

AUTOMOTIVE INDUSTRY STANDARD

**Medical Equipment for
Road Ambulances**

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ON BEHALF OF
AUTOMOTIVE INDUSTRY STANDARDS COMMITTEE

UNDER
CENTRAL MOTOR VEHICLE RULES – TECHNICAL STANDING COMMITTEE

SET-UP BY
MINISTRY OF ROAD TRANSPORT and HIGHWAYS
(DEPARTMENT OF ROAD TRANSPORT and HIGHWAYS)
GOVERNMENT OF INDIA

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Status chart of the standard to be used by the purchaser for updating the record

Sr. No.	Corrigenda	Amendment	Revision	Remark	Date	Misc.

General Remarks:

INTRODUCTION

The Ministry of Road Transport and Highways, Govt. of India set up five Working Groups on 4Es of Road Safety i.e. Education, Engineering (Vehicles), Enforcement and Emergency Care on the recommendation of the National Road Safety Council (NRSC). The Working Group on Emergency Care in its report observed that the real concept of an ambulance is missing in India. Existing ambulances are more like transport vehicles and any vehicle suitable to lay a patient is called an ambulance without consideration to the overall ambulance design. Research has shown that ambulances are more likely to be involved in motor vehicle collisions resulting in injury or death than either fire trucks or police cars. Unrestrained occupants, particularly those riding in the patient-care compartment, are particularly vulnerable. It is, therefore, all the more necessary in an ambulance to take care of occupant safety, patient care ergonomics, medical equipment selection and placement, vehicle engineering and integration, etc.

The working group recommended that there is a need to formulate the procedure for approval of medical equipment with necessary amendments in Central Motor Vehicle Rules (CMVR). In view of this, an Expert Committee comprising the members (Refer Annexure 1) was constituted with approval of the Hon'ble Union Minister for Road Transport & Highways to formulate the guidelines for approval of medical equipment pertaining to various categories of Road Ambulances as covered in AIS-125 (Part 1)

The committee referred the following global best practices / research in this domain:

- a) Ambulance Manufacturers Division (AMD) of the National Truck Equipment Association (NTEA), USA.
- b) NHS, UK: Future Ambulances
- c) ACS, ACEP - USA: Equipments for Ambulances
- d) Gupta SK, Singh AR, Patnaik SK (December 2010). Specifications of Advanced Life Support Ambulances. Department of Hospital Administration, AIIMS, New Delhi
- e) Lechleuthner A, Marten D, Anschütz B, (February 2012). Electrical Systems in Ambulances. Institute of Rescue Engineering, University of Applied Sciences, Cologne, Germa
- f) Lechleuthner A, Marten D, Lohölter M, (February 2012). Emergency Vehicles in India - Standardization of Recognition and Perception. Institute of Rescue Engineering, University of Applied Sciences, Cologne, Germany

The Committee took stock of the existing trends vis-a-vis ambulance construction, design and integration to understand the current scenario, limitations of the existing framework, available technology, manufacturer maturity, local conditions, past trends, etc.

The committee members shared their experiences as regards the Indian reality and deliberated on the reasons behind the pathetic condition of ambulances as on date. The following important points were highlighted during these discussions:

- a) There is no standardization of ambulance design across various procurements in the country and the industry is forced to re-integrate their vehicles every now and then.
- b) Most of the ambulance specifications are written by medical specialists who are unable to translate the user requirements in automobile terminology thereby resulting in a huge gap between the user expectations and industry deliverability.
- c) There are certain inherent limitations in the existing laws which allow goods vehicles to be converted as ambulances for passenger application without incorporating essential safety features in patient compartment like side door, forward backward seating, occupant restraints, certified electrical systems, etc.

The committee initially drafted the standard in line with the global best practices referred above and localized the same to suit Indian requirements. The document was then circulated to Society of Indian Automobile Manufacturers (SIAM)

During the deliberations, it was decided that type approval of vehicles shall be limited to automotive aspect of construction and functional requirements of road ambulance and medical equipment's related details shall not be part of Vehicle Type Approval. This Part 2 of the AIS-125 describes the specific requirements for Medical Equipment and Medical Devices .

The Automotive Industry Standards Committee (AISC) responsible for preparation of this standard is give in Annexure 2

Medical Equipment for Road Ambulances

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1.0 SCOPE

This standard specifies the guidelines for technical requirements for medical equipment which may be used in road ambulances.

