18. QUALITY STANDARDS

Device standard

This device is manufactured to meet the European and United States standards for:

ISO 62471, ISO 15004, ISO 10942, ISO 15004-1, and ISO 15004-2

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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Diagnostix™

Otoscope

Coax Ophthalmoscope

Dermascope

Throat Illuminator

Power Handles

Instruction Manual

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

Diagnostix™ EENT Instruments
Table of Contents

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

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

Nominal power of the transmitter W	Safety distance that applies to the transmitter frequency m		
	150 kHz to 80 MHz	80 MHz to 1000 MHz	1400 MHz to 2.5GHz
	Not applicable	$d = 1.2\sqrt{P}$	$d = 2.3\sqrt{P}$
0.01		0.12	0.23
0.01		0.38	0.73
1		1.2	2.3
10		3.8	7.3
100		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 1400 MHz, the distance for the higher frequency range 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.

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**.

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 Guidelines**
Conducted HF interference according to IEC61000-4-6 Radiated HF rerference cording to C61000-4-3	3 Vrms 150 kHz to 80MHz 3 V/m 80 MHz to 2.5GHz	Not applicable 10 V/m 3 V/m	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: $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80 MHz to 1000 MHz $d = 2.3\sqrt{P}$ 1400 MHz to 2.5 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]
			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 HF 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. In the frequency range of 150 kHz to 80 MHz, the field strength should be smaller than 3 V/m.

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.

Read this booklet thoroughly before using your new instrument.

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 PRECAUTIONS ⚠

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 efficency of these instruments are only guaranteed when genuine ADC parts and accessories are used.

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).

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.

Immunity Tests	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidelines
Electrostatic discharge (ESD) according to IEC61000-4-2	± 6 kV contact discharge ± 8 kV air discharge	± 6 kV contact discharge ± 8 kV air discharge	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 according to IEC61000-4-4	± 2 kV for power lines ± 1 kV for input and output lines	Not applicable	The quality of the supply voltage should correspond to that of a typical business or hospital environment.
Surges IEC61000-4-5	± 1 kV voltage phase-to-phase ± 2 kV voltage phase-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 IEC61000-4-11	<5% UT (>95 % drop in UT) for 0.5 cycles 40% UT (60 % drop in UT) for 5 cycles 70 % UT (30 % drop in UT) for 25 cycles <5% UT (>95 % drop in UT) for 5 s	Not applicable	The quality of the supply voltage should correspond to that of a typical business or hospital environment.
Magnetic field at the mains frequency (50Hz) according to IEC61000-4-8	3 A/m	3 A/m	If image disturbances occur, the Diagnostix instrument may have to be placed further away from the sources of mains-frequency magnetic fields, or magnetic shielding may have to be installed: the mains-frequency magnetic field should be measured at the intended set-up site in order to ensure that it is small enough.

Note - UT is the alternating supply voltage prior to application of the test level.

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 Measurements	**Compliance**	**Electromagnetic Environment Guidelines**
HF emissions according to CISPR 11	Group 1	The Diagnostix instrument employs HF energy solely for an internal function. Its HF emission is therefore very low and it is unlikely that neighboring electronic devices will be affected by interference.
HF emissions according to CISPR 11	Class B	The Diagnostix instrument is intended for use in all facilities, including living quarters and such as are directly connected to a public power supply 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	

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, aphakes, and persons with diseased eyes will be at 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.

Caution: Not made with natural rubber latex.

Attention: There may be a risk of ignition when the instrument is used in the presence of flammable or combustible gases. Work 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.

Never attempt to take the instrument apart! There is a danger of ***life-threatening*** electrical shock. Unplug the instrument before cleaning or when disinfecting.

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
	Important Warning/Caution
	Not made with natural rubber latex
	Phthalate free
	Consult instructions for use
CE	Meets essential requirements of European Medical Device Directive 93/42/EEC
MD	Medical device

Symbol	Definition
EC REP	Authorized European Representative's Information
	Manufacturer's Information
	Indicates this is a product with Type B applied parts.
	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 is contaminated, this directive does not apply.
	Device double-earthed

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 on the following battery handles and can therefore be individually combined.

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

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

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

Screw off the battery cap on the lower part of the handle. Depending on which handle you have purchased and for what voltage, insert the rechargeable battery into the casing such that the positive end points toward the top of the handle (Fig. 1). There is also an arrow next to the plus symbol on the rechargeable battery that shows you the direction to insert into the handle. Screw the battery cap onto the handle to secure.

(Fig. 1)

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

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.

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.

Please Note!

- Never immerse the instrument heads and handles in liquids! Take care to ensure that no liquids get inside the casing!
- This item is not approved for automated reprocessing and sterilization.

Single-Use Ear Specula

For single Use Only

WARNING: Repeated use can cause infections.

Plug-in Rechargeable Handles

Prior to initial use, charge the plug-in handle for up to 24 hours in the mains socket. To charge, remove top portion by unscrewing counter-clockwise to reveal two-prong plug. Plug into electrical outlet.

Standard Rechargeable Handles

To charge standard rechargeable handles, desk charger base (# 5500) is required. Follow Instructions for Use supplied with desk charger.

Rechargable Plug-in Handle

Recharger Base sold separately

⚠ 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.
- New batteries should be inserted once the light intensity of the instrument becomes weaker, even on a full charge.
- To obtain the best possible light output we recommend always fitting high-quality batteries.
- 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.
- To extend the service life of the battery, the battery should only be charged once the light intensity of the instrument has become weaker.
- Plug-in handle should be charged overnight (12 hours) to ensure uninterrupted power supply.

⚠ **NOTE for #5460:** 3.5V for charging in a 120V or 230V wall socket. When using the new 5460BAT, care must be taken to ensure that no insulation is affixed to the spring of the battery-handle cap. If the old 5460BAT is used, an insulation must be affixed to the spring to avoid short circuit.

New Old

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 from your local environmental agency.

5.4. Fitting Instrument Heads

Fit the required instrument head on the receptacle on the upper part of the handle such that the two recesses of the lower part of the instrument head fit on the two protruding guide studs on the battery handle. Press the instrument head lightly on to the battery handle and twist the handle clockwise until securely locked (Fig. 2). The head is removed by reversing 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.

NOTE: Locking the head is recommended on wall-mounted systems 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.

Explanation of the symbol on the plug-in handle:

⚠ **Caution:** Observe the Operating Instructions!

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 blades.

9.2. Technical Data of Lamp

Illuminator Hal/Xen	3.5V 720 mA	mean life span 15h
Illuminator LED	3.5V 28 mA	mean life span 100,000h

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**.

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 / 690 mA / average service life 15h

Coax Plus 3.5V ophthalmoscope: 3.5V / 29 mA / average service life 100,000h

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 28 mA / mean life span 100,000h

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)

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)

(Fig. 3)

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, #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 300 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.

Standard Coax Head (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

Minus: 1-10, 15, 20, 25, 30, 35

Coax Plus 3.5V Ophthalmoscope (Fig. 7)

Plus: 1-45 in single steps

Minus: 1-44 in single steps

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


Premium Coax Plus Head (Fig. 7)

7.3. Apertures

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


Switching Aperture (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.
Polarizations filter:	For precise assessment of tissue colors and to minimize retinal reflections.
Blue filter:	For improving recognition of vascular abnormalities or bleeding, for fluorescence ophthalmology.