doctorgram™

Electronic Stethoscope I

Contents

1.1 Introduction, Warnings, and Safety

The doctorgram Stethoscope DES-I (herein referred to as *DES-I*) is designed to support healthcare professionals in analyzing cardiac and other internal organ sounds. DES-I includes a stethoscope, and a smartphone application.

DES-I features sound amplification and audio transmission to a smartphone via Bluetooth that allows the user to open and playback sounds in a mobile application on compatible iOS smartphones and tablets. The App provides the ability to save sounds and share patient recordings to the others. DES-I is intended for use on pediatric and adult patients.

CAUTION: Federal (USA) law restricts this device to sale to or on the order of a clinician.

1.2 For Help and Assistance

Please report any injury or adverse event to DES-I Devices using any of the contact methods below. For general and product related comments, questions, or concerns, please contact GV Concepts, Inc. directly

GV Concepts, Inc.
3240 South White Road, #286
San Jose, CA
95148 USA

General Assistance and FAQs doctorgram.com/getstarted

Direct Contact ..... support@doctorgram.com

Phone Support 1.408.270.9188

Product Reference and Information www.doctorgram.com

1.3 Safety Related Labels & Symbols

Consult instructions for use.

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.

This product and packaging does not contain natural rubber latex.

This product contains an intentional RF radiator certified by the FCC.

Catalog Number

Batch Number

Serial Number

Humidity Limit (Operational)

Temperature Limit (Operational)

This product is provided non-sterile. Do not attempt to re-sterilize the device.

This product uses wireless Bluetooth communication.

1.4 Signal Word Consequences

CAUTION: Indicates a hazardous situation, which if not avoided, could result in injury and/ or property damage and/or damage to the device.

NOTICE: Indicates a hazardous situation, which, if not avoided, may result in property damage.

⚠ CAUTION:

- To reduce the risk of device interference, keep the DES-I at least 1 meter away from all RF emitters including Wifi routers and radios.

- 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 inaccurate data acquisition store and operate this stethoscope only as instructed in this manual. Though there is an acoustic (non-amplified) mode available with this stethoscope, it is highly recommended that the battery be recharged within 8 eight hours of the LED indicator turning red flashing. Recharge the battery using only the USB power cord and charger provided with the device.

- DO NOT immerse the stethoscope in a liquid or subject it to any sterilization processes other than those described in this manual.

- To reduce the risks associated with very strong electromagnetic fields avoid using the stethoscope near strong radio frequency (RF) signals or portable and/or mobile RF devices. If sudden or unexpected sounds are heard, move away from any radio transmitting antennas. Using accessories, transducers, and cables not produced by the Devices may result in increased RF emissions or decreased immunity of the doctorgram Electronic Stethoscope I.

- Please read, understand, and follow all safety information contained in these instructions prior to using the doctorgram Electronic Stethoscope I. It is recommended that these instructions be retained for future reference.

- DES-I contains a Bluetooth Class 2 wireless data link. The maximum radio frequency field strength generated by the stethoscope is below three volts per meter, a level that is considered safe to use with other medical devices. However, audio, video, and other similar equipment may cause electromagnetic interference. If such devices are encountered

NOTICE:

and cause interference, immediately move DES-I away from that device and/or turn the Bluetooth feature OFF.

- To reduce the risks associated with environmental contamination follow applicable regulations when disposing of this stethoscope. The stethoscope attachment contains a lithium-ion polymer rechargeable battery; please properly dispose of the device as mandated by local directives.
- No modification of this equipment is allowed. There are no repairable parts inside the DES-I.

1.5 EMC Compliance

This device complies with Part 15 of the FCC rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesirable operation.

NO MODIFICATION: Modifications to this device shall not be made without the written consent of GV Concepts, Inc Unauthorized modifications may void the authority granted under Federal Communications Commission rules permitting the operation of this device.

NOTE: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause

harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation.
If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:
-- Reorient or relocate the receiving antenna.
-- Increase the separation between the equipment and receiver.
-- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
-- Consult the dealer or an experienced radio/TV technician for help.

The device can be used in portable exposure condition without restriction.

IC statement:
This device complies with Industry Canada Licence-exempt RSSs. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference, including interference that may cause undesired operation of the device.

Le présent appareil est conforme aux CNR d'Industrie Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes : (1) l'appareil ne doit pas produire de brouillage, et (2) l'utilisateur de l'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.

EMC Compliance Europe
This equipment complies with the EMC requirements of the IEC 60601-1-2.

1.6 Indications for Use

DES-I is intended to be used as a part of a physical assessment of a patient by healthcare professionals for diagnostic decision support in clinical settings. DES-I is intended for use on pediatric and adult patients. It can electronically amplify, filter, and transfer sounds to the accompanying mobile application for storage and sharing. It can be used to record heart sounds and cardiac murmurs, bruits, respiratory sounds and abdominal sounds during physical examination in normal patients or those with suspected diseases of the cardiac, vascular, pulmonary or abdominal organ systems.

