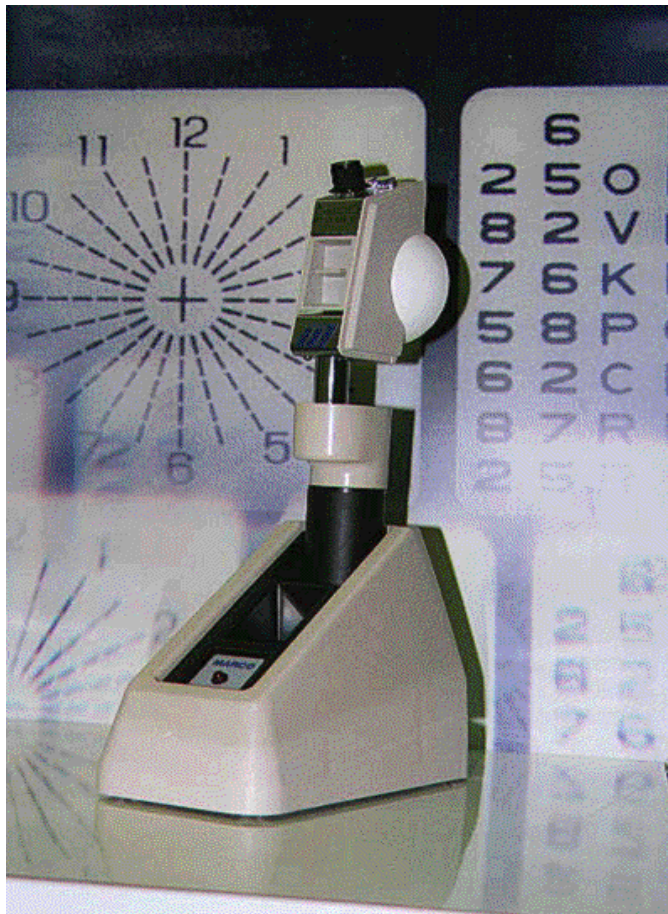


 **MARCO**
OPHTHALMIC, INC.



BAT Brightness Acuity Tester

Product No. BAT-1000
Instruction Manual

INTRODUCTION

The MARCO BAT Brightness Acuity Tester is a hand-held instrument designed for two major visual function tests.

1) **Brightness Acuity Test** – Many people with cataracts and other ocular media opacities are visually disabled in bright light conditions from intraocular light scatter often referred to as glare. The BAT Brightness Acuity Tester provides objective measurements of functional visual acuity in three common bright light conditions while the is in the standard refracting lane.

2) **Macular Photostress Test** – The BAT Brightness Acuity Tester produces a full hemispherical light source to photostress the retina when maculopathy is suspected.

BRIGHTNESS ACUITY TEST

Clinicians are acutely aware of the disparity between functional vision in bright light conditions compared to that measured in a standard dark refracting lane. Significant disparity usually occurs with opacities or distortions in the ocular media such as:

- 1) Corneal opacities, e.g. corneal scars or irregularities.
- 2) Lenticular opacities, e.g. anterior subcapsular, posterior subcapsular and nuclear sclerotic cataracts.
- 3) Posterior capsular opacification following extracapsular cataract surgery.
- 4) Vitreous opacities, e.g. dense central vitreous floaters or asteroid hyalosis.

These phenomena are frequently described as glare producing conditions.

The BAT Brightness Acuity Tester can simulate three bright light conditions: 1) High-direct overhead sunlight; 2) Medium-partly cloudy day; 3) Low-bright overhead commercial lighting. The visual acuity measurements will be similar to those that would be measured in these three conditions using a standard eye chart¹. The result is an assessment of functional visual acuity which can be obtained in the standard refracting lane.

BRIGHTNESS SETTINGS

HIGH (400 ft. lamberts*)
Equivalent to the patient being in direct overhead sunlight (10,000 ft. candles) and standing on a white concrete sidewalk or sandy beach.

MEDIUM (100 ft. lamberts*)
Equivalent to the patient being in indirect sunlight (2500 ft. candles) and standing on a white concrete sidewalk or sandy beach on a cloudy day.

LOW (12 ft. lamberts*)
Equivalent to the patient being in bright overhead fluorescent lighting (300 ft. candles) such as in a department store, plant assembly line or classroom.

*Average bowl luminance for setting.

Brightness Acuity Testing should be performed at all three settings in order to determine the functional visual acuity in various bright light conditions. Some patients may be unable to tolerate the high setting due to photophobia.

PATIENT PREPARATION

The patient should be comfortably seated at the standard distance from the eye chart.

