



# NEK EN 60601 serien, Elektromedisinsk utstyr

Over hele verden brukes IEC 60601 serien som grunnlag for utvikling, produksjon og installasjon av Elektromedisisk utstyr.

Serien er i ca. 60 deler og omhandler sikkerhet-, funksjonalitet/ytelse-, og grunnleggende- egenskaper.

- Del 1 serien omhandler generelle forhold ( general )
- Del 2 serien omhandler spesielle forhold ( particular )

Del 1 foreligger nå samlet, og selges rabattert i en pakke ”IEC 60601-1-SER ed 1.0”.

Deltakelse i NEKs Normkomiteer gir medlemmene en nøkkelposisjon til å påvirke og fange opp endringer og utvidelser tidlig i standardiseringsprosessene.

NEK har over 500 medlemmer fordelt på 160 normkomiteer. NEK har en nasjonal normkomite (speilkomite)NK for hver teknisk komite i IEC og CENELEC.

NK 62 behandler 60601 serien i Norge.

IEC 60601-1 serien			
IEC 60601-1-1 EN 60601-1-1	MEDICAL ELECTRICAL EQUIPMENT - PART 1: GENERAL REQUIREMENTS FOR SAFETY 1: COLLATERAL STANDARD: SAFETY REQUIREMENTS FOR MEDICAL ELECTRICAL SYSTEMS	IEC 60601-1-6 EN 60601-1-6	MEDICAL ELECTRICAL EQUIPMENT - PART 1-6: GENERAL REQUIREMENTS FOR SAFETY - COLLATERAL STANDARD: USABILITY
IEC 60601-1-2 EN 60601-1-2	MEDICAL ELECTRICAL EQUIPMENT - PART 1: GENERAL REQUIREMENTS FOR SAFETY 2. COLLATERAL STANDARD: ELECTROMAGNETIC COMPATIBILITY - REQUIREMENTS AND TESTS	IEC 60601-1-8 EN 60601-1-8	MEDICAL ELECTRICAL EQUIPMENT - - PART 1-8: GENERAL REQUIREMENTS FOR SAFETY - COLLATERAL STANDARD: GENERAL REQUIREMENTS, TESTS AND GUIDANCE FOR ALARM SYSTEMS IN MEDICAL ELECTRICAL EQUIPMENT AND MEDICAL ELECTRICAL SYSTEM
IEC 60601-1-3 EN 60601-1-3	MEDICAL ELECTRICAL EQUIPMENT - PART 1: GENERAL REQUIREMENTS FOR SAFETY - COLLATERAL STANDARD: GENERAL REQUIREMENTS FOR RADIATION PROTECTION IN DIAGNOSTIC X-RAY EQUIPMENT	IEC 60601-1-9 EN 60601-1-9	MEDICAL ELECTRICAL EQUIPMENT - - PART 1-9: GENERAL REQUIREMENTS FOR BASIC SAFETY AND ESSENTIAL PERFORMANCE - COLLATERAL STANDARD: REQUIREMENTS FOR ENVIRONMENTALLY CONSCIOUS DESIGN
IEC 60601-1-4 EN 60601-1-4	MEDICAL ELECTRICAL EQUIPMENT: PART 1-4: GENERAL REQUIREMENTS FOR COLLATERAL STANDARD: PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS		

IEC 60601-1-10 EN 60601-1-10	MEDICAL ELECTRICAL EQUIPMENT -- PART 1-10: GENERAL REQUIREMENTS FOR BASIC SAFETY AND ESSENTIAL PERFORMANCE - COLLATERAL STANDARD: REQUIREMENTS FOR THE DEVELOPMENT OF PHYSIOLOGIC CLOSED-LOOP CONTROLLERS
IEC 60601-1-11 EN 60601-1-11	MEDICAL ELECTRICAL EQUIPMENT -- PART 1-11: GENERAL REQUIREMENTS FOR BASIC SAFETY AND ESSENTIAL PERFORMANCE - COLLATERAL STANDARD: REQUIREMENTS FOR MEDICAL ELECTRICAL EQUIPMENT AND MEDICAL ELECTRICAL SYSTEMS USED IN THE HOME HEALTHCARE ENVIRONMENT
I nettbutikken selger også en serie:  IEC 60601-1-SER ed1.0 0	IEC 60601-1 ed3.0 IEC 60601-1-1 ed2.0 IEC 60601-1-2 ed3.0 IEC 60601-1-3 ed2.0 IEC 60601-1-4 ed1.1 IEC 60601-1-6 ed3.0 IEC 60601-1-8 ed2.0 IEC 60601-1-9 ed1.0 IEC 60601-1-10 ed1.0 IEC 60601-1-11 ed1.0

