Philips Medical Systems
M2600A Telemetry System:

M2601A Medical Telemetry Transmitter

General Information

Manufacturer:

Philips Medical Systems (formerly Agilent Technologies, Inc. and Hewlett Packard, Inc.)
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Andover, MA 01810-1099
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Authorized EU Representative

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Identity of other manufacturing sites for this device: NONE

Product Identification:

Model: M2600A Telemetry System
Starting with Prefix Date Code 4036A for both series B and C transmitters

- (Series B (TV 5.0): use of M2601A with battery extender device)
- (Series C (TV 6.0): same M2601A device but has NBP SW capability for use with M2636A/B TeleMon monitors; a Series B transmitter cannot be used with TeleMon).

General Device Description:
Medical telemetry device

Intended Use:

The Philips/Agilent Telemetry System is a comprehensive ambulatory system solution for the intermediate care unit for adult and pediatric patients. The foundation of the system is a transmitter that can capture and transmit ECG signals and SpO2 values (if available) that are then processed and displayed on the Philips/Agilent Information Center. The information center generates alarms and recordings, thus notifying clinicians of changes in patients' conditions. The Telemetry System communicates with other devices via the Philips/Agilent patient care system.

US law restricts this device to sale by or on the order of a physician. This product is intended for use in health care facilities by trained healthcare professionals. It is not intended for home use

Accessories:

- Battery (9 V Lithium or 8.4 V Zinc Air)
- 3-Wire ECG Lead Sets (AAMI and IEC models M2590A, M2591A, M2594A, M2595A)
- 5-wire ECG Lead Sets (AAMI and IEC models M2592A, M2593A, M2596A, M2597A)
- Combiner shield (3 and 5 wire) models M2598A and M2599A
- ECG Electrodes 14445x
- ECG Electrode kits (M2201A, 40489E, 40493D, 40493E)
- Transmitter pouch (9300-0768-050, 9300-0768-200)
- SpO2 transducers (M1191A, M1192A, M1194A)
- Wristband M1627A
- Nellcor Oxisensor (M1930A/B, M1904A/B)
- Adapter Cable for use with Nellcor disposable transducers (M1943A)
- Battery Extender Device (M2611A)
- M2636A/B TeleMon (separate device and MDD Technical File)

Standards Used:

93/42/EEC	Council Directive 93/42/EEC of 14 June 1993 concerning medical devices	E
EN 330 220-1,-2:1997	Electromagnetic compatibility and Radio Spectrum Matters (ERM); Parts 1 and 2 as applicable.	E
EN 980:1996	Graphical symbols for use in the labeling of medical devices	E
EN 540:1993	Clinical investigation of medical devices for human subjects	E
EN 1041:1998	Information supplied by the manufacturer with medical devices	E
EN60601-1:1996 IEC 60601-1:1995	Medical electrical equipment - General requirements for safety	E
EN60601-1-1:1996 IEC 60601-1-1:1995	MEDICAL ELECTRICAL EQUIPMENT - GENERAL REQUIREMENTS FOR SAFETY - COLLATERAL STANDARD: SAFETY REQUIREMENTS FOR MEDICAL ELECTRICAL SYSTEMS	E
EN60601-1-2:1997 IEC 60601-1-2:1993	Medical electrical equipment - General requirements for safety - Collateral standard - Electromagnetic compatibility - Requirements and tests	E
EN60601-1-4:1996 IEC 60601-1-4:1996	MEDICAL ELECTRICAL EQUIPMENT - GENERAL REQUIREMENTS FOR SAFETY - COLLATERAL STANDARD - PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS	E
21 CFR 801	21 CFR 801 Labeling	E
UL 2601-1:1997	MEDICAL ELECTRICAL EQUIPMENT - GENERAL REQUIREMENTS FOR SAFETY	E
CSA C22.2-601.1:1998	MEDICAL ELECTRICAL EQUIPMENT - GENERAL REQUIREMENTS FOR SAFETY	E
IEC 60529:1989	Degrees of Protection Provided by Enclosures	E
IEC 60878:1988	Graphical Symbols for Electrical Equipment in Medical Practice FDA Guidance "DO IT BY DESIGN – An Introduction to Human Factors in Medical Devices"	E
1999/5/EC	Radio Equipment & Telecommunications Terminal Equipment EU Directive	E
IEC 60601-2-27:1994	Particular Requirements for ECG	E
IEC 60417:1973	Graphical Symbols for Use on Equipment.	E
ETSI/EN 300 220-1:1996	PTT- Post, Telephone & Telegraphy, Radio Licensing, where appropriate.	E
FCC, CFR 47 part 15B	FCC, Code of federal regulations – Telecommunications (Unintentional Radiators)	E
FCC, CFR 47 part 15C	FCC, Code of federal regulations – Telecommunications (Intentional Radiators)	E
FCC, CFR 47 part 90.217	FCC, Code of federal regulations – Telecommunications (Intentional Radiators)	E

Other Notes:

This device does not incorporate any sterile components.
This device does not incorporate a medicinal substance.