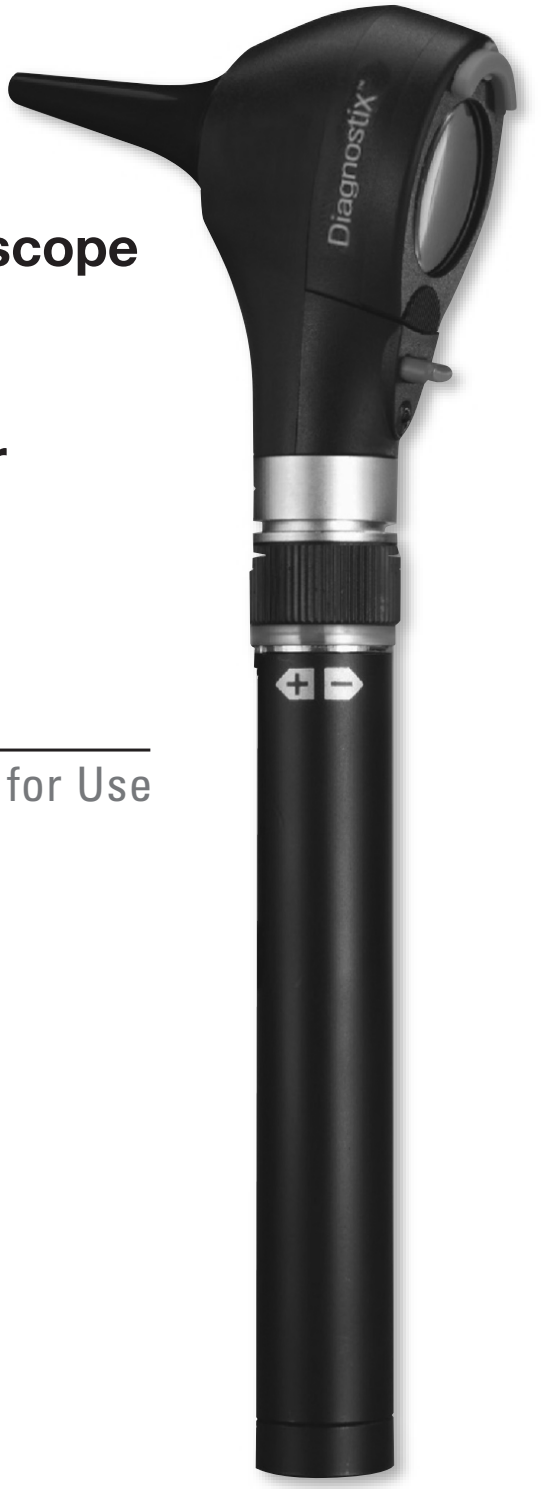
Diagnostix™



Otoscope

Coax Ophthalmoscope

Dermascope

Throat Illuminator

Power Handles

Instructions for Use

Questions?
Call ADC toll free:
1-800-232-2670

AMERICAN DIAGNOSTIC CORPORATION

Diagnostix™ EENT Instruments
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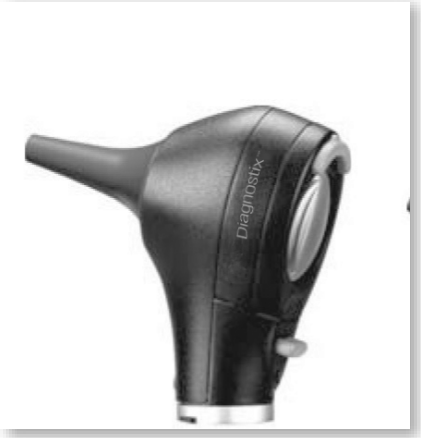
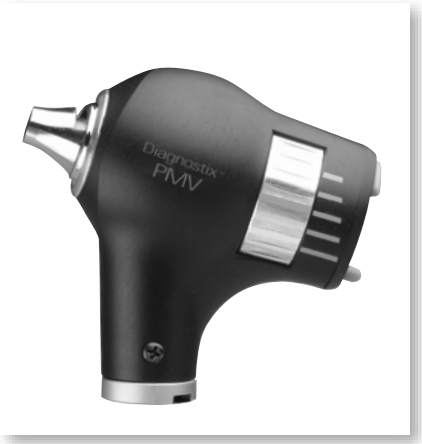
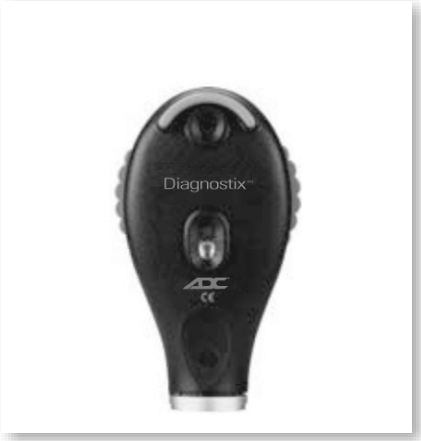


