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

Manufacturer: **Codonics Inc**
17991 Englewood Drive
Middleburg Heights, OH 44130
Phone: (440) 243-1198
Sales: (800) 444-1198
Fax: (440) 243-1334
Email: info@codonics.com
www.codonics.com

Authorized Representative: **CEpartner4U BV**
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3951 DB Maarn
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Fa: +31 343 442 162
info@cepartner4u.com
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SRN: NL-AR-000000111

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.

Attachments:

MEDIA STORAGE & HANDLING Tech Briefs:
DVB, DVC, DVP, CVP

903-201-004 PRODUCT BULLETIN, MEDIA PACKAGING AND STORAGE
901-063-001 CHROMAVISTA LOADING INSTRUCTIONS

DVBT

903-407-001 LIT, PRODUCT BULLETIN, DVBT, MEDIA PACKAGING & STORAGE

DVB5

903-410-001 LIT, PRODUCT BULLETIN, DVB5, MEDIA PACKAGING & STORAGE
903-417-001 LIT, PRODUCT BULLETIN, DVB5, HCM, MEDIA PACKAGING & STORAGE

Quality and Storage Instructions:

900-001-011 MFG CERT OF QUALITY, THERMAL REFLECTIVE/TRANSPARENCY MEDIA, CVP/CVT
900-005-002 MFG CERT OF QUALITY, HARDCOPY THERMAL MEDIA, DVBT
900-007-003 MFG CERT OF QUALITY, HARDCOPY THERMAL MEDIA, DVB/DVC/DVB5
900-008-002 MFG CERT OF QUALITY, THERMAL REFLECTIVE/TRANSPARENCY MEDIA, DVP/CVP

Codonics Media Packaging & Storage

Technical Brief

Summary

This Technical Brief covers the date format, “Best By” date, storage and storage conditions for media used in the Codonics NP-16xx, EP-series and Horizon® Imagers. This brief pertains to all types and sizes of DirectVista® Blue and Clear Base Film, Paper/White Film and ChromaVista® Paper/White Film.

Bulletin Details

The various dates are printed on the media supply cassette and case box for Horizon media. The dates for NP-16xx media can be found on the media box and the case box.

Date Format Clarification

Dates printed on all media packaging are in YYYY/MM format. On the case box, this can include the manufacturing date, indicated as and “Best By” date indicated as .

“Best By” Date

The media will provide optimal performance when used before the “Best By” date and stored in the conditions indicated below. Optimal media performance may be extended if stored in a cool, dark, dry environment.

Storage for Horizon Media

If the media is in the case box, store vertically as indicated by the arrow on the case. For high humidity environments it is recommended the media remain sealed in the original case packaging until just before use. Media cases can be stacked two high, vertically. If the media is taken out of the case box, it should be kept in the brown cardboard sleeve box. Media sleeve boxes should be stored vertically or in the same orientation as in the case box. Media cassettes removed from the sleeve box should be stacked no more than five high and rotated 90° to each other with the label facing up.

Storage Conditions and Requirements

There are three classifications of storage: storage of unprinted media, transportation of unprinted media and archival (extended term) storage of printed media.

- ***STORAGE CONDITIONS OF DirectVista® FILM***

Unprinted in sealed case box: Maximum 25° C and maximum 70% relative humidity

Transportation in sealed case box: Maximum 25° C

Archival: Extended term storage (20 years) maximum 21° C and 20-30% relative humidity

- ***STORAGE CONDITIONS OF DirectVista® PAPER/WHITE FILM***

Unprinted: Maximum 25° C and 20-40% relative humidity

Transportation: Maximum 25° C

Archival: Extended term storage (30 years) maximum 21° C and 20-30% relative humidity

- ***STORAGE CONDITIONS OF ChromaVista® PAPER/WHITE FILM***

Unprinted: Maximum 25° C and 20-40% relative humidity

Transportation: Maximum 25° C

Archival: Extended term storage (20 years) maximum 21°C

and 20-30% relative humidity

Technical Support

If questions arise, contact Codonics Technical Support at any time.

Phone: +1.440.243.1198
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Horizon® Imager
Loading ChromaVista® Media

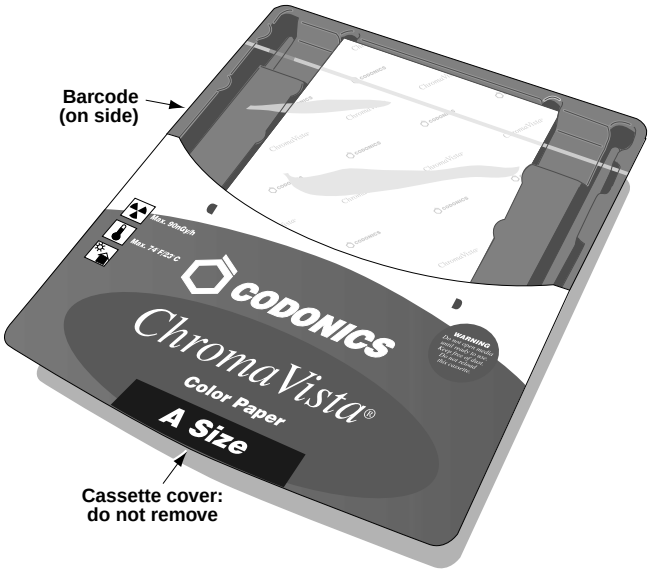
Technical Brief

This technical brief explains how to load **ChromaVista** color media and color ribbon in the Horizon Multi-media Dry Imager.

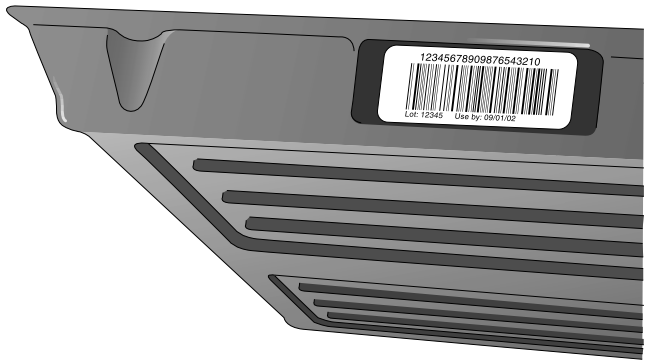
> Note: The color ribbon-related illustrations in the *Horizon Imager User's Manual* show a ribbon cartridge. However, the cartridge is not yet available. For that reason, this technical brief covers how to replace the open spool version of the color ribbon, which is available.

Overview of ChromaVista Paper and Film

ChromaVista color paper and film used with the Horizon imager is prepackaged in factory-sealed, disposable cassettes.



Each cassette contains a barcode that identifies the media type and size, serial number, and sensitometry information. The cassette's lot number and "Use by" date are also printed on the barcode label.



> **CAUTION:** Do not refill a cassette. Do not tamper with or remove the barcode label. The cassette's barcode information is essential for ensuring diagnostic image quality. Compromising the cassette in any way jeopardizes the quality and reliability of the imager.

Cassettes can be loaded into any of the Horizon imager's three supply slots. However, the logical way to load cassettes would be to insert the smaller ones at the top and the larger ones at the bottom. This ensures that you can readily see each cassette's label and see whether there are sheets in any of the receive trays.

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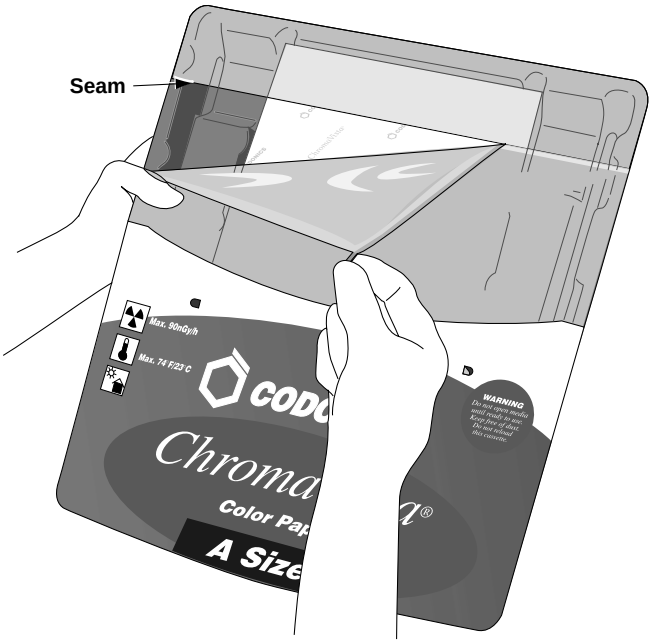
Opening a New Cassette

To open a new cassette, remove the clear wrapping from the cassette. Use the pull strip to tear the clear wrapping open.



> **CAUTION:** Do not remove the printed cassette cover; it protects the media from dust and other contaminants. Always hold and store the cassette with the open side up to prevent the sheets from falling out.

Inserting the Cassette into a Supply Slot

1. Press the imager's PAUSE key, and wait until the imager enters the Paused state.

> **CAUTION:** Do not remove or insert a cassette while a sheet is being printed, or you could affect the image quality of the printed sheet or cause a jam. Always pause the imager first.

2. Remove the cassette if one is currently in the supply slot you want to use—lift the cassette up slightly and slide it from the supply slot.
3. Insert the new cassette into the supply slot, with the cassette label facing you and the barcode label to the left.

4. Slide the cassette into the supply slot until you feel the cassette settle into the retaining detent.

> Note: Not all cassettes are the same length, so larger cassettes will extend out further than shorter ones.

