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 the Model 3100 is used exceeds the applicable RF compliance level above, the Model 3100 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Model 3100.

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

Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the 3M™ Littmann® Electronic Stethoscope Model 3100

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The Model 3100 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Model 3100 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Model 3100 as recommended below, according to the maximum output of the communications equipment.

Rated maximum output	Separation distance according to frequency of transmitters, d [m]			
power of transmitter, P [W]	150 kHz to 80 MHz	80 Mz to 800 MHz d = 1,2 $\checkmark P$	800 MHz to 2,5 GHz d = 2,3 $\checkmark P$	
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 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 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.