2.0 REFERENCES

2.1	AIS-125 (Part 1)	Constructional and Functional Requirements for Road Ambulances
2.2	AIS-004(Part 3)-2009	Automotive vehicles - Requirements for electromagnetic compatibility
2.3	IEC 60068-2-6-Ed7.0-2007	Environmental testing - Part 2-6 : tests - Test Fc: vibration(sinusoidal)
2.4	IEC 60068-2-27-Ed4.0-2008	Environmental testing - Part 2-27: tests - Test Ea and guidance: shock (IEC 60068-2-29 is merged into this edition of IEC 60068-2-27 and hence IEC 60068-part 2-29 are withdrawn)
2.5	IEC 60068-2-31-Ed2.0-2008	Environmental testing - Part 2-31: tests - Test Ec: rough handling shocks, primarily for equipment-type specimens (this edition of incorporates the second edition of IEC 60068-2-32, which stands withdrawn)
2.6	IEC 60068-2-64-Ed2.0-2008	Environmental testing - Part 2-64: tests - Test Fh: vibration, broadband random and guidance
2.7	IEC 60335-1-Ed5.0-2010	Household and similar electrical appliances - Safety - Part 1: General requirements
2.8	IEC 60335-2-29-Ed4.2 Consol. with Am1and2-2010	Household and similar electrical appliances - Safety - Part 2-29: Particular requirements for battery chargers
2.9	IEC 60601-1-8-2006	Medical electrical equipment - Part 1 - 8: General requirements for basic safety and essential performance - Collateral standard: general requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
2.10	IEC 60601-1-SER-Ed1.0-2011	Medical electrical equipment - All parts

2.11	IEC/TRF 60601-1-8- Ed4.0-2010	This test report form applies to IEC 60601-1-8:2006 (second edition) in conjunction with IEC 60601-1: 2005 (medical electrical equipment- Part 1-8: General requirements for basic safety and essential performance - Collateral standard: general requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems)
2.12	IEC/TR 60930-Ed2.0-2008	Guidelines for administrative, medical and nursing staff concerned with the safe use of medical electrical equipment and medical electrical systems (this edition has been aligned with IEC 60601-1:2005, IEC 60601-1-2:2007, IEC 60601-1-8:2006 and IEC 62353:2007. this edition includes medical electrical systems within its scope)
2.13	IEC 61000-3-3-Limitation Ed2.0-2008: public low- ≤16 A	Electromagnetic compatibility (EMC) - Part 3-3: Limits - of voltage changes, voltage fluctuations and flicker in voltage supply systems, for equipment with rated current per phase and not subject to conditional connection
2.14	IEC 61000-6-1-Ed2.0-2005	Electromagnetic compatibility (EMC) - Part 6-1: Generic standards - immunity for residential, commercial and light-industrial environments
2.15	IEC 61000-6-2-ed2.0-2005	Electromagnetic compatibility (EMC) - Part 6-2: generic standards - Immunity for industrial environments
2.16	IS 3224	Valve fittings for compressed gas cylinders excluding liquefied petroleum gas (LPG) cylinders - Specification
2.17	IS 7285	Refillable Seamless Steel Gas Cylinders
2.18	ISO 3795-1989	Road vehicles, and tractors and machinery for agriculture and forestry - Determination of burning behaviour of interior materials
2.19	ISO 5359-2008	Low-pressure hose assemblies for use with medical gases
2.20	ISO 7396-1-2007	Medical gas pipeline systems - Part 1: Pipeline systems for compressed medical gases and vacuum

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2.21	ISO 7396-2-2007	Medical gas pipeline systems - Part 2: Anaesthetic gas scavenging disposal systems
2.22	ISO 9170-1-2008	Terminal units for medical gas pipeline systems - Part 1: Terminal units for use with compressed medical gases and vacuum
2.23	ISO 10079-1-1999	Medical suction equipment - Part 1: Electrically powered suction equipment - Safety requirements
2.24	ISO 10079-2-1999	Medical suction equipment - Part 2: Manually powered suction equipment
2.25	ISO 10079-3-1999	Medical suction equipment - Part 3: Suction equipment powered from a vacuum or pressure source
2.26	ISO 10524-1-2006	Pressure regulators for use with medical gases - Part 1: Pressure regulators and pressure regulators with flow-metering devices
2.27	ISO 10524-3-2005	Pressure regulators for use with medical gases - Part 3: Pressure regulators integrated with cylinder valves
2.28	ISO 10524-4-2008	Pressure regulators for use with medical gases - Part 4: Low-pressure regulators
2.29	ISO 10651-3-1997	Lung ventilators for medical use - Part 3: Particular requirements for emergency and transport ventilators
2.30	ISO 10651-5-2006	Lung ventilators for medical use - Particular requirements for basic safety and essential performance - Part 5: Gas-powered emergency resuscitators
2.31	ISO 11197-2004	Medical supply units
2.32	ISO 14971-2007	Medical devices - Application of risk management to medical devices
2.33	ISO 15001-2010	Anaesthetic and respiratory equipment- Compatibility with oxygen
2.34	ISO 15002-2008	Flow-metering devices for connection to terminal units of medical gas pipeline systems