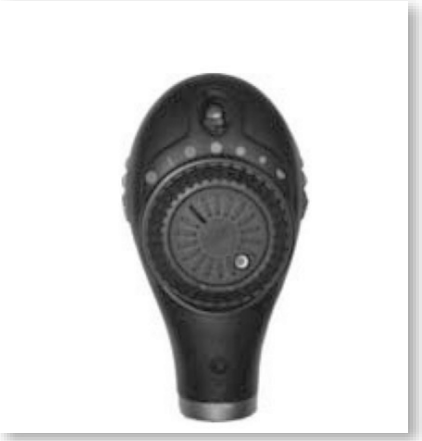
Diagnostix™
Otoscope



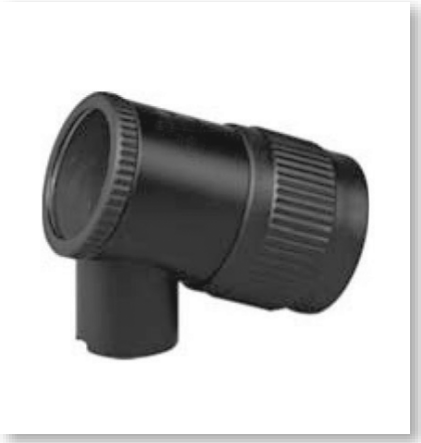
Diagnostix™ PMV
Otoscope



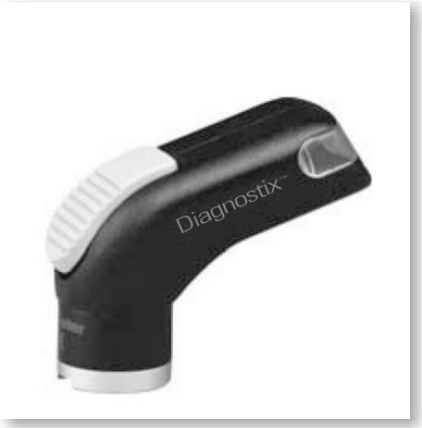
Diagnostix™
Coax Ophthalmoscope



Diagnostix™ Coax Plus
Ophthalmoscope



Diagnostix™
Dermascope



Diagnostix™
Throat Illuminator

1. A SPECIAL THANK YOU

Congratulations on your purchase of an ADC® Diagnostix™ physical exam instrument. ADC professional diagnostic products are the instruments of choice where accuracy and dependability are critical.

This feature-rich instrument was designed to simplify physical exams and non-invasive diagnostics. With proper use and care these instruments will provide many years of dependable service.

2. INTENDED USE

These instruments are designed to facilitate examination of the eye, ear, nose, throat, and skin.

If you have any questions call our toll-free number or visit our website.

Note: Only use ADC parts and accessories to ensure safe and functional use of this product.

3. WARNINGS AND CAUTIONS ⚠

ADC Diagnostix instruments have been manufactured to the highest global standards and are subjected to rigorous quality control.

Read these instructions for use carefully before putting the unit into operation and keep them in a safe place.

If you should have any questions, call our toll-free number or visit our website. Our address can be found on the last page of this booklet.

Please note that all instruments described in these instructions for use are only to be used by suitably trained personnel.

The performance and efficacy of these instruments are only guaranteed when genuine ADC parts and accessories are used.

