

# IDx-DR Product Information

*The first and only autonomous AI system authorized by the FDA*

## Indication for Use

IDx-DR is intended for use by health care providers to automatically detect more than mild diabetic retinopathy (mtmDR) in adults (22 years of age or older) diagnosed with diabetes who have not been previously diagnosed with diabetic retinopathy. IDx-DR is indicated for use with the Topcon NW400.

## How it Works

- 1.) Using the Topcon NW400, the operator captures images of the retina
- 2.) The operator submits the images to the IDx-DR client
- 3.) The IDx-DR diagnostic algorithm uses deep learning based lesion detectors to analyze images for signs of diabetic retinopathy
- 4.) Within one minute after submitting the exam, IDx-DR provides an image quality or disease output with follow up instructions for care

## System Integration

- Comprehensive four-hour operator training session by an IDx certified trainer
- Indicated for use with the Topcon NW400
- Works with existing computers and normal internet connection
- Designed to directly interface with electronic health records systems

## Exam Input

- Uses standard imaging protocol
  - 2 images per eye: 1 disc centered, 1 macula centered
  - 45 degree color images

## IDx-DR Outputs

- Outputs JPG, PDF, and XML files
- Easy to read results with three possible outcomes:
  - Exam quality insufficient
  - Negative for more than mild diabetic retinopathy: Retest in 12 months
  - More than mild diabetic retinopathy detected: Refer to an eye care professional

## Quality Management and Data Protection

- Data privacy and protection processes align with HIPAA
- Quality management system is compliant with FDA Quality System Regulations
- Regular internal and third-party audits