May 12, 2021

Notice of Intent to Sole Source
Physiologic Signal Generator System
FDA_SS_1242196

The Food and Drug Administration (FDA) intends to award a Sole Source firm-fixed price purchase order to Ikonix USA LLC, 28105 North Keith Drive, Lake Forest, IL 60045. In accordance with FAR part 6.302-1, the contractor is the only responsible source who can provide the required services as no other source has been identified to satisfy the agencies requirements.

The purpose of this notice is to inform the public that the FDA anticipates issuing an award to procure one (1) Physiologic Signal Generator System that can convert customizable digital signals to electrical and optical signals that can be sensed by ECG and PPG sensors.

The associated North American Industrial Classification System (NAICS) Code is 334516: Analytical Laboratory Instrument Manufacturing.

MINIMUM REQUIREMENTS:

A. Shall provide the following Electrocardiogram simulation specifications:
    1. Electrical connections for attaching ECG lead wires from device under test either as standard ECG snap on wires or banana clips;
    2. Support at least single lead ECG simulation;
    3. Voltage output range from at least -100 mV to 100 mV;
    4. Signal resolution of 5 uV or less;
    5. Sampling rate of at least 1 KHz.
B. Shall provide the following Photoplethysmographic waveform simulation specifications:
    1. Optical window for sitting device under test PPG sensor (photodetector and LED) above corresponding photodetector and LED in test unit;
    2. Device can perform single PPG simulation at green wavelength in range 520 to 540 nm or dual PPG simulation at red (650 to 670 nm) and infrared (860 to 950 nm) LED wavelengths with adjustable amplitude (AC) and offset (DC) PPG parameters for both wavelengths to modulate SpO2;
    3. Adjustable voltage to control LED output lumen range of at least 100 to 800 Lux;
    4. Adjustable AC/DC ratios from 0.2 to 10%;
    5. Pulse rate configurable from at least 40 to 240 beats/min with accuracy of +/- 1 beat/mi
    6. ;Enable customizable time delays between ECG and PPG signal simulations with resolution less than 2ms
C. Shall include a USB connection to communication with computer.
D. Shall include a dedicated power supply or ability to power unit through USB connections with computer
E. Shall provide software that will meet the following specifications:
    1. Support use on Microsoft Windows 10 PC.
    2. User interface to program test unit for automatically transmitting signals and enable user adjustable ECG and PPG signal properties including:
        a. Adjustments of ECG test signals including ECG waveform feature PRST amplitudes from 0 to 5 mV, QRS duration, and QT interval;

   b. Adjustments of PPG test signals including PPG peak-peak amplitude (AC component) and offset (DC component);
   c. Adjustments of PPG waveform amplitude, pulse period, and baseline modulation at respiratory frequencies from 10 to 20 breaths/min;
   d. Adjustment of time delay between ECG and PPG pulse onsets from 0 to >500 ms.

F. Shall have the ability to enable loading of custom waveforms from previously recorded signals or digitally generated that can be transmitted to and played through test unit.
G. Shall have the ability to transmit digital signals to test unit for conversion to electrical and optical simulations.
H. Shall provide one (1) year warranty from date of acceptance.

This notice is not a request for competitive proposals. However, any party that believes it can meet this requirement as stated herein may submit a written capability statement that clearly supports and demonstrates their ability to perform the requirement.

Capability statements must be received by the response date and time of this notice. Submissions will be reviewed to determine if they can meet the requirement. A determination by the Government to compete this proposed contract based upon responses to this notice is solely within the discretion of the Government.

It is anticipated that an award will be issued to Ikonix USA LLC, within approximately ten (10) days after the date of this notice unless the Government determines that any other organization has the capability to meet this requirement.

Response Date: May 22, 2021 by 10:00AM Eastern Time. Please email responses to Nicole Craig at nicole.craig@fda.hhs.gov. No phone calls will be accepted.