उत्पाद मैनुअल
रोलिंग बीयरिंग — बॉल्स भाग 1 इस्पात बॉल्स
आईएस 17721: 2024 के अनुसर

PRODUCT MANUAL
IN-VITRO DIAGNOSTIC (IVD) DEVICE — ELECTROLYTE ANALYZER
According to IS 17721: 2024

यह उत्पाद नियमावली सभी क्षेत्रीय/शाखा कार्यालयों और लाइसेंसधारियों द्वारा विभिन्न उत्पादों के लिए भारतीय मानक ब्यूरो (अनुरूपता मूल्यांकन) विनियम, 2018 की योजना-I के अंतर्गत प्रमाणन के संचालन में एकरूपता और पारदर्शिता सुनिश्चित करने के लिए संदर्भ सामग्री के रूप में उपयोग की जाएगी। बीआईएस प्रमाणन प्राप्त करने के इच्छुक भावी आवेदक भी इस दस्तावेज़ का उपयोग कर सकते हैं।

This Product Manual shall be used as reference material by all Regional/Branch Offices & licensees to ensure uniformity of practice and transparency in operation of certification under Scheme-I of Bureau of Indian Standards (Conformity Assessment) Regulations,2018 for various products. The document may also be used by prospective applicants desirous of obtaining BIS certification.

1.	**मानक संख्या / IS No.**	:	IS 17721: 2024
	शीर्षक / Title	:	In-Vitro Diagnostic (IVD) Device — Electrolyte Analyzer
	संशोधनों की संख्या **No. of amendments**	:	Nil
2.	**नमूनाकरण दिशानिर्देश / Sampling Guidelines**		
a)	**कच्चा माल** **Raw material**	:	No specific requirement. *Note: This section indicates the requirements for raw material (if specified in the IS) for which compliance is to be established during Grant of Licence/Change in Scope of Licence/Factory Surveillance.*
b)	**समूहीकरण दिशानिर्देश** **Grouping Guidelines**	:	Please refer **ANNEX – A**
c)	**नमूने का परिमाण** **Sample Quantity**	:	1 machine
d)	**परीक्षण अनुरोध में घोषित किए जाने वाले पैरामीटर** **Parameters to be Declared in Test Request**		Same as the parameters given in scope of the licence under S. No. 6. *Note: Apart from the above, any other requirements/ parameters may also be declared as per the standard, as applicable.*
3.	**परीक्षण उपकरण की सूची** **List of Test Equipment**	:	Please refer **ANNEX – B**
4.	**निरीक्षण एवं परीक्षण योजना** **Scheme of Inspection and Testing**	:	Please refer **ANNEX – C**

5.	**एक दिन में संभावित परीक्षण** **Possible tests in a day**	:	General requirements (Clause 5.3) Performance specifications (Clause 6) All Routine tests specified in Annex-F of IS 17724 (Part 1) *Note: This section is for the guidance of BIS Certification Officers/ Technical Auditors of BIS Authorized Outside Surveillance Agencies (OSAs) during factory inspection to provide ready reference regarding the tests which can be witnessed during the inspection in the factory by the officer/ auditor.*

6. लाइसेंस का दायरा / Scope of the Licence:	
"Licence is granted to use Standard Mark as per **IS 17721: 2024** with the following scope:	
Name of the product	In-Vitro Diagnostic (IVD) Device — Electrolyte Analyzer
Model(s)	
Measurable Parameters	Na^+ / K^+ / iCa^{2+} / Cl^- / Li^+ / pH
Type(s)	Fixed / Portable
Rating	Rated Voltage …..V (or) Rated Voltage Ranges(s) ……V, ac / dc 50 Hz (in case of ac) Single / Three Phase Rated Input Current …. A Input power …….W (or) kVA
Protection against electric shock	Class – I / Class – II
Type of Operation	Continuous / Short-term (or) Intermittent

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ANNEX - A
Grouping Guidelines

1. Manufacturer shall submit the declaration for each of the parameters specified in scope of the licence (as per SI. No. 6 above) for each model of 'In-Vitro Diagnostic (IVD) Device — Electrolyte Analyzer' they intend to cover in the scope of licence.

2. For Grant of Licence/ Change in Scope of Licence, each Model of 'In-Vitro Diagnostic (IVD) Device — Electrolyte Analyzer' shall be tested.