The test should be performed without dilating the pupil so that the normal pupillary constriction from bright lights will occur. The patient may then be dilated and retested to see if functional vision improves or worsens with dilation.

Make sure the patient's glasses or contact lenses are clean and not scratched, since dirt or scratches will cause glare and affect the results of the test. Tests should be performed with the best correction in place.

EXPLAINING THE PROCEDURE TO THE PATIENT

To alleviate any anxiety the patient may have, explain that the test simulates various bright light conditions. Explain that you will be turning up the brightness from low to medium to high and recording a visual acuity at each level.

Inform the patient that the purpose of the test is to assess his or her ability to see in various bright light and glare producing conditions.

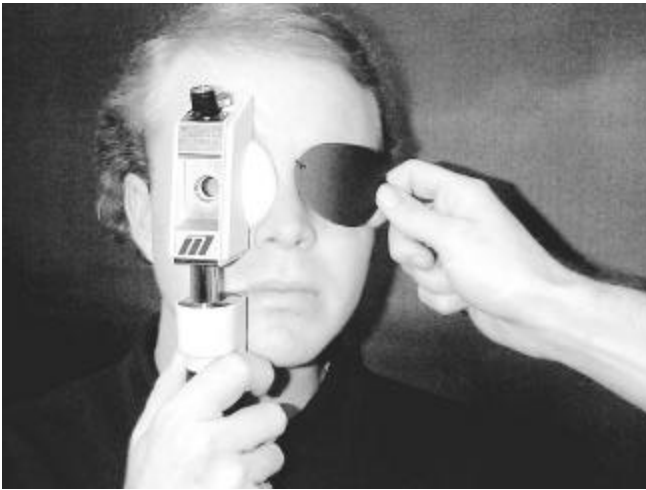
THE EXAMINING ROOM

The examining room should be dark (less than 20 ft. candles) to assure maximum contrast of the projected acuity chart. Make sure that the projected acuity chart is well illuminated and that the letters are in sharp focus.

¹Holliday, J.T., Trujillo, J., T.C. Ruiz, R.S. Brightness Acuity Test (BAT) and outdoor visual acuity in cataract patients. *Journal of Cataract and Refractive Surgery*, Jan. 1987, 67-69

PERFORMING THE BRIGHTNESS ACUITY TEST

1 Make sure the BAT is turned OFF before you begin. Have the best correction in place and occlude the eye you are not testing. Instruct the patient to hold the BAT vertically so he or she can see the projected eye chart through the 12 mm central aperture. Although the patient may rest the instrument lightly against eyeglasses eyebrow, observe to make sure the patient does not press the BAT against the eyelid at any time, since this may distort the eye and affect visual acuity.



2 Using the BAT with the switch set to “OFF”, measure the patient’s vision in the standard manner with the best correction.



3 Turn the BAT to the “LOW” position. Test and record the visual acuity at this level. Adaptation to the bright light may normally take approximately 30 seconds, although more time may be necessary if the patient says their vision is improving. Encourage the patient to read the chart until he or she has read the smallest set of characters. Repeat this procedure with the BAT turned to the “MED” and “HI” positions.

NOTES ON THE PROCEDURE:

1) The patient preferably should be tested wearing his or her own best correction, either eyeglasses or contact lenses.

If the patient’s eyeglasses or contact lenses are not available, the test can be conducted with trial frames. When using trial frames, rimless and thin trial frames are necessary to reduce shadowing of the BAT illumination.

Do not perform the test through a phoropter, as it will occlude significant peripheral illumination and therefore reduce the effectiveness and accuracy of the test.

2) Recording the visual acuity before the patient has adjusted at each luminance level, “LOW, MED and HI” may produce falsely low visual acuities. This is particularly true for some older patients who do not adapt to bright light condition as quickly as younger people. These older patients should therefore be given several seconds longer to adapt to the BAT light before recording the “best” visual acuity.

3) To avoid chart memorization, have the patient begin with the smallest line of letters he or she can see at each light level. It also helps to have the patient alternate the direction the letters are read (i.e., left to right then right to left) at each successive light level.

4) Be careful not to handle or touch the white matte surface on the reflector side of the BAT, as oil from the skin will soil the matte finish. (For cleaning instruction, see “Changing the White Reflector”.)

BRIGHTNESS ACUITY TEST RESULTS

There are three potential outcomes when the Brightness Acuity Test is performed:

1) No change in acuity – The patient’s acuity in bright light conditions is the same as that normally measured in the standard refracting lane. This indicates that no significant ocular opacities or distortions are present. See clinical example 1.

