Records processed under FOIA Request 2022-4717; Released by CDRH on 05-31-2024

August 21, 2015</br></br>

Acceptance Review Notification - Accepted

An administrative acceptance review was conducted on your premarket notification (510(k)) K152261, and it was found to contain all of the necessary elements and information needed to proceed with the substantive review. We will contact you should we require any additional information during the course of the substantive review. The lead reviewer assigned to your submission is Keith Marin.

 *** This is a system-generated email notification ***

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2022-4717; Released by CDRH on 05-31-2024

SECTION 19 PERFORMANCE TESTING –ANIMAL TESTING

No animal testing submitted to support the performance of this system.

This section does not apply.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2022-4717; Released by CDRH on 05-31-2024

Keith,

(b)(4) Deficiencies

Thanks,
Peter

From: Marin, Keith [mailto:Keith.Marin@fda.hhs.gov]
Sent: Monday, September 21, 2015 9:05 AM
To: Peter Nelson
Cc: Chapman, Richard; K152261@docs.fda.gov; 'Charles Henry'; salusventures@aol.com
Subject: RE: additional questions - (b)(4) Deficiencies
Importance: High

Peter,

(b)(4) Deficiencies

Keith

From: Peter Nelson [mailto:petenelson@nostix.com]
Sent: Friday, September 04, 2015 11:34 AM
To: Marin, Keith
Cc: Chapman, Richard; K152261@docs.fda.gov; 'Charles Henry'; salusventures@aol.com
Subject: RE: additional questions - (b)(4) Deficiencies

Keith,

(b)(4) Deficiencies

Thanks,
Peter

Peter Nelson
R&D Manager
Nostix
5541 Central Ave, Suite 170
Boulder, CO 80301
Ph: 303-245-8895 ext. 3#
Fax: 303-245-8909

From: Marin, Keith [mailto:Keith.Marin@fda.hhs.gov]
Sent: Thursday, September 03, 2015 9:39 AM
To: Peter Nelson
Cc: Chapman, Richard; K152261@docs.fda.gov
Subject: additional questions

Peter,

(b)(4) Deficiencies

Thanks.

Keith

From: Peter Nelson [mailto:petenelson@nostix.com]
Sent: Monday, August 17, 2015 12:54 PM
To: Marin, Keith
Cc: K152261@docs.fda.gov; Chapman, Richard; 'Charles Henry'; salusventures@aol.com
Subject: RE: (b)(4) Deficiencies -- attached

Keith,

(b)(4) Deficiencies

Thanks,
Peter

Peter Nelson
Director of Engineering

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Nostix
5541 Central Ave, Suite 170
Boulder, CO 80301
Ph: 303-245-8895 ext. 3#
Fax: 303-245-8909

From: Marin, Keith [mailto:Keith.Marin@fda.hhs.gov]
Sent: Monday, August 17, 2015 10:01 AM
To: petenelson@nostix.com
Cc: K152261@docs.fda.gov; Chapman, Richard
Subject: (b)(4) Deficiencies

Mr. Nelson,

(b)(4) Deficiencies

Thanks.

Keith Marin

Keith Marin, RN, MS, MBA, OCN, RAC
Lieutenant Commander, United States Public Health Service
General Hospital Devices Combination Product Team Lead / Nurse Consultant
FDA/CDRH/ODE/DAGRID/GHDB
10903 New Hampshire Avenue, WO66-2567
Silver Spring, MD, 20993-0002
Telephone: (301) 796-2462, Fax: (301) 847-8109

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Subject: RE: (b)(4) Deficiencies -- attached

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Director of Engineering

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5541 Central Ave, Suite 170

Boulder, CO 80301

Ph: 303-245-8895 ext. 3#

Fax: 303-245-8909

From: Marin, Keith [mailto:Keith.Marin@fda.hhs.gov]

Sent: Monday, August 17, 2015 10:01 AM

To: petenelson@nostix.com<mailto:petenelson@nostix.com>

Cc: K152261@docs.fda.gov<mailto:K152261@docs.fda.gov>; Chapman, Richard

Subject: Letter of authorization

Mr. Nelson,

(b)(4) Deficiencies

Thanks.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2022-4717; Released by CDRH on 05-31-2024

Keith Marin

Keith Marin, RN, MS, MBA, OCN, RAC

Lieutenant Commander, United States Public Health Service

General Hospital Devices Combination Product Team Lead / Nurse Consultant

FDA/CDRH/ODE/DAGRID/GHDB

10903 New Hampshire Avenue, WO66-2567

Silver Spring, MD, 20993-0002

Telephone: (301) 796-2462, Fax: (301) 847-8109

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Silver Spring, MD, 20993-0002
Telephone: (301) 796-2462, Fax: (301) 847-8109

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2022-4717; Released by CDRH on 05-31-2024

<font color='black' size='2' face='Arial, Helvetica, sans-serif'>Keith,

(b)(4) Deficiencies

--

Jim

--

For Nostix LLC, Boulder, Colorado, USA

303 945 5675; salusventures@aol.com

-----Original Message-----

From: Marin, Keith <Keith.Marin@fda.hhs.gov>

To: Peter Nelson <petenelson@nostix.com>

Cc: Chapman, Richard <Richard.Chapman@fda.hhs.gov>; K152261 <K152261@docs.fda.gov>; 'Charles Henry' <cwh@nostix.com>; salusventures <salusventures@aol.com>

Sent: Fri, Sep 25, 2015 12:33 pm

Subject: RE: (b)(4) Deficiencies

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2022-4717; Released by CDRH on 05-31-2024

```
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family:"Calibri","sans-serif";  color:#1F497D;} .aolReplacedBody span.EmailStyle25
{mso-style-type:personal;  font-family:"Calibri","sans-serif";  color:#1F497D;}
.aolReplacedBody span.EmailStyle26  {mso-style-type:personal-reply;  font-
family:"Calibri","sans-serif";  color:#1F497D;} .aolReplacedBody .MsoChpDefault  {mso-
style-type:export-only;  font-size:10.0pt;} @page WordSection1  {size:8.5in 11.0in;
margin:1.0in 1.0in 1.0in 1.0in;} .aolReplacedBody div.WordSection1
{page:WordSection1;} </style>

<div lang="EN-US" class="aolReplacedBody">

<div class="WordSection1">

<div class="MsoNormal"><span style="color:#1F497D">Peter,</span></div>


<div class="MsoNormal"><span style="color:#1F497D"> </span></div>
```

(b)(4) Deficiencies

```
resubmit by Monday September 28, 2015 COB.</span></div>


<div class="MsoNormal"><span style="color:#1F497D"> </span></div>


<div class="MsoNormal"><span style="color:#1F497D">Thanks.<br>

<br>

Keith<br>

<br>

</span></div>


<div class="MsoNormal"><span style="color:#1F497D"> </span></div>


<div>

<div style="border:none;border-top:solid #B5C4DF 1.0pt;padding:3.0pt 0in 0in 0in">

<div class="MsoNormal"><b><span style="font-size:10.0pt;font-
family:&quot;Tahoma&quot;,&quot;sans-serif&quot;">From:</span></b><span style="font-
size:10.0pt;font-family:&quot;Tahoma&quot;,&quot;sans-serif&quot;"> Peter Nelson [<a
removedlink__8c20f907-3b4a-4780-ae03-
ea259b3e58e6__href="mailto:petenelson@nostix.com?">mailto:petenelson@nostix.com</a>]

<br>

<b>Sent:</b> Monday, September 21, 2015 4:58 PM<br>


<b>To:</b> Marin, Keith<br>


<b>Cc:</b> Chapman, Richard; <a removedlink__8c20f907-3b4a-4780-ae03-
ea259b3e58e6__href="mailto:K152261@docs.fda.gov">K152261@docs.fda.gov</a>; 'Charles
```

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Henry'; <a removedlink__8c20f907-3b4a-4780-ae03-ea259b3e58e6__href="mailto:salusventures@aol.com">salusventures@aol.com

Subject: RE: additional questions -- (b)(4) Deficiencies attached

Keith,

Attached is the revised summary letter with your corrections.

Thanks,

Peter

From: Marin, Keith [mailto:Keith.Marin@fda.hhs.gov]

Sent: Monday, September 21, 2015 9:05 AM

To: Peter Nelson

Cc: Chapman, Richard; K152261@docs.fda.gov; 'Charles Henry';

salusventures@aol.com

Subject: RE: additional questions -- (b)(4) Deficiencies attached

Importance: High

Records processed under FOIA Request 2022-4717; Released by CDRH on 05-31-2024

Peter,

(b)(4) Deficiencies

Keith

From: Peter Nelson [mailto:petenelson@nostix.com]

Sent: Friday, September 04, 2015 11:34 AM

To: Marin, Keith

Cc: Chapman, Richard; K152261@docs.fda.gov; 'Charles Henry';

salusventures@aol.com

Subject: RE: (b)(4) Deficiencies

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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attached</span></div>

</div>

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<div class="MsoNormal"> </div>


<div class="MsoNormal"><span style="color:#1F497D">Keith,</span></div>
```

(b)(4) Deficiencies

```
<div class="MsoNormal"><span style="color:#1F497D">Thanks,</span></div>


<div class="MsoNormal"><span style="color:#1F497D">Peter</span></div>


<div class="MsoNormal"><span style="color:#1F497D"> </span></div>


<div class="MsoNormal" style="margin-bottom:12.0pt"><b><span style="font-
size:10.0pt;font-family:&quot;Tahoma&quot;,&quot;sans-serif&quot;;color:black">Peter
Nelson
<br>

R&amp;D Manager <br>

Nostix <br>

5541 Central Ave, Suite 170 <br>

Boulder, CO 80301 <br>

Ph: 303-245-8895 ext. 3#<br>

Fax: 303-245-8909 </span></b><span style="color:#1F497D"></span></div>


<div class="MsoNormal"><span style="color:#1F497D"> </span></div>


<div>

<div style="border:none;border-top:solid #B5C4DF 1.0pt;padding:3.0pt 0in 0in 0in">

<div class="MsoNormal"><b><span style="font-size:10.0pt;font-
family:&quot;Tahoma&quot;,&quot;sans-serif&quot;">From:</span></b><span style="font-
size:10.0pt;font-family:&quot;Tahoma&quot;,&quot;sans-serif&quot;"> Marin, Keith [<a
target="_blank" removedlink__8c20f907-3b4a-4780-ae03-
ea259b3e58e6__href="mailto:Keith.Marin@fda.hhs.gov">mailto:Keith.Marin@fda.hhs.gov</a>]
<br>

<b>Sent:</b> Thursday, September 03, 2015 9:39 AM<br>
```

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2022-4717; Released by CDRH on 05-31-2024

To: Peter Nelson

Cc: Chapman, Richard; K152261@docs.fda.gov

Subject: additional questions

Peter,

(b)(4) Deficiencies

Thanks.

Keith

From: Peter Nelson [mailto:petenelson@nostix.com]

Sent: Monday, August 17, 2015 12:54 PM

To: Marin, Keith

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2022-4717; Released by CDRH on 05-31-2024

Cc: K152261@docs.fda.gov; Chapman, Richard; 'Charles Henry';

salusventures@aol.com

Subject: RE: (b)(4) Deficiencies - attached

Keith,

(b)(4) Deficiencies

Thanks,

Peter

Peter Nelson

Director of Engineering

Nostix

5541 Central Ave, Suite 170

Boulder, CO 80301

Ph: 303-245-8895 ext. 3#

Fax: 303-245-8909

From:<span style="font-

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size:10.0pt;font-family:"Tahoma","sans-serif""> Marin, Keith [mailto:Keith.Marin@fda.hhs.gov]

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To: petenelson@nostix.com

Cc: K152261@docs.fda.gov; Chapman, Richard

Subject: **(b)(4) Deficiencies**

Mr. Nelson,

(b)(4) Deficiencies

Thanks.

Keith Marin

Keith Marin, RN, MS, MBA, OCN, RAC

Lieutenant Commander, United States Public Health Service

General Hospital Devices Combination Product Team Lead / Nurse Consultant

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2022-4717; Released by CDRH on 05-31-2024

```
<div class="MsoNormal" style="mso-margin-top-alt:auto;mso-margin-bottom-alt:auto"><span
style="font-size:10.0pt;font-family:&quot;Arial&quot;,&quot;sans-
serif&quot;;color:black">FDA/CDRH/ODE/DAGRID/GHDB<br>

10903 New Hampshire Avenue, WO66-2567<br>

Silver Spring, MD, 20993-0002 <br>

Telephone: (301) 796-2462, Fax: (301) 847-8109 </span></div>


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</div>


</div>

</div>



</div>
</div>
</font>
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Keith,

(b)(4) Deficiencies

Regards,

Peter

From: Marin, Keith [mailto:Keith.Marin@fda.hhs.gov]
Sent: Monday, September 21, 2015 11:22 AM
To: Peter Nelson
Cc: Chapman, Richard; K152261@docs.fda.gov; 'Charles Henry';
salusventures@aol.com
Subject: RE: additional questions -- (b)(4) Deficiencies attached

Peter,

I have another question:

(b)(4) Deficiencies

From: Peter Nelson [mailto:petenelson@nostix.com]
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Lieutenant Commander, United States Public Health Service

General Hospital Devices Combination Product Team Lead / Nurse Consultant

FDA/CDRH/ODE/DAGRID/GHDB

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Silver Spring, MD, 20993-0002

Telephone: (301) 796-2462, Fax: (301) 847-8109

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2022-4717; Released by CDRH on 05-31-2024

SECTION 4 INDICATIONS FOR USE (FORM FDA 3881)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2022-4717; Released by CDRH on 05-31-2024

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

Device Name

PICC Tip Positioning Aid

Indications for Use *(Describe)*

The PICC Tip Positioning Aid is indicated for the positioning of Peripherally Inserted Central Catheters (PICC) in adult patients. It provides real-time catheter tip location information by using the patient's cardiac electrical activity. The PICC Tip Positioning Aid is indicated for use as an alternative method to chest x-ray or fluoroscopy confirmation of PICC tip placement in adult patients.

Note: In general, devices that utilize ECG technique to observe P-Wave arc limited, but not contraindicated, for patients where cardiac rhythms may change presentation of the P-Wave; including
- Atrial fibrillation
- Atrial flutter
- Severe tachycardia
- Pacemaker-driven rhythm
- Chronic obstructive pulmonary disease (COPD)

Such patients are easily identified prior to PICC insertion. Use of an additional confirmation method is necessary to confirm catheter tip location.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Records processed under FOIA Request 2022-4717; Released by CDRH on 05-31-2024

SECTION 1 MEDICAL DEVICE USER FEE COVER SHEET (FORM FDA 3601)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2022-4717; Released by CDRH on 05-31-2024

Form Approved: OMB No. 0910-0511 Expiration Date: April 30, 2016. See Instructions for OMB Statement.

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION **MEDICAL DEVICE USER FEE COVER SHEET**	PAYMENT IDENTIFICATION NUMBER: (b)(4) Write the Payment Identification number on your check.

A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: http://www.fda.gov/oc/mdufma/coversheet.html

1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)	2. CONTACT NAME
NOSTIX LLC 5541 Central Ave Ste 170 Boulder Colorado CO 803012876 US	Steve Barnard 2.1 E-MAIL ADDRESS sbarnard@nostix.com 2.2 TELEPHONE NUMBER (include Area code) 303-2458895 2.3 FACSIMILE (FAX) NUMBER (Include Area code)
1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) *****0777	

3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm345263.htm

Select an application type:	3.1 Select a center
[X] Premarket notification(510(k)); except for third party	[X] CDRH
[ ] 513(g) Request for Information	[ ] CBER
[ ] Biologics License Application (BLA)	3.2 Select one of the types below
[ ] Premarket Approval Application (PMA)	[X] Original Application
[ ] Modular PMA	Supplement Types:
[ ] Product Development Protocol (PDP)	[ ] Efficacy (BLA)
[ ] Premarket Report (PMR)	[ ] Panel Track (PMA, PMR, PDP)
[ ] 30-Day Notice	[ ] Real-Time (PMA, PMR, PDP)
	[ ] 180-day (PMA, PMR, PDP)

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)

[ ] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA

[X] NO, I am not a small business

4.1 If Yes, please enter your Small Business Decision Number:

5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA?

[X] YES (All of our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within 30 days of FDA's approval/clearance of this device.)

[ ] NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see http://www.fda.gov/cdrh/mdufma for additional information)

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6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.

[ ] This application is the first PMA submitted by a qualified small business, including any affiliates

[ ] The sole purpose of the application is to support conditions of use for a pediatric population

[ ] This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only

[ ] The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

7. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).

[ ] YES [X] NO

PAPERWORK REDUCTION ACT STATEMENT

Public reporting burden for this collection of information is estimated to average 18 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the address below.

Department of Health and Human Services, Food and Drug Administration, Office of Chief Information Officer, 8455 Colesville Road, COLE-14-14253 Silver Spring, MD 20993-0002
[Please do NOT return this form to the above address, except as it pertains to comments on the burden estimate.]

8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION

(b)(4) 27-Jul-2015

Form FDA 3601 (05/13)

"Close Window" Print Cover sheet

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SECTION 18 PERFORMANCE TESTING, HUMAN FACTORS & LITERATURE STUDY REPORTS

No changes have been made to the design of the proposed device from predicate to proposed device.

All data and qualifications from the submission for the predicate device apply to this submission.

Please refer to the letter attached to the cover letter of this 510(k) from the owner of the Predicate Device, Angiodynamics, acknowledging their support of this submission with all data and certification from the predicate submission.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2022-4717; Released by CDRH on 05-31-2024

SECTION 9 DECLARATION OF CONFORMITY TO STANDARDS

While standards are mentioned in this submission, conformity to standards are not used to establish the equivalence of the proposed device to its predicate. Thus, this submission does not contain any Form FDA 3654.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2022-4017; Released by CDRH on 05-31-2024

(b)(4)

Via Email only (cwh@nostix.com)

July 21, 2015

Nostix, LLC
5541 Central Avenue, Suite 170
Boulder, Colorado 80301
Attention: Charles W. Henry, President and CEO

Re: Development and Supply Agreement ("Agreement") between Nostix, LLC ("Nostix") and (b)(4)

Dear Charlie:

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2022-4717; Released by CDRH on 05-31-2024

Mr. Nelson,

(b)(4) Deficiencies

Thanks.

Keith Marin

Keith Marin, RN, MS, MBA, OCN, RAC
Lieutenant Commander, United States Public Health Service
General Hospital Devices Combination Product Team Lead / Nurse Consultant
FDA/CDRH/ODE/DAGRID/GHDB
10903 New Hampshire Avenue, WO66-2567
Silver Spring, MD, 20993-0002
Telephone: (301) 796-2462, Fax: (301) 847-8109

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2022-4717; Released by CDRH on 05-31-2024

September 29, 2015</br></br>

Substantive Review Notification - Proceed Interactively

FDA has completed a substantive review of your submission K152261 and has determined that we will work with you to resolve outstanding deficiencies through an Interactive Review process. Any outstanding deficiencies will be provided to you during the Interactive Review process.

 *** This is a system-generated email notification ***

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2022-4717; Released by CDRH on 05-31-2024

SECTION 10 EXECUTIVE SUMMARY

Trade Name:	PICC Tip Positioning Aid
Common Device Name:	PICC placement accessory
Classification:	21 CFR 880.5970 Percutaneous, implanted, long-term intravascular catheter Class II Product Code LJS
Predicate Device:	K142889 Celerity™ PICC Tip Confirmation System

DEVICE DESCRIPTION:

The PICC Tip Positioning Aid includes the following components listed below.

Monitor

Single-board computer system with graphical display and touch screen running custom data acquisition/control software

- USB connector for connecting flash drive to download patient data and for software updates
- Runs off DC power through a 100-240 VAC 50/60 Hz external AC/DC medical grade power supply with 12VDC output
- Contains rechargeable Lithium-Ion battery with 3 hour runtime
- Includes bracket connection to support pole mount adapter and has the ability to stand upright on a flat surface (e.g. tabletop)
- Isolates all connections to patient-contacting parts to Type CF, heart-connected device, per IEC 60601-1
- Connects to
  Patient ECG Cable - connects to the three snap leads
  Remote Control Cable - connects to the ECG Clip Cable

Remote Control Cable (Reusable)

- Once placed within the sterile cable cover, the Remote Control Cable connects aseptically to the ECG Clip Cable which connects to the catheter stylet.
- Two cable connections; one to the Monitor, one to the ECG Clip Cable
- Three control buttons with icons: left arrow, enter, and right arrow. The buttons allow the user to scroll through and select menu icons on Monitor

ECG Patient Cable (Reusable)

- Connects the Monitor to the ECG Snap Leads
- Sockets are compliant to DIN 42-802 and colored-coded per ANSI/AAMI EC53 - *White [RA], Black [LA] and Red [LL]*

ECG Clip Cable (Single-use)

Alligator style clip for connection to stylet wire and a stereo plug for connection to the Remote Control Cable

ECG Snap Leads (Reusable)

- Set of three, 24" long, ECG snap leads
- Snap lead pin connections are compliant to DIN 42-802 and colored-coded per ANSI/AAMI EC53 - *White [RA], Black [LA] and Red [LL]*
- Snap Leads connect to ECG Adhesive Electrodes (Pads) placed on the patient's chest

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2022-4717; Released by CDRH on 05-31-2024

INDICATIONS FOR USE:

The PICC Tip Positioning Aid is indicated for the positioning of Peripherally Inserted Central Catheters (PICC) in adult patients. It provides real-time catheter tip location information by using the patient's cardiac electrical activity. The PICC Tip Positioning Aid is indicated for use as an alternative method to chest x-ray or fluoroscopy confirmation of PICC tip placement in adult patients.

Note: In general, devices that utilize ECG technique to observe P-wave are limited, but not contraindicated, for patients where cardiac rhythms may change presentation of the P-wave; including

- Atrial fibrillation
- Atrial flutter
- Severe tachycardia
- Pacemaker-driven rhythm
- Chronic obstructive pulmonary disease (COPD)

Such patients are easily identified prior to PICC insertion. Use of an additional confirmation method is necessary to confirm catheter tip placement.

Use Characteristics:

The PICC Tip Positioning Aid is identical to the predicate Celerity System: same device master record, same producer, and same performance---only the names and responsibility for the product has changed.

The following table provides an overview of these products and their usage.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Operating environment	Users	Clinicians trained in placing central venous catheters, including: PICC nurses and Interventional radiologists
	Setting	Health Care Facilities, including: Hospitals, Outpatient-care facilities and Extended-care facilities
Operating configuration	(b)(4)	
Operating principle		

EQUIVALENCE:

As technically, the PICC Tip Positioning Aid is the predicate device, AngioDynamics' Celerity System (K142889), except for names and addresses on the label, it is substantially equivalent based on operating principle, intended use, technology, safety, and performance.

PICC TIP POSITIONING AID DESIGN HISTORY

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2022-4717; Released by CDRH on 05-31-2024

The device being submitted for this 510(k) clearance is for an ECG tip location device.

The proposed PICC Tip Positioning Aid and its predicate Celerity Tip Confirmation System, achieve tip placement confirmation by the same technique, utilization of ECG to observe P-wave changes as the tip approaches the right atrium of the heart via the superior vena cava.

BENCH TESTING

Verification and validation tests were performed in accordance with Design Control requirements per 21 CFR 820.30 on the (b)(4) labeled units. This testing is applicable to the proposed device as well.

BIOCOMPATIBILITY:

The proposed PICC Tip Positioning Aid (Monitor, ECG Patient Cable, Remote Control Cable, Battery, Power Supply, Power Cord, ECG Clip Cable) have no patient contact, therefore biocompatibility testing is not required.

STERILITY / PACKAGING:

Sterile Single Use Procedural Accessory kits are not part of this submission. The ECG Clip Cable and Probe Cover Bag are sterilized and qualified by the kit manufacturer for the ECG Accessories Package, which is not provided by Nostix.

CONCLUSION:

The information presented in this Premarket Notification demonstrates that the proposed PICC Tip Positioning Aid is substantially equivalent to the predicate device, Celerity™ System (K142889) as it is simply a relabeled clone of the predicate.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2022-4717; Released by CDRH on 05-31-2024

DEPARTMENT OF HEALTH AND HUMAN SERVICES **M E M O R A N D U M**

Food and Drug Administration
Office of Device Evaluation
10903 New Hampshire Ave.
Silver Spring, MD 20993

Premarket Notification [510(k)] Review
Traditional
K152261

Date: September 29, 2015

To: The Record
From: Keith Marin

Office: Office of Device Evaluation
Division: DAGRID

510(k) Holder: Nostix LLC
Device Name: PICC Tip Positioning Aid
Contact: Peter Nelson
Address: Nostix, LLC
5541 Central Av, Suite 170
Boulder, CO 80301
Phone: 303-245-8895
Fax: 303-245-8909
Email: petenelson@nostix.com

Dated: August 7, 2015
Received: August 11, 2015

Regulation Number: 21 CFR 880.5970
Regulation Name: Percutaneous, implanted, long-term intravascular catheter
Regulatory Class: Class II
Product Code: LJS
Classification Panel: General Hospital (HQ)

(b)(5)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2022-4717; Released by CDRH on 05-31-2024

(b)(5) FDA drafts

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2022-4717; Released by CDRH on 05-31-2024

(b)(5) FDA drafts

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2022-4717; Released by CDRH on 05-31-2024

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(5) FDA drafts

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2022-4717; Released by CDRH on 05-31-2024

October 21, 2015</br></br> We have completed our review. Please refer to the attached letter for details.

If you have any questions, please contact the lead reviewer assigned to your submission, Keith Marin.

 *** This is a system-generated email notification ***

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2022-4717; Released by CDRH on 05-31-2024

Mr. Nelson,

(b)(4) Deficiencies

Thanks.

Keith Marin

Keith Marin, RN, MS, MBA, OCN, RAC
Lieutenant Commander, United States Public Health Service
General Hospital Devices Combination Product Team Lead / Nurse Consultant
FDA/CDRH/ODE/DAGRID/GHDB
10903 New Hampshire Avenue, WO66-2567
Silver Spring, MD, 20993-0002
Telephone: (301) 796-2462, Fax: (301) 847-8109

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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From: Sung, Charis * [Charis.Sung@fda.hhs.gov]
Sent: 8/11/2015 4:55:21 PM
To: salusventures@aol.com
CC: DCCLetters [DCCLetters@fda.hhs.gov]
Subject: K152261 ACK LETTER
Attachments: K152261.pdf

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Acknowledgment Letter

08/11/2015

Jim Lewis
Executive Consultant
Salus Ventures LLC
5335 Holmes Place
Boulder, CO 80303
United States

Dear Jim Lewis:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has received your submission. This submission has been assigned the unique document control number below. Please refer prominently to this number in all future correspondence that relates to this submission. Failure to do so may result in processing delays. If the 'Applicant' identified below is incorrect, please notify the 510(k) Staff immediately at (301) 796-5640.

Submission Number: K152261
Received: 08/11/2015
Applicant: NOSTIX LLC
Device: PICC Tip Positioning Aid

We will notify you when the processing of your 510(k) has been completed or if any additional information is required. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

If any additional information is required, we will notify you via an Acceptance Review communication, Additional Information (AI) request, and/or Interactive Review communication. For additional information on these types of communication and their effect on the FDA Review Clock (if any), please refer to the following guidance documents:

"FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Goals" at http://www.fda.gov/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm089735.htm.

"Refuse to Accept Policy for 510(k)s" at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM315014.pdf.

"Types of Communication During the Review of Medical Device Submissions" at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm341918.htm.

When responding to an information request that stops the FDA Review Clock (e.g., an AI request or refuse to accept (RTA) decision), you must submit your complete response with valid electronic copy (eCopy) to the Document Control Center (DCC) at the above address. An incomplete response or a response sent any other way (e.g., to another address or via email) will **not** be considered an official response and will not restart the FDA Review Clock. For more information about FDA's eCopy program, including the new technical standards for an eCopy, refer to the guidance document, "eCopy Program for Medical Device Submissions" at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM313794.pdf

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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To learn more about the overall 510(k) submission process, please refer to our website at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/default.htm.

If you have any procedural or policy questions, please refer to our website at http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm or contact the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041, (301) 796-7100, or *DICE@fda.hhs.gov*.

Sincerely yours,

Marjorie Shulman
Director, 510(k) Program
Premarket Notification (510(k)) Staff
Office of Device Evaluation
Center for Devices and Radiological Health

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2022-4717; Released by CDRH on 05-31-2024

Nostix

510(k) Summary

Prepared: 25 September 2015

Submitter

Company	Nostix LLC 5541 Central Av, Suite 170 Boulder, CO 80301
Tel	303 245 8895
Fax	303 245 8909
Contact	Pete Nelson Director of Engineering petenelson@nostix.com

Device

Trade Name	PICC Tip Positioning Aid
Common Name	PICC placement accessory
Class Name	Percutaneous, implanted, long-term intravascular catheter
Product Code	LJS
Regulation	21 CFR 880.5970
Class	2

Predicate

Trade Name	Celerity System
Clearance	K142889, 27 January 2015
Common Name	PICC placement accessory
Class Name	Percutaneous, implanted, long-term intravascular catheter
Product Code	LJS
Regulation	21 CFR 880.5970
Class	2

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2022-4717; Released by CDRH on 05-31-2024

Device Description

The PICC Tip Positioning Aid includes a standalone Monitor containing software, battery and power cord accompanied by an ECG Patient Cable, a Remote Control Cable, probe cover and ECG Clip Cable.

Other procedural accessories; including ECG Snap Leads, ECG Surface Electrodes, Cable Cover, Gloves and Prep Pads; may be provided as a convenience for the clinician but are not in the scope of this submission.

