

SECTION TWO - THEORY OF OPERATION

SYSTEM DESCRIPTION

The NGENUITY™ System is a medical device for ophthalmology. It consists of five major components: camera, computer (also referred to as the Embedded Processing Unit (EPU)), display, cart, and medical-grade isolation transformer (see [Figure 2-1](#)). The camera is mounted on the microscope while the EPU, power supply, and display are mounted on the cart. [Figure 2-2](#) shows a block diagram of the system.

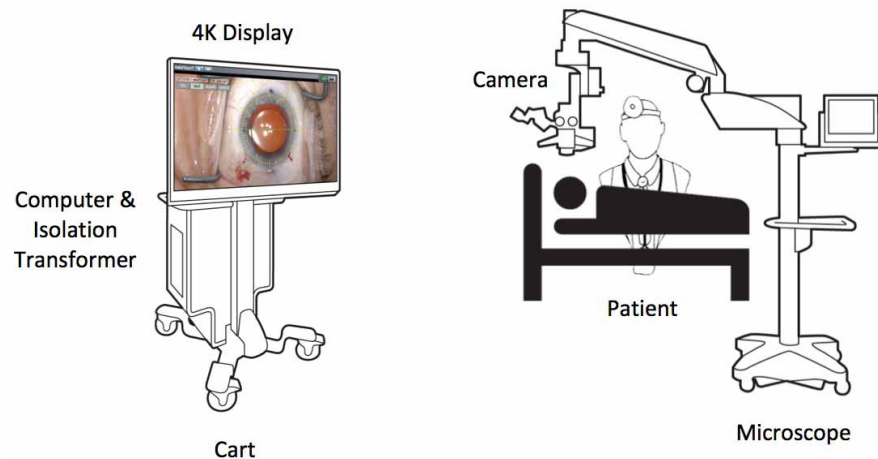


Figure 2-1 System Components

The camera mounted on the microscope head is able to image the surgical site as the surgeon sees it through his or her normal oculars.

The computer runs NGENUITY™ software that processes the live video feed from the camera and outputs it to the display. The computer is also capable of recording the surgery and storing it on the local hard drive.

The display shows the surgical site and graphical user interface (GUI). This allows the surgeon to operate “ocular-free,” i.e., to perform surgery by viewing the surgical site on the display, as opposed to the conventional view through the microscope oculars.

The medical-grade isolation transformer connects to the computer and display. The computer powers the camera.

The primary display is typically located four to six feet in front of the operator, supported by the cart, and is positioned for the viewing comfort of the operator. The keyboard and touchscreen are used to control the operation of the system and may be located for convenient usage by the operating room circulator. The display screen may be positioned to the left or right side of the microscope oculars depending on the relative position of the patient, surgeon, and microscope.

The system also supports additional monitors if required for viewing by observers.

The general flow of surgery using the system is described below. The order of these functions may vary.

1. Power on the NGENUITY™ system and microscope. The NGENUITY™ software automatically boots up.
2. Select or enter the surgeon and patient name (if desired).
3. Perform white balance of the camera, adjust camera, display, viewport, and recording settings as necessary.
4. Adjust display as necessary for best viewing.
5. Surgeon performs surgery using the display to view the surgical site.
6. Record the case to system hard drive (if desired).
7. Transfer case recordings to an external hard drive.