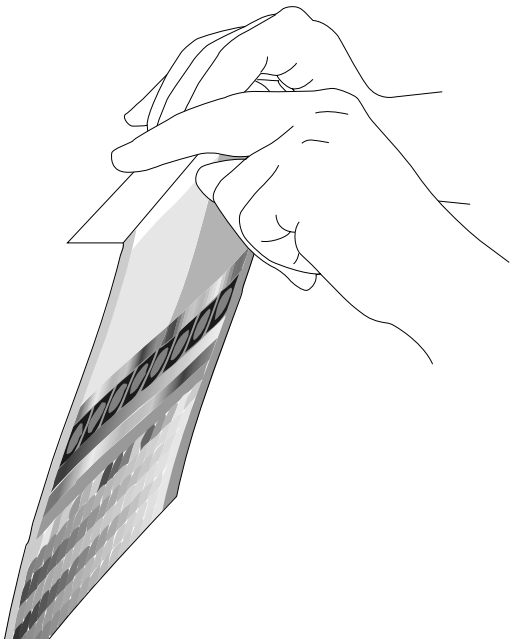
5. Press the PAUSE key to resume printing.

Brake-Off Leaders

ChromaVista color sheets have break-off leaders to allow edge-to-edge printing.

- **ChromaVista** color film has a break-off leader at the top of the sheet.
- **ChromaVista** color paper has a break-off leader at the top and bottom of the sheet.

To remove the break-off leader, bend the leader at the perforation line fully one way, then fully the other way. The leader will break away from the sheet.



Note: Always bend the leader to remove it—do not tear it off—to avoid having stray pieces left on the sheet.

Loading a Color Ribbon

1. Press the imager's MENU key.

   The Main Menu displays.

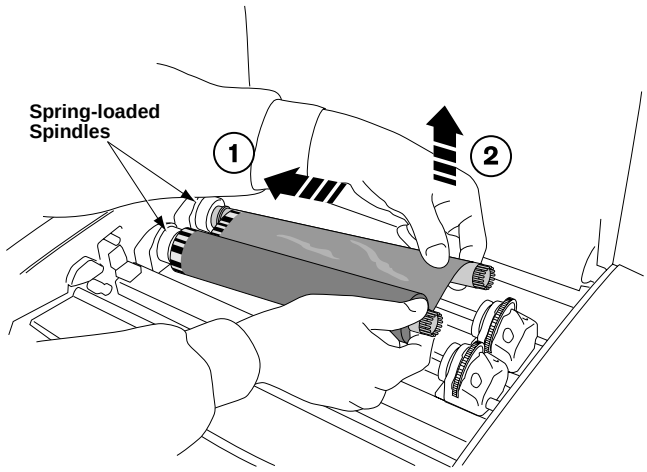
2. Select the Load/Remove Ribbon menu option.

   The imager pauses and, after up to a minute to allow internal components to cool, the top cover pops partially open.

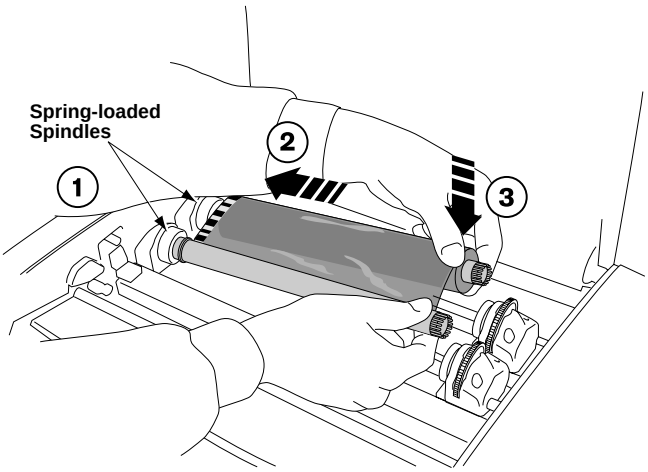
3. Lift the cover all the way open, and locate the ribbon spools.

   WARNING: With the imager cover open, touch only those internal components that are colored green. Remove rings, ties, jewelry, and other items, and tie back hair, so that they do not fall into or get caught in the imager.

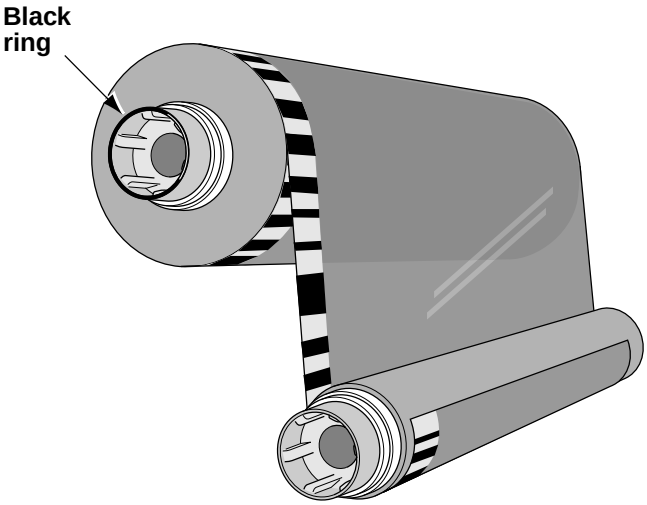
4. Remove the consumed ribbon spools (if applicable), as shown in the following figure.



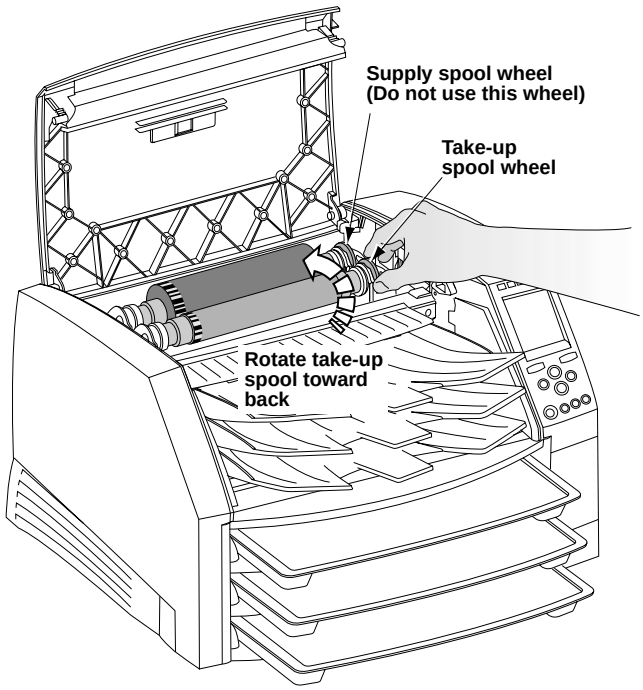
5. Remove the new ribbon spools from their packaging and load them into the imager, as shown in the following figure.



> Note: Make sure that you load the spools with the proper orientation—that is, with the receive spool (empty when new) in the front. The supply spool is identified by a black ring on the left side.



6. To take up any ribbon slack, rotate the top of the take-up spool's wheel (that is, the front wheel) towards the back of the imager, as shown in the following figure.



> Note: Do not use the supply spool (rear) wheel to take up ribbon slack. This would cause spent ribbon to be reused.

7. When you are finished changing the ribbon cartridge, close the top cover.

8. Press the PAUSE key to resume printing.

> **CAUTION:** Used ribbon retains the negative of the color images that were printed using that ribbon. If you are required to ensure patient confidentiality and privacy, consumed ribbon should be destroyed.

> Note: The only time you need to remove the ribbon is if you are cleaning internal components or the ribbon has been consumed. Otherwise, you can leave the ribbon in the imager, even when printing to **DirectVista** grayscale media.

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Codonics DVBT Media Packaging & Storage

Technical Brief

Summary

This Technical Brief covers the date format, "Best By" date, storage and storage conditions for media used in Horizon® Imagers. This brief pertains to all sizes of DirectVista® Blue-T Base Film.

Bulletin Details

The various dates are printed on the media supply cassette and case box for Horizon media.

Date Format Clarification

Dates printed on all media packaging are in YYYY/MM format. On the case box, this can include the manufacturing date, indicated as  and "Best By" date indicated as  .

"Best By" Date

The media will provide optimal performance when used before the "Best By" date and stored in the conditions indicated below. Optimal media performance may be extended if stored in a cool, dark, dry environment.

Storage for Horizon Media

The media should be stored in the sealed case box. Case boxes should be positioned vertically as indicated by the arrow on the case. Media cases can be stacked two high, vertically.

For high- or low-humidity environments (outside of 30% - 60% RH) the media should remain sealed in the original case box until just before use. The media should be removed from the case box one cassette at a time and the bag inside the case box should be re-sealed around remaining cassettes.

If the media is cold, be sure to allow the case box to fully reach room temperature before removing individual cassettes to avoid the risk of moisture condensation on the film.

If the media is taken out of the case box, it should be kept in the brown cardboard sleeve box. Media sleeve boxes should be stored vertically or in the same orientation as in the case box. Media cassettes removed from the sleeve box should be stacked no more than five high and rotated 90° to each other with the label facing up. If the media cassettes are removed from the sleeve box, it is recommended the cassettes remain plastic wrapped until just before use.

The best media performance in high- or low-humidity will be achieved when individual media cassettes are used up within one week of removal from the sealed Codonics case box. If an open cassette of media is to sit for an extended period (over night or weekend), Codonics recommends that the open cassette be sealed in a polyethylene bag until the film is to be used again.

Storage Conditions and Requirements

There are three classifications of storage: storage of unprinted media, transportation of unprinted media and archival (extended term) storage of printed media.

- Unprinted in sealed case box: 10-25° C and 30% - 60% relative humidity
- Transportation in sealed case box: Maximum 25° C
- Archival: Extended term storage (20 years) maximum 25° C and maximum 60% relative humidity

Technical Support

If problems occur that are not covered by this Technical Brief, contact Codonics Technical Support at any time.

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Codonics DVB5 Media Packaging & Storage

Technical Brief

Summary

This Technical Brief covers the date format, "Best By" date, storage and storage conditions for media used in Horizon® Imagers. This brief pertains to all sizes of DirectVista® Blue-5 Base Film.

Bulletin Details

The various dates are printed on the media supply cassette and case box for Horizon media.