<b>PART 2-x</b>	<b>- PART 2-x: PARTICULAR REQUIREMENTS</b>
IEC 60601-2-1 EN 60601-2-1	- PART 2-1: -SAFETY OF ELECTRON ACCELERATORS IN THE RANGE 1 MeV TO 50 MeV
IEC 60601-2-2 EN 60601-2-2	- PART 2-2: SAFETY OF HIGH FREQUENCY SURGICAL EQUIPMENT
IEC 60601-2-3 EN 60601-2-3	- PART 2: PARTICULAR REQUIREMENTS FOR THE SAFETY OF SHORT-WAVE THERAPY EQUIPMENT
IEC 60601-2-4 EN 60601-2-4	- PART 2: PARTICULAR REQUIREMENTS FOR THE SAFETY OF CARDIAC DEFIBRILLATORS AND CARDIAC DEFIBRILLATORS - MONITORS
IEC 60601-2-5 EN 60601-2-5	- PART 2-5: PARTICULAR REQUIREMENTS FOR THE SAFETY OF ULTRASONIC PHYSIOTHERAPY EQUIPMENT

IEC 60601-2-6 FprEN 60601-2-6	- PART 2: PARTICULAR REQUIREMENTS FOR THE SAFETY OF MICROWAVE THERAPY EQUIPMENT
IEC 60601-2-7 EN 60601-2-7	- PART 2-7: PARTICULAR REQUIREMENTS FOR THE SAFETY OF HIGH-VOLTAGE GENERATORS OF DIAGNOSTIC X-RAY GENERATORS
IEC 60601-2-8 EN 60601-2-8	- PART 2-8: PARTICULAR REQUIREMENTS FOR THE SAFETY OF THERAPEUTIC X-RAY EQUIPMENT OPERATING IN THE RANGE 10 kV TO 1 MV
IEC 60601-2-9 EN 60601-2-9	- PART 2: PARTICULAR REQUIREMENTS FOR THE SAFETY OF PATIENT CONTACT DOSEMETERS USED IN RADIOTHERAPY WITH ELECTRICALLY CONNECTED RADIATION DETECTORS
IEC 60601-2-10 EN 60601-2-10	- PART 2: PARTICULAR REQUIREMENTS FOR THE SAFETY OF NERVE AND MUSCLE STIMULATORS
IEC 60601-2-11 EN 60601-2-11	- PART 2: PARTICULAR REQUIREMENTS FOR THE SAFETY OF GAMMA BEAM THERAPY EQUIPMENT
IEC 60601-2-12	- PART 2: PARTICULAR REQUIREMENTS FOR THE SAFETY OF LUNG VENTILATORS FOR MEDICAL USE
IEC 60601-2-13	- PART 2-13: PARTICULAR REQUIREMENTS FOR THE SAFETY OF ANAESTHETIC WORKSTATIONS
IEC 60601-2-14 EN 60601-2-14	- PART 2: PARTICULAR REQUIREMENTS FOR THE SAFETY OF ELECTROCONVULSIVE THERAPY EQUIPMENT
IEC 60601-2-16 EN 60601-2-16	- PART 2: PARTICULAR REQUIREMENTS FOR THE SAFETY OF HAEMODIALYSIS EQUIPMENT
IEC 60601-2-17 EN 60601-2-17	- PART 2: PARTICULAR REQUIREMENTS FOR THE SAFETY OF REMOTE-CONTROLLED AUTOMATICALLY DRIVEN GAMMA-RAY AFTER-LOADING EQUIPMENT
IEC 60601-2-18 EN 60601-2-18	- PART 2: PARTICULAR REQUIREMENTS FOR THE SAFETY OF ENDOSCOPIC EQUIPMENT