2.35	ISO 15223-2-2010	Medical devices - Symbols to be used with medical device labels, labelling, and information to be supplied - Part 2: Symbol development, selection and validation
2.36	ISO 16750-5-2010	Road vehicles - Environmental conditions and testing for electrical and electronic equipment - Part 5: Chemical loads
2.37	ISO 16750-2-2010	Road vehicles - Environmental conditions and testing for electrical and electronic equipment - Part 2: Electrical loads
2.38	ISO 19054-2005	Rail systems for supporting medical equipment
2.39	ISO 20345-2011	Personal protective equipment - Safety footwear
2.40	ISO 21969-2009	High-pressure flexible connections for use with medical gas systems
2.41	ISO 27427-2010	Anaesthetic and respiratory equipment - Nebulizing systems and components
2.42	ISO 80601-2-56-2009	Medical electrical equipment - Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement
2.43	ISO 80601-2-61-2011	Medical electrical equipment - Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment
2.44	ISO 80601-2-55-2011	Medical electrical equipment - Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors
2.45	ISO-32:1977	Typical Specifications for Hydraulic fluids
2.46	ISO 21647	
2.47	ISO/TC 121/SC6	Medical gas systems
2.48	EN 1789:2007	Medical vehicles and their equipment - Road ambulances published by CEN [European Committee For Standardization]
2.49	EN 1865:1999	Specifications for stretchers and other patient handling equipment used in road ambulances published by CEN [European Committee For Standardisation]

2.50	KKK-A-1822F	Federal specification for the star-of-life ambulance - GENERAL SERVICES ADMINISTRATION Federal Supply Service July 1, 2007 - GSA Automotive, [U.S. General Services Administration].
2.51	ASTM International F 2020 - 02a (Reapproved 2009)	Standard practice for design, construction, and procurement of Emergency Medical Services Systems (EMSS) ambulances.

3.0 TERMS AND DEFINITIONS

For the purposes of this standard, the following terms and definitions apply:

3.1 Road Ambulance

Road Ambulance or Ambulance is a vehicle as defined in AIS-125 (Part 1).

3.2 Types of Road Ambulances

Road Ambulances are designated as Type A, B, C and D as defined in AIS- 125 (Part 1).

4.0 REQUIREMENTS FOR MEDICAL DEVICES

4.1 General

The device should be designed for use in mobile situations and in field applications. If a medical device is designated as "portable", which is meant for use inside an ambulance (except patient handling equipment according to Table 1) it should be in accordance with ISO/ IEC 60601-1 and should

- a) Be possible to be carried by one person
- b) Have its own built in power supply (where relevant)
- c) Be capable of use outside the vehicle
- d) Be placed preferably along the street side wall of the patient compartment or along the ceiling ensuring the minimum possible distance to be connected to the patient without hindering the movement of personnel around the main stretcher

4.2 Temperature

4.2.1 Unless otherwise marked on the device, the device should function as described in 4.2.2 and 4.2.3 when brought back to room temperature (20°C) after storage in temperatures ranging from -30°C to 70°C.

4.2.2 Unless otherwise marked on the device, the device should function throughout the temperature range from 0°C to 40°C.

4.2.3 Unless otherwise marked on the device, the device should function for at least 20 min when placed in an environment at -5°C after storage at room temperature (20°C).

4.3 Humidity and ingress of liquids

Devices should comply with ISO/IEC 60601-1 and with particular device standards of the series ISO/IEC 60601-2 where applicable.

4.4 Mechanical strength

4.4.1 General

Where there are not more stringent requirements for mechanical strength in particular devices' standards, then the following mechanical strength requirements should apply to medical devices for use in road ambulances.

4.4.2 Vibration and bump

After vibration tests and bump test in accordance with 4.11 the maintain system and device should function within the tolerances specified by the manufacturer.

