

(1) Introduction

This introductory section covers general information about the Humphrey® Field Analyzer 3 (HFA™3).

Operating Principles

A patient's visual field can be assessed by briefly projecting a spot of light ("stimulus") of known size, brightness, and location on the inside surface of a roughly hemispherical bowl. Bowl illumination is controlled to establish a desired contrast between the stimulus and the area around it. Stimulus location and presentation timing are algorithmically varied to minimize the patient's ability to anticipate stimulus location and timing. Stimulus brightness is algorithmically varied to determine the dimmest stimulus that can be reliably seen at each location. The resulting visual field map is used by a trained and qualified physician as an aid in diagnosis. Historically, also known as the Humphrey Field Analyzer (HFA), this instrument is the gold standard of perimetry worldwide.

In addition to static perimetry, the HFA3 allows you to perform kinetic perimetry that emulates manual standard Goldmann perimetry. You can manually select kinetic isopters, or perform custom scans automatically or step by step.

Intended Use

The Humphrey Field Analyzer is an automatic perimeter which is intended to be used to measure the visual field of the eye.

Indications for Use

The Humphrey Field Analyzer is an automated perimeter intended to identify visual field defects for the purposes of screening, monitoring, and assisting in the diagnosis and management of ocular diseases such as glaucoma and related neurological disorders.

The Carl Zeiss Meditec, Inc. Guided Progression Analysis™ (GPA™) is a software analysis module for the Humphrey Field Analyzer that assists practitioners with the detection, measurement, and management of progression of visual field loss. It aids in assessing change over time, including change from baseline and rate of change. It is intended for use as a diagnostic device to aid in the detection and management of ocular diseases including, but not limited to, glaucoma.



Note: The HFA3 is not intended to be used as the sole diagnostic method for disease.

Patient Population

The HFA3 may be used on all adults and children over the age of six in need of diagnostic evaluation of the eye. This includes (but is not limited to) patients with the following disabilities or challenges:

- Wheelchair user
- Very low or not measurable visual acuity
- Postural problems
- Fixation problems
- Deafness
- Large body, but not those above 99th percentile based on anthropomorphic data

There is a general requirement that the patient be able to sit upright and be able to place his or her face on the chin and forehead rest of the instrument (with or without supplemental human or mechanical support).