Date Format Clarification

Dates printed on all media packaging are in YYYY/MM format. On the case box, this can include the manufacturing date, indicated as and "Best By" date, indicated as .

"Best By" Date

The media will provide optimal performance when used before the "Best By" date and stored in the conditions indicated below. Optimal media performance may be extended if stored in a cool, dark, dry environment.

Storage for Horizon Media

The media should be stored in the sealed case box. Case boxes should be positioned vertically as indicated by the arrow on the case. Media cases can be stacked two high, vertically.

For high humidity environments, the media should remain sealed in the original case packaging until just before use.

If the media is cold, be sure to allow the case box to fully reach room temperature before removing individual cassettes to avoid the risk of moisture condensation on the film.

If the media is taken out of the case box, it should be kept in the brown cardboard sleeve box. Media sleeve boxes should be stored vertically or in the same orientation as in the case box. Media cassettes removed from the sleeve box should be stacked no more than five high and rotated 90° to each other with the label facing up. If the media cassettes are removed from the sleeve box, it is recommended the cassettes remain plastic-wrapped until just before use.

Storage Conditions and Requirements

There are three classifications of storage: storage of unprinted media, transportation of unprinted media and archival (extended term) storage of printed media.

- Unprinted in sealed case box: 0-25° C and 10% - 70% relative humidity
- Transportation in sealed case box: Maximum 25° C
- Archival: Extended term storage (20 years) maximum 21° C and 20-30% relative humidity

Technical Support

If problems occur that are not covered by this Technical Brief, contact Codonics Technical Support at any time.

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Codonics DVB5 Hard Cassette Media Packaging & Storage

Technical Brief

Summary

This Technical Brief covers the date format, "Best By" date, storage and storage conditions for hard cassette media used in Horizon® Imagers. This brief pertains to all sizes of DirectVista® Blue-5 Base Film.

Bulletin Details

The various dates are printed on the media supply pack and case box for Horizon media.

Date Format Clarification

Dates printed on all media packaging are in YYYY/MM format. On the case box, this can include the manufacturing date, indicated as  and "Best By" date, indicated as .

"Best By" Date

The media will provide optimal performance when used before the "Best By" date and stored in the conditions indicated below. Optimal media performance may be extended if stored in a cool, dark, dry environment.

Storage for Horizon Media

The media should be stored in the sealed case box. Case boxes should be positioned vertically as indicated by the arrow on the case. Media cases can be stacked two high, vertically.

For high humidity environments, the media should remain sealed in the original case packaging until just before use. The media should be removed from the case box one pack at a time and the bag inside the case box should be re-sealed around remaining packs.

If the media is cold, be sure to allow the case box to fully reach room temperature before removing individual packs to avoid the risk of moisture condensation on the film.

If the media is taken out of the case box, it should be kept in the cardboard pack box. Media pack boxes should be stored vertically or in the same orientation as in the case box.

Storage Conditions and Requirements

There are three classifications of storage: storage of unprinted media, transportation of unprinted media and archival (extended term) storage of printed media.

- Unprinted in sealed case box: 0-25° C and 10% - 70% relative humidity
- Transportation in sealed case box: Maximum 25° C
- Archival: Extended term storage (20 years) maximum 21° C and 20-30% relative humidity

Technical Support

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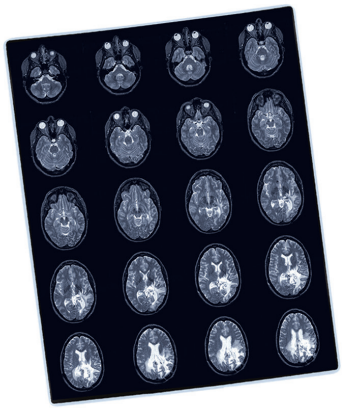
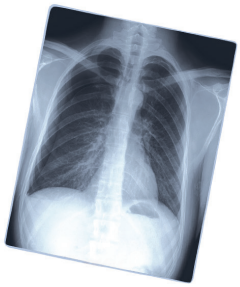
Codonics Film

Codonics DirectVista® Blue-T Base Film delivers superior quality images in a cost-saving array of sizes



14" x 17"
35 x 43 cm



8" x 10"
20 x 25 cm

" The quality is superior to the traditional film imagers we were previously using."

A. Joseph Borelli, M.D., MRI at Belfair - Bluffton, SC

- *Completely digital, our unique direct thermal technology achieves image quality better or equal to "laser quality"*
- *Convenient dry printing eliminates the need for plumbing, special ventilation and siting requirements*
- *Multiple film sizes allow you to lower film costs by printing on the most economical size for your application*

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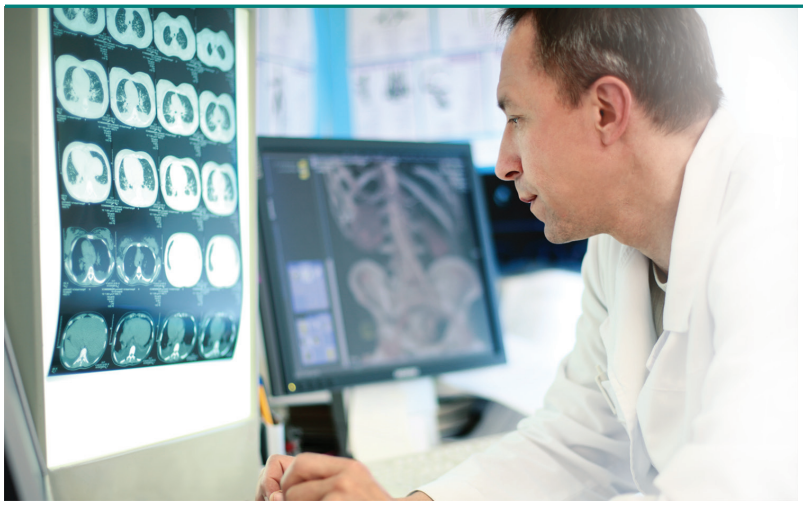
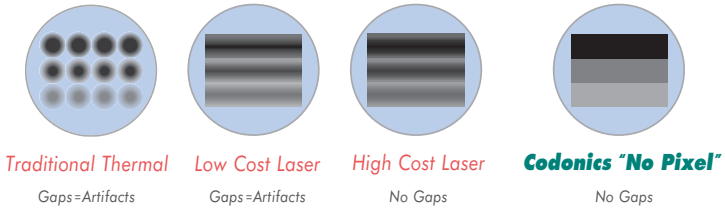
Codonics DirectVista® Thermal Grayscale Diagnostic Blue-T Base Film

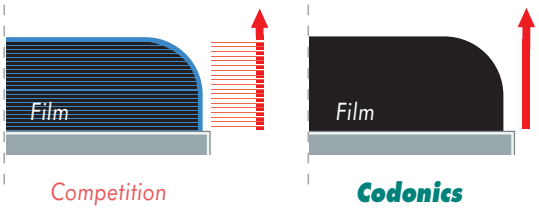


Codonics patented imaging technology outputs superior diagnostic dry film with an unmatched image quality. DVBT film is the ideal solution for the most demanding medical hardcopy applications. Completely eliminating space between lines by advancing the film in a smooth motion, the diagnostic output is precise and consistent. DVBT film is available in 14"x 17" and 8"x 10", giving the user the option to scale the image to the appropriate film size, providing an alternative to print at a lower cost on 150C Series Horizon Imagers.

Depend on Codonics to deliver reliable, consistent images with the highest quality possible.



In thousands of side by side comparisons, board certified radiologists could not tell the difference between images printed on Codonics imagers from those printed on more expensive laser imagers. Codonics patented imaging technology outputs diagnostic film achieving unmatched versatility and image quality.



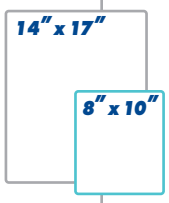
Dynamic Media Transport System (DMTS™) allows Codonics imagers to print while the media advances in a smooth motion eliminating space between lines.

Specifications:

- Compatible with Horizon 150C Series multi-media imagers
- Continuous tone grayscale rendering
- Dmin ≤ 0.29 OD, Dmax ≥ 3.00 OD (transmissive)
- Thickness ~ 0.2mm

Available Sizes:

Horizon Imagers
14"x17" (35 x 43 cm)
8"x10" (20 x 25 cm)



For more information contact Codonics at 800-444-1198 or 440-243-1198 and ask for our Media Sales Department.

