NEUROPTICS

The Neurological Pupil index™

The Pupillary Evaluation

Clinicians routinely check the pupils of critically injured and ill patients to monitor neurological status. The two main components that are checked are pupil size and reactivity to light. Manual pupil measurements (performed using a penlight or ophthalmoscope) have been shown to be inaccurate and not repeatable or consistent. The NeurOptics® NPi™-100 Pupillometer removes subjectivity from the measurement of the pupil size and reactivity and its NPi™ algorithm provides a way to track and trend pupillary reactivity in a consistent, objective and quantifiable way.

What are the limitations of the current method?

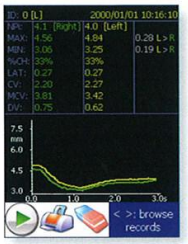
- **Pupil Size:** Pupils should be of equal size. This measurement has traditionally been performed using a pupil gauge to "guestimate" the diameter in millimeters of the pupil at rest before any light is shone into the eye. This method is very subjective and prone to error.
- **Pupil Light Reactivity:** Pupils should react "briskly" to a light stimulus. A light is shone into a patient's eye to make the pupil constrict in reaction to the light. The pupil should dilate again when the light is moved away. The light reaction is graded as "brisk", "sluggish" or "nonreactive." These terms are very subjective and applied without a standard clinical protocol or definition.

What are the benefits of the NPi™?

Rather than classifying pupillary response as "brisk", "sluggish", or "nonreactive", which are subjective terms, the NPi™ scale provides an objective and quantifiable way for clinicians to rate the pupillary light reflex. When using the NPi™-100 Pupillometer, even the newest nurse can evaluate the pupillary light reactivity as accurately as a very experienced clinician. Once a baseline measurement has been obtained, the clinician can track and trend any subtle changes or deteriorations in pupillary responsiveness.

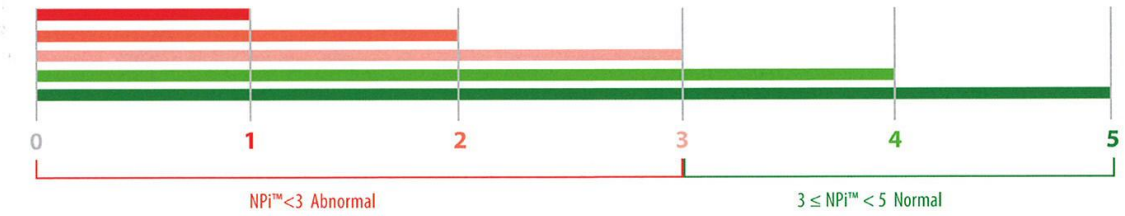
What is NPi™?

NPi™, or "Neurological Pupil index™", is an algorithm developed by NeurOptics® scientists to remove subjectivity from the pupillary evaluation. A patient's pupil measurement (including variables such as size, latency, constriction velocity, dilation velocity, etc.) is compared against a normative model of pupil reaction to light and **automatically graded by the NPi™ on a scale of 0 to 5.**



How do you interpret NPi™?

An individual measurement taken is rated on a scale between 0 and 5. A score equal to or above 3 means that the pupil measurement falls within the boundaries of normal pupil behavior ("brisk") as defined by the NPi™ model. However, an NPi™ value closer to 5 is more brisk than a value closer to 3. An NPi™ score below 3 means the reflex is abnormal, i.e., weaker than a normal pupil response as defined by the NPi™ model ("sluggish"), and values closer to 0 are more abnormal than values closer to 3.



Common Questions: NPi™-100 Pupillometer

How does the use of the Pupillometer improve patient care?

The medical literature shows that pupillary information in Critical Care is clinically important for prognosis, triage, and as an indication for surgical intervention. Given the importance of the pupil, an accurate, precise and reliable assessment -- as provided by the Pupillometer -- is fundamental. The device may also allow clinicians to detect pupillary abnormalities earlier than with the naked eye, thereby allowing them to intervene earlier. (Refer to *Chen JW, Gombart ZJ, Rogers S, Gardiner SK, Cecil S, Bullock RM. Pupillary reactivity as an early indicator of increased intracranial pressure: The introduction of the neurological pupil index. Surg Neurol Int 2011;2:82.*) As we know, "Time is Brain."

Manual human evaluation of the pupillary light reaction is confounded by several issues. Firstly, clinicians are limited by the capability of the human eye and what it can detect. This limitation is further exacerbated when the patient has dark eyes or very small pupils as a result of medications administered in the ICU. Secondly, the examiner's subjectivity and skill/experience level in checking pupils is a factor in the accuracy of the evaluation. Even the terminology used by clinicians to rate the pupillary reactivity (i.e., "brisk", "sluggish", "nonreactive") is highly subjective. Thirdly, external factors including varying ambient light conditions, the examiner's visual acuity, the distance and orientation of the penlight stimulus to the patient's eye and its strength come into play. These factors result in pronounced inter-examiner variability and error in the manual method, which has repeatedly been proven to be inadequate.

The Pupillometer, which uses sophisticated image processing of the pupil video, removes subjectivity from the pupillary evaluation. Extensive testing has proven the very high accuracy of the device. The algorithm inside the device (the Neurological Pupil index™ or NPi™) can classify the pupil reactivity as normal or abnormal, when compared to NeurOptics normative data, rather than leaving it up to someone's subjective judgment. Every clinician, from a nurse just out of nursing school to a neuro-ophthalmologist, will obtain the same results. In addition, the NPi™ scale allows for quantitative trending of pupillary reactivity, whether it shows a neuro deterioration from baseline or an improvement following an intervention.