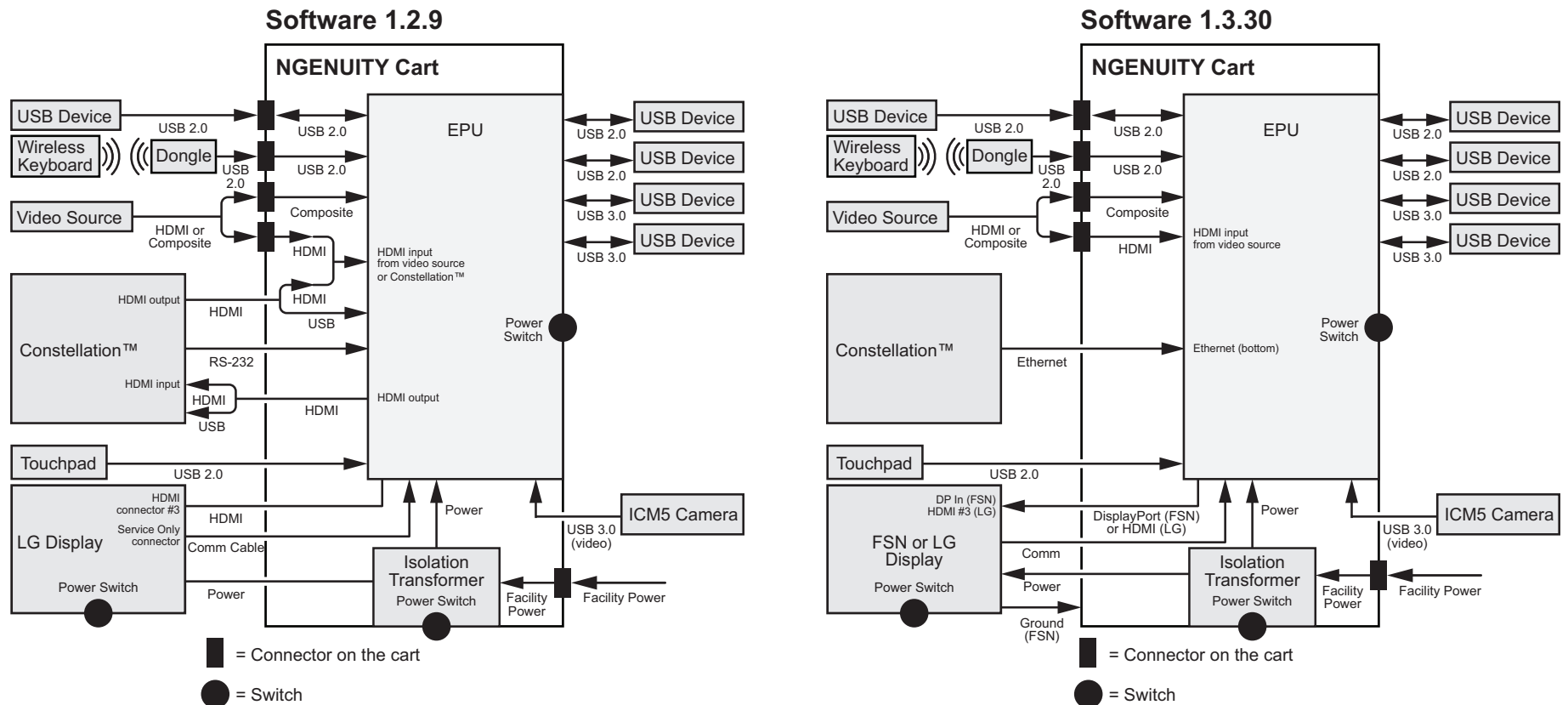


Figure 2-2 System Block Diagrams (1.2.9 on the Left and 1.3.30 on the Right)

NOTE: Do not use unapproved USB devices during operation.

SYSTEM HARDWARE

Camera (or Image Capture Module (ICM))

The camera is a stereoscopic, high-dynamic range (HDR) surgical camera that contains the following features:

- 3D Full HD Progressive Scan, Real-time Video
- Resolution and Frame Rate: Full 1920x1080 HD for Each Eye, 60 fps
- Compatibility: Leica, Zeiss, Alcon and many Surgical Microscopes
- The camera is capable of attaching to both Leica** and Zeiss-style ocular ports, with or without the use of a beam splitter
- Exposure: Automatic Exposure Control (w/optional manual adjustment)
- Aperture: Adjustable Stereoscopic Iris to allow the user to configure the camera for the correct amount of light.
- Dynamic Range: 85 dB
- White Balance: Digital White Balance with Memory
- At the bottom of the camera is an LED indicator to inform the user that the camera is powered on.