Intended Use

The PICC Tip Positioning Aid is intended to provide real time tip location information of a central venous catheter by utilization of ECG to observe P-wave changes as the tip approaches the right atrium of the heart via the superior vena cava.

Indications for Use

The PICC Tip Positioning Aid is indicated for the positioning of Peripherally Inserted Central Catheters (PICC) in adult patients. It provides real-time catheter tip location information by using the patient's cardiac electrical activity. The PICC Tip Positioning Aid is indicated for use as an alternative method to chest x-ray or fluoroscopy confirmation of PICC tip placement in adult patients.

Note: In general, devices that utilize ECG technique to observe P-Wave arc limited, but not contraindicated, for patients where cardiac rhythms may change presentation of the P-Wave; including

- Atrial fibrillation
- Atrial flutter
- Severe tachycardia
- Pacemaker-driven rhythm
- Chronic obstructive pulmonary disease (COPD)

Such patients are easily identified prior to PICC insertion. Use of an additional confirmation method is necessary to confirm catheter tip location.

Technological Characteristics

Technological Characteristics of the subject PICC Tip Positioning Aid are identical to the predicate device. The name and address changes on the labels between the predicate and proposed devices do not raise new technological questions.

Performance Data

As the only differences between the device and its predicate are names, logos, and addresses in the labeling, the following recognized standards from the IEC 60601 (3rd Edition) series continue to be satisfied.

IEC 60601-1-1	Medical electrical equipment—Part 1-1: General requirements for safety—Collateral standard: Safety requirements for medical electrical systems

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2022-4717; Released by CDRH on 05-31-2024

IEC 60601-1-2 Medical electrical equipment—Part 1-2: General requirements for basic safety and essential performance—Collateral standard: Electromagnetic compatibility – Requirements and tests

Human Factors Evaluation - Simulated Use Testing alternate to chest x-ray and fluoroscopy:

Simulated Use / Human Factors Testing has been conducted to evaluate the application of the PICC Tip Placement Aid as embodied in the predicate Celerity System when used to confirm PICC tip position as an alternative method to chest X-ray or fluoroscopy confirmation. The use related events noted in the studies have been adequately reviewed and addressed in order to ensure the appropriate use of the device as an alternate to x-ray techniques for confirmation of tip location of PICC.

Based on the content of the proposed PICC Tip Positioning Aid's Risk Analysis / Use and Design FMEAs, and the content of the Instructions for Use, the PICC Tip Positioning Aid has demonstrated its suitability for its intended purpose.

Substantial Equivalence Conclusion

As this device design and manufacturing are the same as the predicate except for name changes to the device and the manufacturer, the device is clearly equivalent to its predicate.

The proposed device is clearly substantially equivalent to the predicate device based on identical:

- Intended Use
- Indications for Use
- Design
- Production
- Operating principles, characteristics, and user interface
- Technology and specifications
- Labeling

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2022-4717; Released by CDRH on 05-31-2024

SECTION 11 DEVICE DESCRIPTION

The PICC Tip Positioning Aid and its predicate AngioDynamics Celerity System (K142889) are the same device: designed and built by the same companies to the same Device Master Record with the exception of names, addresses, and logos in the labeling of the device.

This section describes these devices.

(b)(4)

Indications for Use (Identical to predicate device)

The PICC Tip Positioning Aid is indicated for the positioning of Peripherally Inserted Central Catheters (PICC) in adult patients. It provides real-time catheter tip location information by using the patient's cardiac electrical activity. The PICC Tip Positioning Aid is indicated for use as an alternative method to chest x-ray or fluoroscopy confirmation of PICC tip placement in adult patients.

Note: In general, devices that utilize ECG technique to observe P-Wave are limited, but not contraindicated, for patients where cardiac rhythms may change presentation of the P-Wave; including
- Atrial fibrillation
- Atrial flutter
- Severe tachycardia
- Pacemaker-driven rhythm
- Chronic obstructive pulmonary disease (COPD)

Such patients are easily identified prior to PICC insertion. Use of an additional confirmation method is necessary to confirm catheter tip location.

Technological Characteristics

The proposed PICC Tip Positioning Aid is still the same device with no change in design, manufacturer, or technological characteristics as compared to the predicate Celerity System.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2022-4717; Released by CDRH on 05-31-2024

As with the predicate Celerity System, the proposed PICC Tip Positioning Aid components are identified in **Table 11.1.**

Table 11.1	
Electronic unit with integrated touch-screen display	Monitor (Fig 11.1) • Touch screen display and single board computer with proprietary software housed in Polycarbonate/ABS plastic case • Custom multilayer electrical printed circuit board with analog and digital electronic sections, providing insolated patient connections, and external connections for DC power and USB • Gathers and displays ECG in real time with "snap shot" capability, status, settings, and alarms • Powered from "mains" External Power Supply/Power Cord (Fig. 11.2) or internal lithium ion rechargeable battery • Stores and transfers ECG/input data to memory or print Packaged with the monitor are the Power Supply, Power Cord, Patient ECG Cable, Remote Control Cable, and commercially available ECG Snap Leads.
Non-sterile reusable components	Remote Control Cable – (Fig. 11.3) • Insulated copper wire • Conductive carbon switches on silicon rubber keypad in Polycarbonate/ABS plastic housing • Standard stereo plug connector ECG Patient Cable - (Fig. 11.4) • Insulated copper wire ECG Snap Leads - commercially available (Fig. 11.5)
Sterile single-use components	ECG Clip Cable - (Fig 11.6) • Insulated copper wire • Stainless-steel spring-loaded alligator clip • Standard stereo jack connector Cable Cover – Polybag, commercially available (Fig. 11.7)
Non-sterile single-use components	ECG Adhesive Electrodes- commercially available ECG prep pads- commercially available

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Figure 11.1 Monitor (front and back).

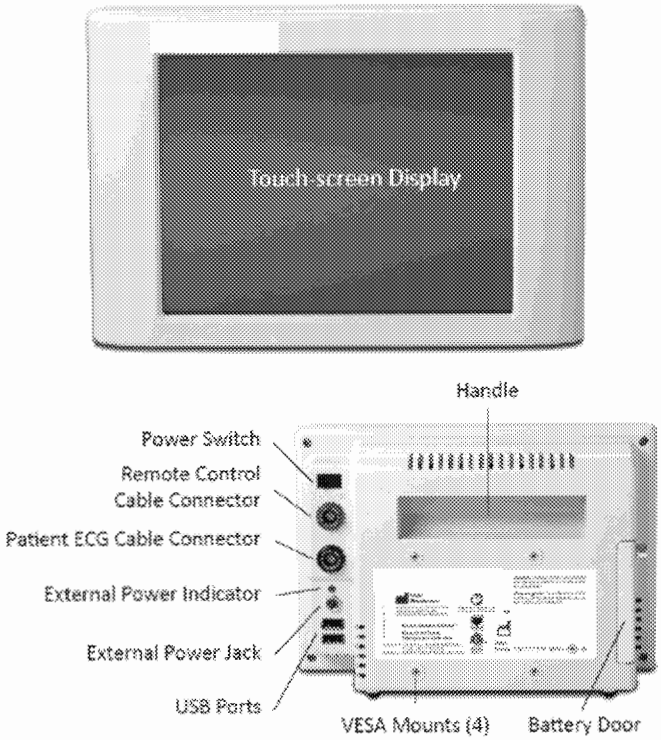

Figure 11.2 Power Supply and Power Cord

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Figure 11.3 Remote Control Cable.

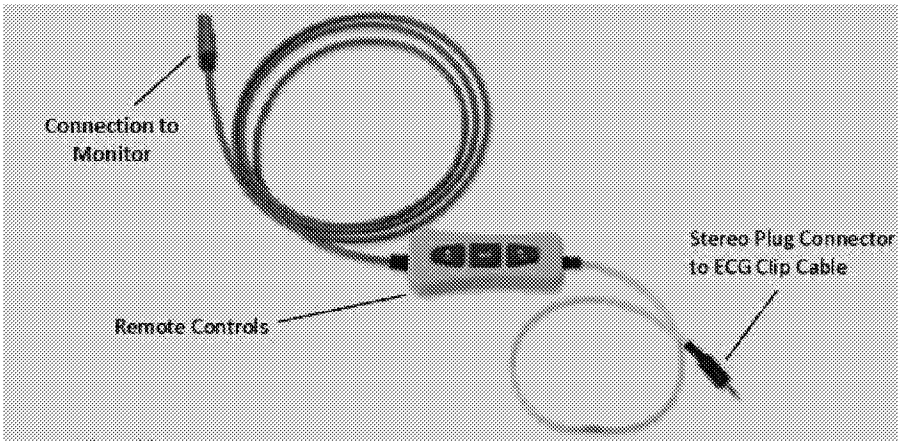

Figure 11.4 ECG Patient Cable.

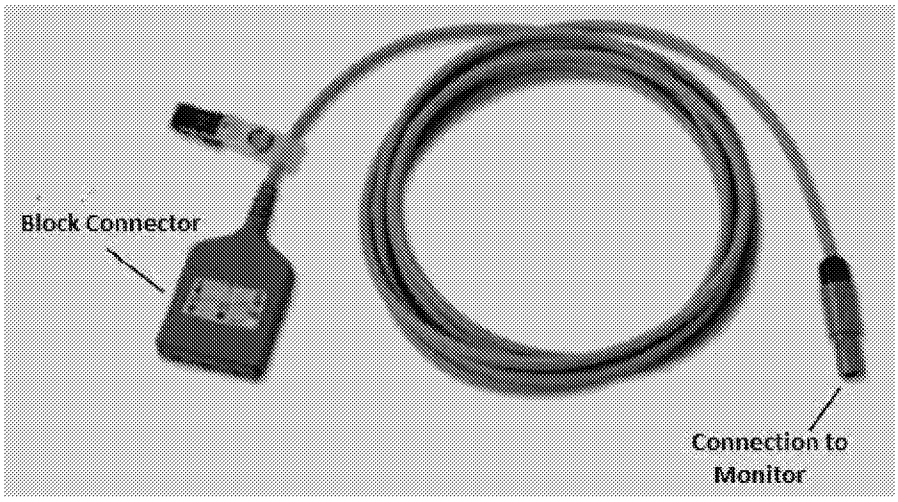

Figure 11.5 ECG Snap Leads.

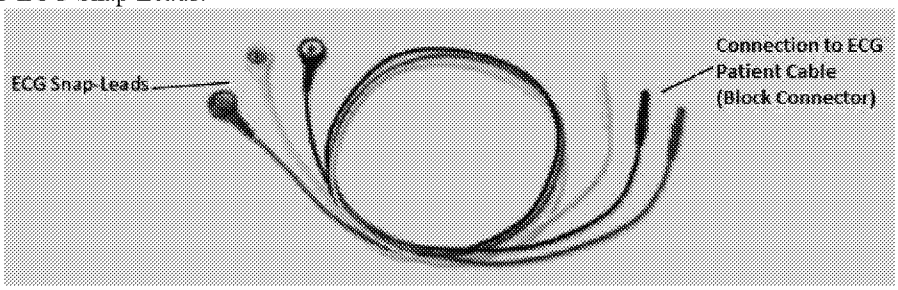

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Figure 11.6 ECG Clip Cable.

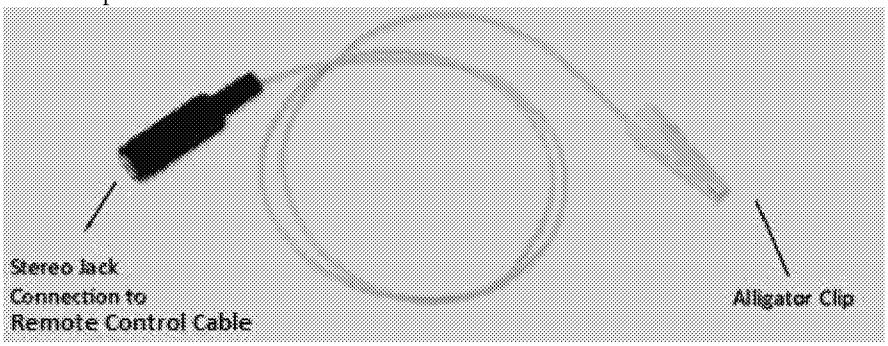
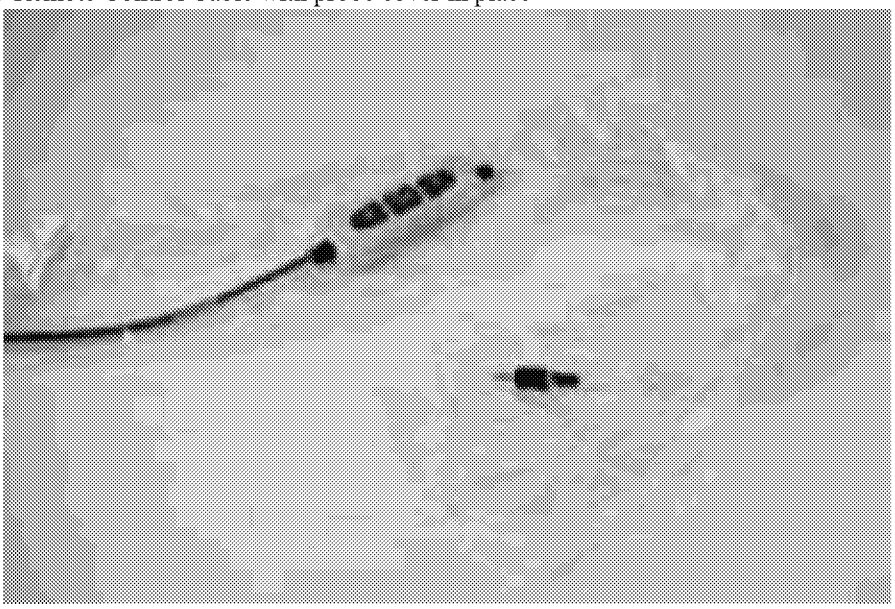


Figure 11.7 Remote Control Cable with probe cover in place



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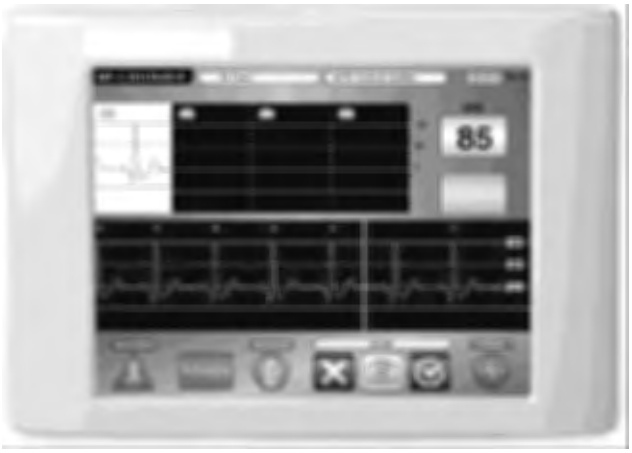
SYSTEM FUNCTIONALITY

The system acquires, displays, stores, and transfers ECG and procedural data (Fig.11.8).

In the 3-lead (surface) mode display, the ECG signal is read from the three surface electrodes. In the PICC mode display, the ECG signal is read from two of the surface electrodes and the stylet wire via the ECG Clip Cable. The system displays the waveforms such that the operator may compare ECG waveform changes as the catheter approaches the right atrium of the heart.

The PICC Tip Positioning Aid is not intended to be used as a diagnostic ECG monitor.

Figure 11.8 Monitor (front panel 3-lead display mode)



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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DEVICE FUNCTION

The PICC Tip Positioning Aid functions by utilizing the shape and amplitude of a patient's P-wave to determine the proximity of a PICC Catheter tip to the sino-atrial node of the heart.

Operating configuration

(b)(4)

Figure 11.9 Aseptic connection of Remote Control Cable to ECG Clip Cable. Black lines below depict:

Top Line: Remote Control Cable

Bottom Line: ECG Clip Cables

Operating principle

Operators

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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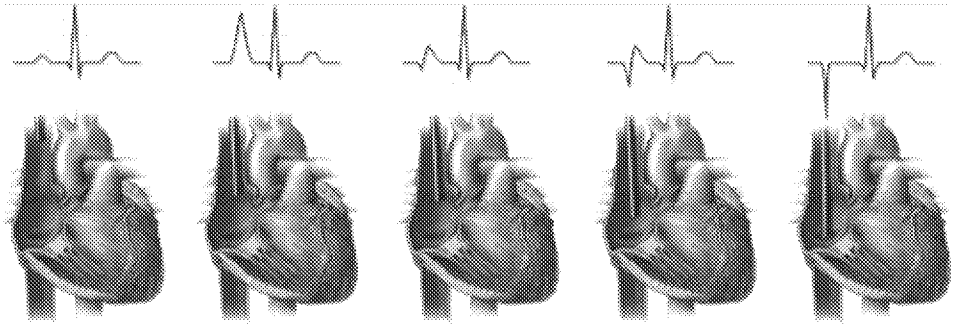
SCIENTIFIC CONCEPT

(b)(4)

Figure 11.10 P wave relative to catheter tip position



*P wave at its maximum height; catheter tip is in the lower 1/3 of the superior vena cava/ right atrial junction

SYSTEM FEATURES

The PICC Tip Positioning Aid allows the clinician to observe and record changes to ECG waveform as the catheter tip approaches the heart. As the PICC approaches the atrium, the P-wave in the ECG waveform shows substantial change. The system is designed to aid visualization of change in P-wave shape and amplitude as catheter is advanced.

System Self-test	• Initiated at power-on • Performs system verification and safety self-tests prior to displaying Patient ID Screen
Create patient record	• Clinician enters patient ID information • Patient information is available for storage and/or hard copy
Automated aids to PICC advancement	• Clinician enters patient-surface measurement and catheter cut length at the start of the procedure and the catheter exposed length when a snap shot is taken. The device will calculate the implanted catheter length.
Start data	• Automatic when the system senses that all leads are connected • Data acquisition is started • ECG waveform displayed

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Select leads	Clinician selects mode for display of ECG signal • 3 surface leads (Surface Mode) • 2 surface leads and stylet (IV) lead (PICC Mode)
Export saved file	Clinician may select (when not in data acquisition mode) to download patient data file(s) in file format (.jpg) to a USB flash drive or print file to an approved printer

SYSTEM ESSENTIAL SPECIFICATIONS

Monitor	Single-board computer system with graphical display and touch screen running custom data acquisition/control software • USB connector for connecting flash drive to download patient data and for software updates • Runs off DC power through a 100-240 VAC 50/60 Hz external AC/DC medical grade power supply with 12VDC output • Contains rechargeable Lithium-Ion battery with 3 hour runtime • Includes bracket connection to support pole mount adapter and has the ability to stand upright on a flat surface (e.g. tabletop) • Isolates all connections to patient-contacting parts to Type CF, heart-connected device, per IEC 60601-1 • Connects to Patient ECG Cable - connects to the three snap leads Remote Control Cable - connects to the ECG Clip Cable
Remote Control Cable (Reusable)	• Once placed within the sterile cable cover, the Remote Control Cable connects aseptically to the ECG Clip Cable which connects to the catheter stylet. • Two cable connections; one to the Monitor, one to the ECG Clip Cable • Three control buttons with icons: left arrow, enter, and right arrow. The buttons allow the user to scroll through and select menu icons on Monitor
ECG Patient Cable (Reusable)	• Connects the Monitor to the ECG Snap Leads • Sockets are compliant to DIN 42-802 and colored-coded per ANSI/AAMI EC53 - *White [RA], Black [LA] and Red [LL]*
ECG Clip Cable (Single-use)	Alligator style clip for connection to stylet wire and a stereo plug for connection to the Remote Control Cable
ECG Snap Leads (Reusable)	• Set of three, 24" long, ECG snap leads • Snap lead pin connections are compliant to DIN 42-802 and colored-coded per ANSI/AAMI EC53 - *White [RA], Black [LA] and Red [LL]* • Snap Leads connect to ECG Adhesive Electrodes (Pads) placed on the patient's chest

AVAILABLE CONFIGURATIONS

The PICC Tip Positioning Aid

Monitor, ECG Patient Cable, Remote Control Cable, Battery, Power Supply, Power Cord, and commercially available ECG Snap Leads

ECG Accessory Kits

Non-Sterile Single-Use Kit: ECG Adhesive Electrodes, ECG Prep Pads

PICC Kit (Optional)

The ECG Clip Cable and Cable Cover may be placed within a PICC kit configuration with the non-sterile single-use kit attached in tandem outside the sterile barrier of the PICC tray.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Sterile Single-Use Kit: Cable Cover, ECG Clip Cable

Replacement Parts

Individual System Components can be ordered as replacement parts, such as ECG Patient Cable, Remote Control Cable, ECG Snap Leads, Battery, Power Supply, Power Cord. These individual system components have all been 510(k) cleared by the FDA. Refer to the Kit configuration Section 21.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Contains Nonbinding Recommendations

Print Form

Acceptance Checklist for Traditional 510(k)s

(Should be completed within 15 days of DCC receipt)

The following information is not intended to serve as a comprehensive review.

510(k) #: K152261 Date Received by DCC: Aug 19, 2015

Lead Reviewer: LCDR Keith Marin

Branch: GHDB Division: DAGRID Center/Office: CDRH/ODE

Note: If an element is left blank on the checklist, it does not mean the checklist is incomplete. It means the reviewer did not assess the element during RTA and the element will be assessed during the substantive review.

Preliminary Questions Answers in the shaded blocks indicate consultations with Center advisor is needed	Yes	No
1) Is the product a device (per section 201(h) of the FD&C Act) or a combination product (per 21 CFR 3.2(e)) with a device constituent part subject to review in a 510(k)? If it appears not to be a device (per section 201(h) of the FD&C Act) or such a combination product, or you are unsure, consult with the CDRH Jurisdictional Officer or the CBER Office Jurisdiction Liaison to determine the appropriate action, and inform division management. *Provide a summary of the Jurisdictional Officer's/Liaison's determination.* If the product does not appear to be a device or such a combination product, mark "No."	X	
Comments?		
2. Is the application with the appropriate Center? If the product is a device or a combination product with a device constituent part, is it subject to review by the Center in which the submission was received? If you believe the application is not with the appropriate Center or you are unsure, consult with the CDRH Jurisdictional Officer or CBER Office Jurisdiction Liaison to determine the appropriate action and inform your division management. *Provide a summary of the Jurisdictional Officer's/Liaison's determination.* If application should not be reviewed by your Center mark "No."	X	
Comments?		
3) If a Request for Designation was submitted for the device or combination product with a device constituent part and assigned to your center, identify the RFD # and confirm the following: a) Is the device or combination product the same (e.g., design, formulation) as that presented in the RFD submission? b) Are the indications for use for the device or combination product identified in the 510(k) the same as those identified in the RFD submission ? If you believe the product or the indications presented in the 510(k) have changed from the RFD, or you are unsure, consult with the CDRH Jurisdictional Officer or appropriate CBER Jurisdiction Liaison to determine the appropriate action and inform your division management. Provide summary of Jurisdictional Officer's/Liaison's determination. If the answer to either question is no, mark "No." If there was no RFD, skip this question.		
Comments?		
4) Is this device type eligible for a 510(k) submission? If a 510(k) does not appear to be appropriate (e.g., Class III type and PMA required, or Class I or II type and 510(k)-exempt), you should consult with the CDRH 510(k) Program Director or appropriate CBER staff during the acceptance review. If 510(k) is not the appropriate regulatory submission, mark "No."	X	
Comments?		

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5) Is there a pending PMA for the same device with the same indications for use? If yes, consult division management and the CDRH 510(k) Program Director or appropriate CBER staff to determine the appropriate action.		X
Comments?		
6) If clinical studies have been submitted, is the submitter the subject of an Application Integrity Policy (AIP)? If yes, consult with the CDRH Office of Compliance/Division of Bioresearch Monitoring (OC/DBM - BIMO) or CBER Office of Compliance and Biologics Quality/Division of Inspections and Surveillance/Bioresearch Monitoring Branch (OCBQ/DIS/BMB) to determine the appropriate action. Check on web at http://www.fda.gov/ICECI/EnforcementActions/ApplicationIntegrityPolicy/ucm134453.htm		
Comments?		

If the answer to 1 or 2 appears to be "No," then stop review of the 510(k) and issue the "Original Jurisdictional Product" letter.
If the answer to 3a or 3b appears to be "No," then stop the review and contact the CDRH Jurisdictional Officer or CBER Office of Jurisdiction Liaison.
If the answer to 4 is "No," the lead reviewer should consult division management and other Center resources to determine the appropriate action.
If the answer to 5 is "Yes," then stop review of the 510(k), contact the CDRH 510(k) Staff and PMA Staff, or appropriate CBER staff.
If the answer to 6 is "Yes," then contact CDRH/OC/DBM-BIMO or CBER/OCBQ/DIS/BMB, provide a summary of the discussion with the BIMO Staff, and indicate BIMO's recommendation/action.

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Organizational Elements

Failure to include these items alone generally should not result in an RTA designation.

	Yes	No
1) Submission contains a Table of Contents	X	
2) Each section is labeled (e.g., headings or tabs designating Device Description section, Labeling section, etc.)	X	
3) All pages of the submission are numbered.	X	
4) Type of 510(k) is identified (i.e., traditional, abbreviated, or special)	X	
Comments?		

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Elements of a Complete Submission (RTA Items)

(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

- Any "No" answer will result in a "Refuse to Accept" decision. - Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.	Yes	No	N/A	Comment
A. Administrative				
1) All content used to support the submission is written in English (including translations of test reports, literature articles, etc.)	X			
2) Submission identifies the following (such as in CDRH Premarket Review Submission Cover Sheet (Form 3514) or 510(k) cover letter):	X			
a) Device trade name or proprietary name	X			
b) Device common name	X			
c) Device class and panel or Classification regulation or Statement that device has not been classified with rationale for that conclusion	X			
3) Submission contains Indications for Use Statement with Rx and/or OTC designation (see also 21 CFR 801.109).	X			
4) Submission contains 510(k) Summary or 510(k) Statement	X			
a) Summary contains all elements per 21 CFR 807.92 *(See also* 510(k) Summary Checklist)	X			
b) Statement contains all elements per 21 CFR 807.93			X	
5) Submission contains Truthful and Accuracy Statement per 21 CFR 807.87(k) *See recommended* format.	X			
6) Submission contains Class III Summary and Certification. *See recommended* content.	X			
7) Submission contains clinical data			X	
8) If submission references use of a national or international standard as part of demonstration of substantial equivalence, submission contains Standards Data Report for 510(k)s (Form 3654) or includes detailed information about how and the extent to which the standard has been followed.	X			
9) The submission identifies prior submissions for the same device for which FDA provided feedback related to the data or information needed to support substantial equivalence (e.g., submission numbers for Pre-Submission, IDE, prior not substantially equivalent (NSE) determination, prior 510(k) that was deleted or withdrawn) or states that there were no prior submissions for the subject device.	X			X
a) If there were prior submissions, the submitter has identified where in the current submission any issues related to a determination of substantial equivalence outlined in prior communications are addressed. For additional information regarding the Pre-Submission process, please refer to the Draft Guidance "Medical Devices: The Pre-Submission Program and Meetings with FDA Staff." Once finalized, this guidance will represent the Agency's current thinking on this topic.	X			
Comments?	**(b)(4) Deficiencies**			
B. Device Description				
10)	Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118			

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a) If there are requirements regarding the device description, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes device description information to establish that the submitter has followed the device-specific requirement.			X	
b) If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes device description information to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach.			X	
11) Descriptive information is present and consistent within the submission (e.g., the device description section is consistent with the device description in the labeling), including:				
a) A description of the principle of operation and mechanism of action for achieving the intended effect.	X			
b) A description of proposed conditions of use, such as surgical technique for implants; anatomical location of use; user interface; how the device interacts with other devices; and/or how the device interacts with the patient.	X			
c) A list and description of each device for which clearance is requested.	X			
12) Submission contains representative engineering drawing(s), schematics, illustrations and/or figures of the device that are clear, legible, labeled, and include dimensions.	X			
13) If device is intended to be marketed with multiple components, accessories, and/or as part of a system				
a) Submission includes a list of all components and accessories to be marketed with the subject device.	X			
b) Submission includes a description (as detailed in item 11(a) and (b) and 12 above) of each component or accessory.	X			
c) A 510(k) number is provided for each component or accessory that received a prior 510(k) clearance.	X			
C. Substantial Equivalence Discussion				
14) Submitter has identified a predicate device.	X			
a) Predicate's 510(k) number, trade name, and model number (if applicable) provided. For predicates that are preamendments devices, information is provided to document preamendments status. *Information regarding documenting preamendment status is available online.*	X			
b) The identified predicate(s) is consistent throughout the submission (i.e., the predicate(s) identified in the Substantial Equivalence section is the same as that listed in the 510(k) Summary (if applicable) and that used in comparative performance testing.	X			
15) Submission includes a comparison of the following for the predicate(s) and subject device				
a) Indications for Use	X			
b) Technology, including features, materials, and principles of operation	X			

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(21 CFR 807.87 unless otherwise indicated)