3. The Scope of Licence may be restricted based on the Manufacturing and testing capabilities of the Manufacturer.

4. During the operation of the Licence, BO shall ensure that all the model(s) covered in the Scope of the Licence are tested in rotation to the extent possible.

Note:

a) Firm shall declare the following parameters for each Model of In-Vitro Diagnostic (IVD) Device — Electrolyte Analyzer:
   (i) Sample size (Cl. 5.3.1)
   (ii) Analysis time (Cl. 5.3.2)
   (iii) Resolution (Cl. 5.3.3)
   (iv) Measuring ranges (Cl. 5.3.4)
   (v) Ingress protection (Cl. 11.6 of IS 17724 Pt.1)
   (vi) Pollution degree
   (vii) List of essential reagents/ Accessories (if any)

b) The manufacturer shall also submit the accompanying documents for each model of In-Vitro Diagnostic (IVD) Device — Electrolyte Analyzer as per Cl. 8 of IS 17721.

ANNEX- B

List of Test Equipments

(Indicative List, For Guidance Only)

Major test equipment required to test as per the Indian Standard

Sl. No.	Cl. Ref.	Tests used in with Clause Reference	Test Equipment
1.	Annex –F IS 17724 (Part 1)	Power Input	Power Input Test Apparatus/ Power Analyzer / Multimeter
2.	5.3 IS 17724 (Part 1)	Durability of markings	70% Isopropyl alcohol Stop Watch
3.	Annex –F IS 17724 (Part 1)	Protective earth	Multimeter
4.	6.4.4 IS 17724 (Part 1)	Impedance	Micro ohm meter Leakage current tester (multimeter)
5.	6.1	Precision/Reproducibility	Reagent packs
6.	6.2	Linearity/Assay Reportable Range	Three electrolytes of ten to eleven equally spaced concentrations/ using chemicals
7.	6.3	Traceability	Standards or certified reference Materials as per Table 3
8.	6.4	Analytical Specificity	Test samples as Quality Levels (Level 1,2 and 3) External controls (Level 1 & 2) Different chemicals and composition
9.	6.5	Comparison Studies	Quality Control samples of different levels

The above list is indicative only and may not be treated as exhaustive.

ANNEX C
Scheme of Inspection and Testing

1. QUALITY ASSURANCE PLAN

1.1 It is expected that during operation of BIS licence manufacturers will implement a Quality Assurance Plan (QAP) i.e. a plan of regular testing and in-process controls, designed to ensure that the product bearing the Standard Mark conforms to all requirements of the Indian Standard.

1.2 The manufacturers shall define a Quality Assurance Plan (QAP) defining the control unit (i.e. lot/batch etc.), the levels of control (i.e. the frequency and number of samples for conducting the different tests as per the Indian Standard) and declare the arrangement for testing i.e. whether in-house or sub-contracting/ sharing for each applicable test and submit the same to BIS Branch Office for information. The manufacturer shall comply with the QAP and maintain test records in accordance with para 2.1.

1.3 Recommended Levels of Control/ Control Unit:

1.3.1 For the guidance of manufacturers in preparing the Quality Assurance Plan, recommended levels of control are given in Table 1. Manufacturer has the discretion of declaring their own levels of control or accept the levels of control given in this document.

1.3.2 The manufacturer shall ensure inspection and testing as per the Quality Assurance Plan submitted by them on the whole production of the factory which is covered by this plan.

1.4 However, all manufacturers shall ensure compliance of their products to all the requirements of the Indian Standard.

2. ENSURING COMPLIANCE THROUGH TESTING

The manufacturers shall ensure compliance of their products to all the requirements of the Indian Standard for which they may have in-house test facilities. However, there is no obligation to maintain in-house laboratory. Licensee may use alternative arrangements for tests of the production as per the declared QAP. Various alternatives are available for operation of BIS certification as given below and the relevant guidelines for availing such relaxations by the manufacturers, as amended from time to time, are to be referred:

i) Shared testing resources like common facility,

ii) Cluster based testing facility,

iii) Sub-contracting to outside laboratories which may either be:

a) BIS recognised/ empanelled laboratories, or

b) Any accredited laboratory as per ISO/IEC 17025

2.1 Test Records- The manufacturers shall maintain test records for the tests carried out (either in-house or at a sub-contracted or at shared test facility) to establish conformity of the product to the Standard for operation of licence. For the tests being subcontracted or conducted at a shared test facility, test results issued by the laboratories or test facilities, shall be made available for inspection by BIS.