⚠ **Warning:** Never disassemble instrument heads or handles. There is a danger of life-threatening electrical shock. Unplug the instrument before cleaning or when disinfecting.

⚠ **Warning:** Do not use batteries, electrical cords, or replacement parts other than those included with this product or supplied by the manufacturer.

⚠ **Warning:** Because prolonged intense light exposure can damage the retina, the use of the device for ocular examination should not be unnecessarily prolonged, and the brightness setting should not exceed what is needed to provide clear visualization of the target structures. This device should be used with filters that eliminate UV radiation (<400 nm) and, whenever possible, filters that eliminate short-wavelength blue light (<420 nm).

The retinal exposure dose for a photochemical hazard is a product of the radiance and the exposure time. If the value of radiance were reduced in half, twice the time would be needed to reach the maximum exposure limit.

While no acute optical radiation hazards have been identified for direct or indirect ophthalmoscopes, it is recommended that the intensity of light directed into the patient's eye be limited to the minimum level necessary for diagnosis. Infants, individuals with aphakia and those with diseased eyes will be at a greater risk. The risk may also be increased if the person being examined has had any exposure with the same instrument or any other ophthalmic instrument using a visible light source during the previous 24 hours. This will apply particularly if the eye has been exposed to retinal photography.

⚠ **Warning:** Otoscope MUST be used with included disposable specula.

Attention: There may be a risk of gases igniting when the instrument is used in the presence of flammable or combustible gases. We recommend working in areas with good ventilation.

Attention: Make sure to charge wall plug-in handles for at least 12 hours before first use and for all subsequent charges to ensure optimal capacity and battery life.

Note: To obtain the greatest performance from your instrument, it is recommended that the instrument be used within a temperature range of 50°F to 104°F (10°C to 40°C), with a 10-95% relative humidity.

4. SYMBOL DEFINITIONS

The following symbols are associated with your diagnostic instrument.

Symbol	Definition
	Follow instructions for use
	**Caution!** Important note in these instructions. The caution symbol indicates a potentially dangerous situation that can lead to minor or moderate injuries. It can also be used to warn of unsafe practices.
	**Warning!** The general warning sign indicates a possible dangerous situation that can lead to serious injuries.
	Not made with natural rubber latex
	Phthalate free
	Consult instructions before use

Symbol	Definition
CE	Medical Device compliant Regulation (EU) 2017/745
EC REP	Authorized representative in the European Community/European Union
	Manufacturer
	Date of manufacture
	**Do not dispose of this product as unsorted municipal waste.** Prepare this product for reuse or separate collection as specified by Directive 2002/96/EC of the European Parliament and the Council of the European Union on Waste Electronic and Electrical Equipment (WEEE). If this product in contaminated, this directive does not apply.

Symbol	Definition
	Protection Class II Unit
	Direct current
	Alternating current
	Batch code
	Catalog Number
	Medical Device
	Unique device identifier
	Non-sterile
	Do not use if the package is damaged
	Importer

Symbol	Definition
	Distributor
	Keep Dry
	Non-ionizing
	Type B applied part
	**Caution!** Federal law restricts this device to sale by or on the order of a Physician (Licensed physician)
	Temperature for transport and storage conditions
	Relative humidity for transport and storage conditions
	Air pressure for transport and storage Air pressure for ambient operation

5. BATTERY HANDLES AND INITIAL USE

5.1. Function

The ADC battery handles described in these instructions supply the instrument heads with power (the lamps are contained in their respective instrument heads).

5.2. Battery Handle Options

All the instrument heads described in these instructions fit onto the following battery handles and can therefore be combined individually.

For Otoscopes, Ophthalmoscopes, Dermascope, Throat Illuminator, Power Handles

	Part#	Voltage
Wall-Mounted Handle (with extension unit)	**#5660E**	3.5V, 230V or 120V
Standard Rechargeable Handle (requires desk charger)	**#5560**	3.5V
Plug-In Rechargeable Handle	**#5460**	3.5V, 230V or 120V
USB Rechargeable Handle	**#5462**	3.5V

Note: These handles are compatible with ADC , Riester*, and Welch Allyn* 3.5V instrument heads.