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

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16) Submission includes an analysis of why any differences between the subject device and predicate(s) do not render the device NSE (e.g., does not constitute a new intended use; and any differences in technological characteristics are accompanied by information that demonstrates the device is as safe and effective as the predicate and do not raise different questions of safety and effectiveness than the predicate), affect safety or effectiveness, or raise different questions of safety and effectiveness (see section 513(i)(1)(A) of the FD&C Act and 21 CFR 807.87(f))	X			
D. Proposed Labeling (see also 21 CFR part 801)				
If *in vitro* diagnostic (IVD) device, criteria 17 & 19 may be omitted.				
17) Submission includes proposed package labels and labeling (e.g., instructions for use, package insert, operator's manual) that include a description of the device, its intended use, and the directions for use.	X			
a) Indications for use are stated in labeling and are identical to Indications for Use form and 510(k) Summary (if 510(k) Summary provided).	X			
b) Submission includes directions for use that - include statements of all conditions, purposes or uses for which the device is intended (e.g., hazards, warnings, precautions, contraindications) AND - includes directions for layperson (see 21 CFR 801.5) OR submission states that device qualifies for exemption per 21 CFR 801 Subpart D	X			
18) If indicated for prescription use, labeling includes the prescription use statement (see 21 CFR 801.109(b)(1)) or "Rx only" symbol [See also Alternative to Certain Prescription Device Labeling Requirements]	X			
19) General labeling provisions				
a) Labeling includes name and place of business of the manufacturer, packer, or distributor (21 CFR 801.1).	X			
b) Labeling includes device common or usual name. (21 CFR 801.61)	X			
20)				
a) If there are requirements regarding labeling, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes labeling to establish that the submitter has followed the device-specific requirement.			X	
b) If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes labeling to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach.			X	
c) If there is a special controls document applicable to the device, the submission includes labeling to establish that the submitter has complied with the particular mitigation measures set forth in the special controls document or uses alternative mitigation measures but provides a rationale to demonstrate that those alternative measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness.			X	
21) If the device is an in vitro diagnostic device, provided labeling includes all applicable information required per 21 CFR 809.10			X	

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E. Sterilization				
If IVD device and sterilization is not applicable, select "N/A" and criteria below will be omitted from checklist.			X	
Submission states that the device and/or accessories are: (one of the below must be checked)				
X provided sterile				
provided non-sterile but sterilized by the end user				
non-sterile when used				
Information regarding the sterility status of the device is not provided.				
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.				
Comments? **(b)(4) Deficiencies**				
22) Assessment of the need for sterilization information				
a) Identification of device, and/or accessories, and/or components that are provided sterile.	X			
b) Identification of device, and/or accessories, and/or components that are end user sterilized.	X			
c) Identification of device, and/or accessories, and/or components that are reusable and cleaning /disinfection instructions are provided.	X			
23) If the device, and/or accessory, and/or a component is provided sterile:				
a) Sterilization method is stated for each component (including parameters such as dry time for steam sterilization, radiation dose, etc.).	X			
b) A description of method to validate the sterilization parameters (e.g., half-cycle method and full citation of FDA-recognized standard, including date) is provided for each proposed sterilization method. *Note, the sterilization validation report is not required.*	X			
c) For devices sterilized using chemical sterilants such as ethylene oxide (EO) and hydrogen peroxide, submission states maximum levels of sterilant residuals remaining on the device and sterilant residual limits.	X			
d) Submission includes description of packaging and packaging contents (e.g., if multiple devices are included within the same package, Tyvek packaging, etc.)	X			
e) Sterility Assurance Level (SAL) is stated.	X			
24) If the device, and/or accessory, and/or a component is end user sterilized:			X	
25)				

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Elements of a Complete Submission (RTA Items)

(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

- Any "No" answer will result in a "Refuse to Accept" decision. - Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.	Yes	No	N/A	Comment
a) If there are requirements regarding sterility, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes sterility information to establish that the submitter has followed the device-specific requirement.			X	
b) If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes sterility information to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach.			X	
c) If there is a special controls document applicable to the device, the submission includes sterility information to establish that the submitter has complied with the particular mitigation measures set forth in the special controls document or uses alternative mitigation measures but provides a rationale to demonstrate that those alternative measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness.			X	
F. Shelf Life				
26) Proposed shelf life/expiration date stated	X			X
Comments? **(b)(4) Deficiencies**				
27) For sterile device, submission includes summary of methods used to establish that device will remain sterile through the proposed shelf life or a rationale for why testing to establish shelf life is not applicable.	X			
28) Submission includes summary of methods used to establish that device performance is not adversely affected by aging or includes a rationale for why the storage conditions are not expected to affect device safety or effectiveness.	X			
G. Biocompatibility				
If IVD device, select "N/A" and the below criteria will be omitted from checklist.				X
Submission states that there: (one of the below must be checked)				
X are direct or indirect (e.g., through fluid infusion) patient-contacting components.				
are no direct or indirect (e.g., through fluid infusion) patient-contacting components.				
Information regarding the patient contact status of the device is not provided.				
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.				
Comments? **(b)(4) Deficiencies**				
29) Submission includes list of patient-contacting device components and associated materials of construction, including identification of color additives, if present	X			

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2022-4772, Released by CDRH on 05-31-2024

Elements of a Complete Submission (RTA Items)

(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

- Any "No" answer will result in a "Refuse to Accept" decision. - Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.	Yes	No	N/A	Comment
30) Submission identifies contact classification (e.g., surface-contacting, less then 24 hour duration, etc.)	X			
31) Biocompatibility assessment of patient-contacting components Submission includes: Test protocol (including identification and description of test article), methods, pass/fail criteria, and results provided for each completed test, OR a statement that biocompatibility testing is not needed with a rationale (e.g., materials and manufacturing/processing are identical to the predicate).	X			
H. Software				X

Submission states that the device: (one of the below must be checked)	
X	does contain software/firmware.
	does not contain software/firmware.
	Information regarding whether the device contains software is not provided.
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.	

Comments? **(b)(4) Deficiencies**

32) Submission includes a statement of software level of concern and rationale for the software level of concern.	X			
33) All applicable software documentation provided based on level of concern identified by the submitter, as described in Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, or the submitter has provided an alternative approach with a rationale.	X			
I. EMC and Electrical Safety				X

Submission states that the device: (one of the below must be checked)	
X	does require EMC and Electrical Safety evaluation.
	does not require EMC and Electrical Safety evaluation.
	Information regarding whether the device requires EMC and Electrical Safety evaluation is not provided.
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.	

Comments? **(b)(4) Deficiencies**

Records processed under FOIA Request 2022-4772, Released by CDRH on 05-31-2024

Elements of a Complete Submission (RTA Items)

(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

- Any "No" answer will result in a "Refuse to Accept" decision. - Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.	Yes	No	N/A	Comment
34) Submission includes evaluation of electrical safety (e.g., per IEC 60601-1, or equivalent FDA-recognized standard, and if applicable, the device-specific standard), OR submission includes electrical safety evaluation using methods or standards that are not FDA-recognized and submission includes information to establish that the submitter has otherwise met the applicable statutory or regulatory criteria through this alternative approach (i.e., the submitter has identified alternate methods or standards with a rationale).	X			
35) Submission includes evaluation of electromagnetic compatibility (e.g., per IEC 60601-1-2 or equivalent FDA-recognized standard and if applicable, the device-specific standard) OR submission includes electromagnetic compatibility evaluation using methods or standards that are not FDA-recognized and submission includes information to establish that the submitter has otherwise met the applicable statutory or regulatory criteria through this alternative approach (i.e., the submitter has identified alternate methods or standards with a rationale).	X			
J. Performance Data - General If IVD device, select "N/A" and the below criteria will be omitted from checklist. Performance data criteria relating to IVD devices will be addressed in Section K.				
36) Full test report is provided for each completed test. A full test report includes: objective of the test, description of the test methods and procedures, study endpoint(s), pre-defined pass/fail criteria, results summary, conclusions, and an explanation of how the data generated from the test supports a finding of substantial equivalence.	X			X
Comments? **(b)(4) Deficiencies**				
37)				
a) If there are requirements regarding performance data, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes performance data to establish that the submitter has followed the device-specific requirement.			X	
b) If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes performance data to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach.			X	
c) If there is a special controls document applicable to the device, the submission includes performance data to establish that the submitter has complied with the particular mitigation measures set forth in the special controls document or uses alternative mitigation measures but provides a rationale to demonstrate that those alternative measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness.			X	
38) If literature is referenced in the submission, submission includes:			X	
39) For each completed nonclinical (i.e., animal) study conducted			X	

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2022-4772, Released by CDRH on 05-31-2024

Elements of a Complete Submission (RTA Items)
(21 CFR 807.87 unless otherwise indicated)

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- Any "No" answer will result in a "Refuse to Accept" decision. - Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.	Yes	No	N/A	Comment
K. Performance Characteristics - In Vitro Diagnostic Devices Only **(Also see 21 CFR 809.10(b)(12))**				
Submission states that the device: (one of the below must be checked)				
	is an in vitro diagnostic device.			
X	is not an in vitro diagnostic device.			

Records processed under FOIA Request 2022-4717; Released by CDRH on 05-31-2024

Decision: (•) Accept ( ) Refuse to Accept

If Accept, notify applicant.

If Refuse to Accept, notify applicant in writing and include a copy of this checklist.

Digital Signature Concurrence Table

Reviewer Sign-Off	Keith G. Marin -S Digitally signed by Keith G. Marin -S DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Keith G. Marin -S, 0.9.2342.19200300.100.1.1=0011250397 Date: 2015.08.19 14:11:49 -04'00'
Branch Chief Sign-Off (digital signature optional)*	
Division Sign-Off (digital signature optional)*	

* Branch and Division review of checklist and concurrence with decision required. Branch and Division digital signature optional.

Records processed under FOIA Request 2022-4717; Released by CDRH on 05-31-2024

Mr. Nelson,

(b)(4) Deficiencies

Please provide this information by Wednesday August 19, 2015.

Thanks.

Keith

From: Peter Nelson [mailto:petenelson@nostix.com]
Sent: Monday, August 17, 2015 12:54 PM
To: Marin, Keith
Cc: K152261@docs.fda.gov; Chapman, Richard; 'Charles Henry'; salusventures@aol.com
Subject: RE: (b)(4) Deficiencies - attached

Keith,

(b)(4) Deficiencies

Thanks,
Peter

Peter Nelson
Director of Engineering
Nostix
5541 Central Ave, Suite 170
Boulder, CO 80301
Ph: 303-245-8895 ext. 3#
Fax: 303-245-8909

From: Marin, Keith [mailto:Keith.Marin@fda.hhs.gov]
Sent: Monday, August 17, 2015 10:01 AM
To: petenelson@nostix.com
Cc: K152261@docs.fda.gov; Chapman, Richard
Subject: Letter of authorization

Mr. Nelson,

(b)(4) Deficiencies

Thanks.

Keith Marin

Keith Marin, RN, MS, MBA, OCN, RAC
Lieutenant Commander, United States Public Health Service
General Hospital Devices Combination Product Team Lead / Nurse Consultant
FDA/CDRH/ODE/DAGRID/GHDB
10903 New Hampshire Avenue, WO66-2567
Silver Spring, MD, 20993-0002
Telephone: (301) 796-2462, Fax: (301) 847-8109

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2022-4717; Released by CDRH on 05-31-2024

Peter,

I have another question:

(b)(4) Deficiencies

From: Peter Nelson [mailto:petenelson@nostix.com]

Sent: Friday, September 04, 2015 11:34 AM

To: Marin, Keith

Cc: Chapman, Richard; K152261@docs.fda.gov; 'Charles Henry'; salusventures@aol.com

Subject: RE: additional questions -- (b)(4) Deficiencies attached

Keith,

(b)(4) Deficiencies

Thanks,

Peter

Peter Nelson

R&D Manager

Nostix

5541 Central Ave, Suite 170

Boulder, CO 80301

Ph: 303-245-8895 ext. 3#

Fax: 303-245-8909

From: Marin, Keith [mailto:Keith.Marin@fda.hhs.gov]

Sent: Thursday, September 03, 2015 9:39 AM

To: Peter Nelson

Cc: Chapman, Richard; K152261@docs.fda.gov<mailto:K152261@docs.fda.gov>

Subject: additional questions

Peter,

(b)(4) Deficiencies

Thanks.

Keith

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Sent: Monday, August 17, 2015 12:54 PM

To: Marin, Keith

Cc: K152261@docs.fda.gov<mailto:K152261@docs.fda.gov>; Chapman, Richard; 'Charles Henry'; salusventures@aol.com<mailto:salusventures@aol.com>

Subject: RE: (b)(4) Deficiencies - attached

Keith,

(b)(4) Deficiencies

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Peter

Peter Nelson

Director of Engineering

Nostix

5541 Central Ave, Suite 170

Boulder, CO 80301

Ph: 303-245-8895 ext. 3#

Fax: 303-245-8909

From: Marin, Keith [mailto:Keith.Marin@fda.hhs.gov]

Sent: Monday, August 17, 2015 10:01 AM

To: petenelson@nostix.com<mailto:petenelson@nostix.com>

Cc: K152261@docs.fda.gov<mailto:K152261@docs.fda.gov>; Chapman, Richard

Subject: (b)(4) Deficiencies

Mr. Nelson,

(b)(4) Deficiencies

Thanks.

Keith Marin

Keith Marin, RN, MS, MBA, OCN, RAC

Lieutenant Commander, United States Public Health Service

General Hospital Devices Combination Product Team Lead / Nurse Consultant

FDA/CDRH/ODE/DAGRID/GHDB

10903 New Hampshire Avenue, WO66-2567

Silver Spring, MD, 20993-0002

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Nostix

PREMARKET NOTIFICATION

TRADITIONAL 510(K)

PICC TIP POSITIONING AID

7 August 2015

Confidential and Proprietary to Nostix LLC

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Subject: RE: additional questions -- (b)(4) Deficiencies attached

Keith,

(b)(4) Deficiencies

Thanks,
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Peter Nelson
R&D Manager
Nostix
5541 Central Ave, Suite 170
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Ph: 303-245-8895 ext. 3#
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Director of Engineering
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Sent: Monday, August 17, 2015 10:01 AM
To: petenelson@nostix.com
Cc: K152261@docs.fda.gov; Chapman, Richard
Subject: Letter of authorization

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Mr. Nelson,

(b)(4) Deficiencies

Thanks.

Keith Marin

Keith Marin, RN, MS, MBA, OCN, RAC
Lieutenant Commander, United States Public Health Service
General Hospital Devices Combination Product Team Lead / Nurse Consultant
FDA/CDRH/ODE/DAGRID/GHDB
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Records processed under FOIA Request 2022-4717; Released by CDRH on 05-31-2024

Mr. Marin

(b)(4) Deficiencies

Thank you.

--

Jim Lewis

--

For Nosix LLC, Boulder, Colorado, USA

303 945 5675; salusventures@aol.com

-----Original Message-----

From: Marin, Keith <Keith.Marin@fda.hhs.gov>

To: Peter Nelson <petenelson@nostix.com>

Cc: K152261 <K152261@docs.fda.gov>; Chapman, Richard <Richard.Chapman@fda.hhs.gov>; 'Charles Henry' <cwh@nostix.com>; salusventures <salusventures@aol.com>; McCabe-Janicki, Margaret <Margaret.McCabe@fda.hhs.gov>

Sent: Mon, Aug 17, 2015 11:50 am

Subject: **(b)(4) Deficiencies**

Mr. Nelson,

(b)(4) Deficiencies

Please provide this information by Wednesday August 19, 2015.

Thanks.

Keith

From: Peter Nelson [mailto:petenelson@nostix.com]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Cc: K152261@docs.fda.gov; Chapman, Richard; 'Charles Henry'; salusventures@aol.com

Subject: RE: (b)(4) Deficiencies -- attached

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(b)(4) Deficiencies

Thanks,

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Peter Nelson

Director of Engineering

Nostix

5541 Central Ave, Suite 170

Boulder, CO 80301

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Fax: 303-245-8909

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Cc: K152261@docs.fda.gov; Chapman, Richard

Subject: (b)(4) Deficiencies

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(b)(4) Deficiencies

Thanks.

Keith Marin

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FDA/CDRH/ODE/DAGRID/GHDB

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Silver Spring, MD, 20993-0002

Telephone: (301) 796-2462, Fax: (301) 847-8109

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DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

October 21, 2015

Nostix LLC
c/o Mr. Jim Lewis
Salus Ventures LLC
5335 Holmes Place
Boulder, Colorado, 80303

Re: K152261
Trade/Device Name: PICC Tip Positioning Aid
Regulation Number: 21 CFR 880.5970
Regulation Name: Percutaneous, implanted, long-term intravascular catheter
Regulatory Class: II
Product Code: LJS
Dated: August 7, 2015
Received: August 11, 2015

Dear Mr. Lewis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2022-4717; Released by CDRH on 05-31-2024

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2022-4717; Released by CDRH on 05-31-2024

DEPARTMENT OF HEALTH AND HUMAN SERVICES **M E M O R A N D U M**

Food and Drug Administration
Office of Device Evaluation
10903 New Hampshire Ave.
Silver Spring, MD 20993

Premarket Notification [510(k)] Review
Traditional
K152261

Date: September 29, 2015

To: The Record
From: Keith Marin

Office: Office of Device Evaluation
Division: DAGRID

510(k) Holder: Nostix LLC
Device Name: PICC Tip Positioning Aid
Contact: Peter Nelson
Address: Nostix, LLC
5541 Central Av, Suite 170
Boulder, CO 80301
Phone: 303-245-8895
Fax: 303-245-8909
Email: petenelson@nostix.com

Dated: August 7, 2015
Received: August 11, 2015

Regulation Number: 21 CFR 880.5970
Regulation Name: Percutaneous, implanted, long-term intravascular catheter
Regulatory Class: Class II
Product Code: LJS
Classification Panel: General Hospital (HO)

(b)(5)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2022-4717; Released by CDRH on 05-31-2024

(b)(5) FDA Reviewer Notes

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2022-4717; Released by CDRH on 05-31-2024

(b)(5) FDA Reviewer Notes

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Records processed under FOIA Request 2022-4717; Released by CDRH on 05-31-2024

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Records processed under FOIA Request 2022-4717; Released by CDRH on 05-31-2024

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Records processed under FOIA Request 2022-4717; Released by CDRH on 05-31-2024

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(b)(5) FDA Reviewer Notes

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2022-4717; Released by CDRH on 05-31-2024

(b)(5) FDA Reviewer Notes

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(b)(5) FDA Reviewer Notes

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(b)(5) FDA Reviewer Notes

Digital Signature Concurrence Table	
Reviewer Sign-Off	Keith G. Marin -S Digitally signed by Keith G. Marin -S DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Keith G. Marin -S, 0.9.2342.19200300.100.1.1=0011250397 Date: 2015.09.29 15:29:07 -04'00'

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Keith,

(b)(4) Deficiencies

Regards,
Peter

From: Marin, Keith [mailto:Keith.Marin@fda.hhs.gov]
Sent: Monday, September 21, 2015 11:22 AM
To: Peter Nelson
Cc: Chapman, Richard; K152261@docs.fda.gov; 'Charles Henry'; salusventures@aol.com
Subject: RE: additional questions -- (b)(4) Deficiencies attached

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Peter Nelson
R&D Manager
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Ph: 303-245-8895 ext. 3#
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Peter Nelson
Director of Engineering
Nostix

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Subject: (b)(4) Deficiencies

Mr. Nelson,

(b)(4) Deficiencies

Thanks.

Keith Marin

Keith Marin, RN, MS, MBA, OCN, RAC
Lieutenant Commander, United States Public Health Service
General Hospital Devices Combination Product Team Lead / Nurse Consultant
FDA/CDRH/ODE/DAGRID/GHDB
10903 New Hampshire Avenue, WO66-2567
Silver Spring, MD, 20993-0002
Telephone: (301) 796-2462, Fax: (301) 847-8109

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2022-4717; Released by CDRH on 05-31-2024

SECTION 5 510(k) SUMMARY

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2022-4717; Released by CDRH on 05-31-2024

Nostix

510(k) Summary

Prepared: 21 September 2015

Submitter

Company	Nostix LLC 5541 Central Av, Suite 170 Boulder, CO 80301
Tel	303 245 8895
Fax	303 245 8909
Contact	Pete Nelson Director of Engineering petenelson@nostix.com

Device

Trade Name	PICC Tip Positioning Aid
Common Name	PICC placement accessory
Class Name	Percutaneous, implanted, long-term intravascular catheter
Product Code	LJS
Regulation	21 CFR 880.5970
Class	2

Predicate

Trade Name	Celerity System
Clearance	K142889, 27 January 2015
Common Name	PICC placement accessory
Class Name	Percutaneous, implanted, long-term intravascular catheter
Product Code	LJS
Regulation	21 CFR 880.5970
Class	2

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Device Description

The PICC Tip Positioning Aid includes a standalone Monitor containing software, battery and power cord accompanied by an ECG Patient Cable, a Remote Control Cable, probe cover and ECG Clip Cable.

Other procedural accessories; including ECG Snap Leads, ECG Surface Electrodes, Cable Cover, Gloves and Prep Pads; may be provided as a convenience for the clinician but are not in the scope of this submission.

Intended Use

The PICC Tip Positioning Aid is intended to provide real time tip location information of a central venous catheter by utilization of ECG to observe P-wave changes as the tip approaches the right atrium of the heart via the superior vena cava.

Indications for Use

The PICC Tip Positioning Aid is indicated for the positioning of Peripherally Inserted Central Catheters (PICC) in adult patients. It provides real-time catheter tip location information by using the patient's cardiac electrical activity. The PICC Tip Positioning Aid is indicated for use as an alternative method to chest x-ray or fluoroscopy confirmation of PICC tip placement in adult patients.

Note: In general, devices that utilize ECG technique to observe P-Wave arc limited, but not contraindicated, for patients where cardiac rhythms may change presentation of the P-Wave; including

- Atrial fibrillation
- Atrial flutter
- Severe tachycardia
- Pacemaker-driven rhythm
- Chronic obstructive pulmonary disease (COPD)

Such patients are easily identified prior to PICC insertion. Use of an additional confirmation method is necessary to confirm catheter tip location.

Technological Characteristics

Technological Characteristics of the subject PICC Tip Positioning Aid are identical to the predicate device. The name and address changes on the labels between the predicate and proposed devices do not raise new technological questions.

Performance Data

As the only differences between the device and its predicate are names, logos, and addresses in the labeling, the following recognized standards from the IEC 60601 (3rd Edition) series continue to be satisfied.

IEC 60601-1-1	Medical electrical equipment—Part 1-1: General requirements for safety—Collateral standard: Safety requirements for medical electrical systems

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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IEC 60601-1-2 Medical electrical equipment—Part 1-2: General requirements for basic safety and essential performance—Collateral standard: Electromagnetic compatibility – Requirements and tests

Human Factors Evaluation - Simulated Use Testing alternate to chest x-ray and fluoroscopy:

Simulated Use / Human Factors Testing has been conducted to evaluate the application of the PICC Tip Placement Aid as embodied in the predicate Celerity System when used to confirm PICC tip position as an alternative method to chest X-ray or fluoroscopy confirmation. The use related events noted in the studies have been adequately reviewed and addressed in order to ensure the safe, effective use of the device as an alternate to x-ray techniques for confirmation of tip location of PICC.

Based on the content of the proposed PICC Tip Positioning Aid's Risk Analysis / Use and Design FMEAs, and the content of the Instructions for Use, the PICC Tip Positioning Aid has demonstrated its suitability for its intended purpose.

Substantial Equivalence Conclusion

As this device design and manufacturing are the same as the predicate except for name changes to the device and the manufacturer, the device is clearly equivalent to its predicate.

The proposed device is clearly substantially equivalent to the predicate device based on identical:

- Intended Use
- Indications for Use
- Design
- Production
- Operating principles, characteristics, and user interface
- Technology and specifications
- Labeling

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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SECTION 5 510(k) SUMMARY

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Nostix

510(k) Summary

(b)(4) Draft

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Nostix

Nostix
5541 Central Ave, Suite 170
Boulder, CO 80301
tel 303-245-8895
fax 303-245-8909

Subject: Letter of Certification

To: Keith Marin
Lieutenant Commander, United States Public Health Service
FDA/CDRH/ODE/DAGRID/GHDB
Silver Springs, MD 20993

From: Charles Henry

Date: 4 Sept. 2015

cc: Jim Lewis, Peter Nelson

Nostix declares, under its sole responsibility, that the product

PICC Tip Positioning Aid

(b)(4)

(b)(6)

Charles Henry
President

Sept 4, 2015
Date of Issue

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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SECTION 8 FINANCIAL CERTIFICATION/DISCLOSURE STATEMENT

There were **NO** clinical trials conducted in support of this submission.

Therefore, ***NO FINANCIAL CERTIFICATION/DISCLOSURE STATEMENT*** is required.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Peter,

(b)(4) Deficiencies

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(b)(4) Deficiencies

Thanks.

Keith Marin

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Lieutenant Commander, United States Public Health Service
General Hospital Devices Combination Product Team Lead / Nurse Consultant
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Silver Spring, MD, 20993-0002
Telephone: (301) 796-2462, Fax: (301) 847-8109

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SECTION 5 510(k) SUMMARY

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Nostix

510(k) Summary

(b)(4) Draft

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SECTION 20 PERFORMANCE TESTING –CLINICAL

No clinical testing was used to characterize the performance of this system.

This section does not apply.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2022-4717; Released by CDRH on 05-31-2024

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K152261

Device Name

PICC Tip Positioning Aid

Indications for Use *(Describe)*

The PICC Tip Positioning Aid is indicated for the positioning of Peripherally Inserted Central Catheters (PICC) in adult patients. It provides real-time catheter tip location information by using the patient's cardiac electrical activity. The PICC Tip Positioning Aid is indicated for use as an alternative method to chest x-ray or fluoroscopy confirmation of PICC tip placement in adult patients.

Note: In general, devices that utilize ECG technique to observe P-Wave are limited, but not contraindicated, for patients where cardiac rhythms may change presentation of the P-Wave; including
- Atrial fibrillation
- Atrial flutter
- Severe tachycardia
- Pacemaker-driven rhythm
- Chronic obstructive pulmonary disease (COPD)

Such patients are easily identified prior to PICC insertion. Use of an additional confirmation method is necessary to confirm catheter tip location.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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SECTION 15 BIOCOMPATIBILITY

The devices subject to this 510(k) (the Monitor, ECG Patient Cable, Remote Cable, Battery, Power Supply Cord, and ECG Clip Cable) **do not come in contact with the patient**; therefore, biocompatibility is not relevant.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Thanks.

Keith Marin

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Lieutenant Commander, United States Public Health Service

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FDA/CDRH/ODE/DAGRID/GHDB

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Silver Spring, MD, 20993-0002

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SECTION 7 CLASS III CERTIFICATION & SUMMARY STATEMENT

The proposed device has been previously classified by the FDA as:

- Class II per 21 CFR §880.5970

Therefore, ***NO Class III Certification & Summary Statement*** is required in support of this submission.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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SECTION 16 SOFTWARE INFORMATION

The only change to software from predicate to proposed device is change of tradename and manufacturer details. These changes do not affect safety or effectiveness of the device.

All data and qualifications from the submission for the predicate device apply to this submission.

(b)(4) Deficiencies

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Subject: Letter of authorization

Mr. Nelson,

(b)(4) Deficiencies

Thanks.

Keith Marin

Keith Marin, RN, MS, MBA, OCN, RAC

Lieutenant Commander, United States Public Health Service

General Hospital Devices Combination Product Team Lead / Nurse Consultant

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FDA/CDRH/OCE
FEB 23 2016
RECEIVED

Teleflex®

February 18, 2016

Teleflex Incorporated
2400 Bernville Rd
P.O. Box 12695
Reading, PA 19612 USA
Phone: 610.378.0131
Fax: 610.374.5360
www.teleflex.com

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

K152261/A002

Subject: **K152261** – ADD TO FILE: Notice of Acquisition

Dear 510(k) Staff,

The purpose of this correspondence is to provide notification of a change of ownership relating to premarket notification K152261 (PICC Tip Positioning Aid). The applicant for K152261, which received premarket substantial equivalence clearance on October 21, 2015, was Nostix, LLC ("Nostix").

On December 22, 2015, Arrow International, Inc. ("Arrow"), a wholly-owned subsidiary of Teleflex Incorporated ("Teleflex"), acquired Nostix. A copy of the press release announcing the transaction is attached for your reference. As a result of this acquisition, Nostix became a wholly-owned subsidiary of Arrow and was subsequently merged with and into Arrow. The acquisition of Nostix includes K152261.

As the new owner of K152261, Arrow has full right of reference to the file for regulatory purposes.

Included with this Add to File K152261 correspondence is an eCopy which is an exact duplicate of the hard copy original. Please feel free to contact me if you have any questions relating to this communication.

Sincerely,

(b)(6)

Karl J. Nittinger
Senior Regulatory Affairs Specialist
Phone: (610) 378-0131, ext. 603384
e-mail: karl.nittinger@teleflex.com

Enclosure

27

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Teleflex®

News Release

Teleflex Acquisition of Nostix, LLC Expands Catheter Tip Placement Solutions

Acquisition Compliments Teleflex's Existing ARROW Vascular Positioning System (VPS) to now include familiar ECG-only technology for the elimination of chest X-ray.

Additionally, an alternative system with novel navigation capability is under development.

WAYNE, Pa.--(BUSINESS WIRE)--Jan. 11, 2016-- Teleflex Incorporated (NYSE:TFX), a leading global provider of medical devices for critical care and surgery, has acquired privately held Nostix, LLC, a Boulder, Colorado developer of innovative tip confirmation systems that are used to increase the accuracy of vascular access device placement. Currently, Nostix's ECG-only system is being marketed in the United States for use in placement of peripherally inserted central catheters (PICC) and is used as an alternative to X-ray confirmation in adult patients.

"Adding the Nostix product line provides our customers with the ability to implement catheter tip placement solutions that meet their specific therapeutic and budget needs," said Benson Smith, Chairman, President and CEO of Teleflex. "The ECG-only product and the range of navigation technologies that are under development will complement our ARROW VPS G4 system by diversifying and strengthening our PICC tip confirmation and navigation portfolio and enhance our ability to meet customer needs globally. Strategically, the addition of this technology will support Teleflex's future expansion into tip confirmation for central venous catheters, chronic hemodialysis catheters and ports. We also gain access to an innovative product development pipeline, which includes integrated ultrasound capabilities that will extend our ability to offer differentiated catheter tip positioning solutions well into the future."

