Otoscope and Accessories Troubleshooting Guide

Trouble Area	Possible Cause	Corrective Action
No light output	Lamp burned out	Replace the lamp
	Wrong lamp Installed	Replace the lamp
	Batteries are depleted	Replace with fresh AA batteries
	Lamp not fully inserted	Re-insert lamp
Instrument head will not connect	Thread/connection is damaged	Service required

Trouble Area	Possible Cause	Corrective Action
Specula will not attach properly	Specula mount is damaged	Service required
Loose or misaligned magnifying lens	Lens mount is damaged	Service required
Poor or obstructed view through lens	Lens is dirty	Clean with lint-free cloth
	Lens is damaged	Service required
	Lamp near end of useful life	Replace the lamp
Dim light output	Batteries are depleted	Replace with fresh AA batteries
Visible corrosion on instrument or accessories	Damage from excessive moisture	Service required

Ophthalmoscope Troubleshooting Guide

Trouble Area	Possible Cause	Corrective Action
No light output	Aperture dial is between positions	Rotate aperture dial
	Lamp burned out	Replace the lamp
	Wrong lamp installed	Replace the lamp
	Batteries are depleted	Replace with fresh AA batteries
Instrument head will not connect	Lamp not fully inserted	Re-insert lamp
	Thread/connection is damaged	Service required
Spot is not centered	The aperture dial is not centered	Move aperture dial to the full detent position
Dim light output	Lamp near end of useful life	Replace the lamp
	Batteries are depleted	Replace with fresh AA batteries
Aperture or lens wheel will not turn or does so with difficulty	Dirt in or damage to mechanism	Service required
Visible corrosion on instrument	Damage from excessive moisture	Service required

Environment

Transportation / Storage:	-4°F to 120.2°F (-20°C to 49°C) Relative Humidity: 95 % 500 hPa – 1060 hPa, Altitude
Environmental Operating Range:	50°F to 120.2°F (10°C to 49°C) RH 95 % (Max) 500 hPa – 1060 hPa, Altitude
Max. Operating:	95°F (35°C)

Diagnostix™
Pocket Diagnostic Instruments
Instructions for Use

AMERICAN DIAGNOSTIC CORPORATION

LIMITED WARRANTY

ADC® warrants its products against defects in materials and workmanship under normal use and service as follows:

1. Warranty service extends to the original retail purchaser only and commences with the date of delivery.
2. The instruments are warranted for two years. The LED lamps are warranted for life.

What Is Covered:

Repair, or replacement of parts, and labor.

What Is Not Covered:

Transportation charges to ADC. Batteries where supplied. Damages caused by abuse, misuse, accident, or negligence. Incidental, special, or consequential damages. Some states do not allow the exclusion or limitation of incidental, special, or consequential damages, so this limitation may not apply to you.

To Obtain Warranty Service:

Devices should be contained in their transport/storage cases when being returned to ADC to ensure that they are not damaged during transport and handling. Do not ship contaminated devices or storage cases to ADC's facility.

Send item(s) postage paid to ADC, Attn: Repair Dept., 55 Commerce Dr., Hauppauge, NY 11788. Please include your name and address, phone no., proof of purchase, and a brief note explaining the problem.

Implied Warranty:

Any implied warranty shall be limited in duration to the terms of this warranty and in no case beyond the original selling price (except where prohibited by law). This warranty gives you specific legal rights and you may have other rights which vary from state to state.

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.

To register your product, visit us at
www.adctoday.com/support/warranty-registration
or scan the QR code below.

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Cases made in Indonesia and China

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Thank you for choosing an ADC Diagnostix™ brand pocket diagnostic set. We're proud of the care and quality that goes into the manufacture of each and every diagnostic instrument that bears our name. Every component has been carefully designed to maximize performance. This booklet refers to both otoscope and ophthalmoscope sets (models 5110N series, 5110E, 5111N series, 5112N series).

