



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-DVC, 1417-DVC

810-DVB5, 1114-DVB5, 1417-DVB5, 1436/1451-DVB5

CODONICS DV FILM	
Medical Classification/Medical Intended Use	
SPECIFICATION	
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/-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 0-25°C, 10-70% RH
Density MAX	≥ 3.0 Blue, ≥ 2.75 Clear
Density MIN	≤ 0.25 Blue, ≤ 0.1 Clear
Linear Dynamic Range	0.25 to 3.0 Blue, 0.1 to 2.75 Clear
STANDARDS	ANSI IT9.11/IT9.19
Harmonized Tariff Code:	3701.30 & 3701.99
Sensitometry of Emulsion DVB/DVC/DVB5	Thermal Sensitivity: 0.2~500 μJ/pixel to produce an O.D. range of 0.25 Dmin to 3.0 Dmax on Blue Film. <i>Emulsion is sensitive to radiation, light, and infrared wavelengths. Care must be taken to properly store unexposed and archive exposed film.</i>
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 18-21°C
Extreme	Max Temp 25°C, Min 0°C and Max 70% Relative Humidity
Sustained	Max 28°C for 3 successive weeks per year, no Humidity Control
Storage Printed Material	
Extended Term Max 21°C and 20-30% Relative Humidity*	
Transport	
Max 25°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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