There are no known contraindications for DES-I, although care should be taken when considering using the device according to the warnings and precautions below.

DES-I is not life-supporting or life sustaining.

1.7 Precautions

The device is intended to be prescribed by licensed medical professionals for use on patients during a physical assessment in a clinical setting. The system provides one source of data that is significant only when used in conjunction with clinician oversight and consideration of other relevant patient information.

DES-I should be used only by qualified clinicians. DES-I is intended for use on patients that can be auscultated on normally with an acoustic stethoscope.

This manual provides instructions for the use of DES-I and mobile applications. It is assumed that the user is familiar with basic website navigation and mobile application use on iOS devices.

This device is only indicated for use in a hospital, physician's office, or other clinical setting. Standard procedures for

auscultation should be followed including background noise reduction and optimal patient positioning.

In order to transmit sounds to the doctorgram App, the stethoscope and device must be connected via Bluetooth.

DES-I uses a Bluetooth Smart wireless data link. The Bluetooth range will be reduced when objects (walls, furniture, people, etc) are between the DES-I and a paired mobile device. To improve Bluetooth connection, reduce the distance and/or allow a line of sight between the DES-I and mobile device.

1.8 Patient Privacy

The privacy of patient health information may be protected by state, federal, or international/foreign laws that regulate how such information can be used, stored, transmitted, and disclosed. The DES-I employs security features that are compliant with HIPAA policies. Third party access may be prohibited to such information without obtaining written authorization from the patient.

The user is fully responsible for understanding and following all laws that regulate storage, transmission, and disclosure of any electronic patient data through the use of software. If the user becomes unable to comply with a law or restriction that applies to use and disclosure of such data, the user should not proceed to collect or save such information.

This application may require entry of individually identifiable health information in order to function. Records are stored and recalled through the use of filename which includes date and name. By entering this information, the user assumes any and all risks of and liabilities incurred with using or transmitting such information.

1.9 Contents and Operation

The package includes (1) stethoscope, (1) headphone, and (1) micro USB cable. For recording functionality, the system requires smart mobile device with Bluetooth Smart capabilities. The compatible hardware and software platforms are listed below.

System Requirements
The mobile app software can be used on iPhone 5/5C/5S and above, iPad* Mini 2/3 and above, iPad Air and above, iPad Pro, iPad 3rd and above with iOS 9.0 and higher. The mobile app software can also be used with Android devices with BLE support (Bluetooth 4.0) and Android 5.0 and above.

DES-I uses Bluetooth Smart; mobile devices used must be compatible with Bluetooth Smart.

*iPhone, iPad, iTunes, and iOS are registered trademarks of Apple, Inc.
*Bluetooth is a registered trademark of Bluetooth SIG, Inc.

2.1 DES-I Use

Charge Battery
The battery of DES-I will need to be charged; insert the included micro USB cable into the USB port on the device and plug the other end into the included USB charger. The LED will begin to yellow, signifying that it is charging. The yellow LED will be off when the device is fully charged.

Power On/Off button
Press “ON” and Green LED will be flashing around 3 seconds. Please wait till Green LED is solid on before releasing “ON” button. Sounds will be amplified and heard via headphone. Press “ON” again to power off the device.

Volume up button
Press “+” to increase volume.

Volume down button
Press “-“ to lower volume.

Bluetooth button
Press “BLUETOOTH” to enable Bluetooth broadcasting and blue LED will be flashing. If there is no connection with mobile device within 30 seconds, it will turn off Bluetooth broadcasting mode automatically. If the device is connected to mobile device, blue LED will be soild ON. During connected to mobile device, press “BLUETOOTH” will turn off Bluetooth function.

Reset button
Press “RESET” will reboot and turn off the device. If the device is malfunction, presses “RESET” for 6 seconds to force the device to be off.

3.1 Cleaning

Cleaning and Disinfecting Procedure
Thestethoscope shouldbecleanedbetweeneach patient use.

Allexternal partsof the hardware can be cleaned with 70% isopropyl alcohol wipes.

NOTE: DO NOT immerse the device in any liquid or subject it to any high-pressure/autoclave sterilization processes.

4.1 Warranty

doctorgram provides a limited warranty for doctorgram Electronic Stethoscope I.
Please visit doctorgram.com/warranty for a full description of the warranty.

5.1 Operating Conditions

Environmental
The operating range of the DES-I is -30°to 40°C (-22°to 104°F), and 15%to 93% relative humidity. The storage and transport range is -40°to 55°C (-40°to 131° F), and 15%to 93% relative humidity. Acceptable pressure is 1 atm.