IEC 60601-2-19 EN 60601-2-19	- PART 2: PARTICULAR REQUIREMENTS OF SAFETY OF BABY INCUBATORS
IEC 60601-2-20 EN 60601-2-20	- PART 2: PARTICULAR REQUIREMENTS FOR THE SAFETY OF TRANSPORT INCUBATORS
IEC 60601-2-21 EN 60601-2-21	- PART 2: PARTICULAR REQUIREMENTS FOR THE SAFETY OF INFANT RADIANT WARMERS
IEC 60601-2-22 EN 60601-2-22	- PART 2: PARTICULAR REQUIREMENTS FOR THE SAFETY OF DIAGNOSTIC AND THERAPEUTIC LASER EQUIPMENT
IEC 60601-2-23 EN 60601-2-23	- PART 2-23: PARTICULAR REQUIREMENTS FOR THE SAFETY, INCLUDING ESSENTIAL PERFORMANCE, OF TRANSCUTANEOUS PARTIAL PRESSURE MONITORING EQUIPMENT
IEC 60601-2-24 EN 60601-2-24	- PART 2-24: PARTICULAR REQUIREMENTS FOR THE SAFETY OF INFUSION PUMPS AND CONTROLLERS
IEC 60601-2-25 EN 60601-2-25	- PART 2-25: PARTICULAR REQUIREMENTS FOR THE SAFETY OF ELECTROCARDIOGRAPHS
IEC 60601-2-26 EN 60601-2-26	- PART 2: PARTICULAR REQUIREMENTS FOR THE SAFETY OF ELECTROENCEPHALOGRAPHS
IEC 60601-2-27 EN 60601-2-27	- PART 2: PARTICULAR REQUIREMENTS FOR THE SAFETY OF ELECTROCARDIOGRAPHIC MONITORING EQUIPMENT
IEC 60601-2-28 EN 60601-2-28	- PART 2: PARTICULAR REQUIREMENTS FOR THE SAFETY OF X-RAY SOURCE ASSEMBLIES AND X-RAY TUBE ASSEMBLIES FOR MEDICAL DIAGNOSIS
IEC 60601-2-29 EN 60601-2-29	- PART 2-29: PARTICULAR REQUIREMENTS FOR THE SAFETY OF RADIOTHERAPY SIMULATORS
IEC 60601-2-30 EN 60601-2-30	- PART 2-30: PARTICULAR REQUIREMENTS FOR THE SAFETY, INCLUDING ESSENTIAL PERFORMANCE, OF AUTOMATIC CYCLING NON-INVASIVE BLOOD PRESSURE MONITORING EQUIPMENT