* Welch Allyn is a registered trademark.

* Riester is a registered trademark

5.3. Inserting, Removing, and Charging Batteries

(Fig. 1)

Handles ship with batteries installed. If you need to remove or replace a battery, remove cap from bottom of handle then insert new battery into the casing. The positive end of the battery should point toward the top of the handle (Fig. 1). Firmly screw cap back on handle to secure.

Plug-in Rechargeable Handles

Rechargeable Plug-in Handle

Unscrew the top portion from the bottom to reveal two-prong plug. Plug in to a standard wall outlet to recharge. Before first use, charge for up to 24 hours; for subsequent use, charge overnight for about 12 hours.

Standard Rechargeable Handles

Standard handles with recharger base (base sold separately)

Standard rechargeable handles use a desk charger base (ADC part #5500). Follow Instructions for Use supplied with desk charger.

USB Rechargeable Handles

USB Rechargeable Handle

USB rechargeable handles use a universal USB-C charging cable (cable included; charging brick sold separately). Handles can be used while charging. Color-coded charging light indicates status: red when charging is needed; flashing green when charging; solid green when fully charged. Full charge takes about 3.5 hours.

This USB rechargeable handle should only be used with a universal USB power supply or power source approved by DIN EN 60950/DIN EN 62368-1 (2 MOOP). Using a USB power supply or power source that is not approved by ADC or does not meet the necessary safety standards can potentially damage the device. It may also void the device's warranty using a non-compliant power source. To ensure the proper functioning and warranty coverage of your device, it's best to use the recommended and approved power sources for ADC's (part #5462BAT) rechargeable Li-ion battery, 3.6V, 2600 mAh, 9.62 Wh. ADC's USB rechargeable handle and power supply are tested and medically approved according to the standard IEC 60601-1: 2005 (Third Edition) + CORR. 1:2006 + CORR. 2: 2007 + A1: 2012.

⚠ **Caution:** If you do not plan to use the device for a long time, or if you travel with it, remove the rechargeable batteries from the handle.

⚠ **Caution:** New batteries should be inserted once the light intensity of the instrument becomes weaker, even on a full charge.

⚠ **Caution:** For the best possible light output, we recommend approved ADC or equivalent rechargeable batteries.

⚠ **Caution:** If you suspect that liquid or moisture could have entered the handle, do not charge under any circumstances. This could lead to a life-threatening electric shock, especially in the case of plug-in handles.

⚠ **Caution:** To extend the service life of the battery, the battery should only be charged once the light intensity of the instrument has become weaker.

⚠ **Caution:** Plug-in handle should be charged overnight (12 hours) to ensure uninterrupted power supply.

Waste Disposal

Please note that rechargeable batteries must be disposed of as special waste. You can obtain the relevant information from your local authority or environmental agency.

5.4. Fitting Instrument Heads

Align head with the receptacle located on the upper part of the handle. Ensure that the two recesses on the lower part match the two protruding guide studs on the handle. Gently press the head onto the handle and rotate the handle in a clockwise direction until it is securely locked (Fig. 2). To remove the head, simply reverse the process.

(Fig. 2)

5.5 Locking Instrument Head

Instrument heads are equipped with a security feature. Use enclosed hex key to lock head onto power handle. To secure, insert hex key into slot on head and tighten by turning clockwise. Keep the hex key in a convenient place in case the head must be removed for cleaning or service. This is recommended for wall and desk mount solutions only.

5.6 Adjusting the Light Intensity

With the ADC Adtronic™ electronic rheostat, it is possible to modulate the light intensity. Smoothly control the applied power by holding the easy-grip dial and turning either clockwise or counter-clockwise, varying the light intensity stronger or weaker.

ATTENTION: At every switch-on of the battery handle the light intensity is at 100%. An automatic safety switches the light off after 180 seconds.