It is recommended to avoid exposure to extreme heat, cold, solvents and oils. Extreme heats and colds will negatively affect the lithium ion battery in the device, and may affect battery life.

Operating Warnings
During charging the battery, it is not recommended to operate the device. Failure to follow care and maintenance recommendations could result in damage to the internal components of DES-I. Internal damage to the product could cause malfunction of the product, possibly leading to complete loss of function. If problems are encountered with DES-I, do not attempt to it. Please notify our support team for assistance.

6.1 DES-I Modes and Corresponding LED States.

All LED OFF	DES-I is OFF
ON	DES-I is ON. Sound will be amplified and output to 3.5mm audio jack.
FLASHING	DES-I is in Bluetooth broadcast mode and wait to connect to mobile device.

ON	DES-I connects to mobile device via Bluetooth
SLOW FLASHING	Low battery level 0.2 second ON and 2 second off
3 SECONDS OF FLASHING	Data Overrun 3 second ON and OFF
ON ON	DES-I is not functioning properly

ON	Battery is being charged
OFF	Battery is fully charged

7.1 doctorgram App Use

Installation for iPhone
Open the iTunes App Store using a supported mobile device. Ensure that the device is connected to the internet and search for the doctorgram App. Follow the instructions to download the doctorgram App and wait until it has finished installing.

Installation for iPad
Open the iTunes App Store using a supported iPad model. Ensure that the device is connected to the internet. When searching the app store for the doctorgram App, make sure to select "iPhone Only" from the search options. Follow the instructions to download the App and wait until it has finished installing.

8.1 Electrical Safety

Guidance and Manufacturer's Declaration - Electromagnetic Emission		
The doctorgram Electronic Stethoscope I is intended for use in the electromagnetic environment specified below. The user of the doctorgram Electronic Stethoscope I should assure that it is used in such an environment.		
Applicable Emissions Test	Compliance	Electromagnetic Environment-Guidance
RF emissions CISPR 11	Group 1	The doctorgram Electronic Stethoscope I 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 doctorgram Electronic Stethoscope I 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 6100-3-2	Not Applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not Applicable	

Warning: The use of accessories other than those specified, with the exception of accessories sold by GV Concepts as replacement parts, may result in increased emissions or decreased immunity of the doctorgram Electronic Stethoscope I.

Warning: The doctorgram Electronic Stethoscope I should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the doctorgram Electronic Stethoscope I should be observed to verify normal operation in the configuration in which it will be used.

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
The doctorgram Electronic Stethoscope I is intended for use in the electromagnetic environment specified below. The user of the doctorgram Electronic Stethoscope I should assure that it is used in such an environment.			
Immunity Test	IEC60601 Test Level	Compliance Level	Electromagnetic Environment-Guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	+/- 6 kV contact +/- 8 kV	+/- 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	+/- 1kV line(s) to line(s) +/- 2 kV line(s) to earth	Not Applicable	
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	< 5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycle 70% U_T (30% dip in U_T) for 25 cycle < 5% U_T (>95% dip in U_T) for 5 sec	Not Applicable	

Immunity Test	IEC60601 Test Level	Compliance Level	Electromagnetic Environment-Guidance
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.
NOTE U_T is the a.c. mains voltage prior to application of the test level			

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
The doctorgram Electronic Stethoscope I is intended for use in the electromagnetic environment specified below. The user of the doctorgram Electronic Stethoscope I should assure that it is used in such an environment.			
Immunity Test	IEC60601 Test Level	Compliance Level	Electromagnetic Environment-Guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	Not Applicable	
Radiated RF IEC 61000-4-3	3V/m 80 MHz to 2.5 GHz	3 V/m 80 MHz to 2.5 GHz	$d = 1.2\ \sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\ \sqrt{P}$ 800 MHz to 2.5 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 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 is affected by absorption and reflection from structures, objects and people.

[a] Field strength 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 address 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 doctorgram Electronic Stethoscope I is used exceeds the applicable RF compliance level above, the doctorgram Electronic Stethoscope I should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the doctorgram Electronic Stethoscope I.

[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 doctorgram Electronic Stethoscope I

The doctorgram Electronic Stethoscope I is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The user of the doctorgram Electronic Stethoscope I can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the doctorgram Electronic Stethoscope I 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 $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
0.01	*0.12*	*0.12*	*0.23*
0.1	*0.37*	*0.37*	*0.74*
1	*1.2*	*1.2*	*2.3*
10	*3.7*	*3.7*	*7.4*
100	*12*	*12*	*23*

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* is meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum 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.

9.1 Manufacturing & Regulatory Information

Manufactured by:

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San Jose, CA 95148 USA

www.doctorgram.com

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