The financial terms of the transaction were not disclosed.

About Teleflex Incorporated

Teleflex is a global provider of medical technologies designed to improve the health and quality of people's lives. We apply purpose driven innovation – a relentless pursuit of identifying unmet clinical needs – to benefit patients and healthcare providers. Our portfolio is diverse, with solutions in the fields of vascular and interventional access, surgical, anesthesia, cardiac care, urology, emergency medicine and respiratory care. Teleflex employees worldwide are united in the understanding that what we do every day makes a difference. For more information, please visit www.teleflex.com.

Teleflex is the home of ARROW®, Deknatel®, Hudson RCI®, LMA®, Pilling®, Rüsch® and Weck® – trusted brands united by a common sense of purpose.

About Nostix, LLC

Nostix, LLC is a privately held medical technology company that develops and commercializes differentiated PICC tip placement confirmation and navigation products. It was founded in 2001 and is headquartered in Boulder, Colorado.

JMP Securities LLC served as exclusive financial advisor to Nostix in the transaction.

Forward-Looking Statements

Any statements contained in this press release that do not describe historical facts may constitute forward-looking statements. Any forward-looking statements contained herein are based on our management's current beliefs and expectations, but are subject to a number of risks, uncertainties and changes in circumstances, which may cause actual results or company actions to differ materially from what is expressed or implied by these statements. These risks and uncertainties are identified and described in more detail in our filings with the Securities and Exchange Commission, including our Annual Report on Form 10-K.

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Teleflex Incorporated
Jake Elguicze
Treasurer and Vice President, Investor Relations
610-948-2836

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Peter,

(b)(4) Deficiencies

Thanks.

Keith

From: Peter Nelson [mailto:petenelson@nostix.com]
Sent: Monday, September 21, 2015 4:58 PM
To: Marin, Keith
Cc: Chapman, Richard; K152261@docs.fda.gov; 'Charles Henry'; salusventures@aol.com
Subject: RE: additional questions -- (b)(4) Deficiencies attached

Keith,

(b)(4) Deficiencies

Thanks,
Peter

From: Marin, Keith [mailto:Keith.Marin@fda.hhs.gov]
Sent: Monday, September 21, 2015 9:05 AM
To: Peter Nelson
Cc: Chapman, Richard; K152261@docs.fda.gov; 'Charles Henry'; salusventures@aol.com
Subject: RE: additional questions -- (b)(4) Deficiencies attached
Importance: High

Peter,

(b)(4) Deficiencies

Keith

From: Peter Nelson [mailto:petenelson@nostix.com]
Sent: Friday, September 04, 2015 11:34 AM
To: Marin, Keith
Cc: Chapman, Richard; K152261@docs.fda.gov; 'Charles Henry'; salusventures@aol.com
Subject: RE: additional questions -- letter of certification attached

Keith,

(b)(4) Deficiencies

Thanks,
Peter

Peter Nelson
R&D Manager
Nostix
5541 Central Ave, Suite 170
Boulder, CO 80301
Ph: 303-245-8895 ext. 3#
Fax: 303-245-8909

From: Marin, Keith [mailto:Keith.Marin@fda.hhs.gov]
Sent: Thursday, September 03, 2015 9:39 AM
To: Peter Nelson
Cc: Chapman, Richard; K152261@docs.fda.gov
Subject: additional questions

Peter,

(b)(4) Deficiencies

Thanks.

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Keith

From: Peter Nelson [mailto:petenelson@nostix.com]
Sent: Monday, August 17, 2015 12:54 PM
To: Marin, Keith
Cc: K152261@docs.fda.gov; Chapman, Richard; 'Charles Henry'; salusventures@aol.com
Subject: RE: Letter of authorization -- attached

Keith,

(b)(4) Deficiencies

Thanks,
Peter

Peter Nelson
Director of Engineering
Nostix
5541 Central Ave, Suite 170
Boulder, CO 80301
Ph: 303-245-8895 ext. 3#
Fax: 303-245-8909

From: Marin, Keith [mailto:Keith.Marin@fda.hhs.gov]
Sent: Monday, August 17, 2015 10:01 AM
To: petenelson@nostix.com
Cc: K152261@docs.fda.gov; Chapman, Richard
Subject: Letter of authorization

Mr. Nelson,

(b)(4) Deficiencies

Thanks.

Keith Marin

Keith Marin, RN, MS, MBA, OCN, RAC
Lieutenant Commander, United States Public Health Service
General Hospital Devices Combination Product Team Lead / Nurse Consultant
FDA/CDRH/ODE/DAGRID/GHDB
10903 New Hampshire Avenue, WO66-2567
Silver Spring, MD, 20993-0002
Telephone: (301) 796-2462, Fax: (301) 847-8109

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

October 21, 2015

Nostix LLC
c/o Mr. Jim Lewis
Salus Ventures LLC
5335 Holmes Place
Boulder, Colorado, 80303

Re: K152261
Trade/Device Name: PICC Tip Positioning Aid
Regulation Number: 21 CFR 880.5970
Regulation Name: Percutaneous, implanted, long-term intravascular catheter
Regulatory Class: II
Product Code: LJS
Dated: August 7, 2015
Received: August 11, 2015

Dear Mr. Lewis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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SECTION 5 510(k) SUMMARY

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Nostix

510(k) Summary

(b)(4) Draft

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(b)(4) Draft

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(b)(4) Draft

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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SECTION 13 LABELING

PROPOSED LABELING

1. Monitor Back Panel Label
2. Monitor Box Label
3. ECG Cable Accessory Pack Box Label
4. ECG Cable Accessory Pack Pouch Label
5. ECG Electrodes and Prep Pad Box Label
6. ECG Electrodes and Prep Pad Pouch Label
7. Owners Manual
8. Accessory Pack IFU
9. ECG and Product Educational Materials

PREDICATE INFORMATION AND LABELING

1. Celerity Monoitor Back Panel Label
2. Celerity Monoitor Box Label
3. Sterile Accessory Kit Box Label
4. Sterile Accessory Kit Box Label
5. Non-Sterile Accessory Kit Box Label
6. Non-Sterile Accessory Kit Pouch Label
7. ECG Electrodes
8. Celerity Owners Manual
9. Sterile Kit Instructions for Use (IFU)
10. ECG Technique and Training Materials

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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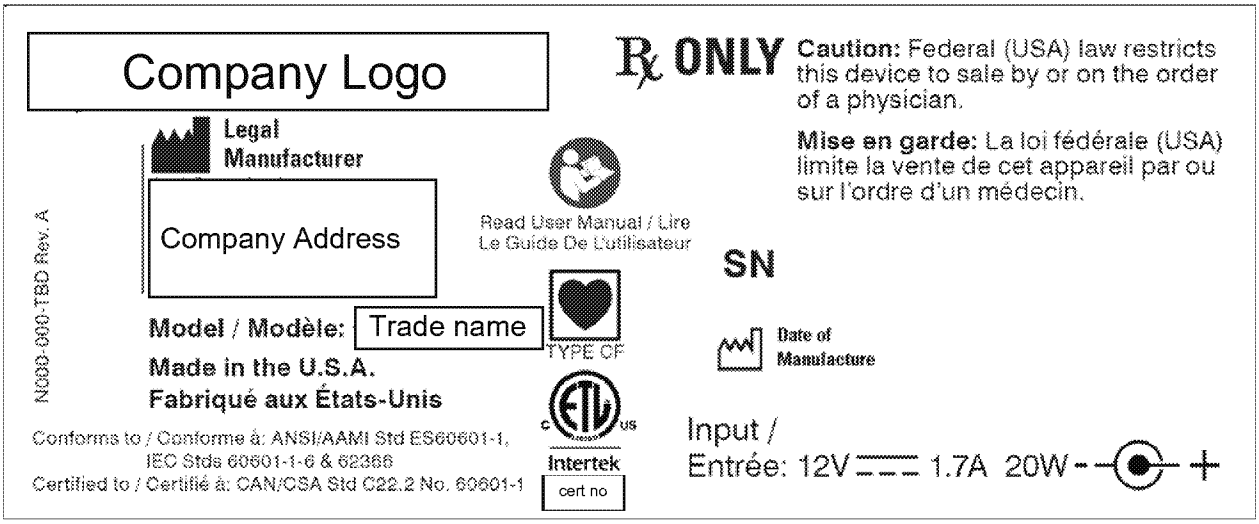
PROPOSED LABELING

1. Proposed Monitor – Back Panel Label



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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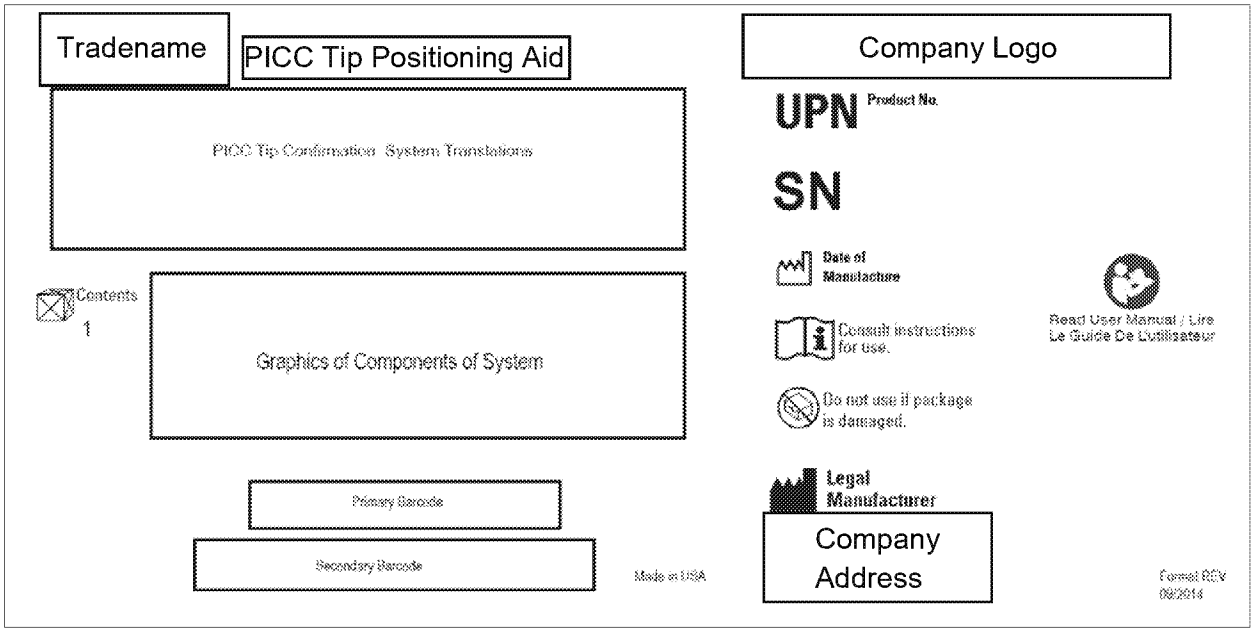
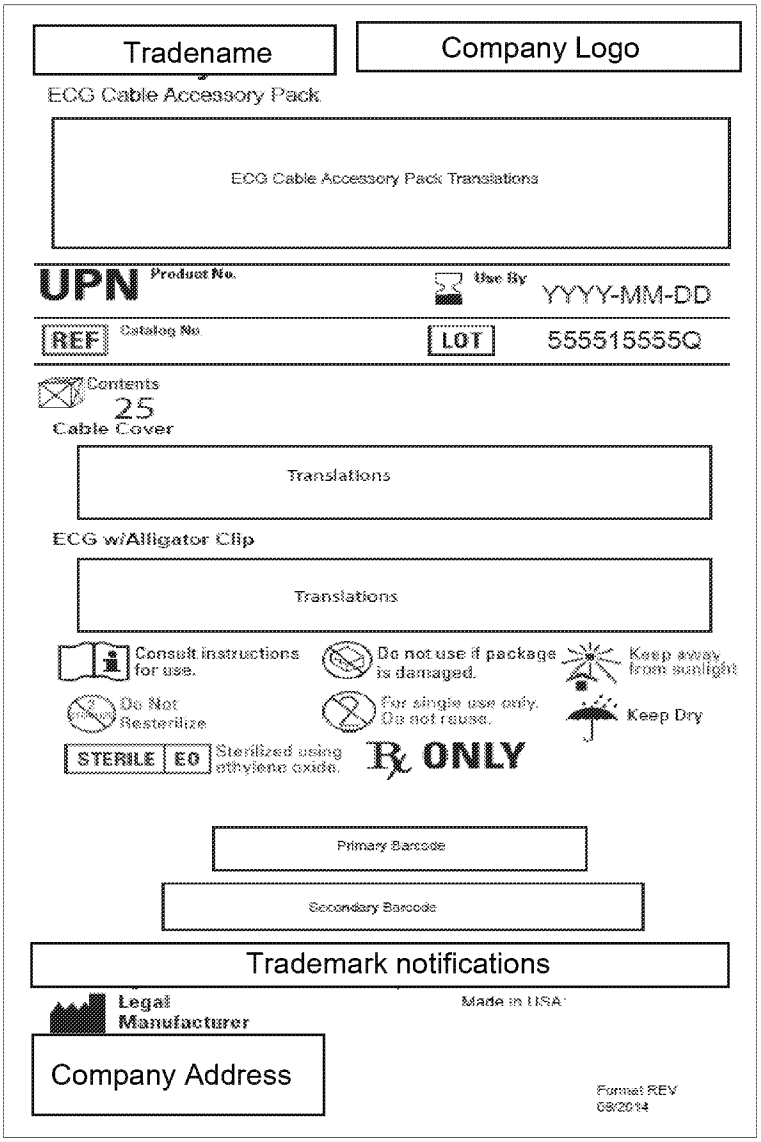
2. Proposed Monitor – Box Label



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2022-4717; Released by CDRH on 05-31-2024

3. Proposed ECG Cable Accessory Pack – Box Label



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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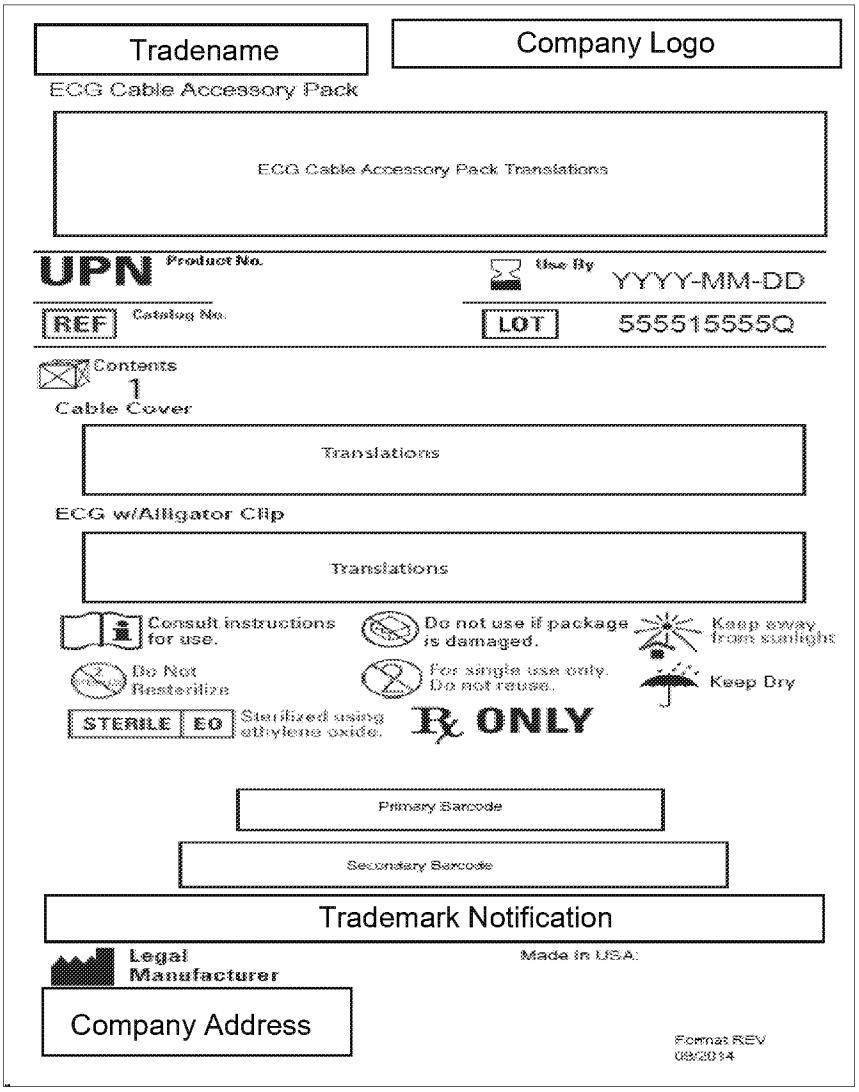
4. Proposed ECG Cable Accessory Pack – Pouch Label



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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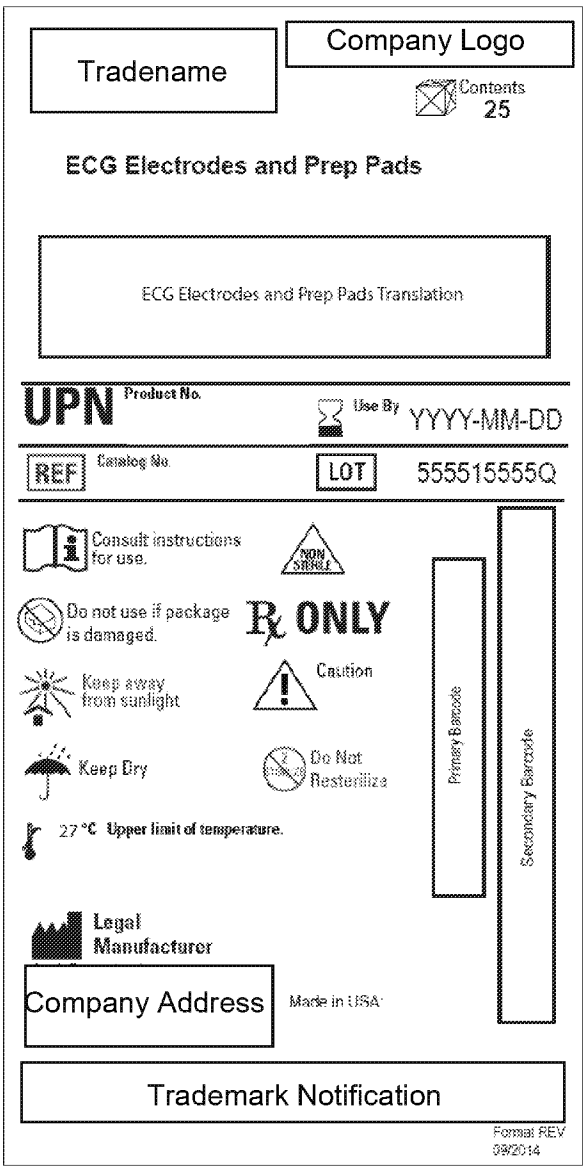
5. Proposed ECG Electrodes and Prep Pad – Box Label



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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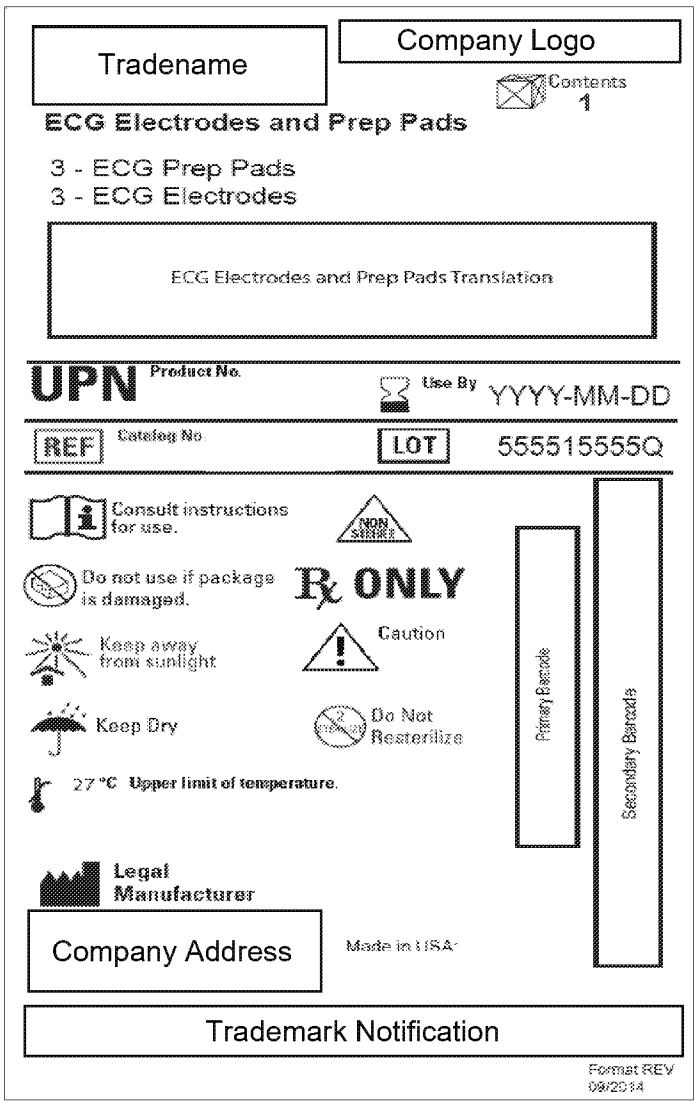
6. Proposed ECG Electrodes and Prep Pad – Pouch Label



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4) Vendor Information

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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7. Proposed Owner's Manual

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Tradename Owner's Manual

ECG-based Tip Positioning Aid

DRAFT

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Table of Contents

DRAFT

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DRAFT

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1. SYMBOL TABLE

	On
	Standby
	Read Accompanying Documents for important safety-related information.
	Rated type CF patient protection.
	Date of Manufacture
SN	Device Serial Number

2. IMPORTANT NOTICES

	Before using this monitor, the operator must thoroughly understand the contents of this manual including all warnings, cautions, contraindications, and intended use.
Warning	This device is only intended for use by qualified and trained medical professionals. Before using this device, the user must be qualified for placement of Peripherally Inserted Central Catheters [PICC] and trained in the proper use of this device.
Caution	Verify the software version of the monitor [shown in power-on screen] agrees with the version listed on this manual – refer to the front page of this manual.

3. INTRODUCTION

The Tradename is designed to provide a continuous display of an electrocardiograph [ECG] waveform to be used as a guide in placement of peripherally-inserted central catheters [PICC] in peripheral veins leading to the heart of the patient. The principle for operation of this system uses three ECG leads placed on the patient's chest and generates a third ECG lead by switching from right arm (RA) to PICC stylet. This system allows the operator to record changes to the ECG waveform as the tip of the catheter approaches the heart. As the PICC catheter approaches the atrium of the heart, the P wave in the ECG waveform shows substantial changes. This system is designed to aid the visualization of changes in P wave amplitude.

The Tradename must only be operated by a skilled nurse, physician, or trained medical professional who has been qualified in placement of PICCs and trained in the proper use of this device.

Warning	Never use a dropped or visibly damaged device. Remove damaged device from service until it can be tested/repaired by a qualified biomedical technician.
Warning	Never submerge the monitor in water or other fluids, serious damage may result, possibly resulting in injury to the user or patient.

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4. INDICATION FOR USE / INTENDED USE

4.1. Indications for Use

The Tradename is indicated for the positioning of Peripherally Inserted Central Catheters (PICC) in adult patients. It provides real-time catheter tip location information by using the patient's cardiac electrical activity. The Tradename is indicated for use as an alternative method to chest x-ray or fluoroscopy confirmation of PICC tip placement.

Note: In general, devices that utilize ECG technique to observe P-wave are limited, but not contraindicated, for patients where cardiac rhythms may change presentation of the P-Wave; including

- Atrial fibrillation
- Atrial flutter
- Severe tachycardia
- Pacemaker-driven rhythm
- Chronic Obstructive Pulmonary Disease (COPD)

Such patients are easily identified prior to PICC insertion. Use of an additional confirmation method is necessary to confirm catheter tip location.

4.2. Intended Use

The Tradename is intended to provide real time tip location information of a central venous catheter by utilization of ECG to observe P-wave changes as the tip approaches the right atrium of the heart via the superior vena cava.

Warning	The Tradename works with the normal sinus rhythm of the heart. Do not rely on ECG signal detection for catheter tip positioning when interpretation of the external or intravascular ECG P-wave is difficult. For example, when: - P-Wave is not present - P-Wave is not identifiable - P-Wave is intermittent
Warning	This device is not intended for use as a diagnostic ECG device as the system is designed to aid the visualization of changes in P wave amplitude.
Warning	**DANGER!** Do NOT use this device in the presence of flammable anesthetics, oxygen-enriched atmospheres, or explosive gases.
Warning	This device has not been tested for use near electrosurgical devices. It is not recommended for use in operating rooms.

5. FEATURES and CONTROLS

The Tradename is composed of a Monitor, a Patient ECG Cable, a Remote Control Cable, ECG Snap Leads and a disposable ECG Clip Cable.

5.1. Monitor

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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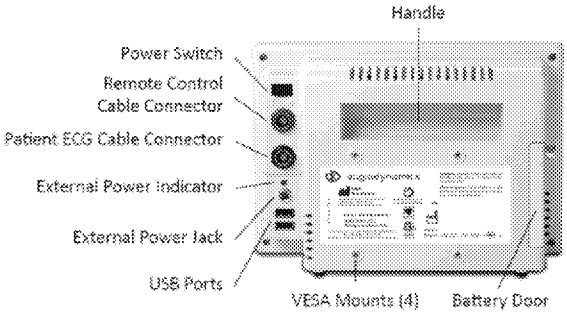
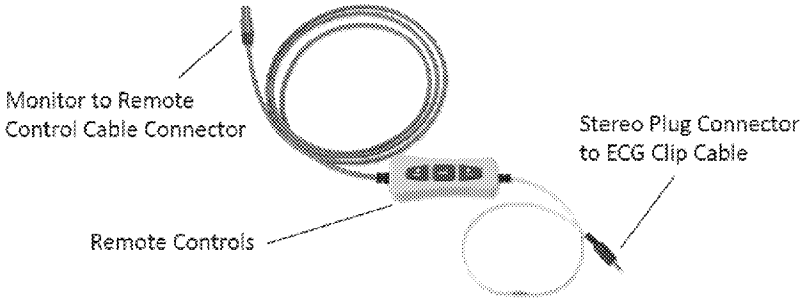


Touch-screen Display	Color graphic display with pressure sensitive touch screen.
Power Switch	On/standby switch. Turns on monitor or places monitor in standby to charge internal battery when external power supply is connected.
Remote Control Cable Connector	Connection for Remote Control Cable. This is latching connector, pull outside of connector body outward to disconnect.
Patient ECG Cable Connector	Connection for Patient Cable. This is latching connector, pull outside of connector body outward to disconnect.
External Power Indicator	Indicator which illuminates when external power is connected to monitor.
External Power Jack	External power jack – **only** use medical grade power supply provided with the monitor.
USB Ports	Two USB ports provided for connection to an approved printer or flash [“thumb”] drive.
Handle	Carrying handle.
VESA Mounts	Four mounting points in VESA standard 75mm square pattern. Use #6-32 screws.
Battery Door	Battery access door. Allows the user to change battery.

5.2. Remote Control Cable

This Remote Cable provides the user the capability to remotely control the monitor and to make a connection to the disposable ECG Clip Cable.



5.3. ECG Clip Cable

This is a sterilized disposable ECG Clip Cable which is part of the disposable kit. This cable makes the ECG connection from the Remote Control Cable to the stylet wire of the PICC catheter. The white alligator clip connects to the stylet, and the jack connector pierces the sterile bag enclosing the Remote Control Cable.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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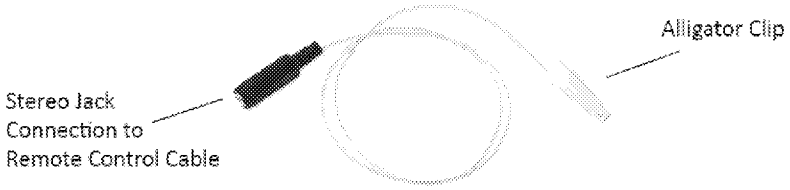
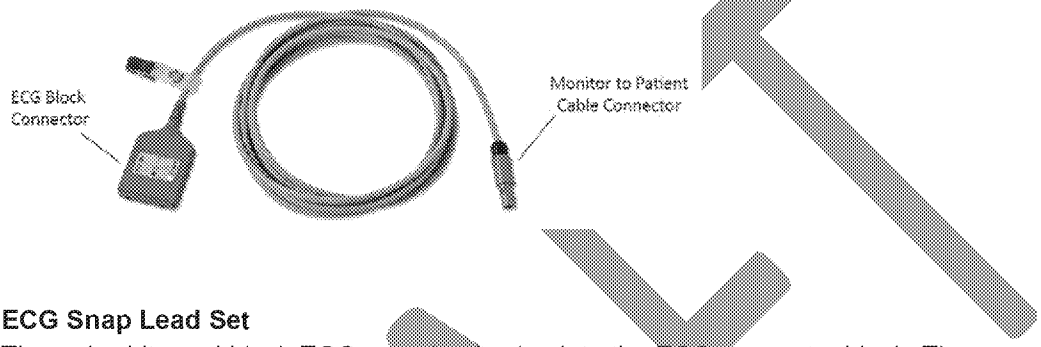


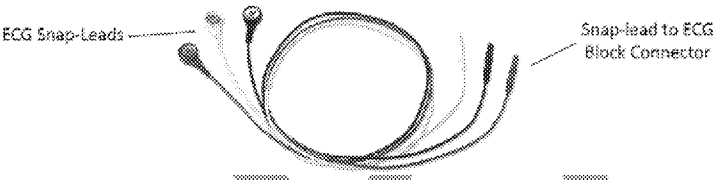
5.4. Patient ECG Cable

This cable allows the user to set up a standard three-lead ECG connection to the patient prior to the start of the PICC location procedure. During the PICC location procedure two leads [red and black] from this cable are used together with the ECG Clip [white] lead on the stylet wire to create the guidance ECG waveform.