6. DIAGNOSTIX OTOSCOPE

6.1. Purpose

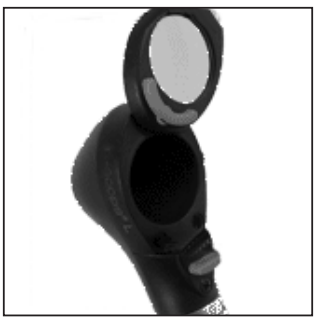
The ADC Diagnostix Otoscope described in these instructions is produced for illumination and examination of the auditory canal in combination with the ear specula. ADC otoscopes are compatible with Riester and Welch Allyn specula.

6.2. Fitting and Removing Ear Specula

Screw the speculum clockwise until noticeable resistance is felt.
To remove the speculum, twist the speculum counter-clockwise.

6.3 Swivel Lens for Magnification

Standard Series: The swivel lens (3x max.) is fixed to the device and can be swiveled 360°. (Fig. 3)



(Fig. 3)

PMV Series: The focusing wheel enables you to adjust the focusing range in the auditory canal (tympanic membrane). The adjustment wheel moves up and down to focus the lens. (Fig. 4)

6.4 Insertion of External Instruments into the Ear

Standard Series only: If you wish to insert external instruments (e.g., tweezers) into the ear, you have to rotate the swivel lens located on the otoscope head 180°.

(Fig. 4)

6.5 Pneumatic Test

To perform the pneumatic test (examination of the eardrum), connect an insufflator (sold separately, ADC part #5122N). Once the tube for the insufflator is attached to the connector port on the right side of the instrument head (Fig. 5), you can carefully insert the necessary volume of air into the ear canal.

(Fig. 5)

6.6 Technical Data of the Lamp

Otoscope Hal/Xen 3.5V	3.5V 720 mA	mean life span 15h
Otoscope LED 3.5V	3.5V 280 mA	mean life span 10,000h

7. DIAGNOSTIX OPHTHALMOSCOPE

7.1. Purpose

The ADC Diagnostix Ophthalmoscope described in these instructions is produced for the examination of the eye.

(Fig. 6)

7.2. Lens Wheel with Correction Lens

The correction lens can be adjusted on the lens wheel. The following correction lenses are available:

Coax 3.5V Ophthalmoscope (Fig. 6)

Plus: 1-10, 12, 15, 20, 40 diopters
Minus: 1-10, 15, 20, 25, 30, 35 diopters

Coax Plus 3.5V Ophthalmoscope (Fig. 7)

Plus: 1-45 in single steps diopter
Minus: 1-44 in single steps diopter

(Fig. 7)

The values can be read off in the illuminated field of view. Plus values are displayed by green numbers, minus values by red numbers.

7.3. Apertures

The following apertures can be selected with the setting wheel (Fig. 8).

(Fig. 8)

Coax Ophthalmoscope

Half-moon, micro/small/large circular aperture, fixation star, and slit.

Coax Plus Ophthalmoscope

Half-moon, micro/small/large circular aperture, fixation star, slit, and grid.

Aperture		Function	Models
	Half Moon	For examinations with turbid lenses	Coax/Coax Plus
	Micro Spot	Allows quick entry into small, undilated pupils	Coax/Coax Plus
	Small Circle	Excellent view of fundus through an undilated pupil	Coax/Coax Plus
	Large Circle	For a dilated pupil and general examination	Coax/Coax Plus
	Karo (Grid)	For topographic determination of retina changes	Coax Plus Only
	Slit	To help determine levels of tumors and lesions	Coax/Coax Plus
	Fixation star	Measuring eccentric fixation or locating lesions	Coax/Coax Plus

7.4. Changing Filters

Using the filter wheel, the following filters can be switched for each aperture.

Coax & Coax Plus Ophthalmoscope

Red-free filter, blue filter, and polarization filter.

Filter	Function
Red-free filter:	Contrast enhancing to assess fine vascular changes, e.g., retinal bleeding.
Polarization filter:	For precise assessment of tissue colors and to minimize corneal reflections.
Blue filter:	For improving recognition of vascular abnormalities or bleeding, for fluorescence ophthalmology.

