--इसरो iडाग

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संदर्भ सं./Ref No: HSFC/Eol/02/2024

29 जुलाई /July 29, 2023

"पहनने योग्य स्वास्थ्य मानीटरन प्रणाली के स्वदेशी विकास हेतु विक्रेताओं की पूर्व अर्हता के लिए अभिरुचि की अभिव्यक्ति" का आमंत्रण INVITATION FOR "EXPRESSION OF INTEREST FOR PRE-QUALIFICATION OF VENDORS FOR DEVELOPMENT OF INDIGENOUS WEARABLE HEALTH MONITORING SYSTEM"

समानव अंतरिक्ष उड़ान केंद्र [एच.एस.एफ.सी., इसरो], भारत सरकार "पहनने योग्य स्वास्थ्य मानीटरन प्रणाली के स्वदेशी विकास हेतु विक्रेताओं की पूर्व अर्हता के लिए अभिरुचि की अभिव्यक्ति"को आमंत्रित करता है । इसका संक्षिप्त विवरण इसरो की वेबसइट <u>www.isro.gov.in</u> पर 'निविदा' के तहत उपलब्ध है ।

Human Spaceflight Centre **[HSFC, ISRO]**, **Government of India invites Expression of Interest for pre-qualification of Vendors for Development of Indigenous Wearable Health Monitoring System.**" Brief Specification is available in the ISRO website <u>www.isro.gov.in</u> under <u>'Tenders'</u>.

इच्छुक विक्रेता जिनके पास पर्याप्त जानकारी, अनुभव, अपेक्षित सुविधाएं और जो वित्तीय रूप से समृद्ध हैं, को, अपनी अभिरुचि की अभिव्यक्ति हस्ताक्षरित एवं मुहरबंद लिफाफे में एच.एस.एफ.सी., बेंगलूरु में जमा कराने के लिए आमंत्रित किया जाता है ।

Interested Vendors having sufficient know-how, experience, required facilities and financial background are invited to express their interest to submit their signed and sealed Envelope to HSFC, Bengaluru.

अभिरुचि की अभिव्यक्ति" के साथ कृपया ब्यौरेवार निम्नलिखित सूचना भी प्रस्तुत करें

Along with "Expression of Interest" please furnish the following information also in detail:

नोट/Note:-मेक इन इंडिया नीति के अनुसार, श्रेणी-। तथा श्रेणी-।। के स्थानीय आपूर्तिकर्ता इस बोली में भाग लेने हेतु पात्र हैं।/ Only Class-I and Class-II Local suppliers as per Make in India policy are eligible to participate in the bid

उपरोक्त सूचना के साथ आपकी अभिरुचि की अभिव्यक्ति निम्नलिखित पते पर भेजी जाए जिसके लिफाफे पर दिनांक 29.07.2024 की ई.ओ.आई. संख्या HSFC/ADVT/02/2023 अंकित हो । ई.ओ.आई. जमा कराने की अंतिम तारीख <u>29 अगस्त 2024 14.00 बजे है (भारतीय मानक समय) ।</u>

The Expression of Interest with all the above information should reach the following address superscribing the envelope as EoI No: HSFC/ADVT/02/2024 dated 29.07.2024. The Due Date for submission of EoI is <u>August 29, 2024 at 14.00 Hours IST</u>.

क्रय एवं भंडार अधिकारी/Purchase & Stores Officer, समानव अंतरिक्ष उड़ान केंद्र/Human Space Flight Centre, इसरो मुख्यालय परिसर/ISRO HQ Campus, न्यू बी.ई.एल.रोड/New BEL Road, अंतरिक्ष भवन/Anthariksh Bhavan, बेंगलूरु/Bengaluru – 560 094