5.5. ECG Snap Lead Set

The red, white and black ECG snap-leads plug into the ECG connector block. The snap leads use DIN standard connections into the connector block. The snaps accommodate standard disposable ECG pads.



5.6. Medical Grade External Power Supply

This external medical grade power supply [12 VDC 20 watts] may be used to operate the monitor during use on a patient. If the monitor is off [power switch is in stand-by] and this supply is plugged into the monitor then the internal battery will be charging.

5.7. Internal Rechargeable Battery

This user replaceable battery provides for operation of the monitor for at least 4 hours. Follow cautions and warnings listed on the battery for handling and disposal of this battery.

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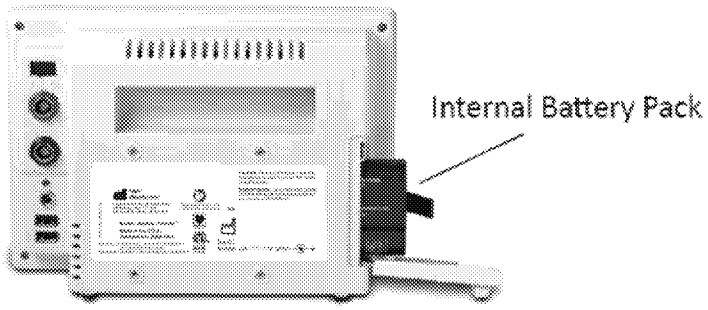

Warning	Do not immerse the external power supply in water or other fluids, as this may create a dangerous shock hazard to the patient and user.
Warning	Only use the Medical Grade Power Adapter provided with the device. Use of unapproved adapter may compromise patient safety or damage the unit.
Warning	Never use a visibly damaged external power supply. Remove damaged supply from service until it can be repaired by a qualified biomedical technician.
Warning	Only use the approved battery provided with this monitor. Use of unapproved battery may compromise patient/user safety or damage the unit.
Warning	To avoid risk of electric shock, this equipment must only be connected to a supply mains with protective earth.

6. TECHNICAL SPECIFICATIONS

Dimensions [monitor only]	9.5" wide x 6.6" high x 3.1" deep [24 cm x 17 cm x 8 cm]
Weight [monitor only]	3.3 lb. [1.5 kg]
Internal Battery Capacity [at 25° C]	Monitor operates at least 4 hours on a fully charged battery. Battery recharges within 8 hours when monitor is in standby.
External Power Supply	Input: 100-240 VAC, 50-60 Hz, 0.5A Output: 12 VDC 1.7A [20 watts]
Normal Operating Conditions	+41° to +104° F [+5° to +40° C] 10 to 90 % non-condensing Relative Humidity
Storage [non-operating] Conditions	-22° to +140° F [-30° to +60° C] 10 to 95 % non-condensing Relative Humidity
Monitor Rating 	Rated type CF patient protection.
External Power Supply Rating	Class I, medical grade external power supply.

Caution	Do not use sharp objects on touch screen, damage to the monitor may occur.
Caution	Do not operate cell phones or portable radio transmitters near this monitor. These devices may interfere with normal operation of the monitor.
Caution	Never use this device near high intensity magnetic fields, e.g. an MRI scanner. Strong magnetic fields may damage the device.
Caution	If significant interference [noise] is observed in the ECG waveform, then operate the monitor on battery power [disconnect AC adapter] to isolate the monitor from the disruptive environment.
Caution	Federal Law in the United States restricts this device to sale by or on the order of a physician.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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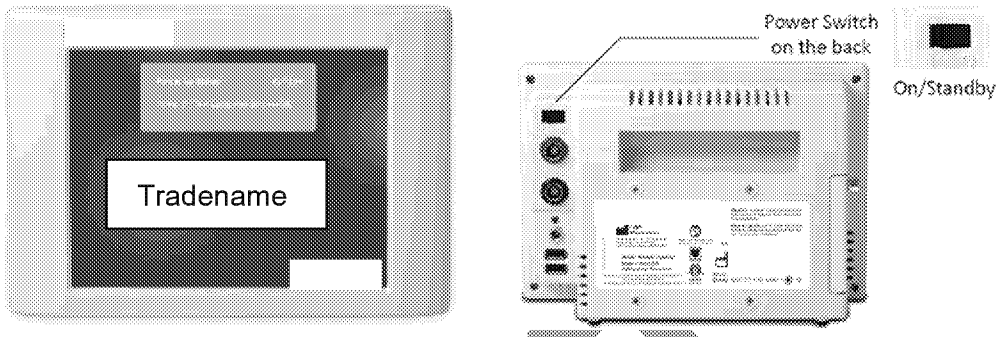
7. MONITOR OPERATION

7.1. Monitor Setup

Turn on monitor using power switch on the back.

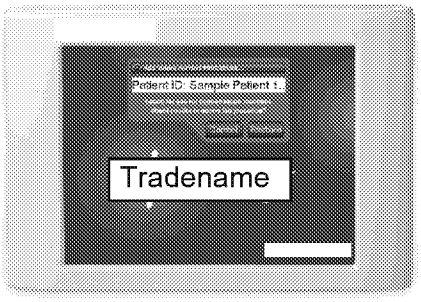
7.1.1.Power-on Testing



If power-on test failure occurs, then remove the unit from service and have it tested by a trained biomedical technician.

7.1.2.**Restart Case [if needed]**

If monitor is shut down before the case is finished it is possible to recover settings and data by pressing "Restore" key; otherwise, select "Cancel" to begin a new case.



7.1.3.**Enter Patient ID**

Use touch keypad to enter a patient ID. This is a one line, 32 character max, field used to create a stored patient data record.

Note: *do not use the patient's name here as this may violate patient privacy rules.*

The "Shift" key switches between lower case and upper case.

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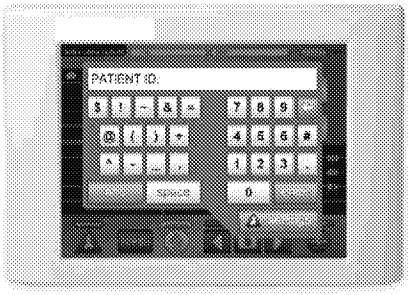
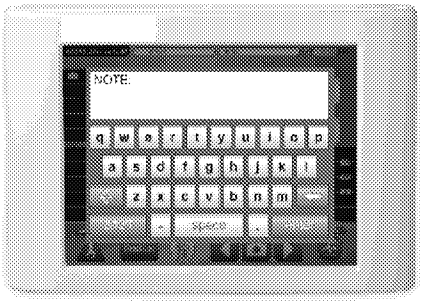


The “&123” key brings up the special characters.

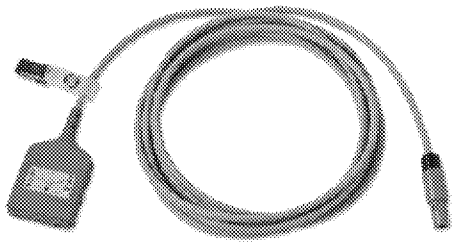
7.1.4. **Enter Note**

Use touch keypad to enter a patient note [if needed]. This is a three line, 96 character max field, used to enter any other pertinent data which is also stored in the patient record.



7.1.5. **Connect Patient ECG Cable**

Plug in the Patient ECG Cable to the monitor. Insure monitor is in surface mode – “person-icon” shows 3 dots and ECG trace is yellow on a blue background. Verify sufficient battery time remaining or elect to operate with external AC power supply



Note: Face arrows up to properly insert cable.

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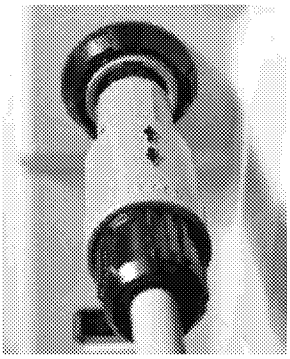


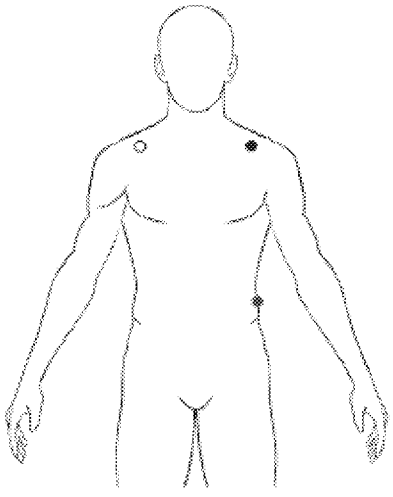
rear-side

7.1.6. **Connect 3 Patient Snap Leads**

Connect the ECG Snap Leads to the corresponding color of the Patient ECG Cable. Snap the disposable ECG Adhesive Electrodes from the kit to the ECG snap leads.

7.1.7. **Apply the ECG Adhesive Electrodes to Patient's Chest**

Clean the patient's skin, remove the ECG Adhesive Electrodes clear backing, apply the ECG pads to the patient – avoid areas with excessive hair. Follow color codes/lettering on ECG block: RA (white) = right arm, LA (black) = left arm, and LL (red) = left leg.



7.1.8. **Verify Surface ECG Signal**

The "Leads Off" advisory message should be cleared. Verify patient's ECG waveform is acceptable for use in guiding PICC location.

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7.1.9. **Collect a Baseline ECG Snapshot During 3-Lead Mode**

[SNAPSHOT] works with both 3-lead and PICC mode.]

Use Remote to select "Snapshot" icon. This takes one ECG sample and displays it on top row.

Keep patient and PICC still while reading the wave forms.

Press retry icon [in green] to retake the snapshot. Scroll left and press "X" to quit without saving.

Scroll right and press "✓" to save the snapshot into the patient record.

7.1.10. **Record Baseline Measurements**

Once "✓" is selected a window will pop up allowing the user to mark the surface measurement using the remote or touch screen.

Once surface measurement is entered, a window will pop up allowing the user to note the cut length using the remote or touch screen.

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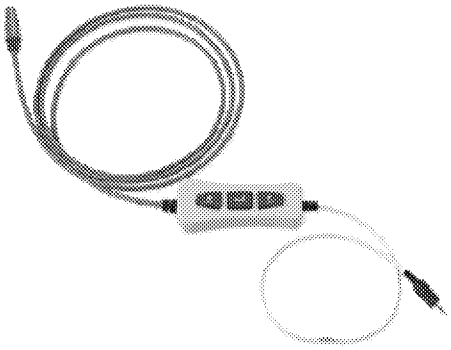
7.1.11. **PICC Mode**

Plug in the Remote Control Cable to the monitor. Insure monitor is in "PICC mode" and ECG trace is white on a black background with blue scroll bar. The "NO PICC SIGNAL" advisory message should be present



Note: Face arrows up to properly insert cable.

rear-side

7.1.12. **Place Remote Cable in Sterile Bag**

Locate Cable Cover and carefully unroll the sterile bag over the Remote Control Cable.

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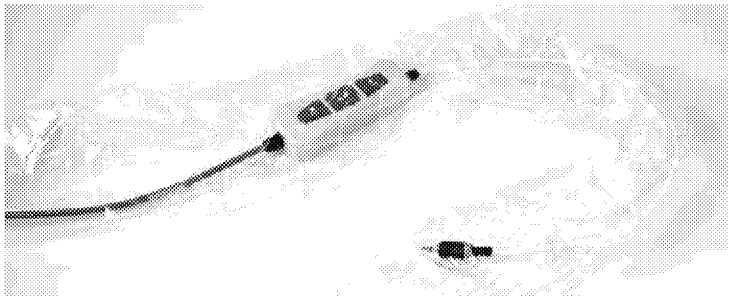
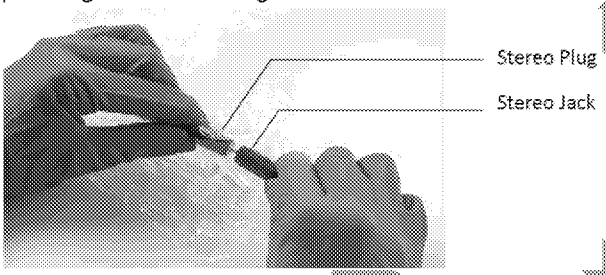


7.1.13. **Connect the Disposable ECG Clip Cable**

Connect the stereo jack of the Clip cable to stereo plug of Remote Control Cable by carefully piercing the sterile bag.

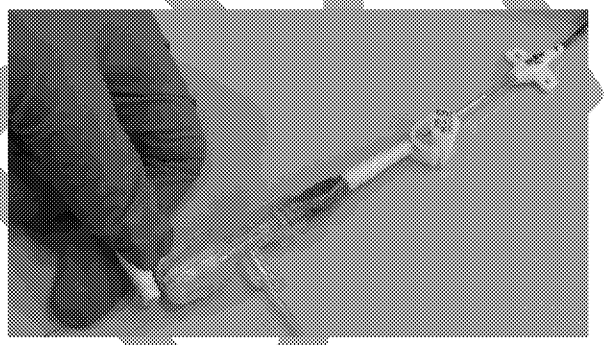


7.1.14. **Connect the ECG Clip Cable to PICC**

Squeeze the alligator clip and place clip over the metal portion of the stylet wire of the PICC catheter. Prepare the PICC catheter per normal procedures.

Note: Only works with conductive [metal] wire.

Note: To prevent guidewire slippage from the tuohy, use AngioDynamics components. AngioDynamics does not certify the compatibility of other manufactured products.



7.1.15. **Verify PICC Lead Plus PICC ECG Signal**

Advance the PICC catheter as normal into the patient. As the PICC advances a few centimeters past the introducer then an ECG connection is completed to the patient and the “NO PICC SIGNAL” advisory message should be cleared.

Note: For best results of wave image user should keep the PICC and patient still when reading waves.

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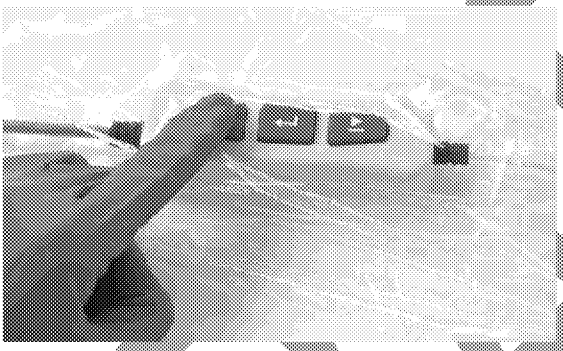
7.2. Monitor Operation

7.2.1. Use Remote Control Cable to Operate Monitor

Remote Box has Left, Enter, and Right controls which allow user to control the collection/tagging of ECG data.



7.2.2. Collect ECG Records as the Catheter Advances

Use Remote to select “Snapshot” icon. This takes another ECG sample and displays it.

Press retry icon [in green] to retake the snapshot. Scroll left and press “X” to quit without saving. Scroll right and press“✓” to save the snapshot into the patient record.

Once “accept” is selected a window will pop up allowing the user to mark the exposed catheter length using the remote. The implanted depth is displayed.

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When more than three snapshots are taken, the arrow left and arrow right buttons allow user to scroll through the snapshots.

7.2.3. **Finish Case when Placement Completed**

Use Finish button to complete the case. This screen also provides a path to file management screen.

Here, cancel returns to current case and the other button “OK” allows user to save/exit the current case, after user has selected yes/no to meeting the bundle protocol criteria.

Note: Bundle protocol can be found in Instructions for Use.

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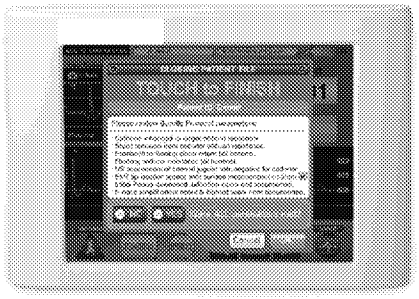
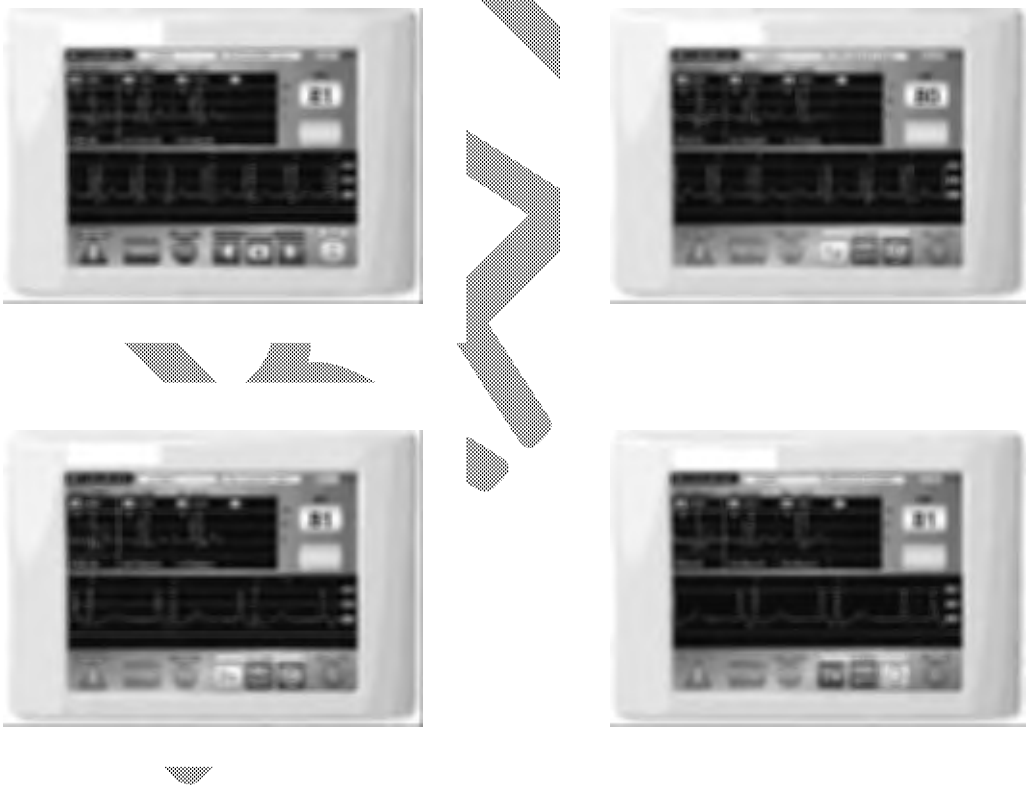


7.3. Additional Monitor Controls

7.3.1. **Sweep Speed**

Touch or use Remote to select “scale/wave” icon. Then select the “1X” icon. Pressing this changes sweep speed to “2X” for viewing higher heart rates. Then select and press the “✓” icon to save changes.



7.3.2. **Selecting Fixed ECG Waveform Scale**

Use Remote to select “scale” then select AUTO which changes to a fixed 1 mv scale, and select button again to change to 2, 5, etc. until you select the best millivolt scale to view the ECG

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waveform. Accept and lock this scale setting by pressing "✓" and return to the previous screen.

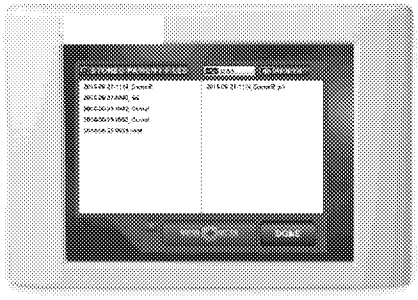
7.3.3. **Surface or PICC-Lead**

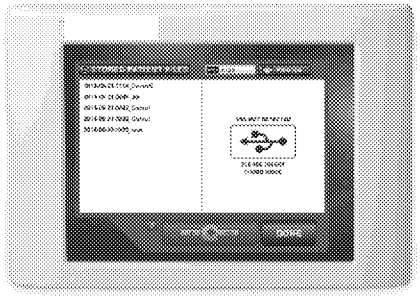
User can select Surface to check the normal chest-leads ECG waveform -- a yellow trace with blue background. Then press again to select PICC lead for viewing the PICC-based ECG waveform -- a white trace with black background. The button icon reflects the current waveform being displayed.

7.4. Copy or Print Patient Files

Selecting Files button brings up the file management screen. Do not copy or print files when operating the monitor on a patient.

Insert USB "thumb" flash drive into either USB port on the back of the monitor. Select the Files button and the following screen appears.





Note: this message indicates flash drive or printer not connected.

7.4.1. **Preview Snapshots**

Highlight file, then select the magnifying glass on the right side of file. While in preview mode you can deselect any image you don't want to print or save to thumb drive by deselecting the "check"

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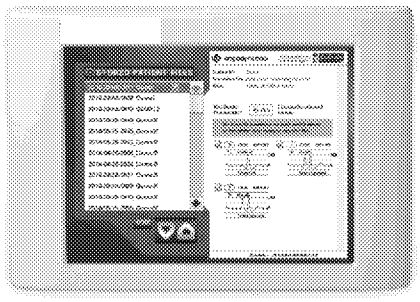
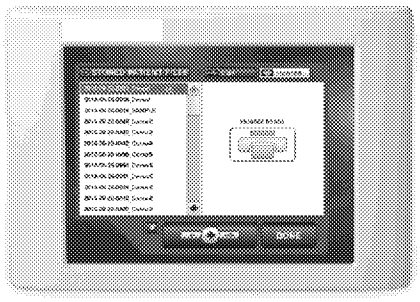
mark.





Insert USB of approved printer. Select printer icon. Select the file you wish to print. Press the move files (arrow) button.

Touch the files in the left column that you wish to copy. Press the move files [arrow] button which copies files to flash, moving them from the left column to the right column. Use Done button to exit.

Caution	If using specified Dymo printer then do not print while in the patients room.
Caution	Do not connect any device to USB port except a printer with supplied cable or compact flash devices which are approved in this manual or other user instructions.
Caution	Do NOT connect an external hard drive or CD/DVD drive to the USB ports. This may result in excessive radio interference from monitor causing disruption of surrounding equipment.

7.4.2. **Deleting Files**

Select the file you want to delete, then select the "X" and then select OK to confirm deletion. Either patient or copied files may be deleted. Once deleted files can NOT be recovered.

7.5. Service Screen

The service screen cannot be entered using the remote control. It is only used in setup or at end of case. The service screen permits user to set date and time or access special service/diagnostic functions.

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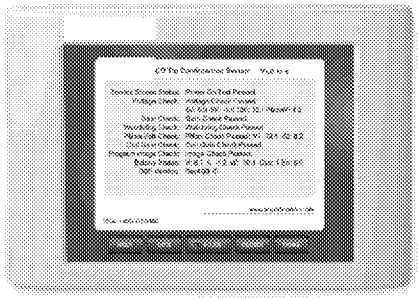
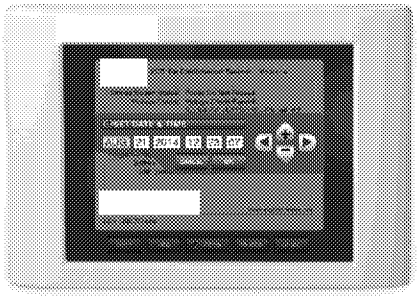
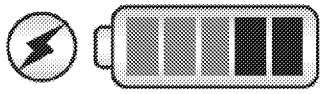


7.5.1. **Set Clock**

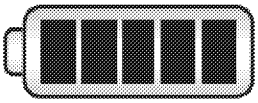
Press Clock on service screen to set the system clock and calendar. Use "+" or "-" arrows to increase or decrease selected date/time value. Use left and right arrow to change selected value. [seconds are not needed]



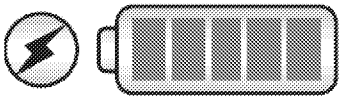
7.6. Battery Power and External AC Power Operation



The AC plug indicates unit is running off external AC power with the percentage of battery charge displayed.



The battery icon without AC plug indicates unit is running off battery power with the remaining run time displayed in hours and minutes.



When battery is removed or has failed and the unit is running on AC power, two question marks appear.

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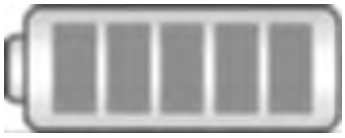

When battery capacity drops to 10%, the battery icon appears larger and begins to flash.

When the battery capacity drops below 1% then a caution screen appears to advise that power failure will occur within a few minutes unless the monitor is plugged into external AC power.
Note: Battery will only accept a charge when the monitor is in normal operating temperature range: +41° to +104° F [+5° to +40° C].

7.7. Warning Screen

This warning screen appears when the monitor software detects an internal failure in the system. User controls may operate – depending upon severity of the failure – to assist in saving patient data.

Warning	If you see this screen, the monitor is not operating correctly. Remove this device from use for repair by a qualified biomedical engineer.

8. CLEANING

The monitor and associated cables [excluding disposables] may be cleaned with the following using your institutions guidelines or disinfectant manufacturer's recommendations.

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Mild detergent and water
Bleach 10% solution with water
Isopropyl Alcohol 70% solution
Surface disinfectants compatible with plastic materials

For best results use cleaning solution on a soft cloth to wipe the monitor and cables.

Caution	Never use organic solvents [acetone, kerosene, strong acids, or strong bases] to clean monitor or cables as this will damage the monitor.
Caution	Never steam sterilize or autoclave the monitor or cables as severe damage will result.

9. PARTS and ACCESSORIES

9.1. Parts

Description
ECG Accessory Pack [ECG Clip & Bag; 25-box]
Remote Cable
ECG Snap Leads Set
Patient Cable
Battery, 7.2V, 63W-hr, Li-ion
Power Cord

9.2. Accessories

Sony Medical Grade USB Printer [Approved for patient bedside use.]
Dymo USB Printer [Office use only. NOT for patient bedside use.]

10. TROUBLESHOOTING GUIDE

10.1. Alarms, Alerts & Informational Messages

Alarm	Priority	Description	Corrective Action
System Failure Alarm [power-on self-test] "Power Supply Failure" "I2C Communication Failure" "Watchdog Failure" "Software Image Failure"	High [Red]	System self-test failure detected at power-on.	Remove monitor from service for repair by qualified biomedical engineer. [Note: button is provided to enter service screen which allows user to recover patient files.]
System Failure Alarm [while operating] "Power Supply Failure" "I2C Communication Failure"	High [Red]	System failure detected while running.	Remove monitor from service for repair by qualified biomedical engineer. [Note: button is provided to enter service screen which allows user to recover patient files.]
Battery Warning: "Extremely Low Battery"	High [Red]	Internal battery is almost fully depleted.	Plug monitor into AC power and continue use. Alarm may be cleared by pressing enter on remote control or by touching "OK" on the screen.
Alert Message: "NO PICC SIGNAL"	Moderate [Yellow]	Patient lead is disconnected.	Check ECG Alligator Clip and connection to Remote Cable.
Alert Message: "RA Off"	Moderate [Yellow]	Patient lead shows poor electrical	Check connections from patient cable to ECG pads on patient. Consider

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"LL Off" "LA Off" "Leads Off"		connection.	replacing ECG pad if excessive noise or wander in ECG waveform.
Informational Message:"…confirm entry…"	Low [Grey]	Confirm selected action, such as "Finish Case", or "Delete File"	None

Note: High priority alarms can be reviewed from settings/service screen by pressing the "LOG" button on the settings service screen. This displays the system log file [with date/time stamp] which shows the results of all power-up tests and high priority alarms.

DRAFT

11. ELECTROMAGNETIC COMPATIBILITY DECLARATION

Table 1

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Guidance and manufacturer's declaration – electromagnetic emissions		
Tradename monitor is intended for use in the electromagnetic environment specified below. The user of the Tradename should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	Tradename™ uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	Tradename™ is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	Tradename™ should be set up and used per instructions in this manual to insure electromagnetic emissions are at acceptable levels.
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Table 2

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
Tradename™ monitor is intended for use in the electromagnetic environment specified below. The user of Tradename™ should assure that it is used in such an environment.			
IMMUNITY Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment – Guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/ burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 s	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 s	Mains power quality should be that of a typical commercial or hospital environment.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

Table 3

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Guidance and manufacturer's declaration – electromagnetic immunity

Tradename™ monitor is intended for use in the electromagnetic environment specified below. The user of Tradename™ should assure that it is used in such an environment.

IMMUNITY TEST	IEC 60601 TEST LEVEL	Compliance Level	Electromagnetic Environment – Guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz outside ISM bands[a]	3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of Tradename™, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1{,}2\sqrt{P}$ $d = 1{,}2\sqrt{P}$ 80 MHz to 800 MHz $d = 2{,}3\sqrt{P}$ 800 MHz to 2,5 GHz where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in metres (m).[b] Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[c] should be less than the compliance level in each frequency range.[c] Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Celerity is used exceeds the applicable RF compliance level above, the Celerity should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Celerity.

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

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Table 4

Recommended separation distances between portable and mobile RF communications equipment and the Celerity™ monitor.			
Tradename™ monitor is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The user of the monitor can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the monitor as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d = 1,2\sqrt{P}$	80 MHz to 800 MHz $d = 1,2\sqrt{P}$	800 MHz to 2,5 GHz $d = 2,3\sqrt{P}$
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

12. MAINTENANCE and SERVICE REQUIREMENTS

12.1. Periodic Maintenance

The monitor together with the external power supply should be tested at least annually by a trained biomedical engineer to verify electrical safety. Testing should be performed immediately if the monitor has been dropped or visibly damaged.