4.4.3 Free fall

If the medical device is fixed, as defined in ISO/IEC 60601-1 it is exempted from the free fall test.

Devices which are taken out of holders and/or carried by hand should be submitted to the free fall test according 4.12 and should then function within the tolerances specified by the manufacturer.

Note: A medical device may consist of fixed and loose components, the free fall test applies to the loose components only.

4.5 Fixation of devices

The fixation system(s), maintain system(s) or storage system(s) should hold the device to withstand accelerations or decelerations of 10 g longitudinal (forward, backward), 10 g transverse (left, right) and 10 g vertical.

Terminal units and electrical socket outlets should not be used as part of the fixation system.

If rails systems are used, they should comply with ISO 19054.

Note: Rail systems consist of e.g. rail supports, rails, rail clamps, equipment mount holders, equipment mounts, equipment pin holders and equipment pins.

4.6 **Electrical safety**

All devices should be selected and mounted so that no harmful influence to the electrical supplies results.

4.7 **User interface**

Buttons, switches, indicators and controls should be easily accessible and visible. SI units (except for blood pressure and airway pressure) and standardised graphical symbols where applicable should be used.

4.8 **Gas installation**

All the components should be certified as per ISO/TC 121/SC6 and ISO-15001:2010 as "Compatibility of Medical Equipment with Oxygen"

4.8.1 **Source of supply**

The source of supply should consist of one or more of the following, as per the requirement of the source supplies in the different types of road ambulances.

- a) Gas in cylinders, e.g. Oxygen
- b) Any other compressed medical gas as required for treatment and therapy of patients.
- c) Vacuum system

Note: All the components of the source of supply should be certified as per ISO: 7396-1-2007.

All compressed gas cylinders except for sizes up to 2.2 L water capacity, must be stored and used in an upright position with the valve end up. Only special compressed gas cylinders designed and certified for use in a horizontal position can be placed in that position.

The valve of the compressed gas cylinder when is at a height of more than 1500 mm. from the ground level, the cylinder compartment should be provided with an retractable / foldable / flushed / enclosed foot step to permit the user to stand comfortably to access the cylinder valve at the time of changing the cylinders

The cylinder compartment should have facility to place the regulators safely at the time of replacing empty cylinders and fitting filled ones.

Ambulances should not be operated with lesser number of cylinders as specified at Table 3.

4.8.2 System design

The ambulance whenever fitted with a stationary oxygen system, should have all the essential components and accessories required for the piped oxygen system which should include as a minimum:

- (i) One no. Pressure Regulator for each of the supply sources (stationary as well as portable)
- (ii) Low pressure, electrically conductive, hose approved for medical oxygen.
- (iii) Oxygen piping concealed and not exposed to the elements, securely supported to prevent damage, and be readily accessible for inspection and replacement.
- (iv) Oxygen piped to a self-sealing duplex oxygen outlet station for the primary patient with a minimum flow rate of 100 LPM at the outlet.

The patient cabin should have a digital display panel for oxygen supply status. The display panel should be certified for use with Medical Oxygen and should have three individual values displayed to constantly indicate the pressure level of both the cylinders as well as the distribution pressure level. The digital displays should show the actual pressure measured by three individual digital pressure sensors as per the pressure level under monitoring (one each for both the cylinders and one for the line pressure).

The changing from one cylinder to the other should not affect the distribution pressure in any way and this change over should occur as fully automatic operation.

The ambulance should have an emergency oxygen outlet for each of the stationary oxygen system available on any of the walls of the patient compartment easily accessible to the patient head end and connected directly at the output of the pressure regulator of the stationary

Oxygen system ensuring that any fault in the oxygen distribution system would ensure uninterrupted oxygen supply to the patient. The terminal outlets should be of the same design and operational criteria as the self-sealing duplex outlets of the distribution system.

Outlets should be adequately marked and identified and not interfere with the suction outlet, whenever provided.

Stationary oxygen system should be accessible from outside of the vehicle and should be physically isolated from the patient as well as the driver compartment

4.8.3 Gas piping

Gas piping shall not pass through cupboards and compartments, all ducts for gas installations or gas piping should be vented.

The use of remote high pressure lines and gauges are not allowed.

4.8.4 Stationary oxygen supply

The stationary oxygen supply shall comprise a source in accordance with Table 3 (under normal temperature and pressure) pressure regulators and terminal units or pressure regulators with flow metering devices. Ambulances should not be operated with lesser number of cylinders as that designated.