Device Description and Intended Use

Ophthalmoscope Attachment (5110N Series, 5110E, 5112N Series)
The ophthalmoscope is a handheld, battery-powered device containing illumination and viewing optics intended to examine the media (cornea, aqueous, lens, and vitreous), the retina, blood vessels, optic nerve, and other structures of the eye. It is intended to be used by a trained healthcare professional.

Otoscope Attachment (5110N Series, 5110E, 5111N Series)
A handheld battery-powered device with magnifying system that provides illumination of the ear canal and tympanic membrane.

This device should be used by a trained healthcare professional.

Contraindications

The use of this device is contraindicated in patients who have already received prolonged or intense light exposure, especially if the patients are infants, aphakes, or persons with diseased eyes. Excessive exposure to light may result in patient injury. See warnings for additional information.

Symbol Definitions

The following symbols are associated with your diagnostic instrument.

Symbol	Definition
	Important Caution
	Not made with natural rubber latex
	Phthalate free
	Consult instructions for use
CE	Meets the general safety and performance requirements of Regulation (EU) 2017/745 of the European Union
EC REP	Authorized Representative in the European Community/European Union
	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.

Symbol	Definition
	Type B applied part
UK REP	Authorized Representative in the United Kingdom
MD	Medical Device compliant with Regulation (EU) 2017/745
LOT	Batch code
REF	Catalog Number
	Manufacturer
	Date of Manufacture
UDI	Unique device identifier
	Non-sterile
	Do not use if package is damaged
	Importer
	Distributor
	Follow instructions for use
	Keep dry

General Warnings ⚠

A warning statement in this manual identifies a condition or practice which, if not corrected or discontinued immediately, could lead to patient injury, illness, or death.

CAUTION: 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.

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 which is 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.

CAUTION: Do not immerse the battery handle in liquid. Consult the cleaning and disinfection instructions for each part for further information about cleaning and disinfecting this product. Never clean or disinfect any device with batteries in it.

CAUTION: Federal law restricts this device to sale by or on the order of a physician or licensed healthcare practitioner.

CAUTION: Turn off instrument when not in use. Avoid powering on without an instrument head attached. When storing this device for extended periods of time, remove the batteries.

WARNING: The carrying cases provided with these devices are intended for long-term storage or transport between facilities or when shipping devices to and from ADC's facility for repair or servicing. Carry cases (including internal liners) cannot be cleaned or disinfected and should be safely discarded if contaminated. Do not carry the case into a contaminated environment.

WARNING: When replacing lamp, allow lamp to cool for five minutes before handling.

WARNING: Only the approved sterilization method included in this IFU has been validated for this device or its corresponding components. Any other sterilization method may compromise the safety and effectiveness of this device. (This includes steam sterilization.)

WARNING: Do not place devices or accessories back into carrying case after use on a patient without first cleaning/disinfecting the device/accessories as described in the cleaning and disinfection section of this manual.

WARNING: Use of any accessories or materials not indicated in the user's manual can degrade the minimum safety of the equipment.

WARNING: Only replace listed accessories (attachments), lamps, or batteries for the device.

WARNING: During use metal components near instrument head can become warm. This is especially true if device is on for extended periods of time. Do not leave device on when not in use.

WARNING: The light emitted from this instrument is potentially hazardous. The longer the duration of exposure, the greater the risk of ocular damage. Exposure to light from this instrument, when operated at maximum intensity, will exceed the safety guideline after 3 minutes and 47 seconds. Exposure times are cumulative for a 24 hour period.

Otoscope Parts and Assembly

The pocket otoscope consists of a AA battery handle (5160N), fiberoptic otoscope instrument head (5120N series) with attached movable viewing lens, and disposable specula (2.75mm and 4.25mm).

Removing and Attaching the Instrument Head

Pocket otoscope heads are threaded and can be removed by rotating the threaded connection counterclockwise, or attached by rotating the threaded connection clockwise.

Viewing Lens

To move during an examination, turn the lens bezel clockwise to lift up. To reposition, reverse procedure.

Attaching the Disposable Specula

Push the flanged end of the desired speculum onto the stainless socket and twist clockwise to engage. Reverse procedure to remove and discard after each use.

