Model No.	Description	Category	GMN BASIC UDI
DVCVHCM01	DirectVista ChromaVista Hardcopy Medical Media	CLASS I	081490502DVCVHCM014Y

INSTRUCTIONS FOR USE-IFU

Direct Vista Blue & Clear film
Direct Vista Blue-5
Direct Vista Blue-T Base

Direct Vista Paper, Direct Vista White Film
Chroma Vista Paper, Chroma Vista White Film

DirectVista Long Film

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CE

Directive Council Directive 93/42/EEC concerning Medical Devices (MDD), as amended

MDD Classification Class 1-Rule 1 (Hardcopy Media)

MDD Conformity Assessment procedure Medical Device Directive, Annex VII

Regulation 2017/745/EU of the European Parliament and of the Council of 5 April 2017 on medical devices (MDR)

MDR Classification Class 1-Applicable rule(s) are 4. NON-INVASIVE DEVICES , 4.1. Rule 1

MDR Conformity Assessment procedure MDR 2017/745/EU, Annex VIII

Intended use

Codonics manufactured DirectVista Film (Blue and Clear), ChromaVista White Film/Paper, and DirectVista White Film/Paper are Radiographic hardcopy films that meet the FDA/MDR device class guidelines as that consists of a thin sheet of radiotransparent or reflective material coated on one or both sides with a photographic emulsion intended to record images during diagnostic radiologic procedures.

The Multimedia features of Codonics Horizon Imagers include film and color, & gray scale reflective media (radiographic film and "white film/paper". The intended uses are identical to other thermal medical imagers in terms of production of radiological output in a variety of image sizes dependent on the specific model including Codonics models of films

Medical Hardcopy printing of diagnostic imaging procedure studies including CT, MRI, US, NM, PET, CR, DR.

Each of these medical medias provide high resolution hardcopy output from diagnostic medical imaging systems for viewing, archiving and referral review purposes.

Long Film:

Exclusive orthopaedic 14" x 36" and 14" x 51" dry long film for digital CR/DR

CVP

•Specifically designed for medical applications, Codonics color paper is FDA approved and fully archivable

•Image quality is far superior to laser and office printers featuring 16.7 million colors

•Color output that truly rivals conventional color photographic film

DVP

Superior quality prints at a fraction of the cost of film

• Image quality far superior to laser and office printers

• Ideal for referring physicians and patient consultations

Patient population

Diagnostic imaging system output Medical Hardcopy printing of diagnostic imaging procedure studies including CT, MRI, US, NM, PET, CR, DR. Any patient population or disease process hardcopy for review or interpretation

Intended purpose

Image data is transmitted per DICOM standards for printing on medical film. Gray scale film, Gray scale white film (paper) and Color white film (paper) output is recorded for review and patients records.

Intended users

Interpretation of images by Radiologists and clinicians skilled in film imaging analysis.

Single / Multiple use

☒ Single use Multiple use

Principles of operation

The image data, in DICOM or an approved/validated OEM manufacturer format, is directed to the Codonics printer/imagers to render the image and produce the hardcopy result.

Image data in digital form analyzed and modulated to an electrical energy output to energize thermal elements (pixel locations) of a Thermal Print Head (TPH). The energy and TPH response is made proportional to the image data content via standard and proprietary algorithms. The TPH response is fit to a specific media in order to formulate a quality image response function from a specified media (Thermal Film, Thermal Reflective, or Dye Diffusion).

In the case of Thermal DV Film, the media coating to the PET (Polyethylene Terephthalate plastic) base is a silver compound that is reactive to heat intensity to the individual TPH elements. Substantially equivalent to other approved thermal based radiographic monochromatic imagers and thermal medias, the image formation of high resolution, wide latitude gray scale output meets or exceeds diagnostic standards.

In the case of Thermal DV Reflective Media, the same silver compound coating to a PET foundation provides the image formation. A super white reflective backing permits the viewing of the diagnostic record in room lighting conditions.

With CV Color Reflective Media, the image data is modulated to an electrical energy output to energize thermal elements of a Thermal Print Head (TPH). The energy and TPH response is made proportional to the image data content via standard and proprietary algorithms. The TPH response is fit to a specific media in order to formulate a quality image response function of color dye ribbon donor which is gaseous diffused to a Polypropylene and Polyethylene Terephthalate based receiver. A super white reflective backing permits the viewing of the diagnostic record in room lighting conditions. The heat reactive dyes produce a high-fidelity color image capable of gray scale and color output.