4.8.5 Portable oxygen supply

The portable oxygen supply shall comprise a source in accordance with Table 3 (under normal temperature and pressure) and a pressure regulator with flow metering device.

4.8.6 Pressure regulators and flow metering devices

The pressure regulators shall be directly connected to the source of supply and should comply with the following as applicable:

ISO 10524-1:2006, Pressure regulators for use with medical gases - Part 1: Pressure regulators and pressure regulators with flow-metering devices.

ISO 10524-3:2005, Pressure regulators for use with medical gases - Part 3: Pressure regulators integrated with cylinder valves.

Flow metering devices for connection to terminal units and for connection to flow-rate control units should be of dial type without any floats and should conform to ISO 15002.

4.8.7 Terminal units

Terminal units should comply with the requirements of ISO-7396-1-2007.

The components of terminal unit should be cleaned as defined in "Compatibility of Medical Equipment with Oxygen" as per ISO/TC 121/SC6 and ISO-15001:2010.

The terminal outlet should have a hexagonal geometrical profile to permit only geometrically matching adapters.

The process of inserting the probe into the terminal unit of the distribution system as well as pressure regulators should be:

- (i) An axial force not exceeding 100N and / or
- (ii) A torque not exceeding 1 N-m

The process of releasing the probe from the terminal outlet should be by

- (i) Applying an axial force having torque not more than 1 N-m and not less than 0.1 N-m.
- (ii) Applying a push or pull force of not more than 110 N and not less than 20 N.

When all locking provisions have been released, disconnection of the probe from the terminal unit should require a force of not more than 100 N.

Danger to personnel can occur as a result of the rapid expulsion of probes from terminal units. The design should prevent this from occurring.

The terminal outlets should be colour coded as per ISO-32:1977 colour coding.

4.8.8 Pneumatic power supply

If the road ambulance is equipped with terminal units, the range of operating pressure should be

- a) For compressed medical gases 3.5 ± 0.5 Bar b) for vacuum ≤ 0.4 Bar absolute pressure and the maximum allowable pressure change between the source of supply and the terminal units should be
- b) For compressed medical gases 10 % at a flow of 40 l/min;
- b) For vacuum 20 % at a flow of 25 l/min.

4.8.9 Additional outlet connectors

For road ambulances complying with 4.8.8, one additional outlet connector (i.e. a terminal unit or a gas specific connection point) complying with the primary outlet should be fitted in addition to the outlet connectors necessary for the devices intended to be normally used.

4.8.10 Test pressure

4.8.11 Pin-Index cylinder valves

Pin-index outlet connections of cylinder valves should comply with IS 3224.

4.8.12 Flexible hoses

Flexible hoses for connecting medical devices to outlet connectors (i.e. terminal units or a gas-specific connection points) should comply with ISO 5359-2008. If flexible hoses are used between the pressure regulators and the terminal units, the requirements of ISO 11197 apply.

4.8.13 Alarms

The alarms provided should be as specified at 4.8.2. The alarm level would be as per IEC 60601-1-8-2006.

4.9 Marking and Instructions

Operating and maintenance instructions, service records and any other appropriate regulations shall accompany the product.

Standardized symbols should be used or it should be written in English or any other local language of the area where the equipment is to be used. Usage of any other local languages are not mandatory but is only advised.

4.10 Maintenance: the manufacturer of medical devices shall supply instructions for carrying out preventive maintenance.

4.11 Vibration and bump test

The medical devices should be submitted to the following tests:

- a) Vibration (sinusoidal) according to IEC 60068-2-6, Test Fc
- b) Frequency range: 10 Hz to 150 Hz
- c) Amplitude/acceleration: $\pm 0,15$ mm/2 g
- d) Sweep rate: 1 octave/minute
- e) Number of sweep cycles: 4 in each axis
- f) Random vibration broad-band – reproducibility medium according to IEC 60068-2-64, Test Fh
- g) Acceleration Spectral Density 10 Hz to 20 Hz: 0,05 g²/Hz
- h) Acceleration Spectral Density 20 Hz to 150 Hz: 0,05 g²/Hz, -3 dB/Octave
- i) Total RMS acceleration 1,6 grms
- j) Duration/axis/mounting: 30 min
- k) Bump according to IEC 60068-2-27, Test Ea
- l) Peak acceleration: 15 g

- m) Acceleration Spectral Density
- n) Pulse duration: 6 ms
- o) Number of bumps: 1000
- p) Direction: vertical, with the medical device in its normal operating position(s)

4.12 Free fall

The medical device should, while functioning, be submitted to the following test:

- a) Free fall according to IEC 60068-2-31, Test Ec
- b) Height of fall: 0,75 m
- c) Number of falls: One on each of the six sides / surfaces of the device

5.0 LIST OF EQUIPMENT

The Tables 1 to 11 designate the recommendatory equipment carried by the road ambulances according to their type A, B, C and D. Supplementary devices may be introduced depending on local requirements. For most items a specific quantity is given. "X" in the column indicates that quantity may be varied in accordance with the local needs of the state / district. Where applicable the equipment should be available across the full age range of patients. sanitary, medical and technical devices in Tables 1 to 11 should be as follows-

- (i) Road ambulance type B 115 kg
- (ii) Road ambulance type C 225 kg
- (iii) Road ambulance type D 260 kg

The equipment should comply with the standards mentioned against them if any. Tests conducted by notified international bodies as per the relevant standards should be acceptable if verifiable certified copies of the test reports and certificates are available.

The medical equipment may not be supplied by the ambulance manufacturer with the ambulance. Also, medical devices supplied with ambulance by ambulance manufacturer, need not be approved as per this standard.

Table 1
Type of Patient Handling Equipment

Sr. No.	Device	Standard	Type of Road Ambulances		
			B	C	D
1	Main Stretcher / Undercarriage	AIS- 125 (Part 1)	1	1	1
2	Pick up stretcher	EN 1865	-	1	1
3	Vacuum Mattress	EN 1865	-	X	X
4	Transfer mattress/ Carrying Sheet	EN 1865	X	X	X
5	Long spinal board complete with head immobilizer and securing straps	EN 1865	-	X	X

Table 2
Type of Immobilization Equipment

Sr. No.	Device	Type of Road Ambulances		
		B	C	D
1	Traction Device	-	X	X
2	Immobilization, Set of fractures	-	1	1
3	Cervical upper spinal immobilization devices Cervical	-	1	1
4	Extended Upper Spinal Immobilization Extrication Devices or Short Spinal Board (one of these)	-	1	1

Table 3
Type of Life SOT Equipment

Sr. No.	Device	Type of Road Ambulances			
		A	B	C	D
1	Stationary Oxygen	X	X	Minimum 2 Nos. of 10L Water Capacity Cylinders at maximum 150 kgf/cm ² filling pressure manufactured as per IS:7285 and certified by Chief Controller of Explosives, Nagpur	Minimum 1 No. of 46.7L and 10L Water Capacity Cylinders each at maximum 150 kgf/cm ² filling pressure manufactured as per IS:7285 and certified by Chief Controller of Explosives, Nagpur

2	Portable Oxygen	Minimum 1 No. of 2.2L Water Capacity Aluminium Cylinder at maximum 150 kgf/cm ² filling pressure manufactured as per IS:7285 and certified by Chief Controller of Explosives, Nagpur	Minimum 1 No. of 2.2L Water Capacity Aluminium Cylinder at maximum 150 kgf/cm ² filling pressure manufactured as per IS:7285 and certified by Chief Controller of Explosives, Nagpur	Minimum 1 No. of 2.2L Water Capacity Aluminium Cylinder at maximum 150 kgf/cm ² filling pressure manufactured as per IS:7285 and certified by Chief Controller of Explosives, Nagpur	Minimum 1 No. of 2.2L Water Capacity Aluminium Cylinder at maximum 150 kgf/cm ² filling pressure manufactured as per IS:7285 and certified by Chief Controller of Explosives, Nagpur
3	Valve for Cylinders at 1 and 2 above	3/8" Bull Nose Valve as per IS:3224	3/8" Bull Nose Valve as per IS:3224	3/8" Bull Nose Valve as per IS:3224	3/8" Bull Nose Valve as per IS:3224

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4	Resuscitator or with oxygen inlet and masks and airways for all ages and oxygen reservoir	X	X	1	1
5	Mouth to mask ventilator with oxygen inlet	1	1	X	X
6	Electric Portable Suction Aspirator with air flow of at least 30 L/min and a vacuum level of at least 600 mm Hg (ISO 10079-1-1999)	X	X	1	1
7	Portable Suction Aspirator, Manual	1	1	1	1