12.2. Service Assistance

Contact the Technical Service Department for assistance: ● Phone:

When calling please have the following information available: Model of unit, serial number, date of purchase, and description of problem.

12.3. Training

Contact your local sales representative to schedule training.

12.4. Returning Unit for Repair

Contact the Technical Service Department. If it becomes necessary to return a unit for repair, then you will be issued a Return Authorization [RA] number.
Clean and decontaminate monitor and cables prior to returning these items for repair.
Package monitor carefully for return and mark the RA number on the outside of the box.
Monitors will not be accepted for service without an RA number.

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Ship monitor to USA service at:

Phone:

Warning	Users should never disassemble the monitor. Refer servicing to qualified biomedical engineer for repair.
Warning	Only a trained biomedical engineer may service this device. Service personnel should disconnect the AC power adapter and remove the battery before servicing the device.
Warning	Never perform unauthorized modifications to the monitor hardware or software. This could result in serious injury to the patient or the user.

12.5. Disposal of Unit

Follow labeling instructions on battery for its disposal. The monitor does not contain any lead products and does not present a hazard for disposal.

13. LIMITED WARRANTY

warrants that reasonable care has been used in the design and manufacture of this instrument. **This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether express or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness for a particular purpose.** Handling, storage, cleaning and sterilization of this instrument as well as other factors relating to the patient, diagnosis, treatment, surgical procedures and other matters beyond control directly affect the instrument and the results obtained from its use. obligation under this warranty is limited to the repair or replacement of this instrument and shall not be liable for any incidental or consequential loss, damage or expense directly or indirectly arising from the use of this instrument. neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this instrument. **assumes no liability with respect to instruments reused, reprocessed, resterilized, modified or altered in any way, and makes no warranties, express or implied, including but not limited to merchantability or fitness for a particular purpose, with respect to such instruments.**

Trademark Notifications

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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8. Proposed Accessory Pack Instructions for Use (IFU)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Tradename

INSTUCTIONS FOR USE

Tradename Instructions for Use: These instructions are for use in conjunction with the Owner's Manual.

Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

INDICATIONS FOR USE

- The Tradename is indicated for the positioning of Peripherally Inserted Central Catheters (PICC) in adult patients. It provides real-time catheter tip location information by using the patient's cardiac electrical activity. T Tradename n is indicated for use as an alternative method to chest x-ray or fluoroscopy confirmation of PICC tip placement in adult patients.

  Note: Limiting, but not contraindicated, situations for this technique are patients where cardiac rhythms may change presentation of the P-Wave:
  - Atrial fibrillation
  - Atrial flutter
  - Severe tachycardia
  - Pacemaker-driven rhythm
  - Chronic Obstructive Pulmonary Disease

  Such patients are easily identified prior to PICC insertion. Use of an additional confirmation method is necessary to confirm catheter tip location.

INTENDED USE

- The Tradename is intended to provide real time tip location information of a central venous catheter by utilization of ECG to observe P-wave changes as the tip approaches the right atrium of the heart via the superior vena cava.

CONTRADICTIONS

- There are no contraindications associated with the Tradename Consult catheter Instructions for Use for Possible Catheter Contraindications.

WARNINGS

- The Tradename works with the normal sinus rhythm of the heart. Do not rely on ECG signal detection for catheter tip positioning when interpretation of the external or intravascular ECG P-wave is difficult. For example, when:
  - P-wave is not present
  - P-wave is not identifiable
  - P-wave is intermittent
- Place ECG adhesive electrodes carefully at locations indicated in these Instructions for Use and ensure good skin-electrode contact. Failure to do so may cause unstable ECG waveforms and/or

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ECG waveforms that are not described in these Instructions for Use.

- All components in the accessory pack are single use items. Do not reuse or reprocess.
- Monitor catheter tip placement during insertion procedure and verify catheter tip location placement using your institutions' guidelines.
- Failure to verify catheter placement may result in serious trauma or fatal complications.
- Inspect package and product prior to use to verify that no damage has occurred during shipping.
- Reuse or reprocessing may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death.
- Reuse or reprocessing may also create a risk of contamination of the device and/ or cause patient infection or cross- infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another.
- Contamination of the device may lead to injury, illness or death of the patient.
- After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

PRECAUTIONS

- NEVER cut the stylet or stiffening wire.
- Never use excessive force to advance/ remove the stylet as it may damage the device or result in patient injury.

PROCEDURAL INSTRUCTIONS

1. **Prepare for Use of Celerity™ System**
   - Prior to use, the clinician must read and understand all labeling and instructions provided with the Tradename (including Owner's Manual).
   - Follow manufacturer's instructions provided with all accessory devices.

2. **Identify Catheter Insertion Site**
   A. Refer to catheter manufacturer's Instructions for use.
   B. Mark planned insertion site on patient's arm.

3. **Determine External Surface Measurement**
   A. For central venous placement, the recommended target tip location is the lower 1/3 of the Superior Vena Cava (SVC)/right atrial junction.
   B. Use the following guidelines during patient positioning and measurement.
      - When possible, ensure patient has both shoulders in contact with the bed. Patient should not be rotated during measurement procedure.
      - When possible, measure directly on patient's skin. Measuring over clothing, bedding, existing ECG adhesive electrodes, wound dressings, or other personal and/or medical equipment may introduce measurement error.

      Note: External surface measurement can never exactly duplicate the internal venous anatomy.

   C. Measure path from the planned insertion site using the following external landmarks:
      - Insertion site to axillary crease.

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- Axillary crease to right clavicular head. Measure to the right clavicular head for both left and right-sided placements.
- Right clavicular head to the right sternal border at the third intercostal space.

Note: The first intercostal space may be difficult to palpate due to its proximity to the clavicle.

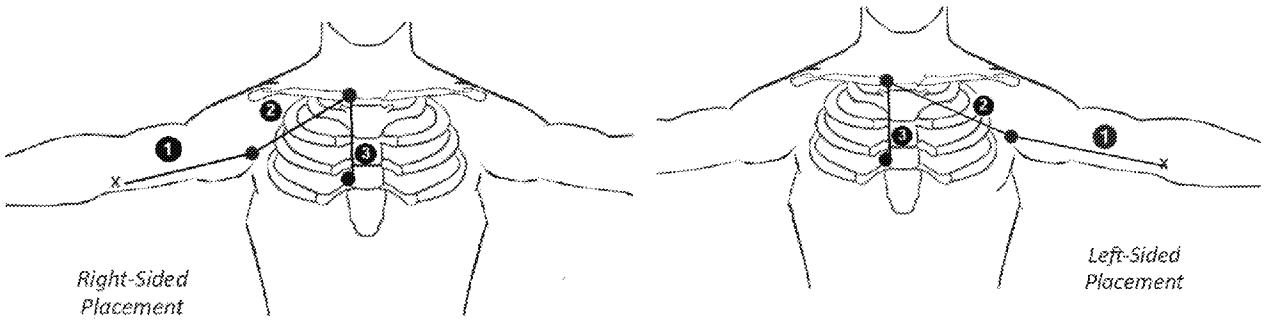

Figure 1. External Surface Measurement

D. Record External Surface Measurement

4. Prepare Electrodes

A. Attach ECG Patient Cable to the three ECG snap leads.
B. Prepare and attach ECG adhesive electrodes per the following steps.

Caution: ECG adhesive electrodes should be applied only to intact, clean skin (e.g. not over open wounds, lesions, infected or inflamed areas). For best results use the supplied ECG adhesive electrodes.

a. Attach ECG adhesive electrodes to all three ECG snap leads.
b. Remove backing and press ECG adhesive electrodes firmly onto skin at the specified locations.

Warning: Place ECG adhesive electrodes carefully at locations indicated in these Instructions for Use and ensure good skin-electrode contact. Failure to do so may cause unstable ECG waveforms and/or ECG waveforms that are not described in these Instructions for Use.

c. Black ECG snap lead/adhesive electrode on the patient's left upper chest.
d. Red ECG snap lead/adhesive electrode on patient's lower left side, inferior to the umbilicus and laterally along the mid-axillary line.

Caution: Placement of red electrode outside of this region may result in reduced ECG performance.

e. White ECG snap lead/ECG adhesive electrode on patient's right upper chest.

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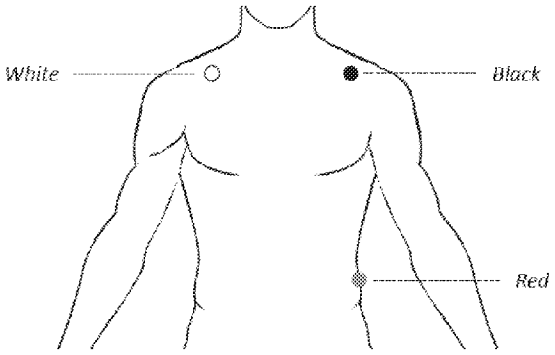

Figure 2. Electrode Placement

Caution: If skin irritation occurs, discontinue ECG adhesive electrode use immediately.

C. Evaluate baseline ECG waveform:

- With Tradename running in Surface Mode, the external ECG waveform should be visible and stable at this time.
- Verify that the P-wave is present, identifiable and consistent on the main screen of the Tradename
- Obtain snapshot of baseline ECG.
- Enter surface external measurement. (See Step 3-D).
- Enter cut length.

5. Prepare Sterile Field

A. Set up sterile field according to catheter Instructions for Use and institutional protocol.
B. Cover the Remote Control Cable with sterile Cable Cover (provided in the ECG Cable Accessory Pack).

6. Prepare Catheter

A. Follow catheter manufacturer's Instructions for Use and institutional protocol.
B. Trim catheter to length per the following steps.

- Determine the desired indwelling catheter length based on clinician measurement technique and experience, typically this is the measurement from the zero mark on the catheter to the predetermined catheter external Surface Measurement, See Step 3-D.
- To ensure adequate catheter length to reach maximum P-wave amplitude, it is recommended the trimmed catheter length is 2cm more than the external/surface measurement.
- Retract the stylet until it is well behind targeted catheter cut location. Do not entirely remove the stylet from the catheter.

Note: Catheter depth markings are generally in centimeters — refer to catheter labeling.

- Follow catheter manufacturer's Instructions for Use for trimming.

Caution: NEVER cut the stylet or stiffening will occur.

- Inspect cut surface to ensure there is no loose material.

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- Ensure stylet tip is intact.

Caution: Never use excessive force to advance/remove the stylet as it may damage the device or result in patient injury.

C. Prior to catheter insertion, ensure that the stylet tip is contained within the catheter, but not more than 1 cm from the trimmed end of the catheter, secure stylet within the catheter manufacturer's Instructions.

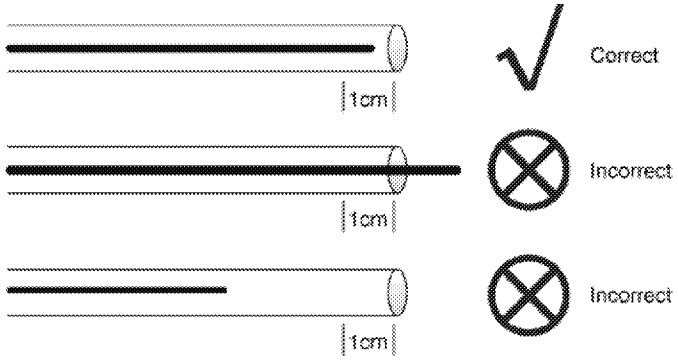

Figure 3. Stylet Tip Position In Catheter

Warning: Ensure that the stylet tip does not extend beyond the trimmed end of the catheter. Extension of the stylet tip beyond the catheter end combined with the kinking and excessive forces may result in vessel damage, stylet damage, difficult removal, stylet tip separation, potential embolism and risk patient injury.

D. Attach saline-filled syringe and flush catheter.
E. Remove the syringe after flushing.

7. Catheter Insertion

A. Perform ultrasound and locate vessel. Follow ultrasound system Instructions for Use.
B. Follow catheter Instructions for Use regarding Venous Access and Catheter Insertion.
C. Connect the end of the Remote Control Cable through the cable cover to the ECG Clip Cable (provide in the ECG Cable Accessory Pack).
D. Secure the ECG Clip Cable (alligator clamp) to the proximal end of the stylet.
E. Place Celerity™ System monitor in 'PICC Mode' and insert catheter per manufacturer's Instructions for Use.
F. Flush catheter with saline and wait for intravascular ECG waveform to stabilize on monitor screen.
G. Verify that the P-wave on the intravascular ECG waveform is present, identifiable, and consistent on monitor screen.

Warning: Do not rely on ECG signal detection for Catheter tip positioning when interpretation of the P-wave is difficult. For example, when:

- P-wave is not present
- P-wave is not identifiable
- P-wave is intermittent

8. Catheter Tip Guidance and Positioning

- Figure 4 shows approximate catheter tip positions and representative intravascular ECG waveforms.

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A: No evident P wave changes – catheter tip positions and representative intravascular ECG waveforms.
B: P wave at its maximum height – catheter tip is in the lower ½ of superior vena cava/right atrial junction.
C: Downward deflection on the leading edge of the P wave – catheter tip is entering the right atrium.
D: Biphasic P wave – catheter tip is within the right atrium.
E: Inverted P wave – catheter is approaching the right ventricle.

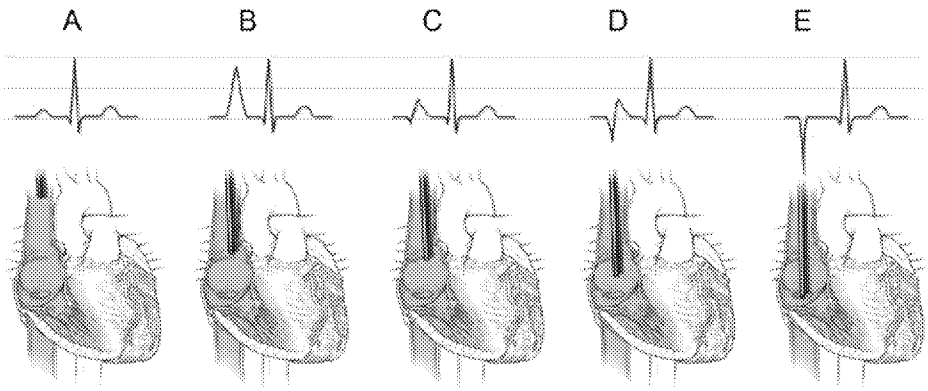

Figure 4. Representative ECG Waveforms

A. As the catheter is advanced toward the SVC/Right atrial junction the P-wave height will increase.
B. Advance Catheter until downward deflection is seen on the leading edge of the P-wave. Select the "snapshot icon" using the Remote Control Cable to save FCG waveforms.
C. Enter Exposed Catheter length
   - 'Exposed length' is measured by the cm of catheter length outside of the body
D. Pull catheter back until maximum P-wave is achieved. Select the "snapshot" icon using the Remote Control Cable to save the ECG waveforms. Refer to the Owner's Manual.

Note: P-wave may continue to increase in amplitude when initial downward deflection is observed. In this case, adjust catheter tip position to maximum P-wave amplitude with no downward deflection as shown below.

9. Complete PICC Placement Procedure

A. Follow catheter Instructions for Use and institutional protocol.
   - Remove stylet
   - Aspirate and flush catheter
   - Secure catheter

Caution: If the catheter is dislodged during insertion (e.g. removal of sheath, securement, or other accidental retraction) repeat steps 8B-E.

B. Select the "Finish icon" using the Remote Control Cable. The Bundle Protocol in Figure 5 will appear on your Tradename Confirm all Bundle Protocol Parameters have been met.

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Catheter Insertion
Catheter advanced to target without resistance?
Stylet removed from catheter without resistance?
Catheter Functionality
Positive/free flow blood return (all lumens)?
Flushing without resistance (all lumens)?
Objective Assessment
US assessment of internal jugular vein negative for catheter?
ECG tip location agrees with surface measurement (+/- 2cm)?
ECG P Wave Assessment
Initial P wave downward deflection noted and documented?
P wave amplification noted & highest waveform documented?

Figure 5. Bundle Protocol Questions

C. Remove drapes and ECG adhesive electrodes and discard according to institutional protocol.

Caution: ECG Adhesive Electrodes may damage the skin if removed carelessly.

D. Disconnect Remote Control Cable from ECG Clip Cable.
E. Dispose of the single use ECG Clip Cable, Cable Cover according to institutional protocol.
F. Retain the reusable ECG Snap Leads, ECH Patient Cable; Remote Control Cable and clean per institutional protocol.

10. Finalize Celerity System

- Using [Tradename], complete the Bundle Protocol to close the patient file.

Warning: If all Bundle Protocol parameters are not met, radiographic confirmation is required before use.

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SYMBOL TABLE

	On
	Standby
	Read Accompanying Documents for important safety-related information.
	Rated type CF patient protection.
	Manufacturer
SN	Device serial Number
	Keep Dry
	Do Not Re-use
	Caution, consult Accompanying Documents
	Keep Away from Sunlight
	Upper Limit of Temperature
STERILE EO	Sterilized Using Ethylene Oxide
	Do Not Use if Package is Damaged
	Use By Date
	Date of Manufacture
LOT	Lot Number
REF	Catalogue Number
	Consult Instructions for Use

WARRANTY

warrants that reasonable care has been used in the design and manufacture of this instrument. **This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether express or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness for a particular purpose.** Handling, storage, cleaning and sterilization of this instrument as well as other factors relating to the patient, diagnosis, treatment, surgical procedures and other matters beyond control directly affect the instrument and the results obtained from its use. obligation under this warranty is limited to the repair or replacement of this instrument and shall not be liable for any incidental or consequential loss, damage or expense directly or indirectly arising from the use of this instrument. neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this instrument. **assumes no liability with respect to instruments reused, reprocessed, resterilized, modified or altered in any way, and makes no warranties, express or implied, including but not limited to merchantability or fitness for a particular purpose, with respect to such instruments.**

Trademark Notifications

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9. Proposed ECG and Product Educational Materials

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Company Name

ECG Education

SECTION 1—CATHETER TIP LOCATION

The Relevance of Catheter Tip Location

There is overwhelming evidence that improper tip location negatively impacts clinical outcomes. A direct link has been observed between central vascular access catheter tips located outside of the optimal position and venous thrombosis, chemical and mechanical vessel erosion, fibrin sleeves, spontaneous malpositions, and catheter dysfunction including persistent withdraw occlusions.

The Guidelines Regarding Catheter Tip Location

In 1998, the National Association of Vascular Access Networks (NAVAN now AVA) issued a position statement recommending that the optimal location for the tip of peripherally inserted central catheter (PICC) is the lower one-third of the superior vena cava (SVC), close to the junction of the SVC and the right atrium. The Intravenous Nurses Society (INS) shares this recommendation in their Infusion Nursing Standards of Practice 2011 stating "central venous access devices (CVADs) shall have the tip dwelling within the superior vena cava (SVC) near it's junction with the right atrium."

Other Organizations with Recommendations on Tip Location Include:

- Oncology Nurses Society—Access Device Guidelines 2010: Distal third of the superior vena cava.
- Society of Interventional Radiologists—Quality Improvement Guidelines 2010: cavo atrial region.

Why The Lower 1/3 Superior Vena Cava/Right Atrial Junction?

- Large vein diameter.
- High velocity blood flow.
- Improved infusate distribution and dilution.
- Position offers the least amount of interference with vein intima.

The Vascular Access Specialist Challenge

- Reduce time to therapy.
- Achieve consistent and accurate catheter placements.
- Reduce catheter malpositions. (Rates documented to be as high as 30%)
- Reduce patient radiation exposure.
- Improve patient satisfaction.
- Improve clinician workflow and efficiency.

SECTION 2—PICC PLACEMENT TECHNOLOGIES

The Intravenous Nurses Society Standards of Practice 2011; 35.8 –"Tip location of CVAD shall be determined radiographically or by other approved technologies prior to initiation of infusion therapy." The traditional practices to ensure proper tip location for peripherally inserted central catheter (PICC) placement has included pre-procedure landmark and anthropometric (surface) measurements followed by post-procedural chest radiography (X-ray). The challenge has been in the inherent inefficiency of radiography and the known inconsistency of the interpretation of the PICC tip position via radiographic image. Considering the clinical significance and the position of peer groups such as AVA and INS regarding proper tip placement, it is not only best practice, but also should be the professional standard of practice to ensure proper central tip placement is achieved. Consequently, clinicians should consider more accurate and efficient technologies to reach this goal.

Navigation vs. Tip Location Technology

Navigation refers to a technology that ascertains information regarding general directionality of a vascular access device. Tip Location refers to a technology that ascertains a precise location of the distal tip of a vascular access device within the superior vena cava (SVC).

1. Electromagnetic Catheter Navigation—Technologies that utilize electro-magnetic field detection to illustrate audibly or visually catheter direction and general position. These systems measure the relationship between the catheter stylet and its external sensor (chest plate or hand held wand). These devices require a custom stylet wire inserted within the catheter. These devices are effective in reducing catheter malpositions, however they do not provide detailed information regarding the catheter's tip location with respect to the heart.
2. Electrocardiograpic (ECG) Tip Location—Technologies that employ a saline column or stylet as an intracavitary electrode to monitor ECG waveform changes as the vascular access device approaches final tip position.

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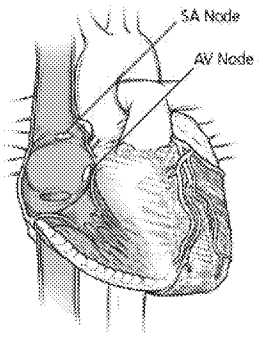
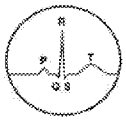
SECTION 3—ELECTROCARDIOGRAPHIC (ECG) TIP LOCATION

Electrophysiology of the Heart



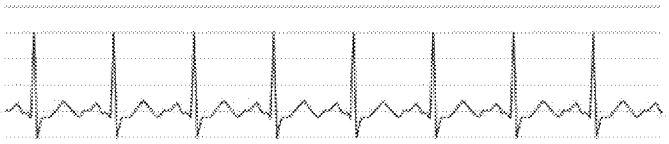
The heart is composed of four chambers: right atrium, right ventricle, left atrium, and left ventricle. These chambers are electrically stimulated to contract in specific timed and paced fashion. The heart's primary pace maker is a bundle of cells, known as the sinoatrial node (SA node), located upper posterior wall of the right atrium. While at rest, the myocardial muscle is negatively charged or polarized. The stimulation, called depolarization, causes these muscles to become positively charged and contract. This depolarization is immediately followed by repolarization. Both depolarization and repolarization are electrical phenomena and can be detected by sensors on the skin. These signals are represented by the deflections we see on an ECG strip. Electrical signals from the brain arrive at the SA node to stimulate a heartbeat. The depolarization spreads from the SA node across the atrium causing the atrial muscle to contract while generating the P-wave. This stimulation reaches the atrioventricular node (AV node) and passes through a set of fibers out to the ventricles. This depolarization then spreads across the ventricles causing the ventricles to contract while generating the QRS wave. The repolarization of the ventricles generates the T-wave as the ventricular muscles relax.

The height or amplitude of the deflection is a measure of voltage. Positive deflections are upward on an ECG, negative deflections are downward. ECG analysis examines the shape, consistency, and the time between waveforms elements (deflections) to assess the functionality of the hearts conduction system.

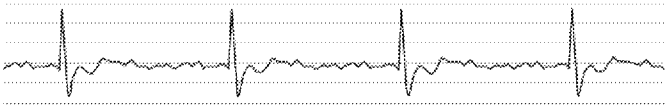


ECG Examples

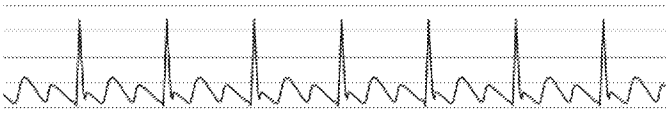
Normal Sinus Rhythm (NSR): Sinus rhythms are a class of rhythms which originate at the SA node. Sinus rhythms generally travel through the heart's entire conduction system without inhibition.
NOTE: NSR is required for reliable ECG tip location.



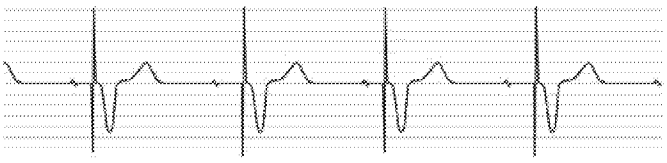
Atrial Fibrillation (A-Fib): Atrial Fibrillation is most common sustained arrhythmia. It affects as many as 10% of patients over 75 yrs. A-Fib is characterized by small, rapid, erratic spikes that may appear like a wavy baseline. A-Fib is caused by an unorganized depolarization of the atrial foci.
NOTE: A-Fib will not allow accurate interpretation of the P-wave response for ECG tip location.



Atrial Flutter (A-Flutter): A-Flutter is recognized by the distinct "saw tooth" pattern of P-waves. It is characterized by a series of identical "flutter" waves in back to back succession.
NOTE: A-Flutter will not allow accurate interpretation of the P-wave response for ECG tip location.



Artificial Pacemaker: With SA node pace failure, an artificial pacemaker may be implanted as a permanent pace making source. The demand feature engages when the inherent rate of the SA node is insufficient.
NOTE: An artificially atrial paced heart will not allow accurate interpretation of the P-wave response for ECG tip location.



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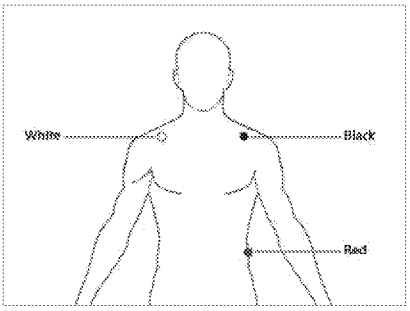
Assessing P-Waves:

1. Are they present?
2. Do they look alike?
3. Do they occur at a regular rate?
4. Is there one P-wave for each QRS?
5. Are they upright?

ECG Tip Location Applied:

Electrodes Defined—Electrodes are placed on the skin surface to detect the faint electrical activity of the heart. ECG tip location generally utilizes 3 electrodes. These electrodes are placed on the body in what is known as Einthoven's Triangle; right arm (RA), left arm (LA), left leg (LL). The three electrodes are colored white (RA), black (LA), and red (LL) in accordance with the American Heart Association (AHA) standards.



NOTE: These color standards are not universal. The International Electrotechnical Commission (IEC) has different color standards, red (RA), yellow (LA), and green (LL). Place electrodes only on clean, dry skin and in areas of minimal muscle activity.

ELECTRODE PLACEMENT MNEMONICS:

"White to the right. Red to the ribs. Black on top."
"White to the right. Smoke (black) over fire (red)."

ECG Tip Location Explained

In ECG tip location, the catheter itself becomes an intracavitary traveling electrode. As the catheter advances toward the SA node the electrical activity is monitored. This activity appears on ECG as a progressively larger P-wave. As the catheter enters the superior vena cava (SVC) the P-wave response will reflect the catheters proximity to the SA node within the upper right atrium. In this fashion, we can identify an anatomical landmark (the SA node), from which to base our catheter tip location.

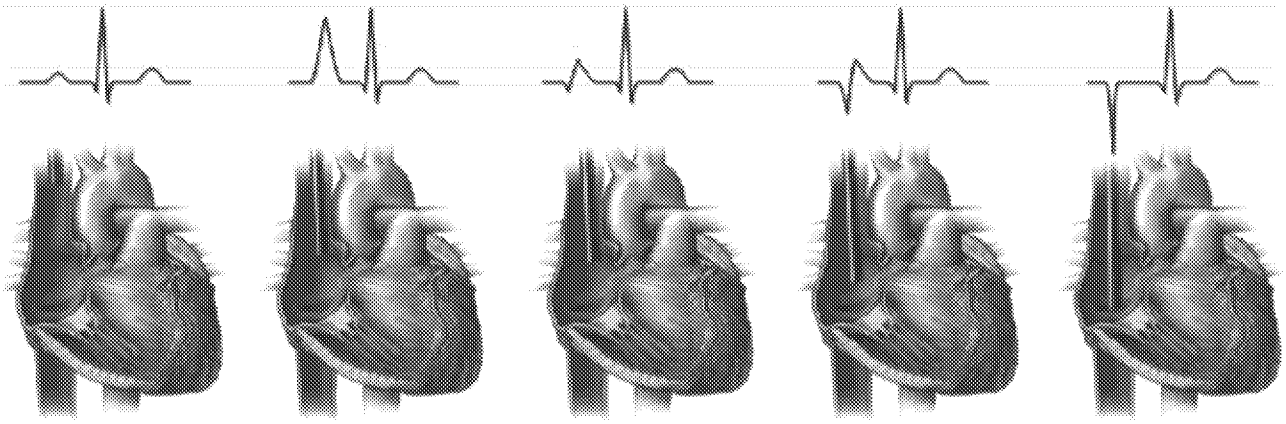


Figure 1
No evident P-wave changes indicates a catheter is not in acceptable position.

Figure 2
A P-wave at its maximum height will indicate the catheter is in the lower 1/3 of superior vena cava/ right atrial junction.

Figure 3
A downward deflection on the leading edge of the P-wave indicates the catheter entering the right atrium.

Figure 4
A biphasic P-wave indicates the catheter is within the right atrium.

Figure 5
An inverted P-wave indicates a catheter is approaching the right ventricle.

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Leads Defined

Two electrodes form a bipolar lead. Lead I is a lateral view from the RA to LA electrodes. Lead II is an inferior view from the RA to the LL electrodes. In ECG tip location it is generally lead I or Lead II that is monitored. For the purposes of central line placement lead I or lead II is generally monitored. Lead I monitoring implies the electrical activity is measured from right arm to left arm. Lead II ECG monitoring implies that the electrical activity is measured from the right arm to the left leg.

