

# Clinical Safety Policy

AI safeguards, medical boundaries, and patient safety protocols for Pranavita AI

Effective: May 18, 2026 · Version 1.0 · Jurisdiction: Republic of India

Pranavita AI is committed to patient safety as the highest priority in product design, AI deployment, and service delivery. This Clinical Safety Policy defines the boundaries of AI assistance, mandatory human oversight requirements, emergency escalation protocols, and the safeguards in place to prevent clinical harm.

## 1. Scope & Clinical Classification

Pranavita AI is classified as a wellness and health information technology platform. We do not seek, claim, or operate as a licensed clinical software or medical device. Our classification under CDSCO's Software as Medical Device (SaMD) framework:

Feature	Classification	Basis
AI health chat / Q&A	NOT a SaMD — informational only	Does not diagnose, treat, or prescribe
Lab report interpretation	NOT a SaMD — educational display	Displays reference ranges; does not diagnose
HealthScore	NOT a SaMD — wellness indicator	Not validated for clinical decision-making
Drug adherence reminders	NOT a SaMD — scheduling tool	Reminders only; no dosage modification
Telemedicine platform	IT Intermediary under IT Act	Facilitates licensed doctor–patient interaction

Any future feature that performs diagnosis, recommends specific treatments, adjusts medication doses, or interprets symptoms for clinical triage WILL require CDSCO SaMD registration before deployment. No such feature will be deployed without appropriate regulatory clearance.

## 2. AI Safety Design Principles

### 2.1 Human-in-the-Loop Requirement

For any AI output that could influence a health decision, our design mandates:

- Clear labelling of all AI-generated content as AI-generated health information
- A mandatory prompt to Consult a doctor before acting on this information on all symptom analysis and medication-related responses
- One-tap access to book a doctor consultation from any AI health response
- No AI response that claims to provide a definitive diagnosis

### 2.2 Refusal Architecture

The AI assistant is trained and prompted to refuse or redirect the following queries:

- Requests for a specific diagnosis based on symptoms alone
- Requests to recommend specific prescription medication doses
- Requests to advise on stopping or changing prescribed medication without doctor involvement
- Any query involving self-harm or harm to others
- Emergency medical situations (user is directed to call 112 immediately)

### 2.3 Hallucination Mitigation

- All AI health responses are bounded to reference established medical literature and drug databases (e.g., CIMS India, WHO guidelines)
- Responses involving drug interactions are prefaced with: This is preliminary information. Confirm with your prescribing doctor or pharmacist.
- AI responses are continuously monitored via a clinical review sampling programme — a licensed clinician reviews a random sample of AI outputs monthly
- Users can flag any AI response as inaccurate via the thumbs-down mechanism, triggering a clinical review

## 3. Emergency Escalation Protocol

Alert Level	Trigger Conditions	Platform Response
CRITICAL — Immediate Emergency	User mentions chest pain, difficulty breathing, loss of consciousness, stroke symptoms, severe allergic reaction	AI immediately displays emergency message with 112 call button. No further health advice is offered until emergency is acknowledged.
HIGH — Urgent Consultation	Critically abnormal lab values (e.g., glucose >400, HbA1c >12, creatinine indicating acute renal failure), dangerous wearable vitals	AI flags urgency, displays 'See a doctor today' prompt with pre-populated consultation booking.
MEDIUM — Prompt Review	Multiple abnormal biomarkers trending wrong, missed medications 3+ consecutive days, abnormal HealthScore decline	In-app alert recommending doctor consultation within the week.
LOW — Informational	Minor borderline values, lifestyle habit questions, general health queries	Standard AI health information with standard disclaimer and doctor-consultation recommendation.

Emergency escalation prompts are a platform safety feature. They do NOT replace emergency medical services. Users must call 112 or go to the nearest emergency room in a life-threatening situation. Pranavita cannot dispatch emergency services.

## 4. Telemedicine Clinical Safety Standards

### 4.1 Doctor Verification

- Every doctor onboarded to the platform must provide a valid MCI/State Medical Council registration number
- Registration is verified against the NMC's digital registry before account activation

- Annual re-verification of registration status; doctors who lose their registration are immediately suspended

#### 4.2 Prescription Safety (NMC Telemedicine Guidelines 2020)

- Prescriptions for Schedule H1 and Schedule X drugs are prohibited in first telemedicine consultations — enforced at system level
- All digital prescriptions must include the doctor's name, MCI registration number, date, patient name, and medication details
- Prescriptions are stored in the patient's health vault and are not modifiable after issuance

#### 4.3 Drug Adherence Safety

- AI-generated medication reminders are a scheduling feature only
- Labels all reminders: Reminder set for your prescribed medication - do not change dose without consulting your doctor
- AI does NOT advise stopping medication, even if the patient reports side effects — it will advise contacting the prescribing doctor

## 5. Lab Safety Standards

### 5.1 Critical Value Thresholds — Immediate Patient Notification Required:

Test	Critical Low	Critical High
Blood Glucose (Fasting)	<50 mg/dL	>500 mg/dL
Serum Potassium	<2.5 mEq/L	>6.5 mEq/L
Haemoglobin	<7 g/dL	>20 g/dL
Serum Creatinine	—	>10 mg/dL
Platelet Count	<20,000/ $\mu$ L	>1,000,000/ $\mu$ L
Serum Sodium	<120 mEq/L	>160 mEq/L

Upon receiving a critical lab value, Pranavita automatically: (1) notifies the patient immediately via push notification, (2) displays an urgent Please consult a doctor today message, (3) logs the event for clinical review.

### 5.2 Quality Dispute Protocol

- Patients can file a quality complaint in-app within 7 days of result delivery
- Pranavita logs the complaint and escalates to the lab within 24 hours
- The lab must respond within 5 business days with a resolution or re-test offer
- Repeated quality complaints against a lab trigger a platform review and potential de-listing

## 6. Adverse Event Reporting

Pranavita maintains an internal adverse event register. An adverse event is any unintended harm to a user potentially attributable to use of the Pranavita platform.

- All adverse event reports are reviewed by a clinical advisor within 7 days
- Serious adverse events (hospitalisation, permanent harm) are investigated within 48 hours
- Where platform design contributed to an adverse event, corrective action is implemented before resuming the affected feature

- Users can report safety concerns via [safety@pranavitahealthtech.com](mailto:safety@pranavitahealthtech.com) or the in-app Help Centre

Every safety report is critical feedback. Users who report safety concerns will receive a personal response from our clinical safety team within 72 hours.

## 7. Clinical Advisory Oversight

Pranavita maintains a Clinical Advisory Board comprising licensed medical professionals. The Board's responsibilities include:

- Reviewing AI response quality on a monthly sampling basis
- Approving any changes to AI health prompts, refusal logic, or critical-value thresholds
- Reviewing adverse event reports and recommending corrective actions
- Advising on clinical evidence bases for HealthScore algorithm updates
- Annual review and update of this Clinical Safety Policy

## Contact & Grievance

<b>Grievance Officer</b>	Subham Pratik Mahanand
<b>Designation</b>	Grievance Officer – Founding Team
<b>Phone</b>	+91-9337039267
<b>Email</b>	<a href="mailto:subham@pranavitahealthtech.com">subham@pranavitahealthtech.com</a>
<b>Safety Email</b>	<a href="mailto:safety@pranavitahealthtech.com">safety@pranavitahealthtech.com</a>
<b>Website</b>	<a href="https://pranavitahealthtech.com">https://pranavitahealthtech.com</a>

For data protection concerns, regulatory queries, or to exercise your rights, contact the Grievance Officer above. Response guaranteed within 48 hours.