IEC 60601-2-31 EN 60601-2-31	- PART 2: PARTICULAR REQUIREMENTS FOR THE SAFETY OF EXTERNAL CARDIAC PACEMAKERS WITH INTERNAL POWER SOURCE
IEC 60601-2-32 EN 60601-2-32	- PART 2: PARTICULAR REQUIREMENTS FOR THE SAFETY OF ASSOCIATED EQUIPMENT OF X-RAY EQUIPMENT
IEC 60601-2-33 EN 60601-2-33	- PART 2: PARTICULAR REQUIREMENTS FOR THE SAFETY OF MAGNETIC RESONANCE EQUIPMENT FOR MEDICAL DIAGNOSIS
IEC 60601-2-34 EN 60601-2-34	- PART 2: PARTICULAR REQUIREMENTS FOR THE SAFETY, INCLUDING ESSENTIAL PERFORMANCE, OF INVASIVE BLOOD PRESSURE MONITORING EQUIPMENT
IEC 60601-2-35 EN 60601-2-35	- PART 2: PARTICULAR REQUIREMENTS FOR THE SAFETY OF BLANKETS, PADS AND MATTRESSES, INTENDED FOR HEATING IN MEDICAL USE
IEC 60601-2-36 EN 60601-2-36	- PART 2: PARTICULAR REQUIREMENTS FOR THE SAFETY OF EQUIPMENT FOR EXTRACORPOREALLY INDUCED LITHOTRIPSY
IEC 60601-2-37 EN 60601-2-37	- PART 2: PARTICULAR REQUIREMENTS FOR THE SAFETY OF ULTRASONIC MEDICAL DIAGNOSTIC AND MONITORING EQUIPMENT
IEC 60601-2-38 EN 60601-2-38	- PART 2: PARTICULAR REQUIREMENTS FOR THE SAFETY OF ELECTRICALLY OPERATED HOSPITAL BEDS
IEC 60601-2-39 EN 60601-2-39	- PART 2-39: PARTICULAR REQUIREMENTS FOR THE SAFETY OF PERITONEAL DIALYSIS EQUIPMENT
IEC 60601-2-40 EN 60601-2-40	- PART 2-40: PARTICULAR REQUIREMENTS FOR THE SAFETY OF ELECTROMYOGRAPHS AND EVOKED RESPONSE EQUIPMENT
IEC 60601-2-41 EN 60601-2-41	- PART 2-41: PARTICULAR REQUIREMENTS FOR THE SAFETY OF SURGICAL LUMINAIRES AND LUMINAIRES FOR DIAGNOSIS

IEC 60601-2-43 EN 60601-2-43	- PART 2-43: PARTICULAR REQUIREMENTS FOR THE SAFETY OF X-RAY EQUIPMENT FOR INTERVENTIONAL PROCEDURES
IEC 60601-2-44 EN 60601-2-44	- PART 2-44: PARTICULAR REQUIREMENTS FOR THE SAFETY OF X-RAY EQUIPMENT FOR COMPUTED TOMOGRAPHY
IEC 60601-2-45 EN 60601-2-45	- PART 2-45: PARTICULAR REQUIREMENTS FOR THE SAFETY OF MAMMOGRAPHIC X-RAY EQUIPMENT AND MAMMOGRAPHIC STEREOTACTIC DEVICES
IEC 60601-2-46 EN 60601-2-46	- PART 2-46: PARTICULAR REQUIREMENTS FOR THE SAFETY OF OPERATING TABLES

IEC 60601-2-47 EN 60601-2-47	- PART 2-47: PARTICULAR REQUIREMENTS FOR THE SAFETY, INCLUDING ESSENTIAL PERFORMANCE, OF AMBULATORY ELECTROCARDIOGRAPHIC SYSTEMS
IEC 60601-2-49 EN 60601-2-49	- PART 2-49: PARTICULAR REQUIREMENTS FOR THE SAFETY OF MULTIFUNCTION PATIENT MONITORING EQUIPMENT
IEC 60601-2-50 EN 60601-2-50	- PART 2-50: PARTICULAR REQUIREMENTS FOR THE SAFETY OF INFANT PHOTOTHERAPY EQUIPMENT
IEC 60601-2-51 EN 60601-2-51	- PART 2-51: PARTICULAR REQUIREMENTS FOR SAFETY, INCLUDING ESSENTIAL PERFORMANCE, OF RECORDING AND ANALYSING SINGLE CHANNEL AND MULTICHANNEL ELECTROCARDIOGRAPHS

**Interessenter fra bransjen kan bli medlemmer i NEKs normkomite NK 62 som arbeider med Elektromedisisk utstyr.**

**NK 62 – Elektrisk utstyr for medisinsk bruk. NK 62 behandler også utstyr for røntgen, høyenergi stråling og nukleærmedisin**

**For mer informasjon om NEK og normarbeid gå inn på vår nyetablerte portal for elektromedisinsk utstyr:**

**<http://medisinsk.nek.no>**

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**Comité Européen de Normalisation Electrotechnique, CENELEC**

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