7.5. Focusing Device (Coax Plus)

Fast fine adjustment of the examination area to be observed is achieved from various distances by turning the focusing daisywheel. (Fig. 9)

(Fig. 9)

7.6. Technical Data on the Lamp

Coax 3.5V ophthalmoscope: 3.5V / 750 mA / average service life 15h

Coax Plus 3.5V ophthalmoscope: 3.5V / 290 mA / average service life 10,000h

8. DIAGNOSTIX DERMASCOPE

8.1. Purpose

The Diagnostix Dermascope described in these instructions is produced for early identification of changes of skin pigmentation (malignant melanomas).

8.2. Focusing

Focus the magnifying glass by rotating the eyepiece ring. (Fig. 10)

(Fig. 10)

8.3. Contact Plates

Two contact plates are supplied:

1) Without a scale.
2) Including a scale of 0 - 10 mm for measuring melanotic skin changes, such as malignant melanoma.

8.4. Technical Data of Lamp

Dermascope LED: 3.5V 280 mA / mean life span 10,000h

9. DIAGNOSTIX THROAT ILLUMINATOR

9.1. Purpose

The throat illuminator described in these instructions is produced for examination of the oral cavity and pharynx in combination with commercial wooden and plastic depressors.

9.2. Technical Data of Lamp

Illuminator Hal/Xen	3.5V 720 mA	mean life span 15h
Illuminator LED	3.5V 280 mA	mean life span 10,000h

10. REPLACING THE LAMP

All Instrument Heads

Remove the instrument head from the battery handle. The lamp is located at the base of the instrument head. Pull the lamp out of the instrument head with thumb and forefinger or a suitable tool. Insert a new lamp. *Use only ADC or Riester lamps.

⚠ **Caution:** The pin on the ophthalmoscope lamp must be inserted into the guide groove on the instrument head.

11. INSTRUMENT HEAD COMPATIBILITY

All ADC 3.5V instrument heads are compatible with Riester and Welch Allyn power handles equipped with bayonet-style mount.

12. SPARE PARTS AND ACCESSORIES

For a complete list of our physical exam instrument spare parts and accessories, please visit our website at **www.adctoday.com**.

13. CLEANING AND DISINFECTION

Cleaning and disinfection of medical devices serves to protect the patient, the user, and third parties, and to preserve the value of the medical devices. Due to the product design and the materials used, no defined limit can be specified for the maximum number of reprocessing cycles that can be carried out. The life span of the medical devices is determined by their function and by gentle handling of the devices. Defective products must undergo the reprocessing procedure described before being returned for repair.

Cleaning and Disinfection

The instrument heads and handles can be cleaned externally with a moist cloth until visually clean. Wipe disinfection as specified by the disinfectant manufacturer. Only disinfectants with proven efficacy should be used, taking into account the national requirements. After disinfection, wipe the instrument down with a moist cloth to remove possible disinfectant residues. The components that come into contact with the skin can be rubbed down with alcohol or a suitable disinfectant.

⚠ **Caution:** Never immerse the instrument heads and handles in liquids! Take care to ensure that no liquids get inside the casing!

⚠ **Caution:** These instruments are not approved for automated reprocessing and sterilization.

Single-Use Ear Specula

For single Use Only

⚠ **Warning:** Repeated use can cause infections.

14. TECHNICAL SPECIFICATIONS

Ambient Temperature:	32°F to 104°F (0°C to 40°C)
Relative Humidity:	30% to 70% non-condensing
Transport and Storage Temperature:	14°F to 131°F (-10°C to 55°C)
Relative Humidity:	10% to 95% non-condensing
Air Pressure:	800 hPa - 1100 hPa

15. MAINTENANCE

These instruments and their accessories do not require any specific maintenance. Should an instrument have to be examined for any specific reason whatsoever, please return it to ADC.

16. ELECTROMAGNETIC COMPATIBILITY

Medical electrical equipment is subject to special precautionary measures with regard to electromagnetic compatibility (EMC).

Portable and mobile high-frequency communication equipment can influence medical electrical equipment. This ME device is intended for operation in an electromagnetic environment as specified below. The user of the device should ensure that it is operated in such an environment.