2) Reduction in acuity – The patient’s functional acuity in bright light conditions is less than what is normally measured in the standard refracting lane. This commonly encountered finding implies that opacities or distortions in the ocular media are present. Probable causes are corneal scars, cataracts, posterior capsular opification or central vitreous floaters. See clinical example 2 and 3.

3) Improvement of acuity – Some patients may actually have an improvement in their acuity in bright light conditions. This is primarily due to the “pinhole effect” from the pupil constricting. It implies a residual refractive error or an opacity/irregularity which is less significant when the pupil is small. Clinical examples include: Residual refractive error, irregular astigmatism, paracentral corneal scars, non-central cortical cataracts and eccentric opacification of the posterior capsule. These patients will have better functional outdoor acuity than in dark or dim light. See clinical example 4.

CLINICAL EXAMPLES

1) Normal Patient

OFF LOW MED HIGH

Right Eye

Left Eye

20/20	20/20	20/20	20/25
20/20	20/20	20/20	20/20

Comment: No significant change with increasing brightness. A line decrease in vision on the high setting is normal.

2) Mild Posterior Subcapsular Cataracts (OS> OD)

OFF LOW MED HIGH

Right Eye

Left Eye

20/25	20/30	20/40	20/50
20/30	20/30	20/50	20/60

Comment: A 3-line decrease in acuity to 20/50 and 20/60 at the maximum brightness. The patient usually only experience difficulty on bright sunny days.

3) Severe Posterior Subcapsular Cataracts (OS> OD)

OFF LOW MED HIGH

Right Eye

Left Eye

20/40	20/60	20/80	20/400
20/50	20/80	20/200	<20/400

Comment: A 7 to 8 line decrease in acuity to 20/400 or worse at the maximum brightness indicates that the patient is legally blind in direct sunlight.

4) Residual Refractive Error with no Opacities (OS> OD)

OFF LOW MED HIGH

Right Eye

Left Eye

20/30	20/30	20/25	20/20
20/40	20/40	20/30	20/25

Comment: The patient actually sees better in bright light due to the "pinnole effect" from pupillary constriction.

MACULAR PHOTOSTRESS TEST

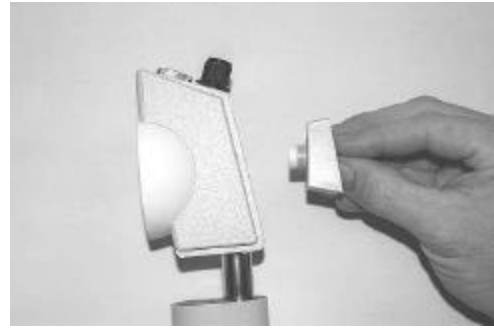
When the aperture occluder is in place, the BAT provides a hemispherical light source which stresses the entire macular region with consistent brightness.

Macular photostress testing is a sensitive test for detecting patients with macular disturbances such as cystoid macular edema, central serous choroidopathy and senile macular degeneration. These disturbances have been shown to have significantly prolonged recovery from photostress.²

Photostress testing is particularly helpful following intraocular surgery when cystoid macular edema is suspected. Prolongation of the recovery time indicates a maculopathy and helps rule out other complicating factors reducing the visual acuity that do not have prolonged recovery such as astigmatism, early capsular opacification or optic nerve disease.

PERFORMING THE MACULAR PHOTOSTRESS TEST

1) Record the patient's acuity with the best correction in place, but without the BAT.



- 2) Close the central 12 mm aperture by inserting the occluder into the aperture.
- 3) Photostress the eye with the BAT for **at least** 10 seconds by having the patient look into the center of the BAT on the **HIGH** setting.
- 4) Remove the BAT and record the length of time for visual acuity to recover to within 2 lines of the initial visual acuity.

RECOVERY TIME RESULTS

- 0-30 seconds Normal recovery time.
- 30-60 seconds Marginal prolonged recovery; maculopathy possible but not definite.
- >60 seconds Definite prolongation of recovery indicating maculopathy.

POWERING THE BAT BRIGHTNESS ACUITY TESTER

The portable, handheld MARCO BAT Brightness Acuity Tester is powered by a special rechargeable battery pack housed in the handle of the instrument. The BAT fits into the well of its own Charger Stand. **It does not fit into other battery charging wells.** This design accommodates the unique power requirements of a special voltage regulator in the BAT. This voltage regulator maintains a constant preset voltage to the lamp to ensure consistent lighting conditions from patient to patient. To maintain consistency, it is recommended that the lamp be changed after approximately 15 hours of use on the "HI" setting.

When not in use for the patient assessment, the BAT should rest in the BAT Charger Stand to keep the batteries refreshed and fully charged. **The red light indicator on the BAT Charger Stand indicates that the battery is being charged.** It does not indicate whether the battery pack is fully charged or not.

