Welch Allyn iExaminer™ Receives 510(k) Clearance from the United States Food and Drug Administration

Welch Allyn

New Ophthalmic Imaging Product Integrates Advanced Eye Exam Technology with iPhone® Application

Welch Allyn, a leading medical diagnostic device company that specializes in helping clinicians improve patient outcomes, today announced it has received 510(k) clearance from the United States Food and Drug Administration (FDA) for the Welch Allyn iExaminer™—a product that consists of a hardware adapter and associated software that allows healthcare providers to capture, store, send and retrieve images from the Welch Allyn PanOptic™ Ophthalmoscope using the iPhone® 4 or 4S. The PanOptic features patented optical technology that creates a viewing area of the fundus and retinal nerve in an undilated pupil that is 5 times larger than that of a traditional ophthalmoscope and increases magnification by 26 percent to more easily see retinal details. Available for shipment on February 11, the iExaminer rapidly captures and transmits the retinal images created by the PanOptic for easy, cost-effective eyeground image documentation.

“The iExaminer allows healthcare providers to easily capture and share the images of a fundus in a moment’s notice, helping to improve the quality of care provided—especially for remote users who may not have easy access to specialists,” said Rick Farchione, senior manager, physical assessment at Welch Allyn. “It will increase workflow efficiency by allowing providers to capture and share images from any clinical environment. It is a low-cost way to digitally capture eye imaging and will also make it easier for providers to share images with their patients, helping to improve patient knowledge and compliance.”

The iExaminer adapter aligns the optical access of the PanOptic to the visual axis of the iPhone 4 or 4S camera to capture high resolution pictures of a patient’s fundus and retinal nerve. The iExaminer software application, available from the Apple App Store, then allows physicians to save images to a patient file, as well as e-mail and print the images.

“This is the first affordable device to give almost anyone, anywhere the ability to capture a picture of the back of the eye,” said Dr. Wyche Coleman, inventor of the iExaminer. “I was able to take this very lightweight, portable, inexpensive iExaminer to the summit of Mount Kilimanjaro in sub-Saharan Africa and take a picture of a patient’s fundus. From the top of the mountain, I then transmitted it to a doctor at Johns Hopkins University in the United States where he was able to analyze the image.”

About the PanOptic™ Ophthalmoscope

The Welch Allyn PanOptic Ophthalmoscope features the patented Axial PointSource™ Optics that gives healthcare professionals a dramatically wider, more panoramic view of the retina, or fundus, of the eye. The technology provides a 25 degree field-of-view, making it possible to see the different features of the fundus more efficiently than the 5 degree field-of-view provided by a standard ophthalmoscope. The design also creates a much greater working distance between the provider and the patient, greatly improving the comfort level of both during the exam, while at the same time delivers a 26 percent increase in magnification to make it easier to see retinal details. The PanOptic works with all Welch Allyn 3.5 volt power source handles.

About Welch Allyn

Welch Allyn is a leading global healthcare company that offers a complete range of digital and connected diagnostic solutions that helps reduce risk and enhance workflow in a variety of clinical settings. Founded in 1915 and headquartered in Skaneateles Falls, N.Y. (USA), Welch Allyn is a family-owned business that employs nearly 2,700 employees in 26 different countries. The company specializes in helping doctors, nurses and other frontline practitioners across the globe enhance care by developing innovative products, breakthrough technologies and cutting-edge solutions that improve patient outcomes, safety and satisfaction. More information about Welch Allyn and its complete line of connected products and solutions may be found at www.welchallyn.com [1].

Source URL (retrieved on *11/21/2014 - 10:05pm*):
http://www.mdtmag.com/news/2013/01/welch-allyn-iexaminer%E2%84%A2-receives-510k-clearance-united-states-food-and-drug-administration?qt-video_of_the_day=0

Links:
[1] http://www.welchallyn.com