The ME device must not be used directly next to or arranged in a stack with other devices. If the device has to be operated near to or in a stacked arrangement with other devices, then the ME device should be monitored in order to verify that it operates as intended in this arrangement. This ME device is intended exclusively for use by professional medical staff. This device can cause radio interference and can disrupt the operation of equipment nearby. Suitable remedial measures, for instance realignment, rearrangement of the ME device, or shielding, may become necessary.

Guidelines and manufacturer's declaration - electromagnetic emissions		
The Diagnostix instrument is intended for operation in an electromagnetic environment as specified below. The customer or the user of the Diagnostix instrument should ensure that it is used in such an environment.		
Emission Test	**Compliance**	**Electromagnetic Environment - Guidance**
RF emissions according to CISPR 11	Group 1	The Diagnostix instrument employs RF energy solely for an internal function. Its RF emission is therefore very low and it is unlikely that neighboring electronic devices will be affected by interference.
RF emissions according to CISPR 11	Class B	The Diagnostix instrument is intended for use in all establishments, including residential areas and those directly connected to a public supply network that also supplies buildings that are used for residential purposes.
Harmonics emissions according to EC61000-3-2	Not applicable	
Voltage fluctuation / flicker emissions according to IEC61000-3-3	Not applicable	

Guidelines and manufacturer's declaration - electromagnetic immunity			
The Diagnostix instrument is intended for operation in an electromagnetic environment as specified below. The customer or the user of the Diagnostix instrument should ensure that it is used in such an environment.			
Immunity Tests	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment- Instructions**
Electrostatic discharge (ESD) IEC61000-4-2	Con: ± 8 kV contact discharge Air: ± 2, 4, 8, 15 kV	Con: ± 8 kV contact discharge Air: ± 2, 4, 8, 15 kV	Floors should be made of wood or concrete or be covered with ceramic tiles. If the floor is covered with a synthetic material, the relative air humidity must be at least 30%.
Fast transient electrical interference/bursts IEC61000-4-4	5/50 ns, 100 kHz, ±2 kV	Not applicable	The quality of the supply voltage should correspond to that of a typical business or hospital environment.
Impulse voltage IEC61000-4-5	± .5 kV voltage phase-to-phase conductor ± 2 kV voltage outer conductor-to-earth	Not applicable	The quality of the supply voltage should correspond to that of a typical business or hospital environment.
Voltage dips, short-time interruptions and fluctuations in the supply voltage according to IEC61000-1-11	<0% UT 0.5 period at 0, 45, 90, 135, 225, 270, and 315 degrees 0% UT 1 period and 70% UT 25/30 periods Single phase: at 0 degrees (50/60 Hz)	Not applicable	The quality of the supply voltage should correspond to that of a typical business or hospital environment.
Magnetic field with energy efficient rated frequencies IEC61000-4-8	3 A/m 50/60 Hz	3 A/m 50/60 Hz	Mains frequency magnetic fields should be at a level characteristic of a typical location in a typical commercial hospital environment.
Note - U_T is the AC source. Mains voltage before the application of the test level.			

Guidelines and manufacturer's declaration - electromagnetic immunity

This Diagnostix instrument model is intended for operation in the electromagnetic environment specified below. The customer or the user of this Diagnostix instrument should ensure that it is used in such an environment.

Immunity Tests	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment- Instructions
IEC61000-4-6 Conducted RF disturbances according to IEC61000-4-6	3 Vrms 150 kHz to 80MHz 6 V is ISM frequency bands between 0.15 MHz and 80 MHz 80% AM at 1 kHz	Not applicable	Portable and mobile radio equipment should not be used within a distance from the Diagnostix instrument, including cables, that is less than the recommended safety distance as calculated by the equation that is appropriate for the transmission frequency. Recommended safety distance: d = 1, 2 x P 80 MHz bias 800 MHz d = 2, 3 x P 800 MHz bias 2,7 GHz Where P is the nominal power of the transmitter in Watts (W) as specified by the manufacturer of the transmitter, and d is the recommended safety distance in meters (m). The field strength of stationary radio transmitters should be less than the compliance level at all frequencies as verified by an on-site test[a]
	3 V/m 80 MHz to 2.7 GHz 380 - 390 MHz 27 V/m; PM 50%; 18 Hz 430 - 470 MHz 28 V/m; (FM ±5 kHz, 1 kHz sine) PM; 18 Hz11 704 - 787 MHz 9 V/m; PM 50%; 217 Hz 800 - 960 MHz 28 V/m; PM 50%; 18 Hz 1700 - 1990 MHz 28 V/m; PM 50%; 217 Hz 2400 - 2570 MHz 28 V/m; PM 50%; 217 Hz 5100 - 5800 MHz 9 V/m; PM 50%; 217 Hz	10 V/m 27 V/m 28 V/m 9 V/m 28 V/m 28 V/m 9 V/m	
Radiated RF IEC 61000-4-3 Proximity fields from RF wireless communications equipment			Interference is possible in the vicinity of equipment marked with the following symbol 