When fully charged, the BAT will operate for approximately 30 minutes. Although it is not necessary to recharge the BAT after every exam, the BAT does require 20 minutes of recharging time for every 5 minutes of use. If the charge is fully depleted, the BAT will return to a full charge in approximately 2 hours.

²Glaser, J.S., Savino, P.J., Summers, K.D., McDonald, S.A. & Knighton, R.W. (1977). The Photostress Recovery Test in the clinical assessment of visual function. American Journal of Ophthalmology, 83 (2), 255-260

SERVICE

Changing the Rechargeable Battery Pack

- 1) Unscrew and remove the end cap from the BAT handle base.
- 2) Allow the battery pack to slide out of the handle.
- 3) Replace with a new battery pack.
- 4) Screw the end cap onto the handle.
- 5) Place in Charger Stand to bring the battery up to a full charge.

Caution: Use only the MARCO Rechargeable Battery Pack Product No. BT-1020. Using other batteries voids the warranty for this product.

Changing the White Reflector

If the white hemisphere becomes soiled or scratched, it should be washed or replaced by following the directions below. Maintaining a clean reflector will ensure the delivery of a constant hemispheric source of light.

To clean or replace the BAT Reflector:

- 1) Remove the retaining screw below the reflector on the front of the BAT.
- 2) Slide the reflector down and out.
- 3) Wash the reflector with mild non-abrasive soap or detergent; make sure the soap does not contain lanolin, other hand lotions or abrasives. Gently dab with a lint free material or allow to thoroughly air dry.

Do not rub matte surface of reflector.

- 4) Replace with a new reflector if it becomes scratched.

To replace the reflector:

- 1) Slide the notch at the top of the reflector rim behind the lamp shield, taking care to also position the smaller, non-central circular opening around the lamp.
- 2) Install the retaining screw below the reflector on the front of the BAT, but do not overtighten.
- 3) The 12 mm aperture in the center of the reflector should align perfectly with the aperture in the housing. If it does not, loosen the screw and gently rotate the reflector until the two apertures are in alignment.
- 4) Tighten the retaining screw.

Changing the BAT Lamp Product No. BT-1010

- 1) Remove the BAT from the Charger Stand.
- 2) Remove the cap from the top of the unit by turning the screw cap counterclockwise (using a coin if necessary).
- 3) Simply invert the BAT and the lamp will drop out.
- 4) Replace the lamp, taking care not to touch the glass surface of the new bulb with your fingers. Ensure that the lamp's filament is correctly orientated from left to right. **NOTE:** Filament alignment affects the accuracy of the light levels.
- 5) Replace the lamp cap into the top of the BAT by turning the screw cap clockwise, making sure it is securely in place.

IMPORTANT: Do not use any lamp other than the MARCO replacement lamp **Product No. BT-1010** to assure safety and accuracy of this device.

SPECIFICATIONS

Model BAT-1000 Brightness Acuity Tester

Light Output:

- HIGH = 400 ft. lamberts
- MEDIUM = 100 ft. lamberts
- LOW = 12 ft. lamberts

Power Input: 5 VDC, 750 ma
Size: 12" H x 2.5" W x 2.5" D
(305 mm H x 64 mm W x 64 mm D)
Weight: 1.2 lbs. (.54 kg), including battery pack

Model BAT-1021 Charger Stand

Input: 110/120V (220V, special order), 50/60 Hz., 5 Watts
Output: 250 ma. Maximum
Size: 5" H x 3.5" W x 7" D
(127 mm H x 89 mm W x 178 mm D)
Weight: 2.5 lbs. (1.1 kg)

WARRANTY

This product is warranted to be free from defects in workmanship or materials. Any product which proves defective in workmanship or materials will be replaced at our discretion, free of charge, up to one year from the date of purchase. This warranty covers all repairs and service of parts that have proved to be defective by manufacture and not by use or mishandling. This type of service will be handled by our trained sales force or, if necessary, in our home office. Shipping charges for returns for repair of non-warranted items will be the responsibility of the customer. Alteration, repair or modification of any product which is performed by persons not authorized by MARCO OPHTHALMIC, INC. will result in the immediate loss of warranty.

Claims for Shortages or Damage

Extra care has been taken in packaging and shipping. If you have any claims for shortages or damage, contact your local MARCO representative or MARCO OPHTHALMIC, INC. within 10 days.

Replacement Parts or Repairs

When ordering replacement parts or repairs, state the model number and serial number of the instrument.

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P/N BAT-1000 Rev. A