NOTE: Otoscope must be used with specula.

Pneumatic Otoscope

To perform, insert tapered end of insufflator fitting (5121N, sold separately), into hole on side of otoscope head. Attach optional bulb assembly (5122N, sold separately).

Ophthalmoscope Parts and Assembly

The pocket ophthalmoscope consists of AA battery handle (5160N) and ophthalmoscope instrument head (5140N Series).

Aperture Selection

This unit is equipped with 5 internal apertures: small, large, semi-circle, red-free, and fixation. To select, rotate the aperture selection wheel at the front of the instrument head.

Corrective Lens Selection

This unit is equipped with 19 corrective lenses from +20 to -20 diopters (negative lenses in red). To select, rotate the corrective lens selection wheel at either side of the instrument head. Selected lenses can be viewed in the lighted panel on practitioner side of instrument.

Turning Instrument On

To illuminate, slide the on/off switch located on the battery handle pocket clip away from the instrument head. Slide the switch in the opposite direction to turn off.

Replacing Lamp

Remove the instrument head by turning counterclockwise. Grab end of lamp from inside base of instrument head and remove. Replace with new lamp, taking care not to touch the glass, and align lamp metal guides on side of lamp with grooves in lamp socket (xenon ophthalmoscope heads only).

NOTE: Allow lamp to cool for five minutes before handling if device has been recently used.

Lamp Replacement Part Numbers

Lamp Type	Otoscope	Ophthalmoscope
Xenon	5111N-4	5112N-4
LED	5120NL*	5112NL-4

***NOTE:** Otoscope LED lamp cannot be replaced, must order new head with lamp.

Battery Replacement

This unit requires 2 AA batteries. For best performance, we suggest alkaline batteries. To replace, remove the battery cap at the base of the handle by turning counter-clockwise and replace batteries, taking care to observe correct polarity.

NOTE: This instrument should be turned off when not in use. If storing for extended lengths of time, remove batteries completely.

Handle Care and Maintenance

Periodically check the condition of both the batteries, making sure there is no sign of corrosion or oxidation. Always replace both batteries. Alkaline batteries are recommended. Remove batteries from handle if instrument will not be used for an extended period of time.

Cleaning and Disinfection

Basic Cleaning Procedure for Battery Handles, Otoscope and Ophthalmoscope Heads.

To clean the exterior of the device, prepare a 70% isopropyl alcohol solution and soak a lint-free cloth. Wipe down the exterior of the ophthalmoscope head and handle, cleaning all external surface areas. Care should be taken to prevent excess liquid from seeping into the components.

Isopropyl alcohol may be substituted with commonly used, EPA-registered hospital disinfectant wipes for cleaning purposes if desired. Please refer to the directions provided by the manufacturer of the wipes for appropriate instructions for use to ensure effective contact time between the wipe and the device.

It is important to note that solution residue on the magnifying lenses may decrease device performance. All excess cleaning fluids must be carefully wiped clean if these surfaces are cleaned. The lenses of the instrument head may be cleaned with a lint-free cloth or lens paper.

Steris Sterilization Processes

This product has been validated with the V-PRO 1 Standard Cycle; V-PRO 1 Plus Lumen and Non Lumen Cycles; V-PRO maX Lumen, Non Lumen, and Flexible Cycles; V-PRO 60 Lumen and Non Lumen Cycles using the V-PRO 60 Low Temperature Sterilization System with VAPPROX HC Sterilant and V-PRO maX Low Temperature Sterilization System.

Disposable Specula Cleaning/Disinfection Instructions

Disposable specula should not be cleaned or disinfected in any way. Disposable specula are single-patient use only and must be discarded after use. Disposable specula should not be used if they appear to be visibly contaminated or have accidentally come into contact with contaminated materials prior to use.

Troubleshooting

The following guidelines should be used to determine if your device has reached its end of life or requires servicing. If the corrective actions described in this section do not resolve your issues, please see the warranty section of this manual to have your device serviced.