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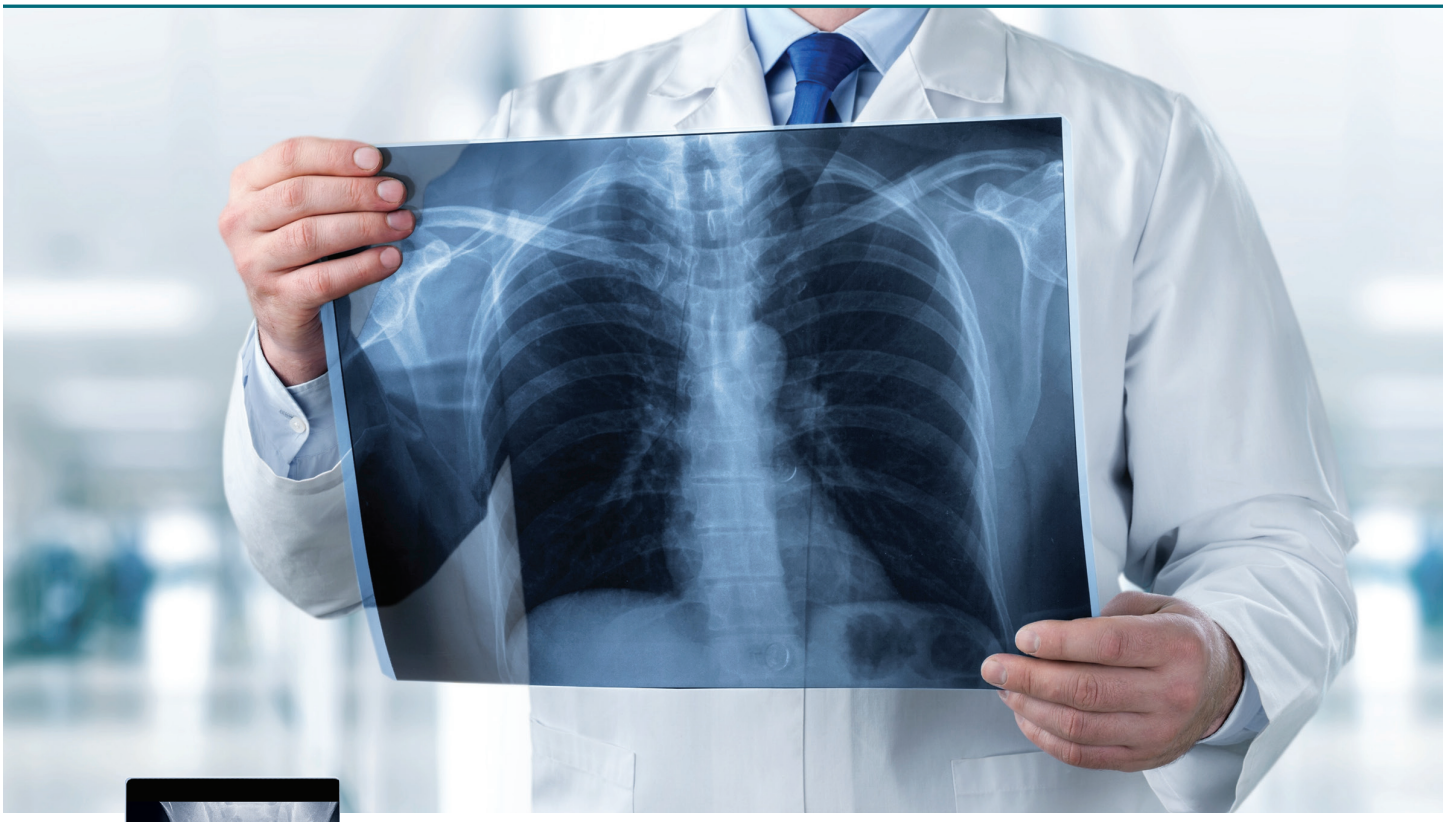
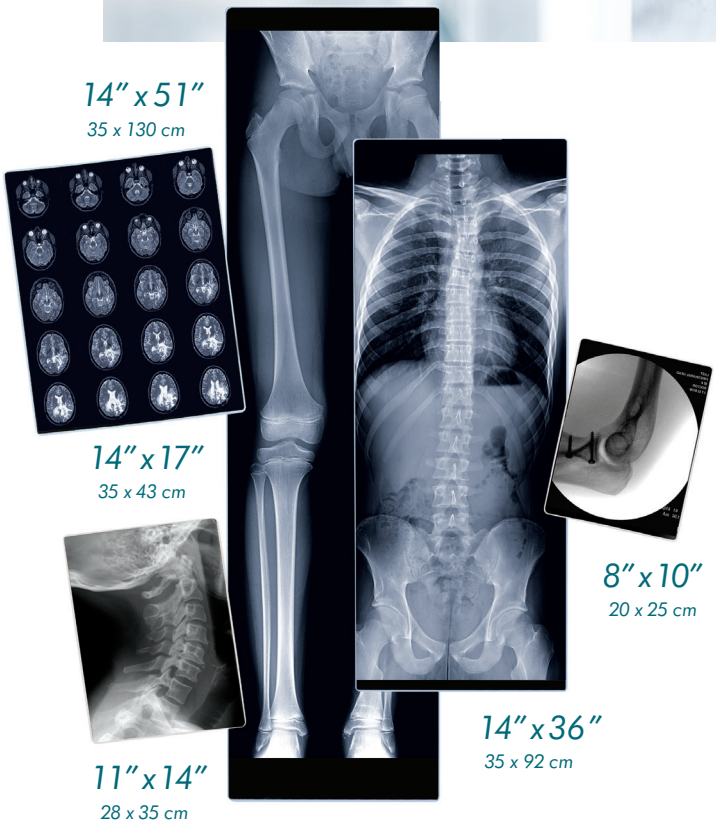
www.codonics.com

900-713-002.01

Codonics Film

Codonics DirectVista® Blue-5 Base Film delivers superior quality images in a cost-saving array of sizes





" The quality is superior to the traditional film imagers we were previously using."

A. Joseph Borelli, M.D., MRI at Belfair-Bluffton, SC

- *Completely digital, our unique direct thermal technology achieves image quality better or equal to "laser quality"*
- *Convenient dry printing eliminates the need for plumbing, special ventilation and siting requirements*
- *14" x 36" and 14" x 51" long film for digitally stitched true-size images on one continuous film*
- *Multiple film sizes allow you to lower film costs by printing on the most economical size for your application*

CODONICS®

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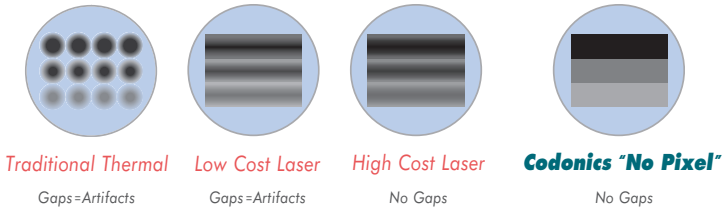
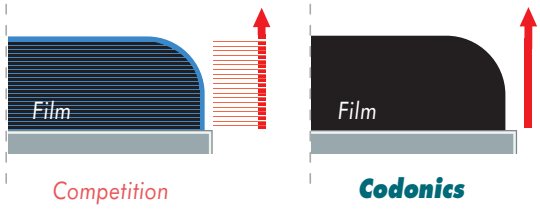
Codonics DirectVista® Thermal Grayscale Diagnostic Blue-5 Base Film

Codonics patented imaging technology outputs superior diagnostic dry film with an unmatched image quality. DVB5 film is the ideal solution for the most demanding medical hardcopy applications. Completely eliminating space between lines by advancing the film in a smooth motion, the diagnostic output is precise and consistent. DVB5 film is available in 14"x17", 11"x14" and 8"x10", giving the user the option to scale the image to the appropriate film size, providing an alternative to print at a lower cost. Plus, our exclusive 14"x36" and 14"x51" long film provides specialized orthopaedics with "digitally stitched" true-size images for long bone and scoliosis studies on one continuous film.

Depend on Codonics to deliver reliable, consistent images with the highest quality possible.



In thousands of side by side comparisons, board certified radiologists could not tell the difference between images printed on Codonics imagers from those printed on more expensive laser imagers. Codonics patented imaging technology outputs diagnostic film achieving unmatched versatility and image quality.



Dynamic Media Transport System (DMTS™) allows Codonics imagers to print while the media advances in a smooth motion eliminating space between lines.

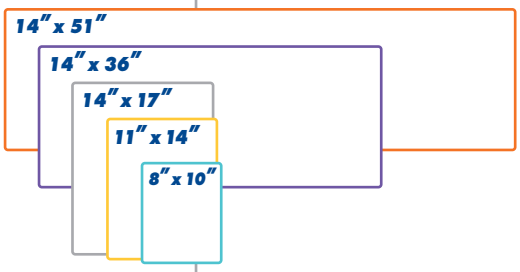
Specifications:

- Compatible with Horizon multi-media imagers with suitable software version*
- Continuous tone grayscale rendering
- Dmin ≤ 0.25 OD, Dmax ≥ 3.00 OD (transmissive)
- Thickness ~ 0.2mm

Available Sizes:

Horizon Imagers

14"x 51" (35 x 130 cm)
14"x 36" (35 x 92 cm)
14"x17" (35 x 43 cm)
11"x14" (28 x 35 cm)
8"x10" (20 x 25 cm)



For more information contact Codonics at 800-444-1198 or 440-243-1198 and ask for our Media Sales Department.

*Contact your Codonics representative or Support for model configurations and media availability. DirectVista Film is available for use in most Codonics imagers, some model and size restrictions apply. Specifications are subject to change without notice.

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Codonics Long Film

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

14" x 51"
35 x 130 cm

14" x 36"
35 x 92 cm

"The dry long film from Codonics provides the orthopaedic surgeon the perspective and confidence in their measurements and angles, lost with the minified image. It is the perfect solution for our orthopaedic needs."

Helene Pavlov, M.D., FACR, Radiologist-in-Chief, Hospital for Special Surgery, New York, NY
Professor of Radiology, Professor of Radiology in Orthopaedic Surgery
Weill Medical College of Cornell University

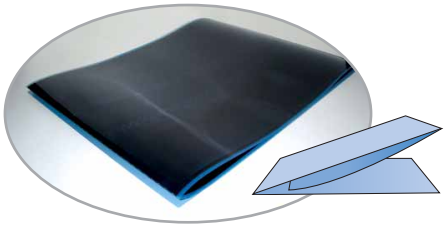
- *Only Horizon® XL provides orthopaedics with dry long film ideal for scoliosis, long bone, pediatric and adult spines*
- *Available in two sizes, our 14" x 36" and 14" x 51" film is daylight safe and easy to handle*
- *Digitally stitched images from CR/DR are printed on one, continuous film*
- *Horizon XL offers "true-size" imaging up to 51" in length*

CODONICS

Codonics DirectVista® Dry, Diagnostic Long Film

Codonics Horizon XL Multi-media Dry Imager provides the only means of printing long film in today's digital age of CR/DR, printing digitally stitched 'true-size' images on one continuous film. Available in two sizes, our 14" x 36" and 14" x 51" long film folds to 14" x 17" to fit conveniently in a standard film jacket. In addition to long film, the XL prints on several other sizes of film, plus 14" x 17", A/A4 low-cost grayscale paper and A/A4 color paper.