ECG Connection Techniques

Guidewire Technique—In this method the metal guidewire or stylet within the catheter is used as our conductive material to receive the electronic signals from the heart (SA node). In this technique the wire must not advance beyond the tip of the catheter being placed.

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Introduction to Tip Location [1,2]

The correct position of a central venous access catheter tip is just above the level of the right atrium, in the lower (distal) third of the SVC.

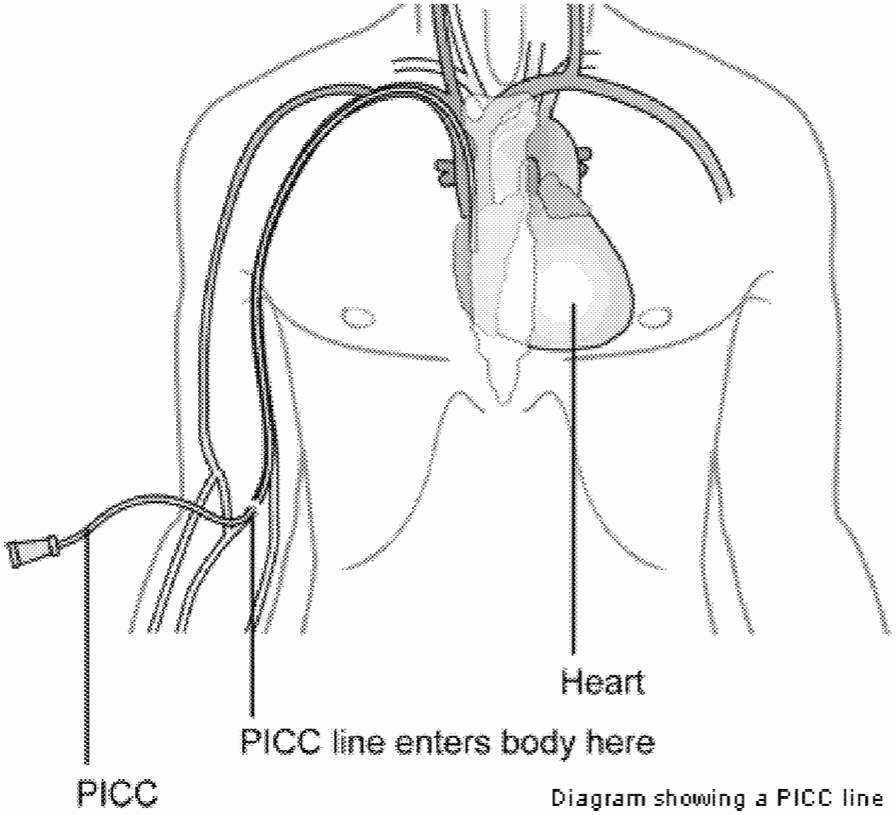
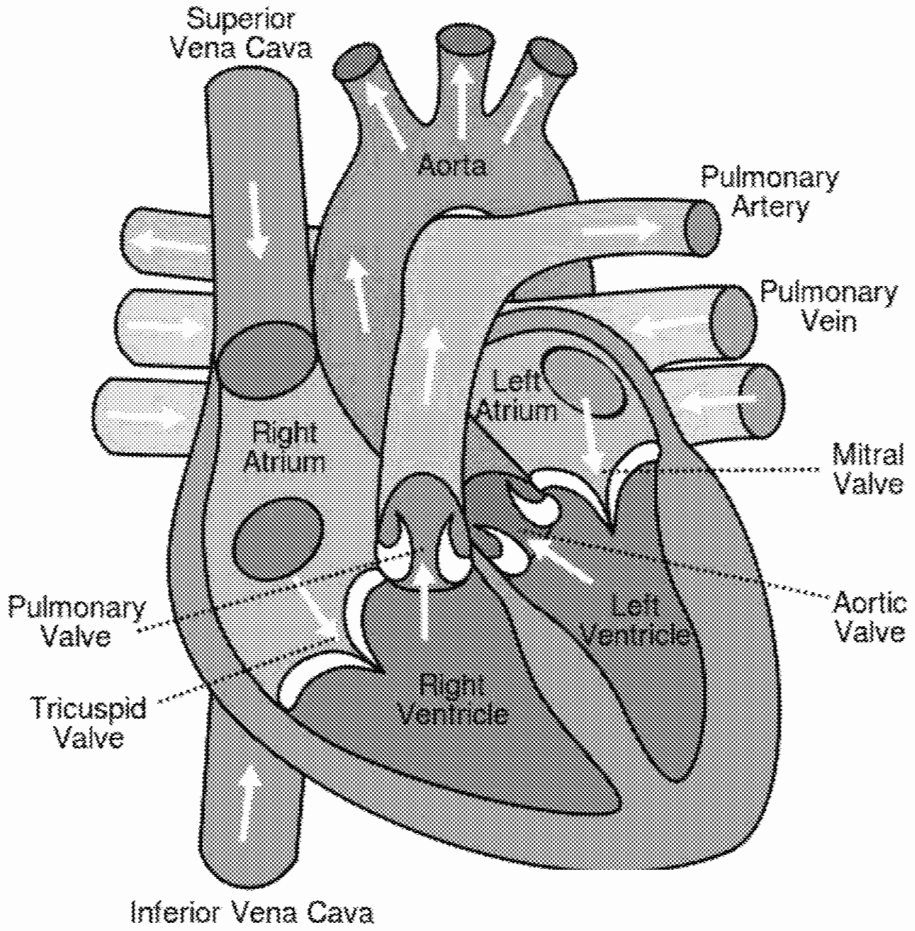


Diagram showing a PICC line



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Guidelines Regarding Catheter Tip Location [1,2,3,4]

Organization	Recommendation
The Association for Vascular Access (1998)	Lower one-third of the superior vena cava (SVC), close to the junction of the SVC and the right atrium
Infusion Nurses Society (2011)	Central venous access devices (CVAD) shall have the tip dwelling within the SVC near its junction with the right atrium.
Oncology Nurses Society (2010)	Distal third of the SVC
Society of Interventional Radiologists (2010)	Cavoatrial region

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Locating the Cavo-Atrial Junction [1,3,4]

The cavo-atrial junction (CAJ) is the point at which the superior vena cava meets the right atrium. This area of high blood volume (hemodilution) and turbulence creates a favorable location for delivery of IV medication.

- Catheter tip is too short (proximal SVC or in the innominate veins)
  - 10% to 50% increased risk of venous thrombosis , fibrin sleeve, vein erosion, catheter dysfunction
  - Spontaneous malposition (up into IJ)
- Catheter tip is too long (in the lower portion of the RA, RV, or beyond)
  - increased risk of arrhythmia, tricuspid valve dysfunction, atrial thrombosis, myocardial erosion (cardiac tamponade)

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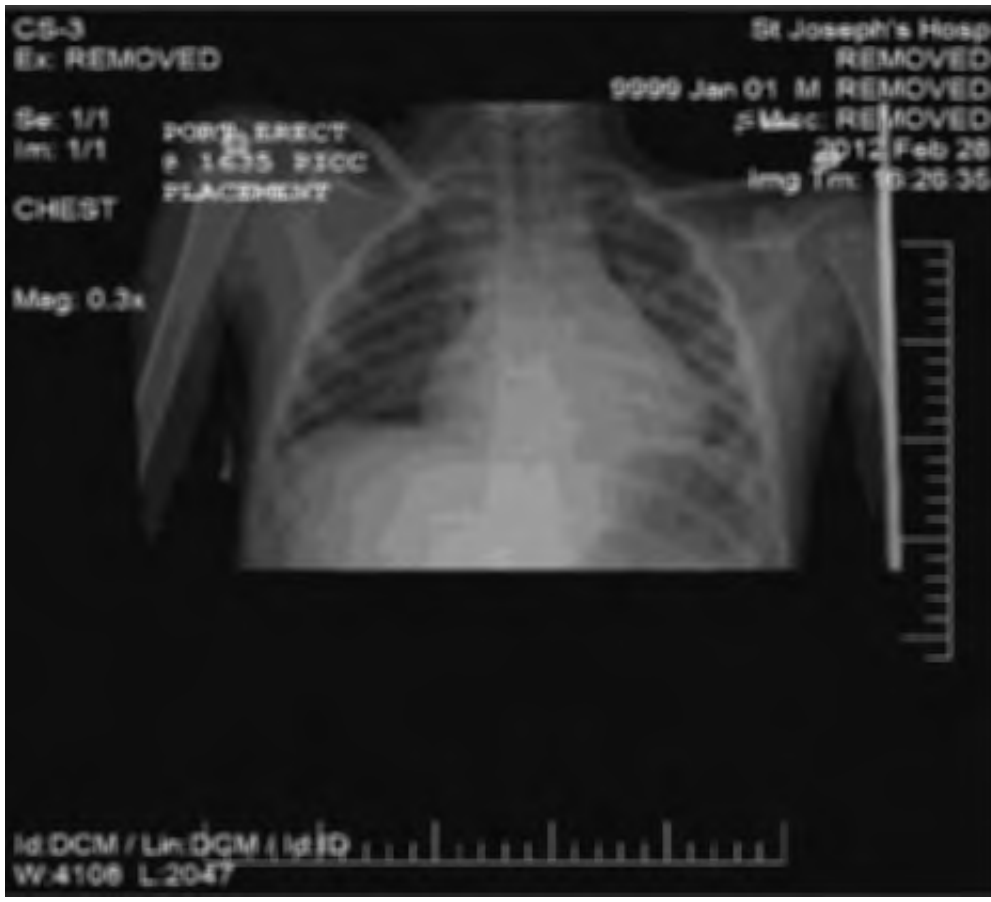
PICC Tip Positioning without ECG [2,3,7,8]

Traditional practices- included procedure landmark and anthropometric measurements followed by post-procedural chest radiography (x-ray).



Challenges with this practice include:

- Inefficient placement (malpositions) requiring repeat x-rays
- Inconsistency in required post-procedure x-ray interpretation by MDs
- Delays in clearing the PICC for use

Tip location of central venous access devices shall be determined radiographically or by other approved technologies prior to the initiation of infusion therapy. *(Infusion Nurses Society, 2011)*

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Navigation vs. Tip Location [3,4,7,8]

- **Navigation**
  - Refers to technology that ascertains information regarding general directionality of a vascular access device.
  - Utilizes electro-magnetic detection to illustrate audibly or visually catheter direction and general direction.
  - Require a custom stylet wire to be inserted within the catheter
  - Are effective in reducing catheter malpositions; however they **DO NOT** provide information regarding the catheter's tip location with respect to the heart
- **Tip Location**
  - Utilizes technology based on ECG to determine a catheters tip position in relation to the location of the heart
  - Rely on a stylet to serve as an intracavitary electrode to detect P-wave changes as the catheter nears the sinoatrial node
  - Approved tip location devices are used as an alternative or supplement to chest x-ray or fluoroscopy for PICC catheter line clearance.

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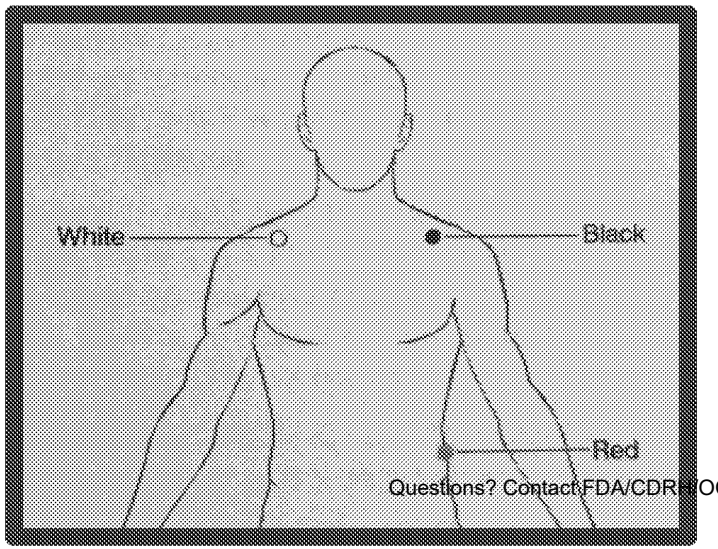
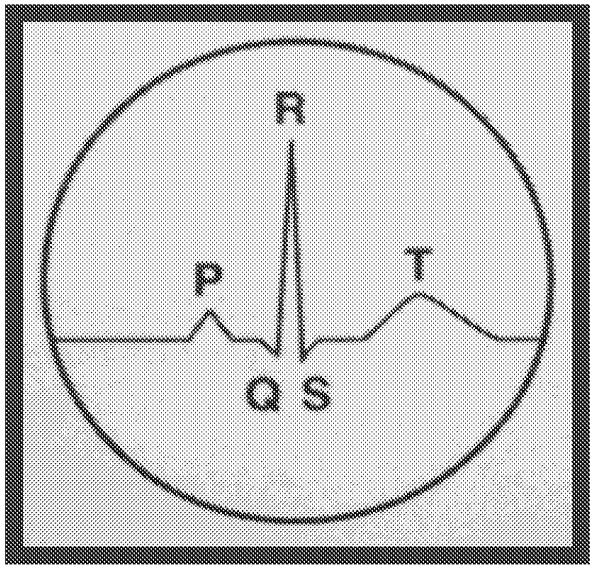
Electrocardiogram (ECG) Guidance [3,4,7,8]

- The catheter tip location is verified by observing the ECG
- An intra-cavitary electrode connected to the PICC (stylet, guidewire, or saline column) and three surface electrodes are placed on the patient's skin.
- The voltage across the electrodes indicates changes in the p wave as the catheter approaches the SA node (primary pacemaker of the heart)

"White on the right, smoke over fire"





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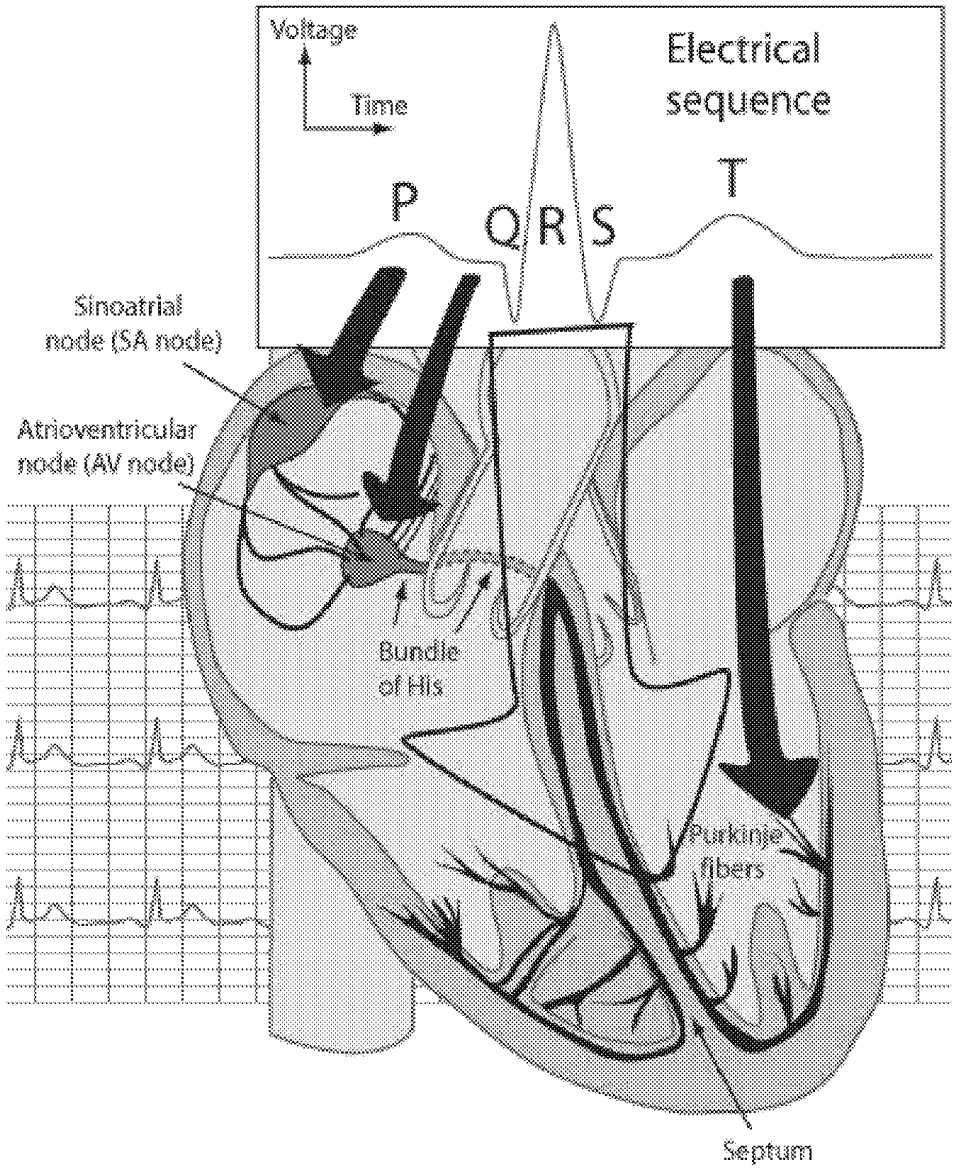
How ECG tip verification works [4,8,9]

- The PICC is advanced while monitoring the p wave and observing changes in amplitude
- The heart's **primary pacemaker** is a bundle of cells, known as the sinoatrial node or **SA node** and is located in the upper posterior wall of the right atrium.
- As PICC nears the SA node the exact catheter position can be determined by these changes
- When the p wave is at its maximum amplitude just prior to downward deflection the tip is at the CAJ



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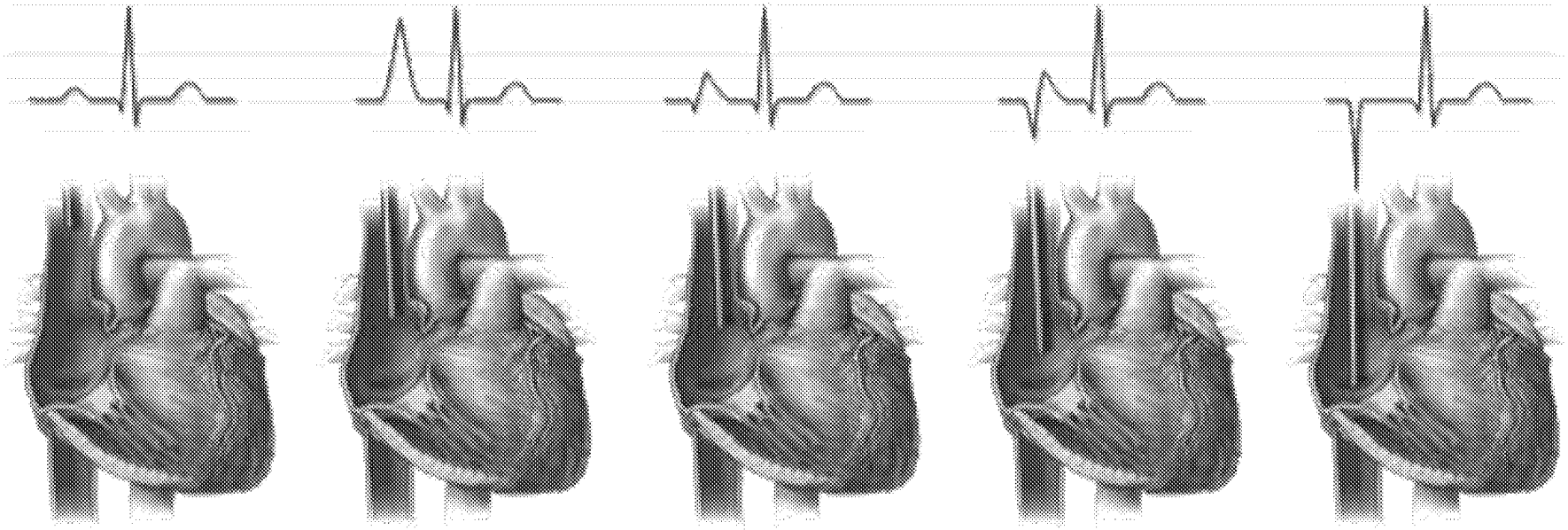
P-Wave Correlates to Catheter Proximity [4,8]



No evident P wave changes indicates a catheter is not in acceptable position.

A P wave at its max height will indicate the catheter is in the lower 1/3 of SVC

A downward defection edge of P wave indicates the catheter entering the right atrium

A biphasic P wave indicates the catheter is within the right atrium.

An inverted P wave indicates a catheter is approaching the right ventricle

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Limitations

Limiting, but not contraindicated, situations for this technique are patients where cardiac rhythms may change presentation of the P-wave:

- Atrial fibrillation
- Atrial flutter
- Severe tachycardia
- Pacemaker-driven rhythm
- Chronic obstructive pulmonary disease (COPD)

Such patients are easily identified prior to PICC insertion

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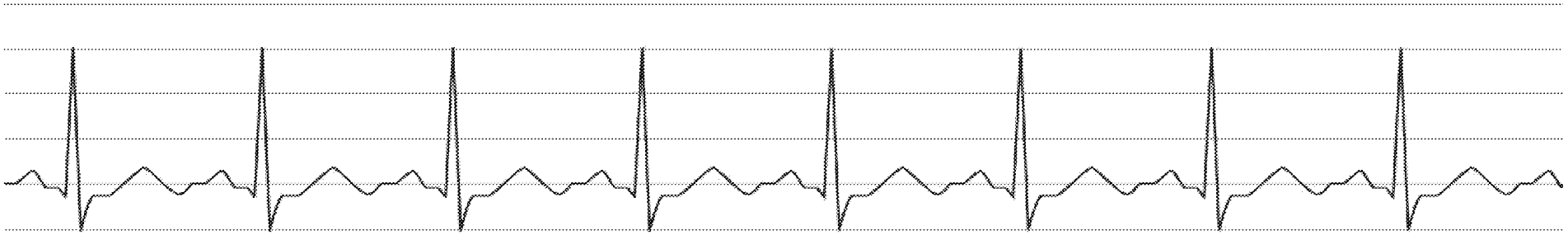
Assessing P Wave [9]

- Are P waves present?
- Do they look alike?
- Do they occur at a regular rate?
- Is there one P wave for each QRS?
- Are they upright?



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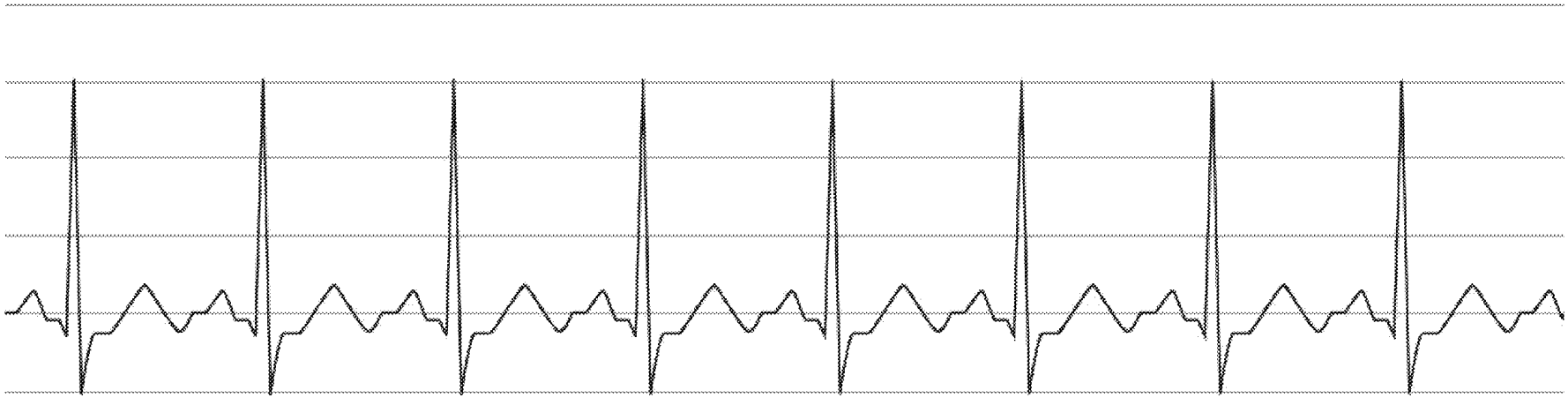
Normal Sinus Rhythm [9]

- Sinus rhythms originate at the SA node & generally travel through the heart's entire conduction system without inhibition. This is a "normal" rhythm.
- Rate 60-100 beats per minute*



* Sinus bradycardia looks similar but with rate less than 60
Sinus tachycardia likewise but with rate greater than 100

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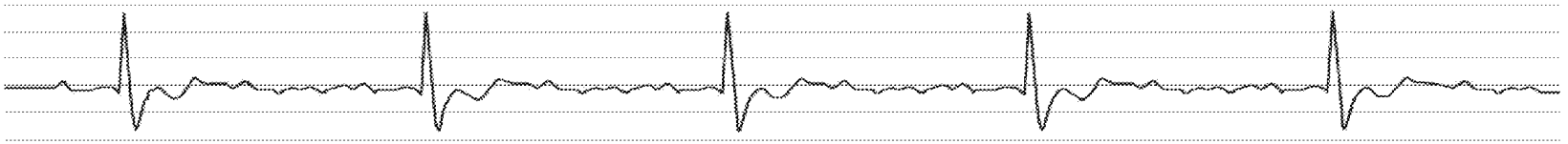
Atrial Fibrillation [9]

- Atrial fibrillation is the most common sustained arrhythmia. It affects as many as 10% of patients over age 75.
- A multitude of foci initiate impulses causing a chaotic irregular atrial rhythm having no pattern or shape
- Atrial rate can exceed 400 beats per minute but most are blocked by the AV node and considered under control by medication when heart rate is between 60-100 beats per minute
- Mistaken for Atrial Tachycardia but AT has p waves with multiple shapes that vary and a rate 120-150

A-Fib will not allow accurate P wave interpretation for ECG tip location



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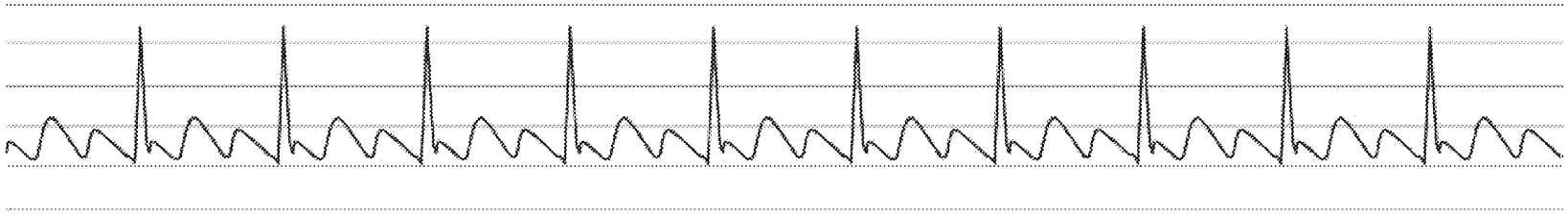
Atrial Flutter [9]

- Atrial flutter is recognized by P-waves with a “saw-tooth” pattern or resemble a “picket fence”
- Characterized by a series of identical flutter waves in a rapid, repetitive fashion
- Atrial rate is between 250-400 but most impulses are blocked by the AV node.

A-Flutter will not allow accurate P wave interpretation for ECG tip location



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Artificial Pacemaker [9]

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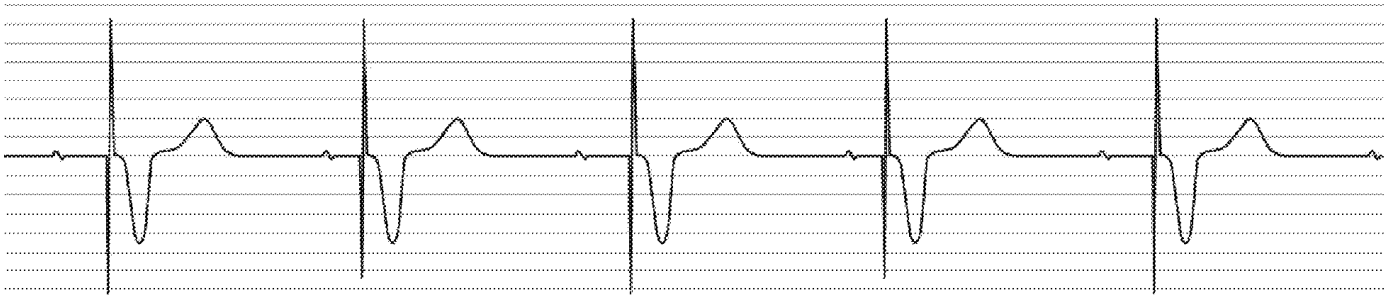
An artificially atrial paced heart will not allow accurate interpretation of the P wave response for ECG tip location.



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7. Pittiruti, M., La Greca, A., & Scoppettuolo, G. (2011). **The electrocardiograph method for positioning the tip of central venous catheters**. *J Vasc Access*. DOI: 10.5301/JVA.2011.8381
8. Moureau, N., et al. (2010). **Electrocardiogram (EKG) guided peripherally inserted central catheter placement and tip position: Results of a trial to replace radiological confirmation.** *JAVA*. 15(1): 8-14
9. Huff, J. (1997). ***ECG Workout: Exercises in Arrhythmia Interpretation.*** **(3rd ed).** Lippincott, New York

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Tradename

ECG-Based PICC Tip Confirmation System

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Indications for Use

The Tradename is indicated for use as a supplemental aid in positioning for Peripherally Inserted Central Catheters (PICC) in adult patients.

It provides real-time catheter tip location information by using the patients cardiac electrical activity. Confirmation of tip placement should be verified according to clinical judgment and established hospital protocol (e.g. chest x-ray, fluoroscopy).

