INSTITUTIONAL PROCUREMENT DOCUMENTATION

Procurement Pack — NIBRA-CS®

Technical specifications, regulatory approvals, clinical validation summary, and deployment information for hospitals, diagnostic centres, and academic institutions evaluating the NIBRA-CS® Autonomic Neurofunction Testing System.

CDSCO Licensed · Class B | Made in India | Patent Granted

Model NCS-3.0
Inovocare Healthsoft Solutions Pvt. Ltd.

www.nibracs.com
July 2026

Product Overview

The NIBRA-CS® (Model NCS-3.0) is a non-invasive diagnostic device for autonomic nervous system (ANS) function assessment. It acquires Lead II ECG and cuff-based blood pressure signals during a standardised battery of cardiovascular reflex tests — based on Ewing's Battery — and delivers an automated, structured report by email. It is designed to support earlier, standardised detection of autonomic dysfunction — including Cardiac Autonomic Neuropathy (CAN) in diabetes mellitus, which is frequently underdiagnosed until relatively advanced.

Tests performed (fixed sequence, guided by the device)

TEST	ASSESSES	ANS BRANCH
Resting ECG	Baseline heart rate and rhythm	Both
Deep Breathing	Heart rate variation with controlled breathing (E:I ratio)	Parasympathetic
Response to Standing	Heart rate response to postural change (30:15 ratio)	Parasympathetic
Valsalva Maneuver	Heart rate / BP response to intrathoracic pressure change	Parasympathetic
Postural Hypotension	Blood pressure change on standing	Sympathetic
Sustained Handgrip	Blood pressure rise during sustained muscle effort	Sympathetic

Two testing modes

MODE	COMPOSITION	REPORT	BEST FOR
Full Test Battery	All 6 tests above, plus the 5-minute HRV recording (7 elements)	6 pages — full CAN diagnosis	Complete autonomic work-up
Short Test	5-minute HRV recording only — passive, no BP cuff, Valsalva assembly, or handgrip required	3 pages — HRV status only	Rapid screening, follow-up visits, or patients unable to perform active maneuvers

A Short Test can always be followed by a Full Test Battery at a later visit if the HRV screen indicates further assessment is warranted.

Intended use

Non-invasive acquisition and analysis of ECG (Lead II) and blood pressure signals during standardised autonomic function tests in adult patients, by trained healthcare professionals in clinical environments. Supportive assessment data — not a standalone diagnosis.

Why institutions choose NIBRA-CS®

- CDSCO-licensed Class B device, manufactured in India
- Patented autonomic assessment methodology
- Automated cloud report generation, no manual scoring
- On-site installation, commissioning & training included

SECTION 02

Technical Specifications

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Physical specifications

PARAMETER	SPECIFICATION
Device dimensions	320 × 230 × 86.8 mm (L × W × H)
Weight	1,570 g
Enclosure material	Medical-grade polymer
Operator interface	Touchscreen display
Patient display	External LED / timer-based display unit
External connections	ECG Inlet, BP Inlet, Valsalva Inlet, 12V Input, Patient Display connector
Configuration	Tabletop clinical device, active air cooling

Electrical & environmental

PARAMETER	OPERATING	STORAGE
Power supply	12V DC ±5% via supplied adapter (12V, 5A) · ≤6W consumption	
Temperature	10°C to 40°C	−20°C to 70°C
Humidity	30% to 85% RH, non-condensing	Non-condensing
Environment	Indoor clinical environment only	Clean, dry, dust-free indoor location

Performance specifications

PARAMETER	SPECIFICATION
ECG acquisition	Lead II, 5-lead ECG cable
ECG measurement range / resolution	0.15–5.5 mV / 2.36 µV per LSB
Heart rate range / accuracy	15–300 BPM (adult) / ±1 BPM
NIBP measurement range / resolution / accuracy	0–300 mmHg / 1 mmHg / ±2 mmHg or ±1%, whichever is greater
Valsalva pressure target	40 mmHg

Communication & data handling

PARAMETER	SPECIFICATION
Wireless connectivity	Wi-Fi, IEEE 802.11 b/g/n
Data processing	Cloud-based automated analysis
Report generation	Automated PDF, delivered to configured email address
Data transmission	Encrypted — HTTPS/TLS

ECG output is used for heart rate / HRV analysis within the test battery and is not intended as a standalone diagnostic electrocardiogram.