ई.ओ.आई. के लिफाफे पर "भेजने वाले" का पता और एच.एस.एफ.सी. की संदर्भ संख्या अंकित की जानी चाहिए। किसी भी स्पष्टीकरण के लिए कृपया +91-080-2217 2675/79 तथा ई-मेल <u>smitha-hsfc@isro.gov.in</u>. पर हमसे संपर्क कर सकते हैं । अंतिम तारीख और समय के बाद प्राप्त ई.ओ.आई. पर मूल्यांकन हेतु विचार नहीं किया जाएगा । एच.एस.एफ.सी. के पास बिना कारण बताए सभी या किसी ऐसी अभिरुचि की अभिव्यक्ति को स्वीकार करने या अस्वीकार करने का अधिकार है ।

The Eol cover should indicate "SENDERS" Address and HSFC Reference Number. For any clarification you may please contact us on +91-080-2217 2675 / 79 and email ID <u>smitha-hsfc@isro.gov.in</u>. Eol received after due date and time will not be considered for evaluation. HSFC reserves the right to accept or reject all or any such "Expression of Interest"; without assigning any reasons what so ever.

Expression of Interest for Pre-Qualification of Vendors for Indigenous Development of Wearable Health Monitoring System

1. Background

Space exploration poses unique challenges to human health and safety due to the extreme environments and prolonged duration of missions. Biomedical devices are instrumental in addressing these challenges by enabling continuous monitoring, diagnosis and treatment of medical conditions among astronauts. These devices are essential for monitoring astronauts' health before the mission on ground, during spaceflight mission and postspaceflight recovery and rehabilitation.

As part of the Gaganyaan project under India's Human Spaceflight Programme, the development of wearable health devices specifically to measure physiological stresses on human body due to intense physical exertion is crucial for HSFC to meet the programmatic requirements. In addition, wearable medical devices will also aid in studying the physiological and psychological conditioning of human body in controlled space-analogous environment. These devices must be comparable to similar research-grade medical equipment used under ambulatory care settings.

The purpose of this EOI is to assess the profile and technical capability of India-registered enterprises including start-ups (DPIIT registered) for development of medical-grade wearable health monitoring systems and associated analytics.

The enterprise profile and technical capability will be used to prequalify enterprises which fulfil the selection criterion (given in Section 4) for the following activities:

- End to end design and development of wearable health monitoring system which includes associated hardware, software, data storage and transmission using wired/ wireless medium to secure private cloud/storage device along with integrated health data analytical engine with appropriate GUI
- Limited field trials for system validation
- Certification compliance
- Training, maintenance and support for the proposed solution along with comprehensive documentation

2. System Requirements

The proposed system would be multi-functional providing real-time health data to users. The continuous monitoring device shall be worn by the user and accountable to collect and transfer data either to an internal storage, or to a dedicated system via wired or wireless interface. Biomarker analytical device shall be compact and portable for periodic sample collection and assessment and transfer data either to an internal storage, or to a dedicated system via wired or wireless interface. It should be noted that in case of wireless transmission, the data must be stored on a private cloud in the premise of ISRO.

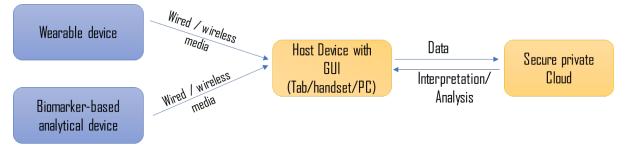


Figure 1: System configuration

The EOI aims for the development of two models of wearable system and a biomarkerbased analytical device with capability to acquire research-grade physiological data nonobtrusively and non-invasively for monitoring day-to-day activities of the subject. **The EOI accepts solution for either of the models, or multiple of them, or may incorporate all functionalities in an individual system, as much as feasible without compromising any requirements.** In the developmental phase through Model-1 it is proposed to make compact health monitoring system for crew training activities at ground. However, at later stage the equipment should be upgraded to Model-2 to perform similar training activities on crew/astronauts in-orbit. The details of the models are as follows:

Criterion	Model-1	Model-2
Intended use	 Health monitoring under analog space environments for physiological & psychological conditioning studies Internal load monitoring during physical training comprising of treadmill, cycling, swimming, weight training, circuit training, etc. Health monitoring under analog Post-training assessment sleep monitor brain activity Crew health n during space act 	
System form & portability	Completely wearable	
Heart function	ECG with arrhythmia detection capability (3-lead ECG or higher)	3-lead ECG or higher
Brain activity	No	Yes, 6-lead EEG or higher with sleep quality indicator, REM & N-REM stages
Blood pressure	Non-invasive & continuous	Non-invasive & continuous
Skin	Yes	Yes

temperature			
Respiratory rate	Yes	Yes	
SpO2	Yes	Yes	
Data storage & transfer	7 days storage capacity with data transfer within 5min duration		
Interface	Wired over USB, wireless over BLE		
Biocompatibility	As per ISO 10993		
	Biomarker-based analytical dev	<u>rice</u>	
Media	Yes, saliva/sweat biomarkers	Yes, saliva/sweat biomarkers	
System form & portability	Compact & portable device		
Cardiovascular response	Yes Yes		
Musculoskeletal response	Yes Yes		
Neuro- psychological response	Desired Yes		

3. Submission Requirements

3.1	Enterprise profile	Details to be furnished
A	Business entities involved in	Company name & address
	development, sales and	 Business Registration details
	marketing of wearable health	 Product & services portfolio
	monitoring devices	 Details of users/clients
		 Last three years' financial statement
		 MSME category based on investment &
		turnover
		 Details of in-house human resource
		 Details of collaborations – if any
В	Start-ups (DPIIT registered)	 Company name & address
	involved in development, sales	DPIIT Registration details
	and marketing of wearable	 Profile of founder members and leads
	health monitoring devices	 Products & services portfolio
		 Funding stage & Valuation details
		 Details of in-house human resource
		 Details of collaborations – if any
3.2	Technical capability	Details to be furnished
А	Business entities involved in	Details of prior experience in design,
	development, sales and	development and qualification of medical
	marketing of wearable health	devices (wearable/ non-wearable)
		 Details of in-house design, qualification and

	1		
	monitoring devices		manufacturing facilities
		•	Certification compliance and details
В	Start-ups (DPIIT registered)	•	Details of product development in
	involved in development, sales		wearable/non-wearable medical devices
	and marketing of wearable	•	Details of benchmarking the device with
	health monitoring devices		standard medical equipment
		•	Details of in-house technical expertise and
			facilities
3.3	Brief description of proposed	•	For existing device which meets major
	<u>solution</u>		requirement: Brief description of solution
			including hardware & software
		•	For a device which is under development -
			brief description of development status and
			further plans
		•	For new device development – brief
			description of technology and validation
			challenges

The EOI with all applicable documents must be submitted in a sealed envelope indicating "SENDERS" address and HSFC Reference Number to following address:

Purchase & Stores Officer, Human Space Flight Centre, ISRO HQ Campus, New BEL Road, Anthariksh Bhavan, Bengaluru – 560094

The due date for submission of EoI is **29.08.2024 at 14.00 Hours IST**. For any clarification you may please contact us on 080-2217 2675 / 2679 or email ID "smitha-hsfc@isro.gov.in" EOI received after due date and time will not be considered for evaluation.

4. Methodology for pre-qualification and selection criteria

The evaluation criteria to pre-qualify enterprises participating in the EOI is tabulated below according to the Evaluation Criteria Number (ECN):

		Score	
ECN	Evaluation Criteria	Business entities	Start- ups
4.1.	Enterprise profile		
4.1.1.	Company name & address with business registration details	5	5
4.1.2.	Products & services portfolio	10	10
4.1.3.	Last three years' financial statement	10	NA
4.1.4.	DPIIT registration details, profile of founding members and leads	NA	10

4.1.5.	Details of users/clients and collaborations	5	5
	Sub-total	30)
4.2.	Technical capability		
4.2.1.	Prior experience in design, development and qualification of wearable/ non-wearable medical devices	10	NA
4.2.2.	Existing product in wearable/non-wearable health monitoring segment	NA	10
4.2.3.	Design documentation of developed/underdevelopment product	20	20
4.2.4.	Certification compliance and details	5	NA
4.2.5.	Benchmarking the device with standard medical equipment	NA	5
4.2.6.	Adequacy of in-house technical resources for design and development	5	5
	Sub-total	40)
4.3.	Brief description of proposed solution		
4.3.1.	System configuration for Model-1	15	15
4.3.2.	System configuration for Model-2	15	15
	Sub-total	30)
	Total Maximum Score	10	0
	Minimum score for pre-qualification	60)

