



## Rajasthan Medical Services Corporation Limited, Jaipur

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CIN : U24232RJ2011SGC035067

Website : www.rmssc.nic.in

No.F-8(52)RMSC/EPM/M-5/17-18/Breast Cancer Device/ 3899

Dated : 14/9/17

UE Lifesciences (India) Pvt Ltd  
A-102, Universal Paradise, Nanda Patkar Road,  
Vile Parle (East), Mumbai-400057  
[info@uelifesciences.com](mailto:info@uelifesciences.com)

विषय :- I-Breast Exam (iBE) System and iBE Scanhead Cartridge की दरें प्रस्तुत करने के क्रम में।

महोदय,

उपरोक्त विषयान्तर्गत लेख है कि राज्य सरकार की स्वीकृति के अनुसार 28 I-Breast Exam (iBE) System का क्रय किया जाना है। जिसके स्पेसिफिकेशन एवं शर्तें निम्नानुसार हैं। कृपया अपने दरों से सम्बन्धित प्रस्ताव दिनांक 29.09.17 तक प्रस्तुत करें। I-Breast Exam (iBE) System में काम आने वाली iBE Scanhead Cartridge की दरें भी प्रस्तुत करें। I-Breast Exam (iBE) System / iBE Scanhead Cartridge की दर संविदा की जावेगी जिसके आधार पर विभिन्न जिला अस्पतालों में मांग होने पर उपलब्ध करानी होगी।

### Specification for i-Breast Exam

1. Non-invasive, radiation-free, breast examination.
2. Ultra-Portable and light-weight probe. Probe size: 13 x 6.5 x 8.5cm, weight : 0.5kg. Full system with case size : 27 x 26 x 11cm, weight : 2kg.
3. Operable with rechargeable battery (1000 to 2000mAh). Recharging Power : Input 110-220V 50/60Hz at 0.3-0.5A and Output 5V at 2A.
4. Wireless operation using Bluetooth 2.0 standard protocol.
5. Regulatory Clearances & Approvals
  - a. US FDA Cleared Registration# K142926
  - b. CE Marked Certificate# CE-RS-1700-1558
  - c. ISO 13485 Certificate# MDMS 0716 020092
  - d. WHO - GMP Certificate# WGMP 0117 020092
6. Storage capacity for 100,000 breast examination scans and full reports.
7. Custom Windows Application for Breast Examination with capabilities to:
  - a. Perform breast examination.
  - b. Review the breast examination.
  - c. Store the breast examination data and
  - d. Print the final report.
8. Replay feature enables the physician to replay a breast examination performed in the past, frame by frame.
9. Approved for Electromagnetic compatibility (EMC) testy 1409-054EA REV. A Test Standards: IEC 60601—1-2:2007 (3<sup>rd</sup> Edition) & IEC 60601-1-2:2014 (4<sup>th</sup> Edition).
10. Approved for the following Electrical and Mechanical Safety Tests
  - a. IEC 60601-1 Ed.3 (2005) + Am.1 (2012) = IEC 60601-1Ed.3.1 (2012).
  - b. The following national Deviation were included in the evaluation AAAMI/ANSI ES 60601-1:2005(R) 2012/A1
  - c. EN 60601-1 Ed.3 (2007) + Am.1 (2003).
  - d. CSA C22.2 No. 60601-1: 2014
11. Clinical study validation performance characteristics:

- FI/P/M
- a. Sensitivity is 84%
  - b. Specificity is 94%
  - c. Negative Predictive Value is 98%
  - d. Positive Predictive Value is 60%
12. Storage, Transport and Operating conditions:
- a. Temperature range : 10° C to 50° C
  - b. Maximum relative humidity : 90%
  - c. Atmospheric Pressure range : 700-1060 hPa
13. Guarantee: Three years on equipment from the date of installation.
14. CMC: CMC shall be given @ 5 % of net rate excluding GST (as applicable). The CMC may be awarded for five years (on yearly basis) after Guarantee period of three years.
15. The company should mention the make & model name/number of the quoted equipment and submit the technical brochure of the quoted model .

नियम एवं शर्त :-

1. मूल Manufacturing कम्पनी UE Lifesciences Inc., 3711 Market Street , Suite 800, Philadelphia, PA19104 का Authorization Certificate भारत में विक्रय हेतु प्रस्तुत करना होगा ।
2. Patented Item Certificate.
3. Import -Export Certificate. (IEC Certificate).

भवदीय

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कार्यकारी निदेशक(ई.पी.एम.)  
राजस्थान चिकित्सा सेवा निगम,  
जयपुर

No .F-8(52)RMSC/EPM/M-5/17-18/Breast Cancer Device/ 3899

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प्रतिलिपि: निम्न को सूचनार्थ एवं आवश्यक कार्यवाही हेतु प्रेषित है:-

1. ए.जी.एम (आई.टी), आरएमएससी को भेजकर लेख है कि उपरोक्त सूचना SPPP Portal एवं निगम की वेबसाईट पर सूचना अपलोड करवाने हेतु प्रस्तुत है।

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