Can the Pupillometer be used on a patient with dark irises and/or small pupils?

In fact, the Pupillometer is ideal for a patient with dark irises because the device uses infrared technology and enables the clinician to visualize pupils which are difficult or impossible to see with the naked eye. The Pupillometer can also very accurately measure the size and reactivity of very small (even "pin-point") pupils which also may be impossible to measure with the naked eye.

How is the NPi™ calculated?

The NPi™ is based on the comparison of the characteristics of the measured pupillary response against a normative model of pupil reaction to light. The range of the NPi™ scale (0 to 5) represents the distance between the single measurement and the normative distribution. (For more information, refer to *Chen JW, Gombart ZJ, Rogers S, Gardiner SK, Cecil S, Bullock RM. Pupillary reactivity as an early indicator of increased intracranial pressure: The introduction of the neurological pupil index. Surg Neurol Int 2011;2:82.*)

Is periodic calibration or maintenance required?

No. When used in accordance with the instructions for use, no calibration is required.

How can I prevent the spread of infection when several patients are being measured with the same device?

The device itself can be wiped down using a disinfectant specified in the instruction manual. The headrests are single patient use and may be used on that specific patient for as long as he/she is in the hospital.

How do drugs used in the ICU affect pupillary responsiveness and size?

Most drugs used in the ICU will affect the absolute baseline pupil size but not the pupillary light reactivity. Notable exceptions are propofol in very large doses as well as barbiturates which can make the pupils nonreactive.

Can the Pupillometer be used on someone who has had cataract surgery?

Having an intraocular lens (IOL) or a cataract does not affect the pupil. As long as the pupils were intact and there has been no damage to the structure or function of the iris before admission, the Pupillometer can be used.

What if the patient has anisocoria (unequal pupil size) as a pre-existing condition?

The presence of physiologic anisocoria of > 0.4mm has been estimated at 20% of the normal population, so some degree of pupil difference may be expected in at least 1 in 5 clinic patients. It is therefore important to get a baseline measurement of pupil size and track any changes in pupil symmetry.

How can we get data out of the device?

The Pupillometer stores close to 3,000 measurements in memory. The user can scroll through previous measurements to view them on the device's screen. The user can also record measurements on a data collection sheet (samples available) which stays in the patient's chart. Another option is to work with the hospital's IT department to add fields which clinicians want to track (e.g., NPi-right, NPileft, MAX-right, MAX-left, etc.) Another option is to print measurements using an optional printer which communicates with the device via infrared. The printed record can then be placed in the patient's chart.

Can the device be used on pediatric patients?

Yes, the Pupillometer can be used on both pediatric and adult patients.

How can we interpret the information coming from the Pupillometer?

The pupil evaluation includes checking for pupil size and equality and the briskness of reactivity to light.

For EQUALITY: MAX is the maximum pupil diameter in millimeters. The green column is the right eye and the yellow column is the left eye. The 3rd column shows the difference in size between the two eyes (e.g., 0.28 L>R).

For REACTIVITY: The NPi™ (Neurological Pupil index™) is a function of various calculated parameters (e.g., Constriction Velocity-CV, Dilation Velocity-DV, Latency-LAT). Some clinicians track the NPi™ value as a proxy for pupillary reactivity. Other clinicians also track other parameters such as CV, etc. (sample protocols are available.)

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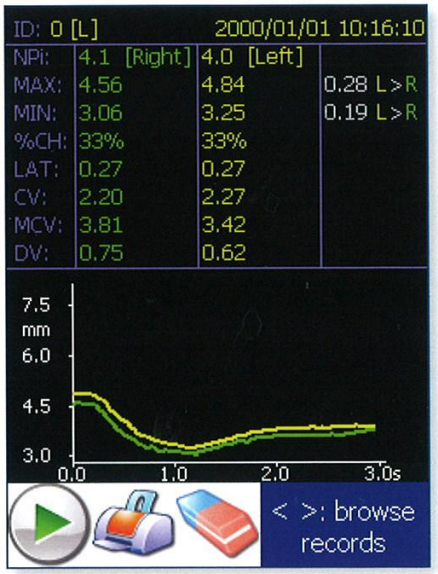
Interpreting the Information from the Pupillometer

Parameter on Measurement Results Screen	Unit of Measure	Definition/Calculation
NPi™ (Neurological Pupil index™)	Scalar value 0-5	Algorithm that takes all variables below as inputs and compares to a normative model to give a composite score of pupillary response
MAX/MIN	mm	MAX = initial resting pupil size MIN = pupil size at peak of the constriction
%CH	%	Constriction % or Percentage Change ([MAX – MIN] / MAX)
LAT	Seconds	Latency = time difference between initiation of retinal light stimulation and onset of pupillary constriction
CV/MCV	mm/sec	Average Constriction Velocity (CV) = amount of the constriction divided by duration of constriction Maximum Constriction Velocity (MCV) = peak value of velocity during constriction
DV	mm/sec	Average Dilation Velocity (DV) = amount of pupil size recovery (after the constriction) divided by duration of recovery



video playback

used to send information to the printer

designed to clear information from the device

- **Product Evaluation:** Comprehensive evaluation program to trial Pupillometer prior to purchase
- **Clinical Education:** Clinical Education Specialists (all RNs) available to train healthcare providers. Detailed instruction manual provided and educational materials available.
- **Simple to use** – very user friendly
- **Helpline:** Customer Support/Technical Assistance Helpline at +1 (949) 250-9792 if you have questions or need support

NPi

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