Recommended Room Requirements

- Do not place the unit near windows or in a room that cannot be sufficiently darkened to allow the patient's pupils to dilate naturally
- Ambient operational temperature range: 60° – 80°F (15° – 27°C)
- Humidity: Relative humidity no less than 35% and no greater than 65% (non-condensing)
- Barometric pressure range: 11 – 16 psi (76 – 110 kPa)

Storing Requirements Before Installation

When storing the system before installation, adhere to the following storage requirements:

- Storage temperature must be between 41° to 104°F (5° to 40°C) at a relative humidity no less than 35% and up to 65% (non-condensing)

Product Description

The iDESIGN® Refractive Studio System measures the wavefront of the eye within a defined range using the Hartmann-Shack sensor. The sensor evaluates the deflection of rays emanating from a small beam of light projected onto the retina. The measurements determine regular (sphero-cylindrical) refractive errors and irregularities (aberrations) that cause reduced visual function. The iDESIGN® Refractive Studio also measures and displays corneal topography, pupil size, and keratometry. Wavefront-laser assisted in situ keratomileusis (LASIK) treatments can be calculated using measurements obtained from the iDESIGN® Refractive Studio. Treatment calculations for wavefront-guided LASIK include full gradient topography for propagating the wavefront and compensating for the cosine effect (peripheral loss of laser energy due to corneal curvature).
INDICATIONS: The STAR S4 IR® Excimer Laser System and the iDESIGN® Refractive Studio are indicated for wavefront-guided laser assisted in situ keratomileusis (LASIK) to achieve monovision by the targeted retention of myopia (≤1.25 D to ≤2.00 D) in the non-dominant eye of presbyopic myopes. 40 years or older who may benefit from increased spectacle independence across a range of distances with useful near vision, with myopic astigmatism, up to -6.00 D spherical equivalent as measured by iDESIGN® Refractive Studio, with cylinder up to -3.00 D, and a minimum pre-operative myopia in their non-dominant eye at least as great as their targeted myopia; with an agreement between manifest refraction (adjusted for optical infinity) and iDESIGN® Refractive Studio refraction as follows: Spherical Equivalent: Magnitude of the difference is less than or equal to 0.5 D; Cylinder: Magnitude of the difference is less than or equal to 0.5 D; 18 years of age or older, and with refractive stability (a change of 1.0 D in sphere or cylinder for a minimum of 12 months prior to surgery).

REFERENCE: iDESIGN® 2.0 US Manual 0110-0651 Rev. A

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