Table 4
Type of Diagnostic Equipment

Sr. No.	Device	Standard	Type of Road Ambulances			
			A	B	C	D
1	Manual B. P. Monitor Cuff Size: 10 cm. - 66 cm.	-	-	-	1	1
2	Automatic B P Monitor, Cuff Size 10 cm. - 66 cm. A doppler type should operate accurately in the conditions of electrical interference and vibration specified in 4.3.1 and 6.3.4	-	-	-	X	X
3	Oximeter	ISO 9919	-	-	1	1
4	Stethoscope	-	-	-	1	1
5	Thermometer Minimum Range: 28 ^o C to 42 ^o C	-	-	-	1	1
6	Device for Blood Sugar Determination	-	-	-	1	1
7	Diagnostic Light	-	-	-	1	1

Table 5 Type of Drug					
Sr. No.	Type of Drug	Type of Road Ambulances			
		A	B	C	D
1	Pain Relief	-	-	X	X

Table 6 Type of Infusion Material or Equipment					
Sr. No.	Device	Type of Road Ambulances			
		A	B	C	D
1	Infusion Solutions, Litre	-	-	4	4
2	Equipments for injections and infusions set	-	-	2	2
3	Infusion Mounting	1	1	2	2
4	Pressure Infusion Device	-	-	-	1

Table 7 Type of Equipment for Management of Life Threatening Problems^a						
Sr. No	Device	Standard	Type of Road Ambulances			
			A	B	C	D
1	Defibrillator with rhythm and patient data recording	ISO 60601-2-4	-	X	X	1
2	Cardiac Monitor	ISO 60601-2-4	-	-	X	1
3	External Cardiac Pacing	ISO 60601-2-4	-	-	X	1

4	<p>Portable airways care system (p.a.c.s.) Manual resuscitator Mouth to mask ventilator with oxygen inlet Airways oro- or nasopharyngeal airway Aspirator Suction catheter</p>	-	-	-	1	-
5	<p>Portable advanced resuscitation system (p.a.r.s.) Contents of portable airways care System (p.a.c.s.) Infusion equipment - to include suitable venous indwelling cannulae Infusion administration sets Infusion solutions Adhesive fixing materials Intubation equipment-to include laryngoscope handle(s) with suitable blades Magill forceps Insertion stylets Endotracheal tubes with connectors Inflation tube clamp Inflation syringe Tube fixing material Stethoscope Drug administration equipment</p>	-	-	-	-	1

6	Nebulization Apparatus	-	-	-	1	1
7	Thorax Drainage Kit	-	-	-	-	1
8	Volumetric Infusion Device	-	-	-	-	1
9	Central Vein Catheters	-	-	-	-	1
10	Requirements for emergency and transport ventilators	ISO 10651-3	-	-	-	1
11	PEEP Valve, Adjustable or Set	-	-	-	-	1
12	Capnometer	ISO 21647	-	-	-	1
a. If desired two or more of these functions can be combined within one device.						

**Table 8
Bandaging and Nursing**

Sr. No.	Device	Type of Road Ambulances			
		A	B	C	D
1	Material for treatment of wounds	1	1	1	1
2	Materials for treatment of burns and corrosives	1	-	1	1
3	Re-plantation container to maintain the internal temperature at $(4 \pm 2)^{\circ}\text{C}$ for at least 2 h	-	-	X	X
4	Kidney Bowl	1	2	1	1
5	Vomiting Bag	1	2	1	1
6	Bed Pan	X	X	X	X
7	Non-Glass Urine Bottle	1	2	1	1
8	Sharps Container	1	1	1	1

9	Gastric Tube with Accessories	-	-	X	X
10	Sterile Surgical Gloves, Pairs	X	X	5	5
11	Non-Sterile Gloves for Single Use	100	100	100	100
12	Emergency Delivery Kit	X	X	1	1
13	Waste Bag	1	1	1	1
14	Clinical Waste Bag	X	X	X	X
15	Non-Woven Stretcher Sheet	1	1	1	1

Table 9					
Personal protection Equipment (for Each Member of the Crew for Protection and to Identify the Staff as Road Ambulance Personnel)					
Sr. No.	Device	Type of Road Ambulances			
		A^a	B^a	C^a	D^a
1	Basic protective clothing including high visibility reflective jacket or tabard	1	2	1	1
2	Advanced Protection Wear	-	-	X	X
3	Safety / Debris Gloves, Pair	1	1	1	1
4	Safety Shoes, Pairs	X	X	1	1
5	Safety Helmet	-	-	1	1
6	Personal Protection Equipment against Infection	-	-	1	1
a. Numbers are quoted per crew member					