The table below draws the scheme for evaluation criteria, referring the Evaluation Criteria Number (ECN) from above table:

ECN	Scoring Scheme	Remarks
4.1.1.	 Score of 5 rewarded, if all details are furnished 	Non-submission of details will lead to disqualification
4.1.2.	 Score of 10 rewarded, if portfolio comprises of clinical- grade or research-grade medical devices Score of 5 rewarded, if portfolio comprises of consumer-grade medical devices 	Portfolio not fitting in medical domain will lead to disqualification
4.1.3.	 Score of 10 rewarded, if financial statement is audited by third-party Score of 5 rewarded, if financial statement is internally audited 	Non-submission of details will lead to disqualification
4.1.4.	 Score of 10 rewarded, if all details are furnished Score of 5 rewarded, if details furnished 	
4.1.5.	 Score of 0 rewarded, in either case 	

	 Score of 4 rewarded, if experienced in design & development 	
4.2.1.	 Score of 3 rewarded, if experienced in manufacturing 	
	 Score of 3 rewarded, if experienced in qualification 	
	Score will be a sum of all three aspects mentioned	
	• Score of 10 rewarded, if product is developed and	
	commercially available	
4.2.2.	 Score of 7 rewarded, if product is developed & under 	
	limited trial	
	 Score of 3 rewarded, if product is under development 	
	Scoring will be on the discretion of RFP evaluation panel	Non-submission of
4.2.3.	based on design concept, hardware configuration,	details will lead to
	software architecture, test plan and user manual	disqualification
4.2.4.	 Score of 5 rewarded, if details are furnished 	
	 Score of 0 rewarded, in either case 	
425	Score of 0 rewarded, in either caseScore of 5 rewarded, if details are furnished	
4.2.5.		
-	• Score of 5 rewarded, if details are furnished	
4.2.5. 4.2.6.	 Score of 5 rewarded, if details are furnished Score of 0 rewarded, in either case 	
4.2.6.	 Score of 5 rewarded, if details are furnished Score of 0 rewarded, in either case Score of 5 rewarded, if all details are furnished 	Minimum submission
-	 Score of 5 rewarded, if details are furnished Score of 0 rewarded, in either case Score of 5 rewarded, if all details are furnished Score of 0 rewarded, in either case 	Minimum submission of one configuration
4.2.6.	 Score of 5 rewarded, if details are furnished Score of 0 rewarded, in either case Score of 5 rewarded, if all details are furnished Score of 0 rewarded, in either case Scoring will be on the discretion of RFP evaluation panel, 	
4.2.6.	 Score of 5 rewarded, if details are furnished Score of 0 rewarded, in either case Score of 5 rewarded, if all details are furnished Score of 0 rewarded, in either case Scoring will be on the discretion of RFP evaluation panel, under the metrics including but not limited to design 	of one configuration

5. Disclaimer

- 5.1. This EOI does not entail any commitment on the part of HSFC, ISRO or any other participating ISRO agencies, either financial or otherwise. HSFC, ISRO reserves the right to accept or reject any or all EOI without incurring any obligation to inform the affected supplier/s of the grounds.
- 5.2. The technical specifications and design guidelines for the device will be detailed in the RFP which will be released after evaluation of the quotes received in EOI.
- 5.3. Requests for Proposal (RFP) and any subsequent purchase order (PO) will be issued in accordance with the rule and procedures of HSFC, ISRO and other participating ISRO agencies.

EOI	Expression of Interest
RFP	Request for Proposal
РО	Purchase Order
HSFC	Human Space Flight Centre
Start-up	As defined by Ministry of Commerce and Industry, Government of India

6. Glossary of Terms

DPIIT	Department for Promotion of industry and Internal Trade
ECG	Electrocardiogram
HRV	Heart Rate Variability
COTS	Commercial off-the-shelf