SECTION 03

Regulatory, Certifications & IP

04

Regulatory status

NIBRA-CS® (Model NCS-3.0) is manufactured under CDSCO Manufacturing Licence **No. MFG/MD/2025/000789**, granted on Form MD-5 under the Medical Device Rules, 2017, classifying the device as **Class B**. This is India's CDSCO risk classification for the device as a medical product — a separate framework from the electrical safety classification below.

Applicable safety & performance standards

STANDARD	SCOPE
IEC 60601-1	General requirements for basic safety and essential performance of medical electrical equipment
IEC 60601-1-2	Electromagnetic compatibility requirements
ISO 10993 (relevant parts)	Biological evaluation of patient-contact components
ISO 15223-1	Symbols used with manufacturer-supplied device information

Electrical safety classification

PARAMETER	CLASSIFICATION
IEC 60601-1 device class	Class I
Applied part type	Type BF (Body Floating)
Patient contact	Non-invasive, electrically isolated from earth ground

> **Note on classification terminology:** "Class B" (CDSCO) describes the device's clinical risk category under Indian medical device law. "Class I / Type BF" (IEC 60601-1) is a separate, internationally standard electrical-safety classification describing how patient-contact parts are electrically isolated. NIBRA-CS® carries both classifications simultaneously — there is no conflict between them.

Intellectual property

The core autonomic assessment methodology and device architecture are protected under granted **Patent No. 565433** (granted 23 April 2025).

Full source documents

Complete copies of the CDSCO manufacturing licence and the granted patent certificate are available in the Procurement Documentation section of `www.nibracs.com`, and on direct request to our institutional partnerships team.

SECTION 04

05

Clinical Validation & Deployments

800+

Patients Evaluated across all institutions

300+

Patients tested in a completed paid clinical pilot

5+

Institutions with Ethics Committee approval

AIIMS Kalyani — Clinical Validation Study

Clinical validation study conducted at AIIMS Kalyani — one of India's premier public medical institutions — establishing the clinical evidence base for NIBRA-CS®.

Paid Clinical Pilot — 300+ Patients

A paid clinical pilot was successfully completed with 300+ patients tested, demonstrating real-world clinical throughput and institutional deployment readiness at scale.

RIMS Ranchi — First Commercial Deployment

The first commercial unit was deployed at RIMS Ranchi, with PHC-level screening integration currently underway — marking the transition from clinical validation to active institutional deployment.

Multi-Site Ethics Approval

Clinical pilots have been conducted with institutional ethics approval secured across more than five distinct organisations, contributing multi-site validation data for the autonomic assessment protocol.

> The evaluation programme above reflects deployments and studies to date. Institutions may request reference introductions or site visits, subject to the participating institutions' consent, through our partnerships team.

SECTION 05

06

What’s Included & Installation

Standard package contents

ITEM	QTY	DESCRIPTION
Main Processing Unit	1	NIBRA-CS® NCS-3.0 device
ECG Cable	1	5-lead, with lead wires and electrodes
NIBP Cuff	1	Standard adult size
Valsalva Pipe Assembly	1	With disposable mouthpiece
Patient Display Monitor	1	With connecting cable
Power Supply Adapter	1	12V DC, 5A
Operator’s Manual & Test/Report Reference	1 set	Core manual plus companion test reference document

Consumables & replacement

CONSUMABLE	REPLACEMENT
ECG electrodes	Single use, per patient session
Valsalva disposable mouthpiece	Single use, mandatory per patient
Blood pressure cuff	When worn, damaged, or unable to maintain seal
ECG lead wires	When frayed, cut, or clip is damaged

Site & installation requirements

REQUIREMENT	SPECIFICATION
Ambient temperature	10°C to 40°C
Humidity	30% to 85% RH, non-condensing
Ventilation	Clean, dry, well-ventilated area
Power supply	Stable, grounded, using the supplied adapter only
Surface	Stable, flat, with adequate clearance around the device
EMI clearance	Minimum 1 metre from other electrical/medical equipment and wireless devices
Network	Stable Wi-Fi (802.11 b/g/n) required for cloud upload and report generation

> Every institutional deployment includes on-site installation, system commissioning, and operator training — see Section 07 for training scope.

