

Limited Warranty

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

1. Warranty service is extended to the original retail purchaser only and begins on the date of delivery for a period of 12 months.
2. The optical system is warranted for life.

What is Covered: Repair, or replacement of parts, and labor.

What is Not Covered: Transportation charges to and from 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: 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 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.

For our European Customers:

A printed copy of this manual can be sent to you at no charge within seven calendar days.

Our website 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.



EC REP

UK REP

CH REP

Inspected, assembled and
packaged in the U.S.A.
Components made in Pakistan



Printed in U.S.A.

IB p/n 93-5312-00 rev 2 (12/13/2024)

ADC® 5312 Dermascope

Instructions for Use



A Special Thank You

Thank you for choosing an ADC® Dermascope. We're proud of the care and quality that goes into the manufacture of each and every product that bears our name.

Only the finest materials are used to assure you of a timeless instrument designed for optimum performance.

You'll quickly appreciate the results, for you now own the finest dermascope that money can buy.

With proper care and maintenance your ADC Dermascope is sure to provide you with many years of dependable service.

Please read the following instructions and general information which will prove helpful in allowing you to enjoy your ADC product.

Thank you for your patronage. It is indeed our pleasure to serve you.

Sincerely,
American Diagnostic Corp.

Device Description and Intended Use

The dermascope is used for pre-operative evaluation of cutaneous pigmented lesions with the aim of differentiating early melanoma, which requires excision from non-melanomatous pigmented lesions that may safely be left untreated. Use of the dermascope three-color test could reduce excision of benign melanocytic naevi, and thus prevent both unnecessary minor surgical work and patient morbidity.

The dermascope has an optical magnifying lens which enhances the view of skin surface during an examination. The dermascope head is used along with a battery-powered handle for outer skin examination.

The dermascope is intended for transient use and examination.

Features:

1. Halogen light for true tissue color
2. Graduated skin contact plate to measure pigmented skin lesions
3. Significant 10X magnification
4. Focal range $\pm 5D$ (correction)
5. Focal length is 25mm
6. Autoclavable contact plates

This dermoscope provides a reliable bayonet locking system and is equipped with a 2.5V halogen lamp to be powered by two 1.5V C type batteries.

Symbol Definitions

The following symbols are associated with your ADC Dermoscope.

Symbol	Definition
	Important Caution
	Not made with natural rubber latex
	Phthalate free
	Consult Instructions for Use
	Meets the general safety and performance requirements of Regulation (EU) 2017/745 of the European Union
	Authorized representative in the European Community/European Union
	Manufacturer
	TYPE B. Indicates this is a product with Type B applied parts
	Keep dry
	Batch Code
	UK Representative
	Unique Device Identifier

Symbol	Definition
	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.
	Date of Manufacture
	Catalog Number
	Medical Device
	Non-Sterile
	Do not use if package is damaged
	Importer
	Exporter
	Authorized Representative in Switzerland
	Humidity limitation and temperature limit

Recommended Operating Environment

Operation	Temperature 50°F to 86°F (10°C to 30°C) Humidity 30% to 75% Air Pressure 700hPa to 1060hPa
Altitude	0-13, 123 feet (0-4,000 meters)
Temperature	-4°F to 140°F (-20°C to 60°C)
Storage & Transport	Humidity 10% to 95% (without condensation) Air Pressure 500hPa to 1060hPa

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.

WARNING: This product is not allowed to enter or be used in areas with strong magnetic fields e.g. MRI scanners.

WARNING: Don't use the equipment in case it is damaged. Return to your retailer/dealer.

WARNING: Do not exceed temperature of 275°F (135°C) and pressure of 28 psi during autoclaving.

WARNING: Ultrasonic is not recommended.

WARNING: Store in clean environment and preserve in normal temperature.

WARNING: Don't use abrasive materials to clean the lenses and lamp as they will scratch the coated surface of the lenses.

CAUTION: Dermoscope can only be used by trained professional and qualified medical personnel in a healthcare facility.

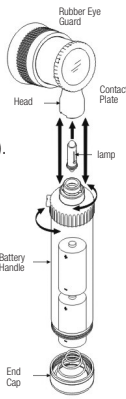
CAUTION: Use the instrument properly to extend its shelf life. Avoid exposing it to salty or humid environments for prolonged periods.

Operating Instructions

Before using, it is necessary to install the battery components into the handle.

1. The dermoscope handle can be powered by two 1.5V C type batteries. Alkaline batteries are highly recommended for optimum performance.
2. To connect the Dermoscope head to the battery handle, align the slots on the head with the handle and push down. You must twist the head clockwise to lock it in place.

3. Push the white button on the handle and twist the black knob clockwise. The unit is now in operation. The intensity of the light can be adjusted by turning the knob clockwise or counter-clockwise.
4. Gently rest the contact plate on the lesion such that the lesion is in the center of the contact plate and examine its surface structure. To reduce glare from stratum corneum, apply oil (Mineral oil, Petroleum Jelly, etc.).
5. With your index finger on the rubber focusing ring, adjust for optimal focus while your eye is resting on the rubber eye guard.
6. Observe the illuminated and magnified lesions, making notes for treatment.
7. To measure pigmented skin lesions, the graduated contact plate must be used.
8. Switch off the unit after use to preserve batteries. Twist the black knob counter-clockwise until an audible click sound is heard and the button comes to its off position.



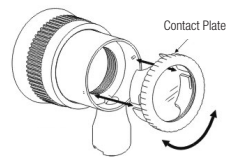
Care and Maintenance

NOTE: Periodically check the battery conditions, making sure that no sign of corrosion or oxidation is present.

Cleaning and Sterilization

1. Contact Plate

- The contact plate must be taken off after each examination.
- The contact plate can withstand cleaning or disinfection by soaking in alcohol solution, cidex, etc.
- The contact plate can also be autoclaved up to 275°F (135°C) and pressure of 28 p.s.i.



NOTE: Clean the contact plate with a cleaning solution prior to autoclaving.

2. Lens

- The lens can be cleaned by using a moistened cotton-tipped applicator with alcohol or a solution of water with mild detergent.
- Do not use abrasive materials to clean the lenses as they will scratch the coated surface of the lens.

3. Handle

- The handle can be cleaned with a moist cloth.
- Battery handle shell should not be immersed in water. Remove battery components while cleaning.

Lamp Replacement

NOTE: Before removing the lamp, make sure that the device has been turned off for a few minutes to avoid the risk of being burnt. Lamps may be hot, so it's necessary to let it cool.

- Remove dermoscope head from the power source as advised in operating instructions.
- Pull the lamp downward and out from the bulb holder with tweezers or similar tool (if necessary).
- Use ADC recommended lamp (part no.# 5312-4) for replacement. Carefully align the pin on the lamp shaft with the slot in the dermoscope head, then push the lamp in until it is securely sealed.



Battery Replacement

NOTE: Handle batteries carefully when removing, as the liquid in them can irritate the skin and eyes. Dispose of the used batteries properly. Replace with alkaline type "C" batteries.

- Open the battery compartment by turning the end cap counter-clockwise.
- Once opened, insert the batteries making sure the direction of the poles are correct.
- Close the battery compartment by turning the cap clockwise.

Storage

Since this product is made of corrosion-proof materials suitable for environmental conditions encountered during normal use, it does not require special care. However, this device should be stored at room temperatures, in a protected area free of dust and dirt to ensure its hygienic properties.