2.2 TECHNICAL FILE- Licensee shall maintain a Technical File for each model being manufactured by them. The Technical file shall be submitted to BIS at the time of Grant of Licence/ inclusion/ surveillance.

2.2.1 The Technical File shall be maintained till the End of Life of the model.

2.2.2 Licensee shall declare the frequency for periodic review in Technical file to BIS and record of review to be maintained. In case of any change in the Technical file due to any periodic review/ change in the product, the licensee shall inform the same to BIS at the earliest and provide the copy of the latest version of Technical File to BIS within 30 days of issue of the revised/ modified Technical File.

2.2.3 For changes in the product which shall affect the Scope of the Licence, the modified product shall be treated as a different model and separate Technical File shall be maintained for the same.

2.2.4 The technical file shall consist of the following documents:

a) A general description of the product;
b) Product Manual and/ or Instructions for use;
c) Instructions for repair/ service for the product/ components, if required;
d) Frequency of periodic repair/ service for the product/ components, if required;
e) Conceptual product design and manufacturing drawings and, where appropriate, list of components, electrical circuit design, etc with descriptions and explanations needed for the understanding of these drawings;
f) A list of the all Indian/ International standards applied in full or in part during the conformity assessment process with copy of test certificate/ test report;
g) Test reports/ Test Certificates and risk assessment file for the product and/ or components as per relevant Clauses of the Indian Standard;
h) Copies of conformity assessment documentation for critical product components;

2.3 RISK MANAGEMENT FILE- The licensee shall maintain a Risk Management File for each model in the scope of licence as per the requirement of IS 17721: 2024. The Risk Management File shall be submitted to BIS at the time of Grant of Licence/Inclusion/Surveillance.

2.3.1 The Risk Management File shall be maintained till the End of Life of the model.

2.3.2 Licensee shall declare the frequency of periodic review of the Risk Management File to BIS and record of review in the file to be maintained. In case of any change in the Risk Management File due to any periodic review/ change in the product, the licensee shall inform the same to BIS at the earliest and provide the copy of the latest version of Risk Management File to BIS within 30 days of issue of the revised/ modified Technical File.

3. PACKING AND MARKING

The Standard Mark as given in the Schedule of the licence shall be incorporated legibly and indelibly on each In-Vitro Diagnostic (IVD) Device provided always that the In-Vitro Diagnostic (IVD) Device so marked conforms to each requirement of the specification.

3.1 **Additional Marking requirements**: The In-Vitro Diagnostic (IVD) Device shall also be marked with the following additional requirement on the product/packaging:

a) "For BIS certification details please visit www.bis.gov.in"

4. REJECTION

The production which conforms to the Indian Standard and covered under the scope of this licence shall be marked with the Standard Mark. Disposal of non-conforming product shall be done in such a way so as to ensure that there is no violation of provisions of BIS Act, 2016.

TABLE-1

(Recommended Levels of Control by BIS- for Guidance Only)

