iDESIGN® Refractive Studio

Specifications For Site Preparation/Installation

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).

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)

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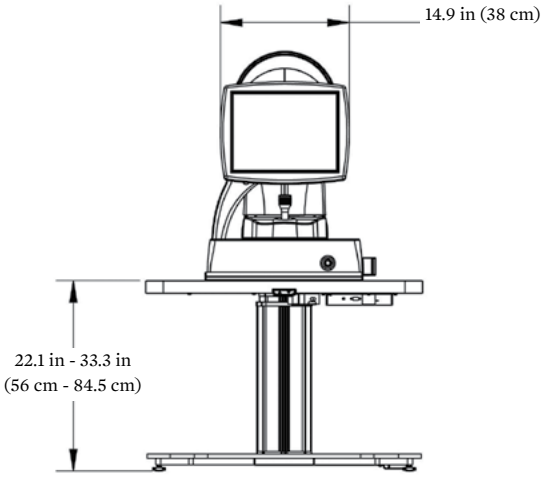
System Specifications

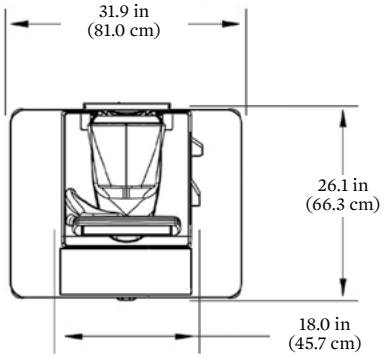
- Optical Head
  - Physical dimensions: (L, W, H) 20”, 18”, 27”, (50.8 cm, 45.7 cm, 68.6 cm), including base
  - Weight: 80 lbs (36 kg)
  - Enclosure construction: Aluminum and plastic
  - Class 1 Laser Product: 840 nm, 100uW max
- Table
  - Physical dimensions: (L, W, H) 32.0 in, 26.1 in, 22.1 in - 33.3 in (mix-max), (81.3 cm, 66.3 cm, 56 cm - 84.5 cm)
  - Weight: 102.4 lbs (46.4 kg)
  - Electrical ratings are 100-120/200-240 AC Voltage, 50/60 Hz, 750 VA

- Optical Specifications
  - Measurable Range: Sphere and Cylinder measurements in 0.01 D increments. Spherical equivalent range (6 mm pupil) - 16 to +12 D. Cylinder range (6 mm pupil) 8 D
  - Axis in 1° increments
  - Pupil measurements 2.0 to 9.5 mm, with 0.1 mm resolution
  - Maximum wavefront diameter 8.5 mm
  - Zernike terms displayed through the sixth order
  - Measurement spatial resolution 0.177 mm (approximately 1250 measurement points for a 7 mm pupil)
  - Integrated corneal topographer 37 x 37 spot measurement grid
  - Integrated pupilometer: Provides automatic acquisition of low mesopic and photopic image
  - Topographer grid extent (X and Y) ±4.1 mm for eye with 8 mm radius of curvature
  - Illumination ranging from 535 to 940 nm

Hardware Components

The ***iDESIGN***® Refractive Studio hardware components include power supply, computer, networking device, and monitor. The computer Central Processing Unit (CPU) is housed inside the ***iDESIGN***® Refractive Studio. The USB port is located on the right-hand side of the computer case. The computer keyboard is not integrated into the table.





IMPORTANT SAFETY INFORMATION

INDICATIONS: The ***STAR S4 IR***® Excimer Laser System and the ***iDESIGN***® Refractive Studio is indicated for wavefront-guided laser assisted in situ keratomileusis (LASIK) to achieve monovision by the targeted retention of myopia (-1.25 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 0.625 D; Cylinder: Magnitude of the difference is less than or equal to 0.50 D; Cylinder Axis: If either the manifest cylinder entered into the ***iDESIGN***® Refractive Studio or the ***iDESIGN***® Refractive Studio cylinder selected for treatment is less than 0.50 D, there is no requirement for axis tolerance. When both cylinders have a magnitude of at least 0.50 D, the axis tolerance is linearly reduced from 15° (0.5 D) to 7.5° (7.0 D or greater) based on the average magnitude of both cylinders. With documented evidence of a change in manifest refraction of no more than 0.50 D (in both cylinder and sphere components) for at least one year prior to the date of pre-operative examination; and with a successful preoperative trial of monovision or history of monovision experience. The ***STAR S4 IR***® Excimer Laser System and ***iDESIGN***® ***Advanced WaveScan Studio*** System/***iDESIGN***® Refractive Studio is indicated for wavefront-guided laser assisted in situ keratomileusis (LASIK) in patients: With hyperopia with and without astigmatism as measured by ***iDESIGN***® ***Advanced WaveScan Studio*** System/***iDESIGN***® Refractive Studio up to +4.00 D spherical equivalent, with up to 2.00 D cylinder; with mixed astigmatism as measured by ***iDESIGN***® ***Advanced WaveScan Studio*** System /***iDESIGN***® Refractive Studio where the magnitude of cylinder (1.0 D to 5.0 D) is greater than the magnitude of sphere, and the cylinder and sphere have opposite signs; with myopia as measured by ***iDESIGN***® ***Advanced WaveScan Studio*** System/***iDESIGN***® Refractive Studio up to -11.00 D spherical equivalent, with up to -5.00 D cylinder; with agreement between manifest refraction (adjusted for optical infinity) and ***iDESIGN***® ***Advanced WaveScan*** Studio System/***iDESIGN***® Refractive Studio refraction as follows: Spherical Equivalent: Magnitude of the difference is less than 0.625 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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