Table 10					
Rescue and Protection Material					
Sr. No.	Device	Type of Road Ambulances			
		A	B	C	D
1	Cleaning and disinfection material	1	1	1	1
2	Rescue tools ^a	X	X	X	X
3	Seat belt cutter	1	1	1	1
4	Warning Triangle Lights	2	2	2	2
5	Spotlight	1	1	1	1
6	Fire Extinguisher, ABC Type (minimum 2 kg capacity complying with IS:13849 or IS:2171)	1	1	2	2
a. Wherever the Ambulance will be used for Crash Rescue, the ambulance must be equipped with Electrically / Hydraulically / Pneumatically powered rescue tools including Cutters, Spreaders, Rams and Lifters or should be supported by rescue vehicles equipped with the same					

Table 11					
Communication					
Sr. No.	Device	Type of Road Ambulances			
		A	B	C	D
1	Mobile Radio Transceiver	X	X	X	X
2	Portable Radio Transceiver	X	X	X	X
3	Access to the public telephone network e.g. via the normal radio transmitter or by mobile (cellular) telephone	1	-	1	1
4	Internal communication between driver and patient compartment	-	-	1	1

ANNEXURE 1 (See Introduction)	
COMPOSITION OF EXPERT COMMITTEE *	
Name	Organization
Dr. Shakti Kumar Gupta (Chairman)	Head, Department of Hospital Administration and Medical Superintendent (Dr. Rajendra Prasad Centre of Ophthalmic Sciences and JPNA Trauma Centre), AIIMS, New Delhi
Dr. D. K. Pawar	Professor, Department of Anaesthesiology, AIIMS, New Delhi
Brig. (Med.) Pawan Kapoor	Army Medical Corps, HQ 16 Core, C/o 56 APO.
Mr. A. Akbar Badusha	Deputy Director and Head, Vehicle Evaluation Lab, ARAI, Pune
Dr. A. R. Goyal	Director, Finance, MoRTH, Govt. of India
Mr. Rajeev Lochan	Director (RS), MoRTH, Govt of India
Col. Sunil Kant	Directing Staff, Officers Training College, AMC Centre and College, Lucknow
Mr. S. N. Das	C.E. (Mech), MoRTH, Govt. of India
Mr. R. P. Khandelwal	CGM (Safety), NHAI, Govt. of India
Dr. Chaman Prakash	CMO, Dt.GHS, MoHFW, Govt. of India
Dr. Ritu Rawat	Senior Medical Superintendent, Apollo Hospitals
Lt. Col. S. K. Patnaik	Medical Officer, Hospital Services, Military Hospital, Hissar
Dr. Angel Rajan Singh	Senior Resident Administrator, Department of Hospital Administration, AIIMS, New Delhi
Mr. R. K. Chawla	DGM (CM), NHAI, Govt. of India
Mr. K. C. Sharma	E.E. (M), MoRTH, Govt. of India
Mr. Jashvant Prajapati	Chief Operating Officer at GVK EMRI- Gujarat
Dr. G. V. Ramanarao	Head, EM Learning Centre and Research, GVK EMRI
Mr. B. N. Mishra	Under Secretary (RS), MoRTH, Govt. of India
Mr. Kamal Gulati	AIIMS, New Delhi
Mr. K. K. Gandhi	Representing SIAM and its members

* At the time of approval of this Automotive Industry Standard (AIS)

ANNEXURE 2
(See Introduction)
COMMITTEE COMPOSITION *
Automotive Industry Standards Committee

Chairperson	
Mrs. Rashmi Urdhwareshe	Director The Automotive Research Association of India, Pune
Members	Representing
Representative from	Ministry of Road Transport and Highways (Dept. of Road Transport and Highways), New Delhi
Representative from	Ministry of Heavy Industries and Public Enterprises (Department of Heavy Industry), New Delhi
Shri S. M. Ahuja	Office of the Development Commissioner, MSME, Ministry of Micro, Small and Medium Enterprises, New Delhi
Shri Shrikant R. Marathe	Former Chairman, AISC
Shri N. K. Sharma	Bureau of Indian Standards, New Delhi
Director Shri D. P. Saste (Alternate)	Central Institute of Road Transport, Pune
Director	Indian Institute of Petroleum, Dehra Dun
Director	Vehicles Research and Development Establishment, Ahmednagar
Representatives from	Society of Indian Automobile Manufacturers
Shri T. C. Gopalan	Tractor Manufacturers Association, New Delhi
Shri Uday Harite	Automotive Components Manufacturers Association of India, New Delhi

Member Secretary
Mr. A. S. Bhale
General Manager
The Automotive Research Association of India, Pune

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