Embedded Processor Unit (EPU) Computer

The EPU is the system computer and contains the following components:

- Processor Intel Core i7-6700 or better RAM 16GB or better
- Operating System - Windows** 10 IoT Ent LTSB
- Graphics Card - nVidia GTX 980 or newer
- 128 GB SSD boot drive or better, 2 TB storage/recording drive or better
- Front Panel Ports: USB 2.0 (2); USB 3.0 (2) (accessible through the cart side panel)
- Rear Panel Ports:
 - DVI out (1)
 - HDMI in (1)
 - RS-232 (2)
 - Ethernet (1)
 - USB 2.0 (4)
 - USB 3.0 (2)

3D Display

The flat panel display, integrated onto the mobile cart, has a full resolution of 3840x2160 and uses a top-bottom 3D format with a resolution of 1920x1080p for each eye to display 3D images. The display has a circularly-polarized, micro-polarizing filter that displays the right and left image alternately. The screen dims when not in use to avoid burning in. Circularly-polarized glasses are worn to ensure that the left eye only sees the left image and the right eye only sees the right image. The flat panel has a refresh rate of 60 frames per second (FPS) simultaneously for each eye.

A removable screen protector is included that is recommended to be installed when the display is not in use or when the system is being moved.

Isolation Transformer

The system includes a Medical-grade Isolation transformer, certified to 60601-1. The isolation transformer is configured for international use at 240 V (do not change this setting). In this configuration, it accepts the following input ratings:

- 100 VAC, 50/60 Hz
- 120 VAC, 60 Hz
- 220-240 VAC, 50 Hz

AC power is supplied to the EPU and display through the isolation transformer AC ports. There is one power switch accessible through the cart to turn on the transformer and all connected devices. This power switch has an LED indicator that illuminates when power is turned on.

Cart

The console cart contains the following features:

- Display Mount - The cart supports the display and allows it to maintain position after the user has moved it, including tilt, swivel, and height (range of at least 3-5 ft. off the ground).
- Storage - The cart provides storage for 3D glasses, the user interface (keyboard/touchscreen/tablet), and a cable wrap for the display and/or power cables.
- Cable wrap - The cart has cable wraps for power and camera cables on exterior of the cart.
- Push Handle - For mobility the cart has a push handle to move the display stand.
- Caster Wheels - The cart has four lockable casters, each capable of full rotation.
- Exterior ports - The cart houses the following exterior ports:
 - USB 2.0 ports (2)
 - HDMI (in) to image capture card (not available with Constellation™ video overlay and NGENUITY™ software 1.2.9)
 - Composite port
- Lower access panel - The cart has the following exterior ports:
 - USB 2.0 (2)
 - USB 3.0 (2)

Input Devices

The system is designed to use the following input devices:

- Wireless keyboard
- Wired keyboard
- Touchpad

Cables

- Camera Cable - ICM5 to EPU (USB 3.0) - The camera cable connects between the computer and camera with strain-relief on both ends. The camera cable is 8 meters long and wherever possible should be strapped to the microscope arm so that it does not hang near the surgical site or is positioned on the floor. It is important that the cable is mounted so that the normal movement of the microscope is unimpeded.
- EPU to Display (Serial/Comm) Cable - The serial display cable is used to place the system in 3D mode upon boot up.
- EPU to Display (DVI-HDMI) Cable - The EPU supports DVI output to the display HDMI #3 input.
- EPU to cart exterior (USB 2.0) Cable – The exterior USB 2.0 ports are used for items such as the keyboard or external media used to transfer video files.
- EPU to cart exterior (HDMI in) Cable – The external HDMI port is used for external input of images used for the PIP feature.
- AC Power Cables – There are several AC power cables to route power from the external AC source and distribute to the system components.