Note 1: At 80 MHz and 800 MHz, the higher value applies.

Note 2: These guidelines may not apply in all situations. The propagation of electromagnetic waves is influenced by reflection and absorption by buildings, objects and people.

a. The field strength of stationary transmitters, such as base stations of wireless telephones and mobile field radio services, amateur radio stations, AM and FM radio and television transmitters cannot be precisely determined theoretically in advance. In order to determine the electromagnetic environment due to stationary RF transmitters, an investigation of the location is advisable. If the field strength determined at the location of the Diagnostix instrument exceeds the compliance level indicated above, then the Diagnostix instrument must be monitored with regard to its normal operation at each place where it is used. If unusual performance characteristics are observed, additional measures such as re-alignment of the Diagnostix instrument or its removal to another place may be necessary.

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

Recommended safety distances between portable and mobile RF communication devices and the Diagnotix®

This Diagnostix instrument is intended for operation in an electromagnetic environment in which the radiated RF interference is monitored. The customer or user of this Diagnostix instrument can help prevent electromagnetic interference by observing minimum distances between portable and mobile RF communication equipment (transmitters) and this Diagnostix instrument in accordance with the maximum output power of the communication equipment.

Rated maximum output of the transmitter (W)	**Safety distance that applies to the transmitter frequency m**		
	150 kHz to 80 MHz Not applicable	**80 MHz to 800 MHz**	**800 MHz to 2.7GHz**
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 whose nominal power is not indicated in the table above, the distance can be determined using the equation belonging to the respective column, where P is the nominal power of the transmitter in Watts (W) as specified by the manufacturer of the transmitter.

Note 1: At 80 MHz and 800 MHz, the separation distance applies to the higher frequency range.

Note 2: These guidelines may not apply in all situations. The propagation of electromagnetic waves is influenced by reflection and absorption by buildings, objects and people.

17. WARRANTY

This Diagnostix instrument is warranted for two years on instruments and lifetime on LED lamps, from date of purchase. The warranty does not apply to damage caused by improper handling, accidents, improper use, or alterations made to the instrument by third parties. The warranty is only valid after the product is registered online at **https://www.adctoday.com/register**.

For our European Customers

A printed copy of this manual can be sent to you at no charge within seven calendar days. To request a copy, e-mail us at **info@adctoday.com**.
Our website, **https://www.adctoday.com**, where these instructions for use are available fulfills the requirements of personal data protection, according to Directive 95/46/EC and GDPR on the protection of individuals with regard to the processing of personal data and on the free movement of such data.
Any serious incident that has occurred in relation to this medical device should be reported to ADC and the competent authority of the Member State in which the user and/or patient is established.

For Australian Consumers

Our goods come with guarantees that cannot be excluded under the Australian Consumer Law. You are entitled to a replacement or refund for a major failure and compensation for any other reasonably foreseeable loss or damage. You are also entitled to have the goods repaired or replaced if the goods fail to be of acceptable quality and the failure does not amount to a major failure.

18. QUALITY STANDARDS

This device is manufactured to meet the European and United States standards for: IEC60601-1-2

Electromagnetic compatibility

Device fulfills the stipulations of the International standard IEC60601-1-2

19. HOW TO CONTACT US

To register your product and obtain further detailed user information about our products and services visit us at:

www.adctoday.com

and follow the links.

For questions, comments, or suggestions call us toll free at:

1-800-232-2670

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