A total solution for all of your orthopaedic radiology needs, Horizon XL weighs less than 70 pounds and takes only two feet of counter space. Using long film for true-size imaging, 14" x 17" and 8" x 10" size film for extremity MR, low-cost grayscale paper for surgical planning, referral copy and patient files, and color for arthroscopy and 3D color CT, Horizon XL covers all your orthopaedic print needs in one compact device.



Codonics long film contains perforations for easy folding and storage in a standard 14" x 17" film jacket.

Specifications:

- DirectVista long film is compatible with Horizon XL only
- Continuous tone grayscale rendering
- Dmin < 0.10 OD, Dmax > 3.00 OD (transmissive)
- Thickness ~ 0.2mm

Horizon XL Media Sizes:

DirectVista Film

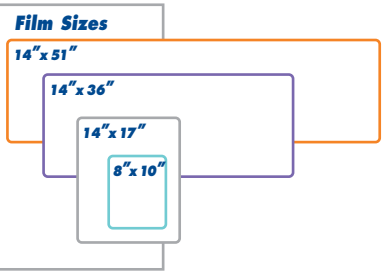
14"x 51" (35 x 130 cm)
14"x 36" (35 x 92 cm)
14"x17" (35 x 43 cm)
8"x10" (20 x 25 cm)

DirectVista Grayscale Paper

14"x17" (35 x 43 cm)
A (8.5" x 11") A4 (210mm x 297mm)

ChromaVista® Color Paper

A (8.5" x 11") A4 (210mm x 297mm)



For more information contact Codonics at 800-444-1198 or 440-243-1198 and ask for our Orthopaedic Global Sales Manager.

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900-320-001 Rev B

Codonics Grayscale Paper / White Film

Ideal for patient consultations, referring physicians and operating room reference without sacrificing image quality using Codonics exclusive DirectVista® Grayscale Paper

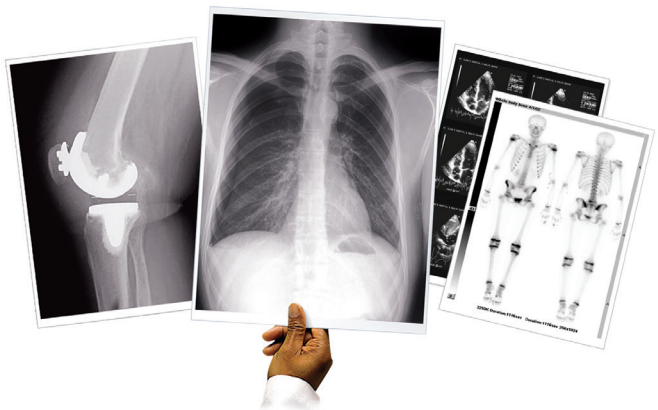
"Paper printing is a boon to radiology, by realizing significant savings in workflow and other soft-costs."
John C. Litchney, MBA, RT, Administrator for The Cleveland Clinic, Department of Regional Radiology

"This paper-like media offers many advantages to the end user over traditional film."
Dr. David Stemerman, Radiologist, Open High-Field MRI and CT of Westchester, NY

11" x 14"
28 x 36 cm

14" x 17"
35 x 43 cm

A and A4 Size



- *Image quality is far superior to laser and office printers*
- *Ideal for referring physicians, patient consultations and operating room use*
- *Letter size allows it to fit conveniently into a referring physician report or patient's chart for quick reference*
- *No toner, wax or ribbons to ever replace*
- *No lightbox required*
- *Provides a great alternative to traditional film*

CODONICS®
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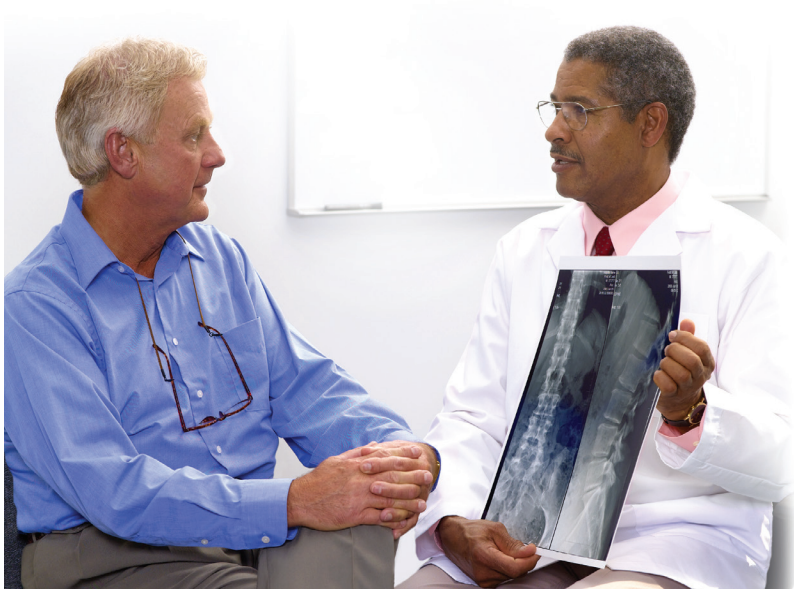
Codonics DirectVista®
Grayscale Paper / White Film



DirectVista® Grayscale Paper / White Film is specifically created for medical applications. This high quality media is ideal for referring physicians who prefer to view images in room light without a light box.

Exclusively for Codonics imagers, DirectVista Paper is available in a variety of sizes, including 14"x17" and 11"x 14". Plus, A and A4 size output fits conveniently into a chart so that the image can follow the patient and doctors can easily flip to it, like a note or report.

DirectVista Paper/White Film produces stunning grayscale prints with outstanding contrast ratios. There is no toner, wax or ribbon to replace – ever. It's the ideal media for patient and referral copies as well as archiving.

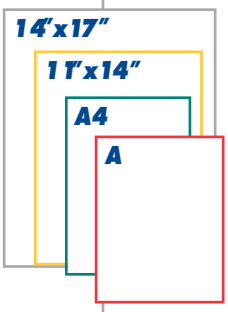
DirectVista Grayscale Paper/White Film has a heavy, photo-weight base material that resists water and tearing. Since there is no ink or toner, images never smear or transfer onto hands or other prints.

Specifications:

- Compatible with the Horizon family of multi-media imagers
- Continuous tone grayscale rendering
- Dmin < 0.10 OD, Dmax > 2.00 OD (transmissive)
- Thickness ~ 0.2mm
- Complies with ISO 18911 standards for storage of photographic media
- Fully archivable for a minimum of 10 years with proper storage

Available Sizes:

14"x17" (35 x 43 cm)
11" x 14" (28 x 35 cm)
A (8.5" x 11")
A4 (210mm x 297mm)



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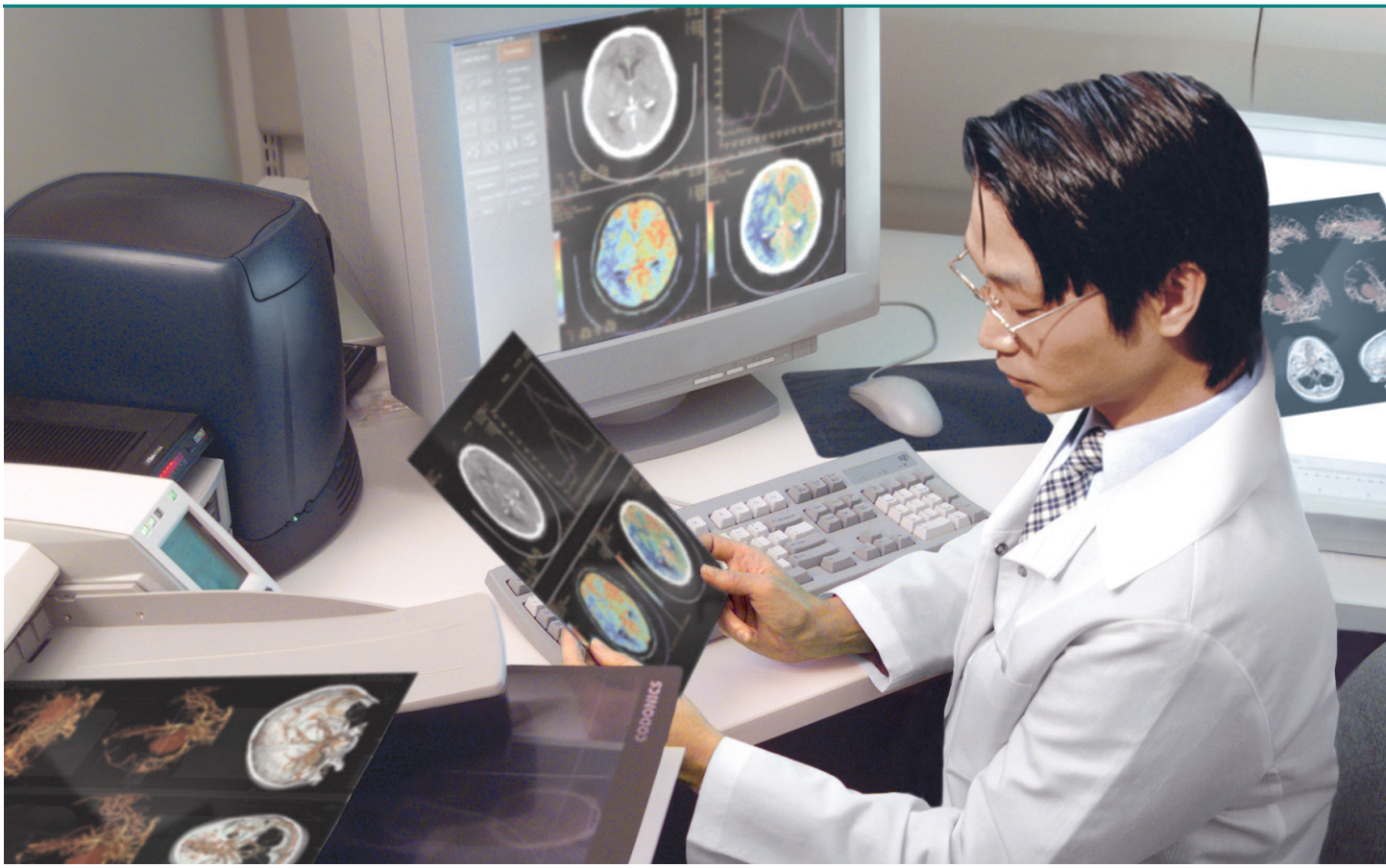
QUALITY SYSTEM CERTIFICATION DNV·GL ISO 13485