(1) Test Details				(2) Levels of Control		
Cl.	**Requirement**	**Test Methods**		**No. of sample**	**Frequency**	**Remarks**
		Clause	**Reference**			
5.1	Safety Requirements					
	Marking and documentation	5	IS 17724 (Part 1)	Each IVD Device		
	Marking	5.1				
	General	5.1.1				
	Identification	5.1.2				
	MAINS supply	5.1.3				
	Fuses	5.1.4				
	Terminals, connections and operating devices	5.1.5				
	Switches and circuit- breakers	5.1.6				
	Equipment protected by double insulation or reinforced insulation	5.1.7				
	Field-wiring terminal boxes	5.1.8				
	Warning markings	5.2				
	Durability of markings	5.3				
	Documentation	5.4				
	General	5.4.1				
	Equipment ratings	5.4.2				
	Equipment installation	5.4.3				
	Equipment operation	5.4.4				
	Equipment maintenance and service	5.4.5				
	Integration into systems or effects resulting from special conditions	5.4.6	IS 17724 (Part 1)	One	Once in every six months for each type of model manufactured during that period	
	Protection against electric shock	**6**	IS 17724 (Part 1)	One		
	Determination of accessible parts	6.2				
	Limit values for accessible parts	6.3				
	Primary means of Protection	6.4				
	Enclosures and protective barriers	6.4.2				
	Basic insulation	6.4.3				
	Impedance	6.4.4				
	Additional means of protection in case of single fault conditions	6.5	IS 17724 (Part 1)	One	Once in every six months for each type of model manufactured during that period	
	Protective bonding	6.5.2				
	Supplementary insulation and reinforced insulation	6.5.3				
	Protective Impedance	6.5.4				
	Automatic disconnection of the supply	6.5.5				
	Current- or voltage- limiting device	6.5.6				
	Connections to external circuits	6.6				
	General	6.6.1				
	Terminals for external circuits	6.6.2				
	Circuits with terminals which are hazardous live	6.6.3				
	Insulation requirements	6.7	IS 17724 (Part 1)	One		
	Terminals for stranded conductors	6.7.1				
	General	6.7.1.1				
	Clearances	6.7.1.2				

	Creepage Distances	6.7.1.3	IS 17724 (Part 1)	One	Once in every six months for each type of model manufactured during that period
	Solid insulation	6.7.1.4			
	Requirements for insulation according to type of circuit	6.7.1.5			
	Insulation for mains circuits of overvoltage category II with a nominal supply voltage up to 300 V	6.7.2			
	Clearances and Creepage distances	6.7.2.1			
	Solid insulation	6.7.2.2			
	Insulation for secondary circuits derived from mains circuits of overvoltage category II up to 300 V	6.7.3			
	General	6.7.3.1			
	Clearances	6.7.3.2			
	Creepage distances	6.7.3.3			
	Solid insulation	6.7.3.4			
	Procedure for voltage tests	6.8			
	General	6.8.1			
	Humidity preconditioning	6.8.2			
	The a.c. voltage test	6.8.3.1			
	The 1 min d.c. voltage test	6.8.3.2			
	The impulse voltage withstand test	6.8.3.3			
	Constructional requirements for protection against electric shock	6.9			
	General	6.9.1			
	Insulating materials	6.9.2			
	Colour coding	6.9.3			
	Connection to the mains supply source and connections between parts of equipment	6.10			
	MAINS supply cords	6.10.1			
	Fitting of non- detachable mains supply cords	6.10.2			
	Cord entry	6.10.2.1			
	Cord anchorage	6.10.2.2			
	Plugs and connectors	6.10.2.3			
	Disconnection from supply source	6.11			
	General	6.11.1			
	Exceptions	6.11.2			
	Requirements according to type of equipment	6.11.3			
	Permanently Connected Equipment and multi-phase equipment	6.11.3.1			
	Single-phase cord- connected equipment	6.11.3.2			
	Disconnecting devices	6.11.4			
	General	6.11.4.1			
	Switches and circuit- breakers	6.11.4.2			
	Appliance couplers and plugs	6.11.4.3			
	Protection against mechanical hazards	**7**	IS 17724 (Part 1)	One	Once in every six months for each type of model
	Sharp edges	7.2			
	Moving parts	7.3			
	Stability	7.4			

