



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: 20151846, 20180099

Types Covered: 1417-DVBT, 810-DVBT Blue-T Media (Film)

	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/-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	≥ 3.0
Density MIN	≤ 0.29
Linear Dynamic Range	0.29 to 3.0
STANDARDS	ANSI IT9.11/IT9.19
Harmonized Tariff Code:	3701.30 & 3701.99
Sensitometry of Emulsion	Thermal Sensitivity: 0.2~500 μJ/pixel to produce an O.D. range of 0.29 Dmin to 3.0 Dmax. <i>Emulsion is sensitive to radiation, light, and infrared wavelengths. Care must be taken to properly store unexposed and archive exposed film.</i>
STORAGE AND TRANSPORT REQUIREMENTS	
Storage Unprinted Material	
Nominal	10-25°C and 30-60% Relative Humidity
Extreme	Max Temp 40°C ≤ 10 days
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

*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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