900-310-003.01

Codonics Color Paper / White Film

With more of today's medical systems using color applications, Codonics leads the industry with our ChromaVista Color Paper

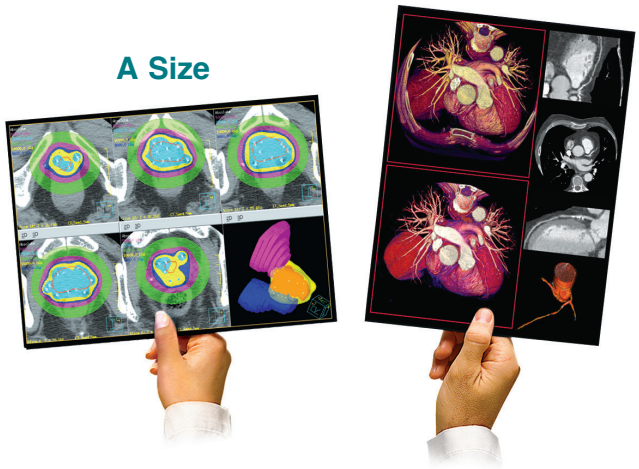


"We work with a neurology group that was thrilled when they saw how our razor-sharp color studies on paper could be slipped conveniently into patient charts. It literally changed their practice."

John C. Litchney, MBA, RT, Administrator for The Cleveland Clinic, Department of Regional Radiology

A4 Size

A Size



- *Codonics exclusive Medical Color Matching (MCM™) ensures prints match soft-copy monitors*
- *Ideal for referring physicians and patient take-homes*
- *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*
- *The only color output in the industry that truly rivals conventional color photographic film*

CODONICS®

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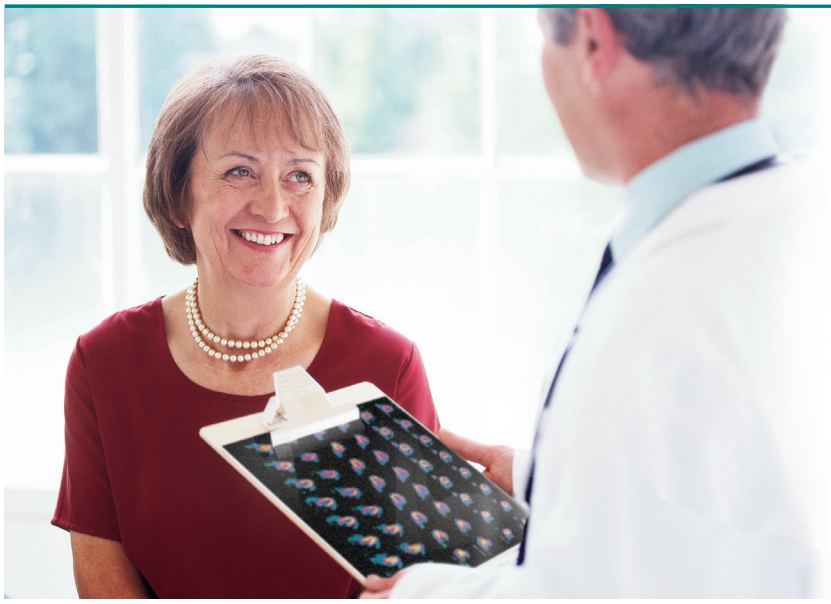
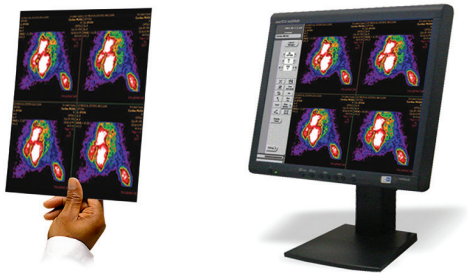
Codonics ChromaVista®
Color Paper / White Film

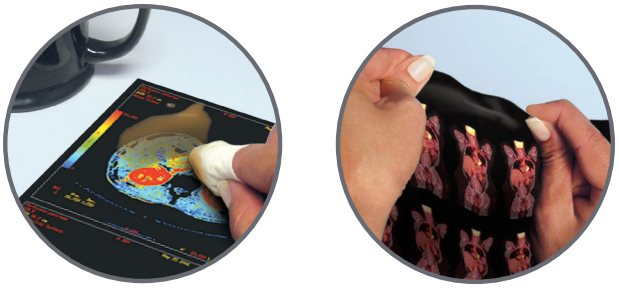


Codonics introduced the world's first DICOM color imager and has been pioneering multi-media imagers for over two decades. We are the industry leader in color imagers with nearly 30,000 installations worldwide.

Our Horizon Multi-media Imager features stunning edge-to-edge color printing, maximizing imaging size and reducing waste. Codonics exclusive Medical Color Matching (MCM™) is an advanced image processing feature that adjusts printed output colors to accurately match soft-copy monitors. This process corrects differences in hue, saturation, and intensity between the imager and soft-copy review stations. User's can easily determine the best match for their screen using the automatic MCM bracketing feature which is built into every Codonics imager.



Color prints always match softcopy monitors with our exclusive Medical Color Matching (MCM™) feature. Consistency, clarity and saturation with Codonics color dye-diffusion technology far exceeds that of wax or inkjet printers.



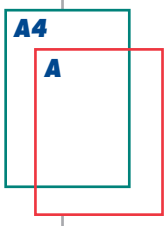
ChromaVista Color Paper / White Film has a heavy, photo-weight base material that resists water and tearing. Since there is no ink or toner, images never smear or transfer onto hands or other prints.

Specifications:

- Compatible with the Horizon family of multi-media imagers
- Continuous tone color rendering
- Dmin < 0.10 OD, Dmax > 2.50 OD (reflective)
- Thickness ~ 0.2mm

Available Sizes:

A (8.5" x 11")
A4 (210mm x 297mm)



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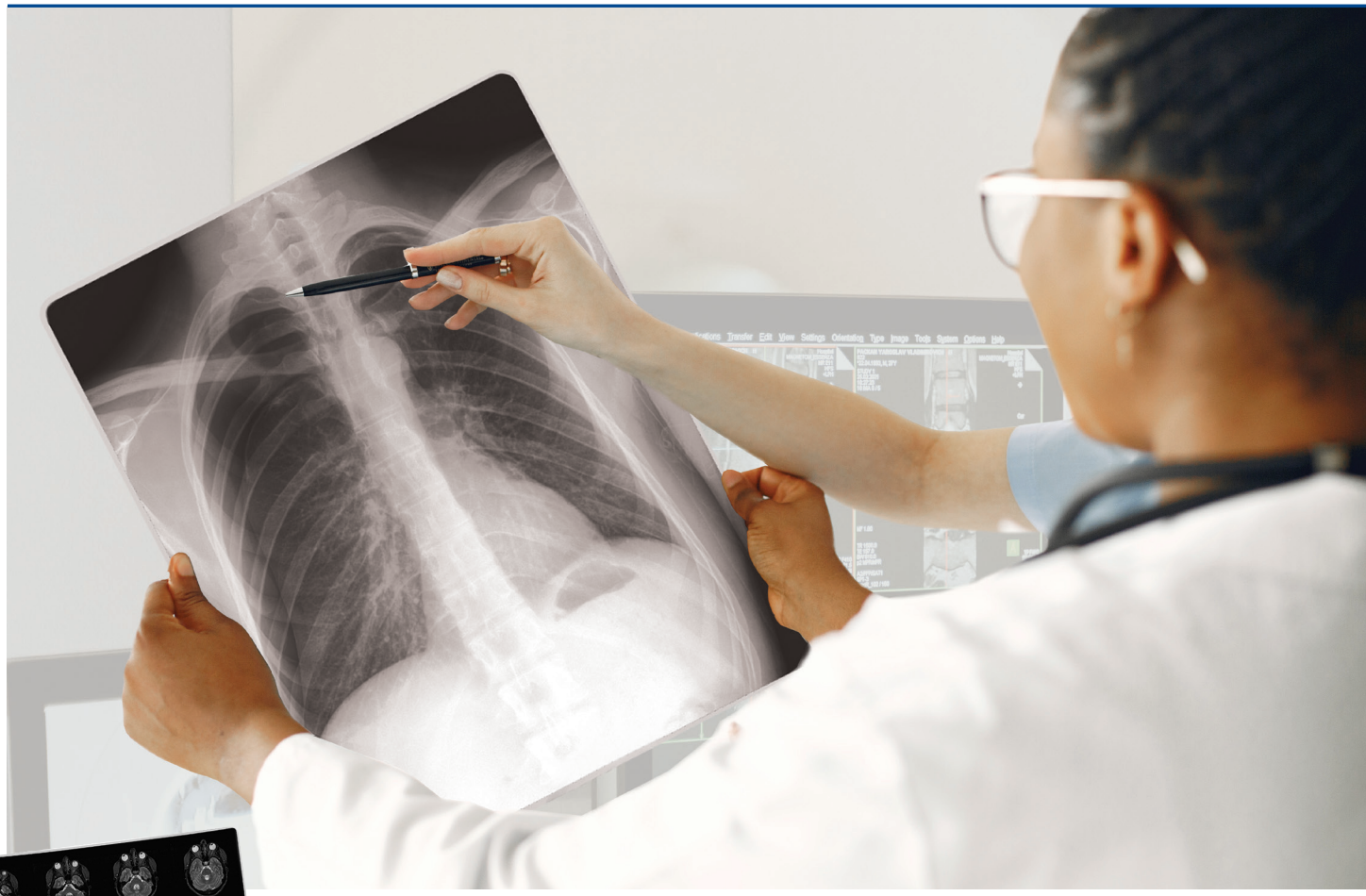
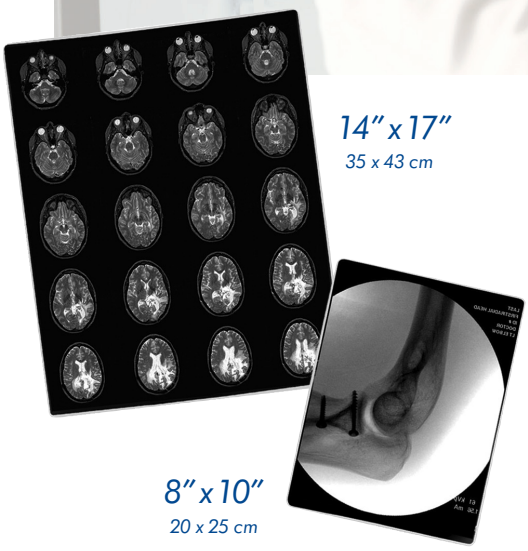
QUALITY SYSTEM CERTIFICATION DNV·GL ISO 13485