	Provisions for lifting and carrying	7.5	IS 17724 (Part 1)	One	manufactured during that period
	Expelled parts	7.6			
	Resistance to mechanical stresses	**8**	IS 17724 (Part 1)	One	Once in every six months for each type of model manufactured during that period
	General	8.1			
	Enclosure rigidity tests	8.2			
	Static test	8.2.1			
	Impact test	8.2.2			
	Drop test	8.3			
	Protection against the spread of fire	**9**	IS 17724 (Part 1)	One	Once in every six months for each type of model manufactured during that period
	General	9.1			
	Eliminating or reducing the sources of ignition within the equipment	9.2			
	Containment of fire within the equipment, should it occur	9.3			
	Limited-energy circuit	9.4			
	Requirements for equipment containing or using flammable liquids	9.5			
	Overcurrent protection	9.6			
	Equipment temperature limits and resistance to heat	**10**	IS 17724 (Part 1)	One	Once in every six months for each type of model manufactured during that period
	Surface temperature limits for protection against burns	10.1			
	Temperatures of windings	10.2			
	Other temperature measurements	10.3			
	Conduct of temperature tests	10.4			
	Resistance to heat	10.5			
	Integrity of clearances and creepage distances	10.5.1			
	Non-metallic enclosures	10.5.2			
	Insulating material	10.5.3			
	Protection against hazards from fluids	**11**	IS 17724 (Part 1)	One	Once in every six months for each type of model manufactured during that period
	Cleaning	11.1			
	Spillage	11.2			
	Overflow	11.3			
	Battery electrolyte	11.4			
	Specially protected equipment	11.5			
	Specially protected equipment	11.6			
	Fluid pressure and leakage	11.7			
	Maximum pressure	11.7.1			
	Leakage and rupture at high pressure	11.7.2			
	Leakage from low- pressure parts	11.7.3			
	Overpressure safety device	11.7.4			
	Protection against radiation, including laser sources, and against sonic and ultrasonic pressure	**12**	IS 17724 (Part 1)	One	Once in every six months for each type of model manufactured during that period
	General	12.1			
	Equipment producing ionizing radiation	12.2			
	Ionizing radiation	12.2.1			
	General	12.2.1.1			
	Equipment intended to emit radiation	12.2.1.2			
	Equipment not intended to emit radiation	12.2.1.3			
	Accelerated electrons	12.2.1.4			

	Ultraviolet (UV) radiation	12.3	IS 17724 (Part 1)	One	Once in every six months for each type of model manufactured during that period	
	Microwave radiation	12.4				
	Sonic and ultrasonic pressure	12.5				
	Sound level	12.5.1				
	Ultrasonic pressure	12.5.2				
	Laser sources	12.6				
	Protection against liberated gases and substances, explosion and implosion	**13**	IS 17724 (Part 1)	One	Once in every six months for each type of model manufactured during that period	
	Poisonous and injurious gases and substances	13.1				
	Explosion and implosion	13.2				
	Components	13.2.1				
	Batteries and battery charging	13.2.2				
	Implosion of cathode ray tubes	13.2.3				
	Components and subassemblies	**14**	IS 17724 (Part 1)	One	Once in every six months for each type of model manufactured during that period	
	General	14.1				
	Motors	14.2				
	Motor temperatures	14.2.1				
	Series excitation motors	14.2.2				
	Over-temperature protection devices	14.3				
	Fuse holders	14.4				
	Mains voltage selection devices	14.5				
	Mains transformers tested outside equipment	14.6				
	Printed wiring boards	14.7				
	Circuits or components used as transient overvoltage limiting devices	14.8				
	Protection by interlocks	**15**	IS 17724 (Part 1)	One	Once in every six months for each type of model manufactured during that period	
	General	15.1				
	Prevention of reactivating	15.2				
	Reliability	15.3				
	Hazards resulting from application	**16**	IS 17724 (Part 1)	One	Once in every six months for each type of model manufactured during that period	Testing and Assessment to be done as specified in Risk Assessment Documentation
	Reasonably foreseeable misuse	16.1				
	Ergonomic aspects	16.2				
	Risk assessment	**17**	IS 17724 (Part 1)	One	Once in every six months for each type of model manufactured during that period to ensure that the risks have been eliminated or that only tolerable risks remain	

Annex F	*Routine Tests (As per Annex F of IS 17724 (Part 1): 2023*				
	General	F.1	IS 17724 (Part 1)	Each IVD Device	
	Protective earth	F.2			
	Mains Circuits	F.3			
	General	F.3.1			
	Mains Circuits with voltage limiting devices	F.3.2			
	Floating circuits	F.4			
5.2	EMC Requirements	5.2	IS 17784 (Part 2)	One	Once in every three years for each type of model manufactured during that period
5.3	General Requirements	5.3	IS 17721	Each IVD Device	
6	Performance Specifications	6			
6.1	Precision/Reproducibility	6.1			
6.2	Linearity/Assay Reportable Range	6.2			
6.3	Traceability	6.3			
6.4	Analytical Specificity	6.4			
6.5	Comparison Studies	6.5			
6.6	Expected Values/Reference Range	6.6			
6.7	Operator Menu Flowchart	6.7			
7	Marking and Labelling	7			
8	Accompanying Documents	8			
9	Packaging and Transportation	9			