SECTION 06

07

Warranty, Service & Training

Warranty coverage

NIBRA-CS® is covered for **12 months from the date of purchase**, covering manufacturing defects, defects in materials and workmanship, and functional issues not caused by external damage, misuse, or unauthorised modification. Defective components are repaired or replaced at the discretion of Inovocare or an authorised service provider.

Warranty exclusions

EXCLUSION	EXAMPLES
Improper use or installation	Operating outside specified environmental conditions, incorrect power adapter
Unauthorised accessories/modification	Non-approved cuffs, electrodes, or internal modifications
Physical damage	Dropping, impact, liquid ingress, mechanical shock
Power-related damage	Voltage spikes, non-approved power source
Normal consumable wear	ECG electrodes, Valsalva mouthpieces, blood pressure cuffs
Failure to maintain	Not following cleaning, inspection, or storage guidelines

Training & support (included)

- Device-specific operator training before independent use
- Supervised first session before independent operation
- Installation and initial setup assistance
- Troubleshooting and fault resolution
- Consumable and accessory ordering
- Service and repair coordination

Training scope covers

- Device setup, connection, and Wi-Fi configuration
- Patient eligibility screening and preparation
- Full test-battery execution and signal monitoring
- Reading the generated report and referral thresholds
- Common troubleshooting and escalation paths
- Cleaning, inspection, and consumable replacement

> All service and repair work is performed only by Inovocare or an authorised service partner. Annual measurement verification is recommended; the device does not support user-performed internal calibration.

SECTION 07

Commercial & Service Terms

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All commercial and service terms below are confirmed as of July 2026.

Pricing structure

LINE ITEM	BASIS
Device unit price	Contact us for current pricing — **WhatsApp +91 81002 68525**
Installation & commissioning	Depends on installation location and institution — confirmed at quotation stage
Operator training (initial)	Provided by Inovocare on request. The included Operator's Manual (Core + Test/Report Reference) covers full independent operation on its own
Extended warranty & AMC (Year 2 onward)	**10% of selling price + GST, per year** — starts once the 12-month standard warranty ends; includes full AMC coverage (see below)
Consumables (per test)	Depends on recharge volume, consumable mix, and language — confirmed at quotation stage
Multi-unit / bulk institutional discount	**Available** — confirmed per institution at quotation stage

Consumable and recharge pricing is confirmed per institution based on test volume, consumable mix, and report language requirements.

AMC & service commitments

ITEM	DETAIL
AMC coverage scope	Parts, manufacturing defects, software updates & issue resolution — included above. Damage from user error or misuse is not covered.
Preventive maintenance frequency	**1 visit per year** included (free); additional visits chargeable
Service response time (post-warranty)	**24–48 hours**
Loaner / standby unit during repair	**Provided if required**
AMC renewal cycle	**Annual**

Order & delivery

ITEM	DETAIL
Lead time, PO to installation	**6–8 days** if the unit is in stock; longer for bulk orders or if not in stock — communicated at enquiry stage
Payment terms	**40% advance** with PO · **50%** before dispatch · **10%** on installation sign-off

SECTION 08

09

Data Handling & Next Steps

Data handling & compliance, in brief

Test data is transmitted from the device to a cloud processing platform over encrypted HTTPS/TLS connections, and reports are delivered by email. Patient data is retained on the cloud platform only for the period required for processing and report delivery.

Under India's Digital Personal Data Protection Act, 2023, the healthcare institution operating the device is responsible for obtaining patient consent, maintaining consent records, and ensuring reports are shared only with authorised personnel. Inovocare provides the secure transmission infrastructure and is not responsible for institutional data-handling practices beyond the device's intended operation.

> The complete data-handling and privacy terms are published at `www.nibracs.com/privacy-policy.html`. Institutions should review this alongside their own data protection policy before deployment.

Next steps for institutional procurement

- **Submit an enquiry** — via the institutional enquiry form at www.nibracs.com or directly to partnerships@nibracs.com.
- **Product demonstration** — our team schedules a demonstration for your clinical, biomedical, or purchase committee.
- **Customised quotation** — pricing is prepared per institution based on deployment scale, consumables, and service terms. No pricing is fixed in this document — contact our team for a formal quotation.
- **Deployment** — on confirmed procurement: on-site installation, system commissioning, and operator training are scheduled and delivered.

Contact

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