900-311-002.01

Codonics Film

Codonics DirectVista® Clear Film cost-effectively delivers superior quality images in two sizes





14" x 17"
35 x 43 cm

8" x 10"
20 x 25 cm

"The quality is superior to the traditional film imagers we were previously using."

A. Joseph Borelli, M.D., MRI at Belfair - Bluffton, SC

- *Completely digital, our unique direct thermal technology achieves image quality better or equal to "laser quality"*
- *Convenient dry printing eliminates the need for plumbing, special ventilation and siting requirements*
- *Multiple film sizes allow you to lower film costs by printing on the most economical size for your application*

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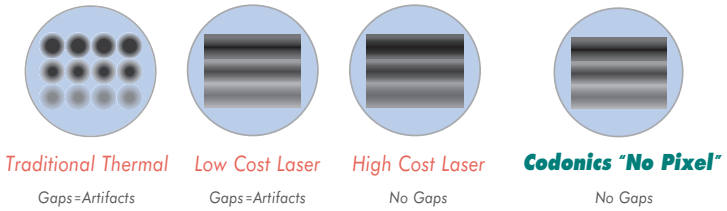
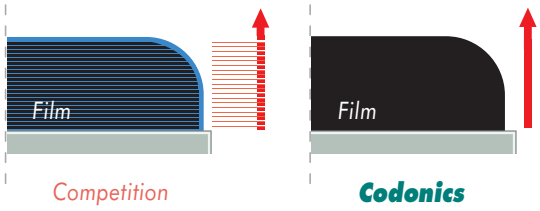
Codonics DirectVista® Thermal Grayscale Diagnostic Clear Film

Codonics patented imaging technology outputs superior diagnostic dry film with an unmatched image quality. DVC film is the ideal solution for the most demanding medical hardcopy applications. Completely eliminating space between lines by advancing the film in a smooth motion, the diagnostic output is precise and consistent. DVC film is available in 14"x17" and 8"x10", giving the user the option to scale the image to the appropriate film size, providing an alternative to print at a lower cost.

Depend on Codonics to deliver reliable, consistent images with the highest quality possible.



In thousands of side by side comparisons, board certified radiologists could not tell the difference between images printed on Codonics imagers from those printed on more expensive laser imagers. Codonics patented imaging technology outputs diagnostic film achieving unmatched versatility and image quality.



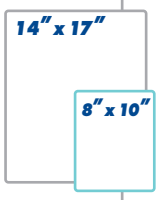
Dynamic Media Transport System (DMTS®) allows Codonics imagers to print while the media advances in a smooth motion eliminating space between lines.

Specifications:

- Compatible with Horizon multi-media imagers
- Continuous tone grayscale rendering
- Dmin ≤ 0.10 OD, Dmax ≥ 2.75 OD (transmissive)
- Thickness ~ 0.2mm

Available Sizes:

Horizon Imagers
14"x17" (35 x 43 cm)
8"x10" (20 x 25 cm)



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DirectVista Paper/White Film

Technical Brief

Revolutionary DirectVista® Paper/White Film

Codonics has developed and perfected a direct thermal grayscale paper for use in our Horizon® family of multi-media imagers. This state-of-the-art direct thermal technology produces stunning grayscale prints and offers the same photographic quality you have come to expect with dye-diffusion technology. The paper has a heavy base material for a photographic paper "look and feel."

Specifications

- 320 DPI spatial resolution with Horizon Imagers
- Continuous tone grayscale rendering
- Dmin < 0.10 OD, Dmax > 2.00 OD
- Thickness ~ 0.2mm

Size	Width (mm)	Length (mm)	Width (inches)	Length (inches)
14"x17"	354	429	14.0	17.0
11"x14"	278	354	11.0	14.0
A4	210	297	8.3	11.7
A	215	279	8.5	11.0

Size	Horizon (pixel image area)
14"x17"	4322 x 5025
11"x14"	3376 x 4072
A4	2514 x 3374
A	2580 x 3164

Shelf Life

Greater than or equal to 24 months at optimal storage conditions from date of manufacture (0-25 C°, 20-40% RH).

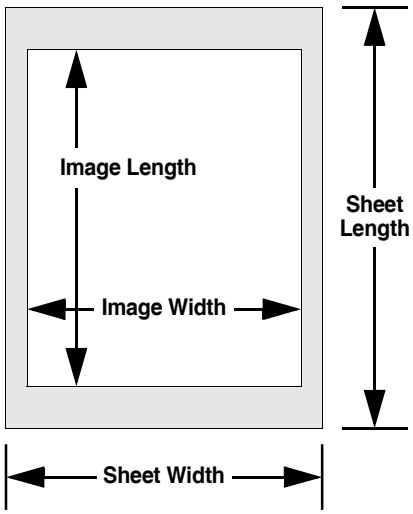
Archival

DirectVista Paper/White Film complies with ISO 18911 standards for storage of photographic media. Accelerated testing shows that DirectVista Paper/White Film is fully archivable for a minimum of 10 years when stored at medium-term conditions (max 25 C°, 20-50% RH) and for a minimum of 30 years when stored at extended-term conditions (max 21 C°, 20-30% RH).

Ordering Information

Imager	Media Size	Catalog Number
Horizon	14"x17"	1417-DVP
Horizon	11"x14"	1114-DVP
Horizon	A	A-DVP
Horizon	A4	A4-DVP

- DirectVista Paper /White Film is shipped five boxes to the case (80 sheets/box).



Technical Support

If questions arise, contact Codonics Technical Support at any time.

Phone: +1.440.243.1198
Email: support@codonics.com
Website: www.codonics.com

Get it all with just one call +1.440.243.1198

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Farglory Plaza, Building B, Unit 1412
No. 317 Xian Xia Rd.
Changning District, Shanghai PRC
Phone: +86.21.62787701
Fax:: +86.21.62787719

DirectVista® Film

Technical Brief

DirectVista Film

Codonics DirectVista Film is as a state-of-the-art direct-thermal film ideally suited for CT, MRI, ultrasound, functional imaging (nuclear medicine), CR, DR mammography, dental, portable X-ray, and other medical imaging applications.

Specifications

- 320 DPI spatial resolution with Horizon Imagers
- Continuous tone grayscale rendering
- Blue Dmin ≤ 0.25 OD, Dmax ≥ 3.00 OD
- Clear Dmin ≤ 0.10 OD, Dmax ≥ 2.75 OD
- Thickness ~ 0.2mm

Size	Width (mm)	Length (mm)	Width (inches)	Length (inches)
14"x51"	354	1294	14.0	51.0
14"x36"	354	913	14.0	36.0
14"x17"	354	429	14.0	17.0
11"x14"	278	354	11.0	14.0
8"x10"	201	252	8.0	10.0

Size	Horizon (pixel image area)
14"x51"	4322 x 15885
14"x36"	4322 x 11095
14"x17"	4322 x 5025
11"x14"	3376 x 4072
8"x10"	2406 x 2790

Shelf Life

84 months when stored at optimal storage conditions from date of manufacuture (0-25 C° 10-70% RH).

Archival

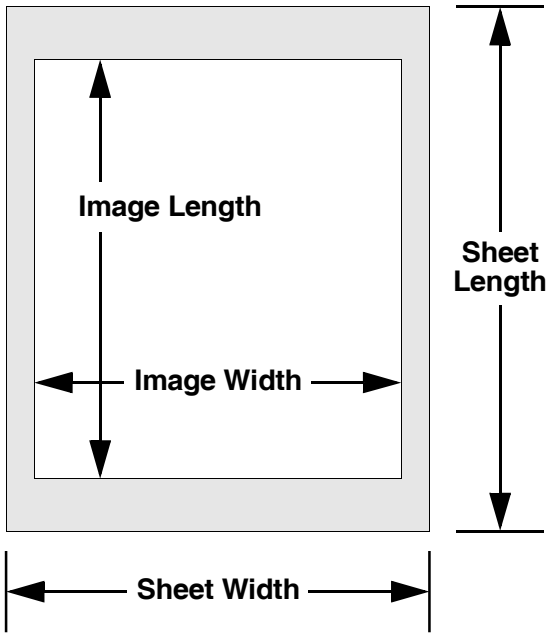
DirectVista Film complies with ISO 18911 standards for storage of photographic media. Accelerated testing shows that DirectVista Film is fully archivable for a minimum of 20 years when stored at extended storage conditions (Max 21 C° and 20-30 % RH).

