



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/-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. <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 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. Copyright © 2022 Codonics, Inc.



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