

# ECG RECORDING PAPER

NON-STERILE | DISPOSABLE | SINGLE USE | LATEX FREE | DEHP FREE | PVC FREE | BPA FREE

## DEVICE MANUFACTURING SPECIFICATIONS

Product Family	Vital Signs Gridded ECG Recording Papers
Manufacturer	AirLife Finland Oy
Manufacturer Address	Kuortaneenkatu 2, FI-00510 Helsinki, Finland
Country of Origin/Made In	Switzerland
Classification - EU	Class Im, Rule 1
CE Mark/Notification Body	CE
EMDN Code	Z1302 - Diagnostic Registration Papers
GMDN Code	16754 - Electrocardiographic Recording Paper
UMDNS Code	16754 - Paper, Recording, ECG
UNSPSC Code	14111539 - Medical Monitoring or Tracing or Recording Paper
Usage	Single-Use
Patient Population	Any Patient Population Requiring ECG Monitoring
Sterility	Non-Sterile
Shelf Life	3 Years (Use by Shelf Life)
Storage Conditions	Store in cool, dark, and dry locations. Temperature below 80°F (27°C). Relative humidity <65%. Avoid exposure to bright lights or UV sources such as sunlight, fluorescent, and similar lighting. Store separately in a a manila folder to ensure maximum trace and patient date image life. Do not store with carbon and carbonless forms, plastic documents protectors, or pressure sensitive tapes or labels

**Description:** Gridded ECG recording paper is a device prepared from a thin sheet of fibrous material with preprinted graphics and designed for recording the output of an electrocardiograph (ECG), or other device, in the form of measured physiologic parameters as an electrocardiogram (ECG).

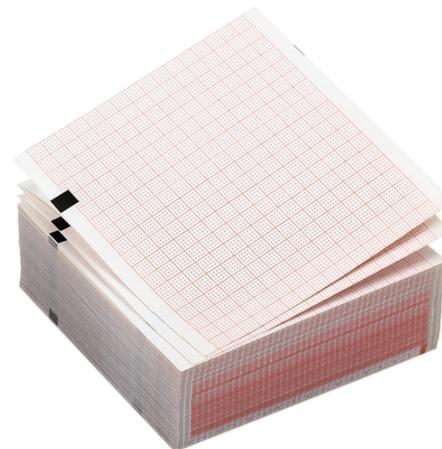
**Intended Purpose:** ECG recorder paper is used to retain printed ECG waveforms and the associated ECG information. The paper provides a preprinted grid to facilitate measurements. ECG recorder paper shall be used by or under the direction of a licensed health care practitioner. The ECG recorder paper is intended to be used primarily in the hospital but can be used in clinics, physician offices, outreach centers or wherever ECGs are acquired.

**Contraindications:** None Known.

## TECHNICAL SPECIFICATIONS

ITEM	IMAGED ARCHIVAL LIFE	SIZE	QUANTITY	COMPATIBILITY WITH ECG PRINTERS/MONITORS
22616605	8 Years	A4 (210 x 297 mm)	150 Sheets/Each, 10 Each/Packs	MAC1600, MAC2000
22616702	8 Years	90 x 90 mm	360 Sheets/Each, 10 Each/Packs	MAC500
2030887-001	8 Years	80 x 90 mm	280 Sheets/Each, 10 Each/Packs	MAC400
2036970-001	8 Years	110 x 140 mm	200 Sheets/Each, 10 Each/Packs	MAC800
22616611	25 Years	A4 (210 x 297 mm)	150 Sheets/Each, 10 Each/Packs	MAC1600, MAC2000

- Grid is perpendicular to paper within ±0.5%
- Grid ruling as a tolerance of ± 2% per 1mm



## DEVICE MATERIAL

COMPONENT	MATERIAL
Gridded Paper (22616605, 2030887-001, 2036970-001, 22616702)	Thermal Paper, RS72
Gridded Paper (22616611)	Thermal Paper, RS15
Packaging	Cardboard Box

**Biocompatibility:** The devices do not contain DEHP, natural rubber latex or BPA. These devices are REACH compliant and do not contain 3TG conflict minerals. These devices do not contain blood derivatives or materials derived from animal or human tissue.

PART	DESCRIPTION	BOX GTIN
22616605	Vital Signs ECG Paper, MAC Series, 8 Years Imaged Archival Life, A4, Red Grid, Z-Fold	20889483578671
22616611	Vital Signs ECG Paper, MAC Series, 25 Years Imaged Archival Life, A4, Red Grid, Z-Fold	20889483578695
22616702	Vital Signs ECG Paper, MAC Series, 8 Years Imaged Archival Life, 90 mm, Z-Fold	20889483578701
2030887-001	Vital Signs ECG Paper, MAC Series, 8 Years Imaged Archival Life, 80 mm, Red Grid, Z-Fold	20889483576493
2036970-001	Vital Signs ECG Paper, MAC Series, 8 Years Imaged Archival Life, 110 mm, Red Grid, Z-Fold	20889483576554