Ordering Information

Imager	Media Size	Catalog Number
Horizon	14"x51"	1451-DVB
Horizon	14"x36"	1436-DVB
Horizon	14"x17"	1417-DVB, 1417-DVC, 1HCG-BF533 (DVB5)
Horizon	11"x14"	1114-DVB 1HCJ-BF533 (DVB5)
Horizon	8"x10"	810-DVB, 810-DVC, 1HCE-BF533 (DVB5)

* A suffix of "B" indicates blue base film and "C" indicates clear base film.

- DirectVista Film is shipped five boxes to the case (100 sheets/box).
- 14"x51" and 14"x36" DirectVista Film is shipped four boxes to the case (25 sheets/box).



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Manufacturers Certificate of Quality

Hardcopy Thermal Reflective/Transparency Media
Product Code: 90 IWZ Radiographic Film

FDA Regulation: 21CFR 892.1840
Japan KYOKA/Listing: 13B3X1019400003 (CVP)
13B3X1019400004 (DVP)
MDR (Medical Device Regulation EU): 2017/745
CHINA CFDA: 20151846, 20180099

Types Covered: A-DVP/A4-DVP, 1114-DVP, 1417-DVP Media (Grayscale Reflective)
A-CVP/A4-CVP Horizon Media (Color Reflective)

	CODONICS DVP/White Film	CODONICS CVP/White Film
	Medical Classification/Medical Intended Use	
Grayscale	4096	256 level/16.7M Colors
Resolution	12.6 pixels/mm	12.6 pixels/mm
Continuous Tone	YES	YES
Abrasion Resistant	YES	YES
Chemical/Water Resistant	YES	YES
Stability/Consistency	Densitometry Controlled	Color Matching Controlled
Archiveability	>20 YEARS	>20 YEARS
Tear Resistance	YES, Polystyrene, Polypropylene Layer	YES, Polypropylene Layer (P), PET(T)
Image Fade/Change	HEAT SENSITIVE/ NONE W/NORMAL VIEWING AND STORAGE	HEAT SENSITIVE/ NONE W/NORMAL VIEWING AND STORAGE
Repeatable Results	TESTED and PASS	TESTED and PASS
Weight/Thickness	JIS P8143	JIS P8143(weight) JIS 8118 (thickness)
Minimum Shelf Life*	18 MO Under Suggested Storage Conditions	18 MO Under Suggested Storage Conditions
Density	> 2.2 MAXD	> 2.2 MAXD
Linear Dynamic Range	<.25, > 2.2	<.25, > 2.2
STANDARDS	ANSI IT9.11/IT9.19	ANSI IT9.11/IT9.19
Harmonized Tariff Code:	3703.90.60 & 4811.51.2300	
STORAGE AND TRANSPORT REQUIREMENTS		
Storage Unprinted Material		
Nominal	Average Temp 18 C and 21 C	
Extreme	Max Temp 25 degrees C, Min 0 degrees C	
Sustained	Max 28 degrees C for 3 successive weeks per year, no Humidity Control	
Storage Printed Material	Extended Term Max 21 degrees C and 20-30% Relative Humidity*	
Transport	Max 25 degrees C and Max 32 C for 1 week (total transport period)	

*Shelf Life from processing date at Codonics, Storage conditions critical to stated performance.
Refer to Media Labels for *Best Used By* Lot# Expiration date.

Contact your Codonics representative for model configurations and media availability. Specifications are subject to change without notice.
Medical Intended Use as applied to Horizon imaging systems manufactured by Codonics. Imager and Media Claims void when not used as a system.

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Manufacturers Certificate of Quality

Hardcopy Thermal Media
Product Code: 90 IWZ Radiographic Film

FDA Regulation: 21CFR 892.1840
MDR (Medical Device Regulation EU): 2017/745
CHINA CFDA: 20151847, 20180100

Types Covered: 810-DVB, 1114-DVB, 1417-DVB, 1436/1451-DVB,
810-DVB5, 1114-DVB5, 1417-DVB5, 1436/1451-DVB5
810-DVC, 1417-DVC

	CODONICS DV FILM
SPECIFICATION	**Medical Classification/Medical Intended Use**
Gray Scale	4096 (Horizon Series)
Resolution	12.6 pixels/mm
Continuous Tone	YES
Abrasion Resistant	YES
Chemical/Water Resistant	YES
Stability/Consistency	Densitometry Controlled
Archiveability*	>20 YEARS
Tear resistance	YES, PET 195um (0.2mm+0.0/-.01mm)
Image Fade/Change	HEAT SENSITIVE/ NONE W/NORMAL VIEWING AND STORAGE
Repeatable Results	TESTED and PASS
Weight	JIS P8143
Minimum Shelf Life*	18 Months at 5-25 degrees C, 10-70% RH
Density MAX	≥ 3.0 B OD +/- 0.10, > 2.75 C OD +/- 0.20)
Density MIN	≤ 0.25 Dmin (≤ 0.25 B, ≤ 0.1 C)
Linear Dynamic Range	≤ 25, ≥ 3.0
STANDARDS	ANSI IT9.11/IT9.19
Harmonized Tariff Code:	3701.10.00
Sensitometry of Emulsion DVB/DVC/DVB5	Thermal Sensitivity: 0.2~500 μJ/pixel to produce an O.D. range of 0.20 Dmin to 3.20 Dmax. *Emulsion is sensitive to radiation, light, and infrared wavelengths. Care must be taken to properly store unexposed and archive exposed film.*
**DVB5	DirectVista Blue-5 Film is available for use in most Codonics Horizon multi-media imagers with suitable software version**, some model and size restrictions apply
STORAGE AND TRANSPORT REQUIREMENTS	
Storage Unprinted Material	
Nominal	Average Temp 18 C and 21 C
Extreme	Max Temp 25 degrees C, Min 0 degrees C
Sustained	Max 28 degrees C for 3 successive weeks per year, no Humidity Control
Storage Printed Material	Extended Term Max 21 degrees C and 20-30% Relative Humidity*
Transport	Max 25 degrees C and Max 32 C for 1 week (total transport period)

*Shelf Life from processing date at Codonics, Storage conditions critical to stated performance.
Refer to Media Labels for *Best Used By* Lot# Expiration date.

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Manufacturer's Certificate of Quality

Hardcopy Thermal Reflective/Transparency Media
Product Code: 90 IWZ Radiographic Film

FDA Regulation: 21CFR 892.1840
MDR (Medical Device Regulation EU): 2017/745
Japan KYOKA/Listing: 13BY6387
China CFDA: 20180099

Types Covered: A-CVP/A4-CVP Horizon Media, 1600P-A/A4 CVP Media (Color Reflective)
1600T-A/A4 CVT Media (Color Transparency Film)

	CODONICS CVP/T
	Medical Classification/Medical Intended Use
Gray Levels	256 level/16.7M Colors
Resolution	12.6 pixels/mm
Continuous Tone	YES
Abrasion Resistant	YES
Chemical/Water Resistant	YES
Stability/Consistency	Color Matching Controlled
Archiveability	>20 YEARS
Tear resistance	YES, Polypropylene Layer (P), PET(T)
Image Fade/Change	HEAT SENSITIVE/ NONE W/NORMAL VIEWING AND STORAGE
Repeatable Results	TESTED and PASS
Weight/Thickness	JIS P8143(weight) JIS 8118 (thickness)
Minimum Shelf Life	12 MO Under Suggested Storage Conditions
Density	> 2.2 MAXD
Linear Dynamic Range	<.25, > 2.2
STANDARDS	ANSI IT9.11/IT9.19
Harmonized Tariff Code:	3703.90.60 & 4811.90.8000
STORAGE AND TRANSPORT REQUIREMENTS	
Storage Unprinted Material	Extended Term Max 21 degrees C and 20-30% Relative Humidity
Nominal	Average Temp 18 C and 21 C
Extreme	Max 25 degrees C, Min 4 degrees C
Sustained	Max 28 degrees C for 3 successive weeks per year
Transport	Max 25 degrees C and Max 32 C for 1 week (total transport period)

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Manufacturers Certificate of Quality

Hardcopy Thermal Media
Product Code: 90 IWZ Radiographic Film

FDA Regulation: 21CFR 892.1840
MDR (Medical Device Regulation EU): 2017/745
CHINA CFDA: 国械备 20151846, 20180099

Types Covered: 1417-DVBT, 810-DVBT Blue-T Media (Film) 热敏胶片 白色基底灰阶热敏胶片

	CODONICS DVBT FILM
SPECIFICATION	**Medical Classification/Medical Intended Use**
Gray Levels	4096 (Horizon Series)
Resolution	12.6 pixels/mm
Continuous Tone	YES
Abrasion Resistant	YES
Chemical/Water Resistant	YES
Stability/Consistency	Densitometry Controlled
Archiveability*	Approximately 20 Years at 25°C, ≤ 60% RH
Tear resistance	YES, PET 195um (0.2mm+0.0/-.01mm)
Image Fade/Change	HEAT SENSITIVE/ NONE W/NORMAL VIEWING AND STORAGE
Repeatable Results	TESTED and PASS
Weight	JIS P8143
Minimum Shelf Life*	18 Months at 10-25°C, 30-60% RH
Density MAX	3.2±0.2
Density MIN	0.24±0.03
Linear Dynamic Range	UD 0.25 to 3.2
STANDARDS	ANSI IT9.11/IT9.19
Harmonized Tariff Code:	3701.10.00
Sensitometry of Emulsion	Thermal Sensitivity: 0.2~500 μJ/pixel to produce an O.D. range of 0.24±0.03 Dmin to 3.2±0.2 Dmax. *Emulsion is sensitive to radiation, light, and infrared wavelengths. Care must be taken to properly store unexposed and archive exposed film.*
STORAGE AND TRANSPORT REQUIREMENTS	
Storage Unprinted Material	
Nominal	10 ～ 25°C 30～60%RH
Extreme	Max Temp 40°C ≦ 10 day
Sustained	< 30°C for 3 successive weeks per year
Transport	<25°C up to 36 months <30°C ≦30 days <40°C ≦10 days <50°C ≦1 day

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