Note: Limiting but no contraindicated, situations for this technique are patients where cardiac rhythms may change presentation of the P-wave: Atrial fibrillation, Atrial flutter, Severe tachycardia, Pacemaker-driven rhythm and COPD. Such patients are easily identified prior to PICC insertion. Use of an additional confirmation method is necessary to confirm catheter tip location.

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Intended Use

- The Tradename is intended to provide real time tip location information of a central venous catheter
- Utilizes ECG to observe P-wave changes as the tip approaches the right atrium of the heart via the superior vena cava

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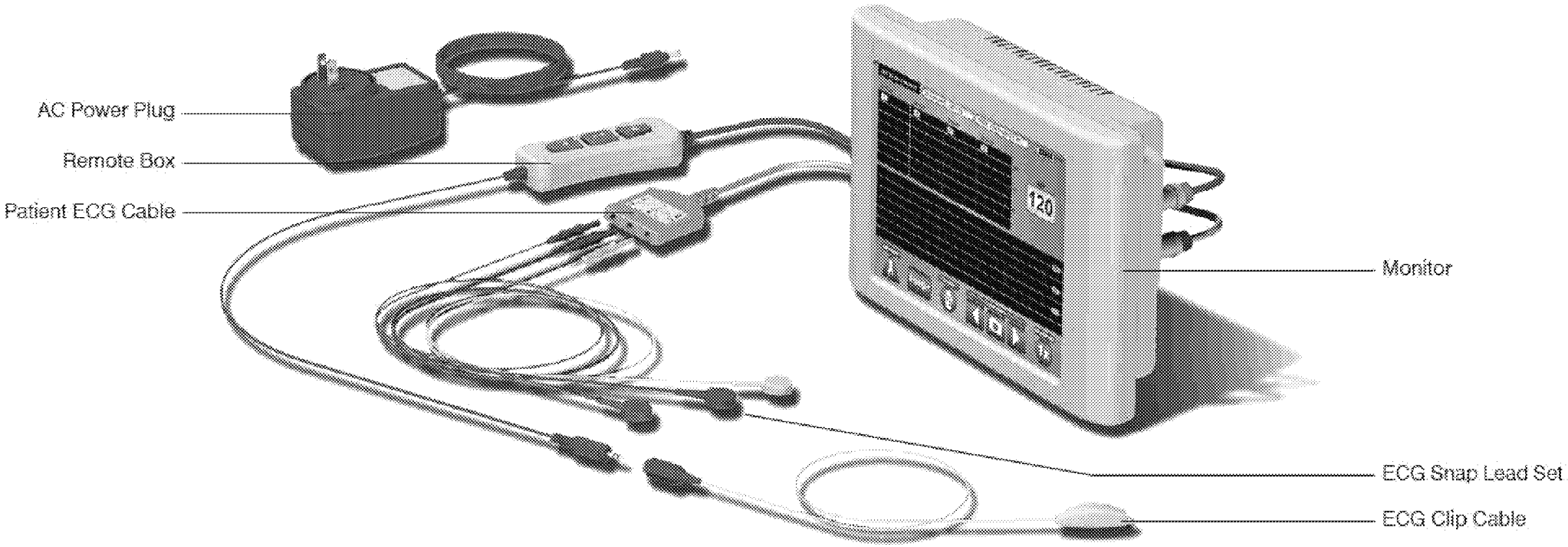
Tradename



- Monitor
- Patient ECG Cable
- Remote Box
- ECG Clip Cable

- AC Power Plug
- ECG Snap Lead Set
  Disposable ECG Clip Cable

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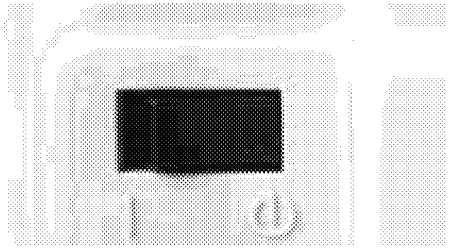
Power it on



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Patient ID

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ECG Screen

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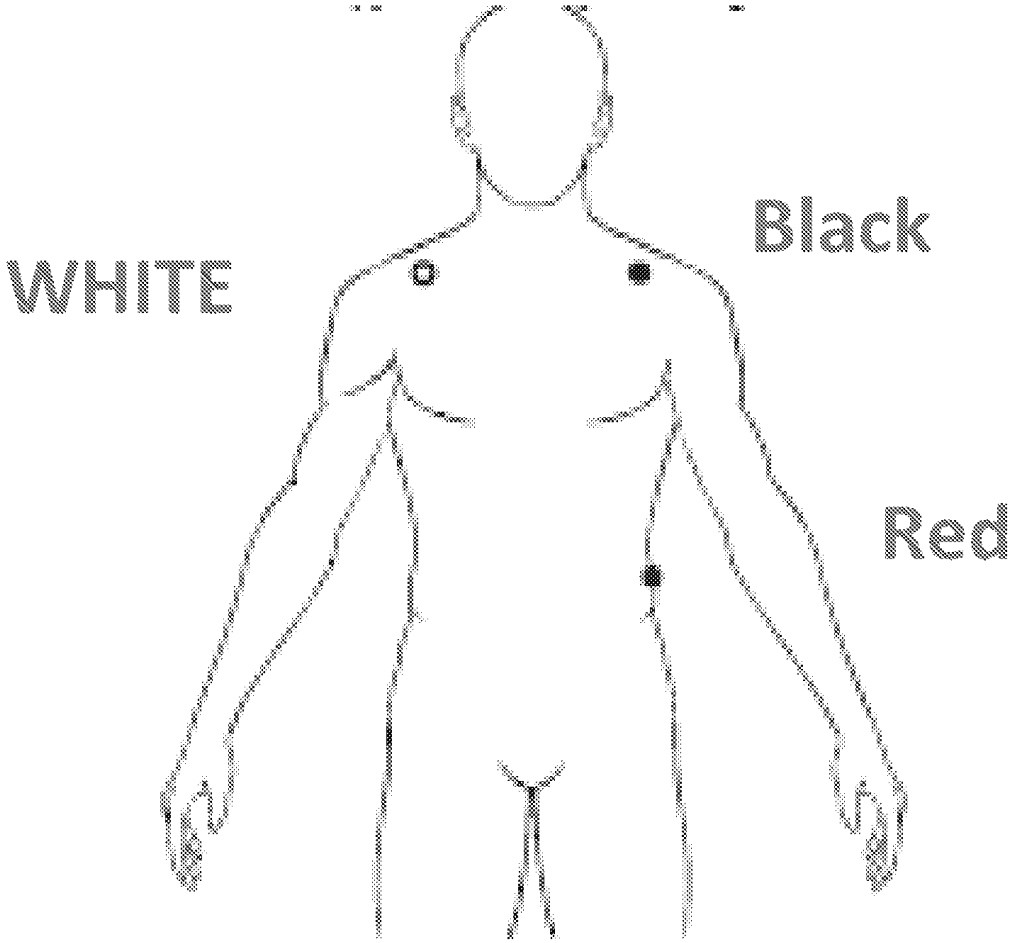
Connect Surface Leads



"White on the right, smoke over fire"

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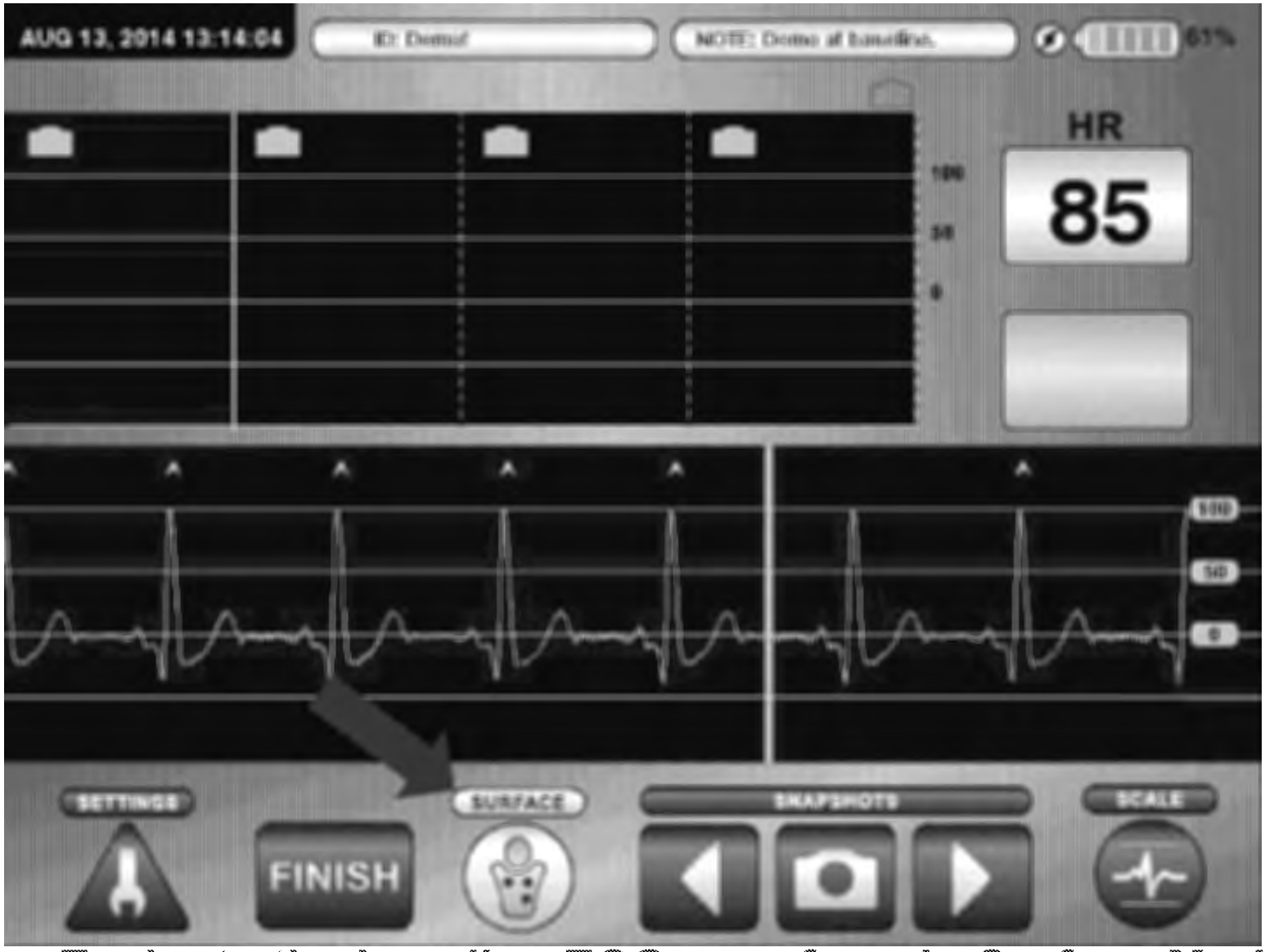
Surface ECG



Evaluate the baseline ECG waveform in Surface Mode

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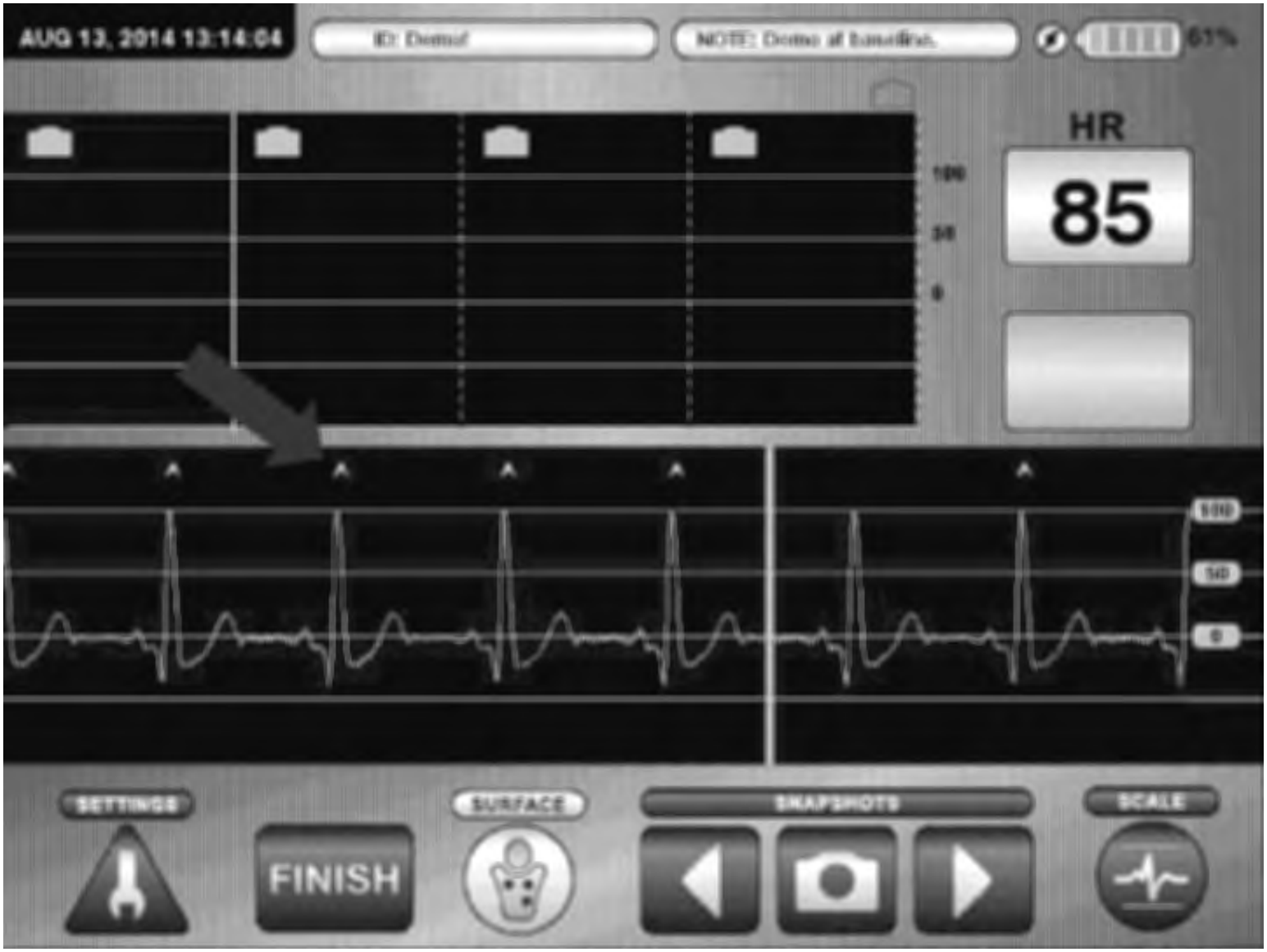
Normal Sinus Rhythm



Use the snapshot icon to obtain an image of the baseline ECG

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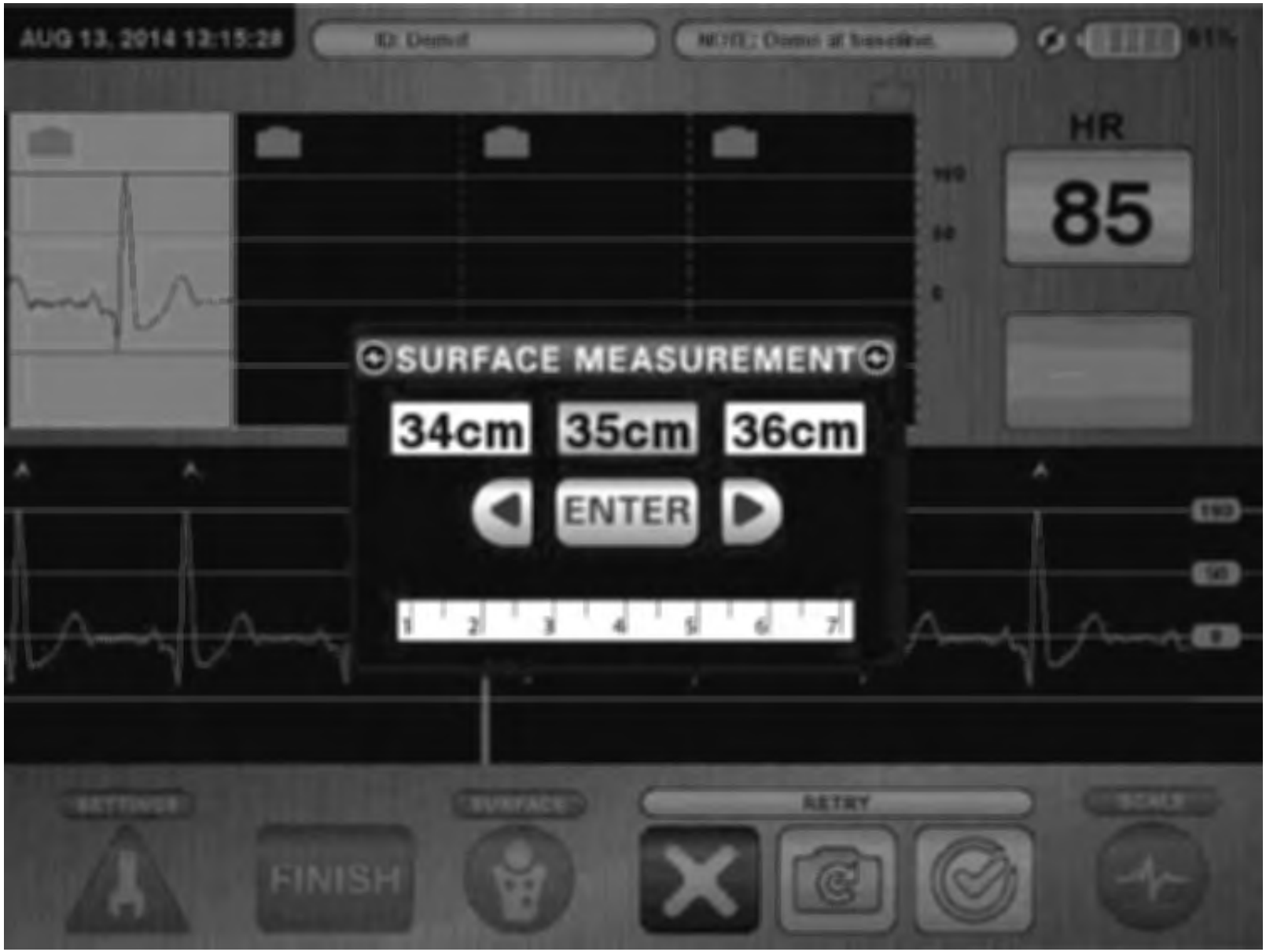
Surface Measurement



Enter the surface measurement

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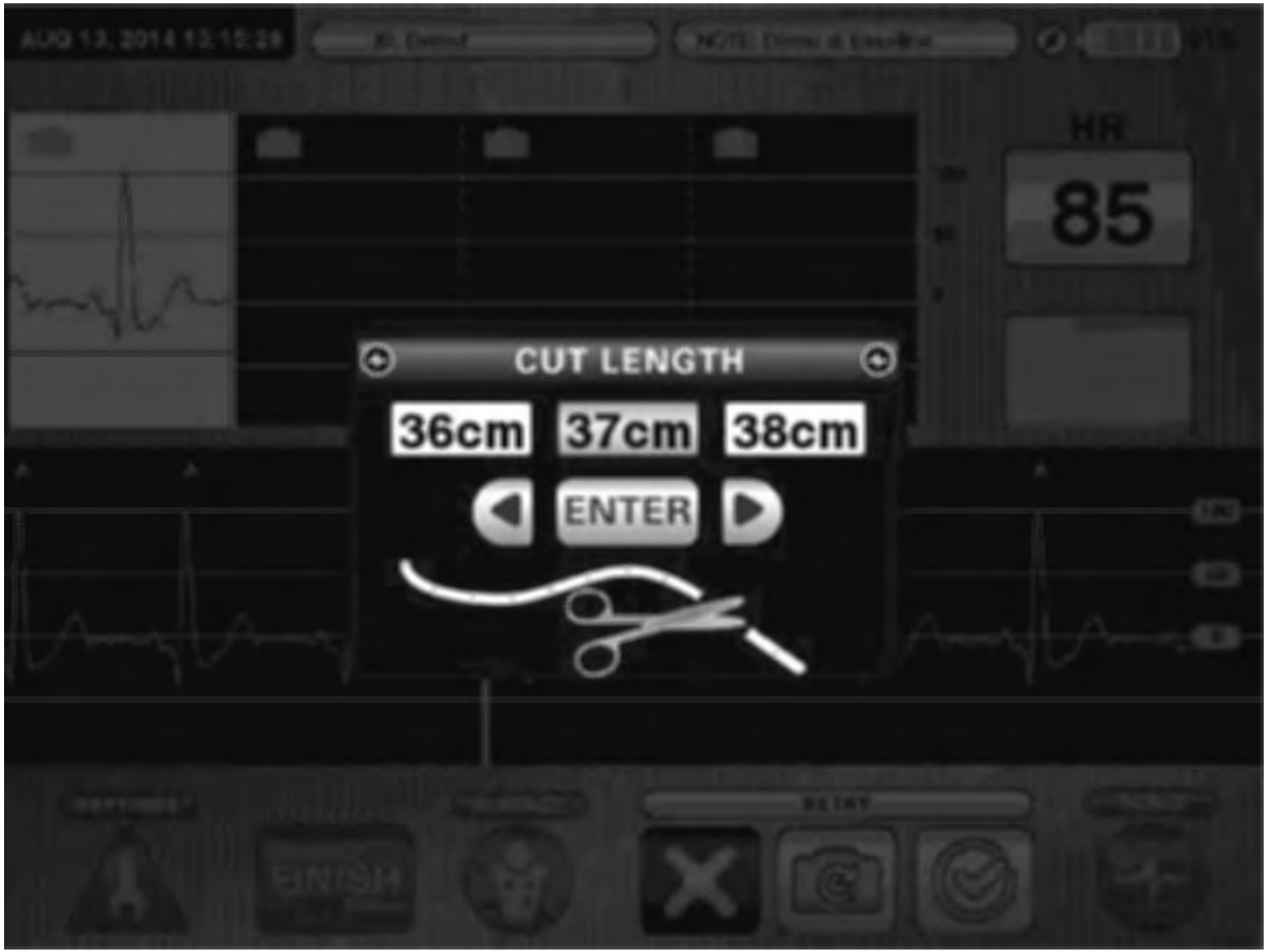
Cut Length



Enter the surface measurement

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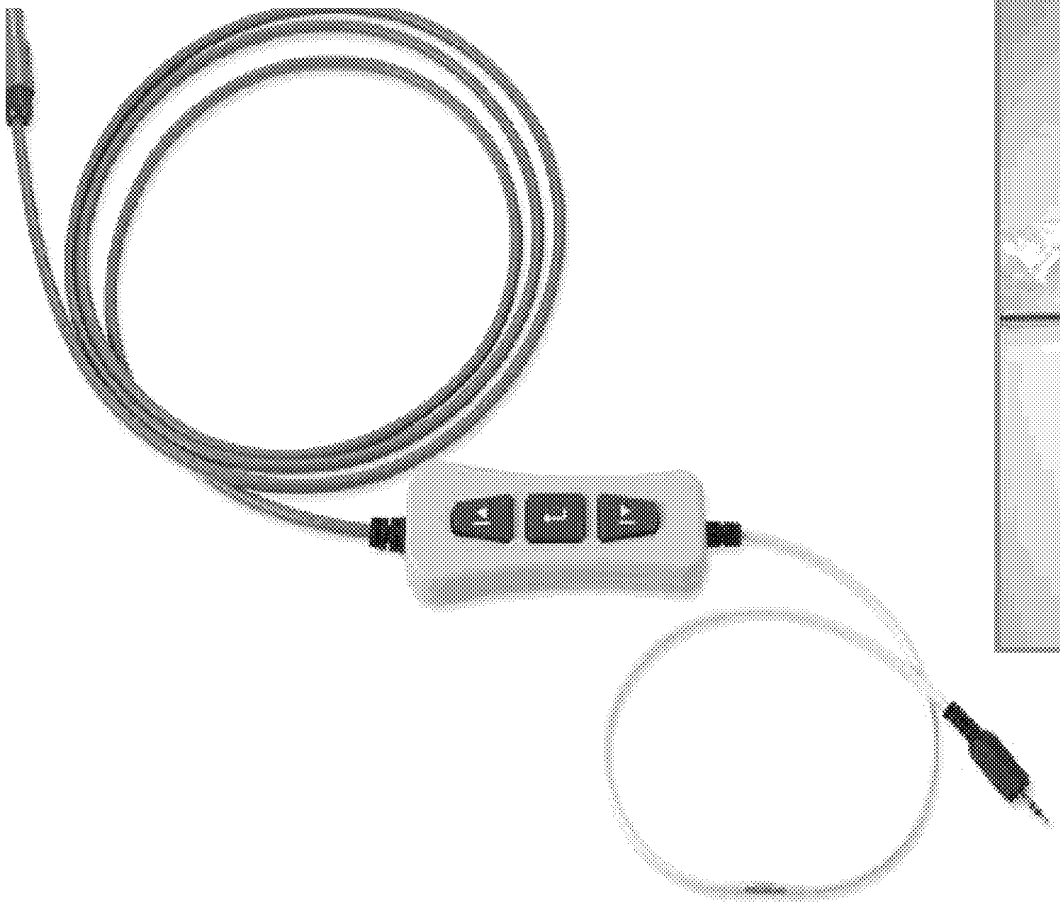
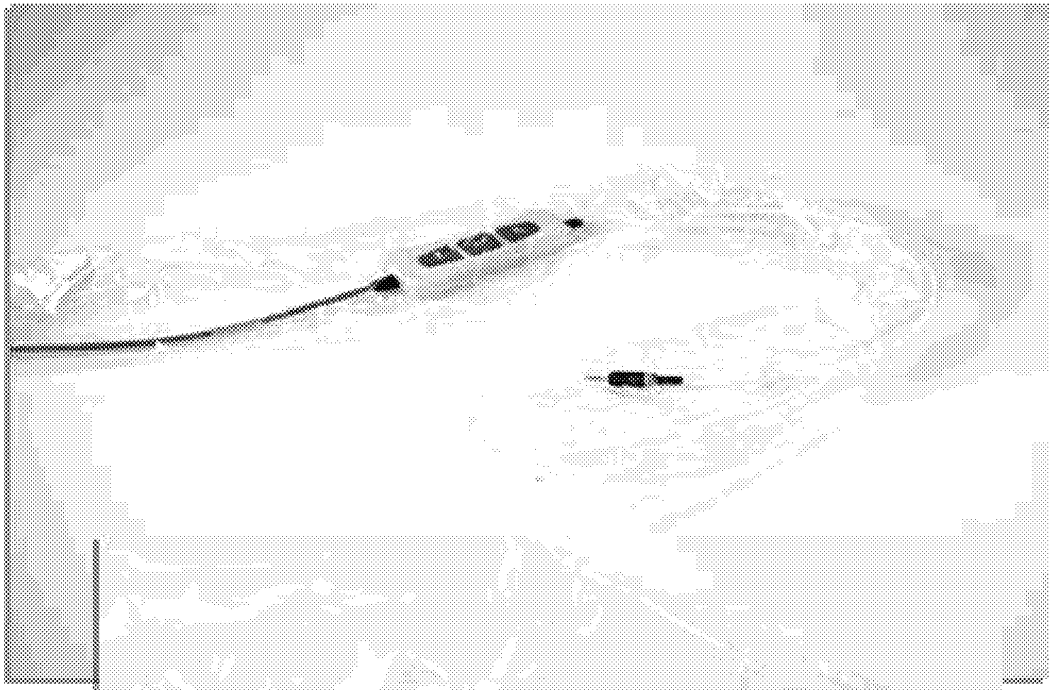
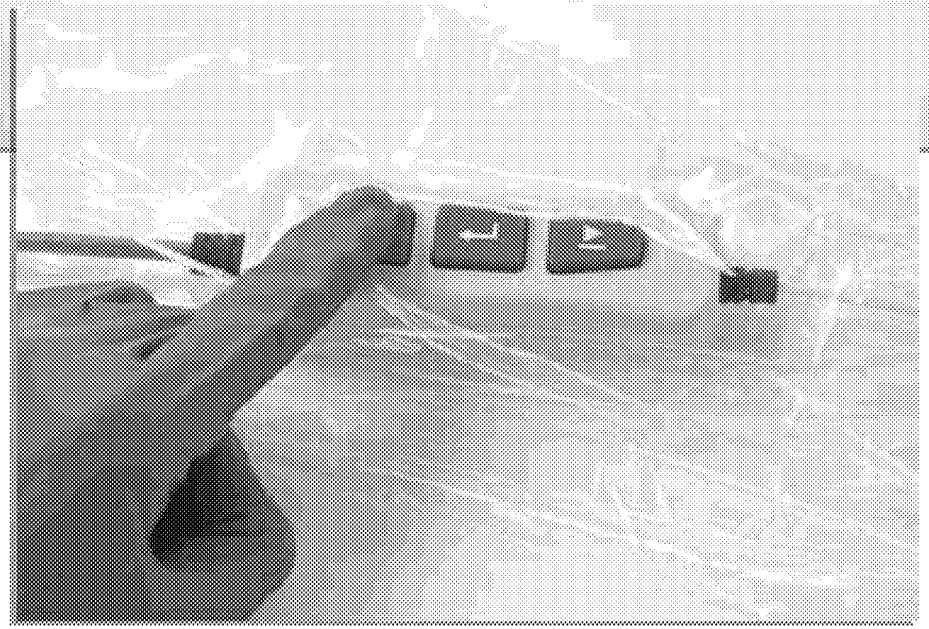
Remote Cable







Cover the remote cable with the sterile cable

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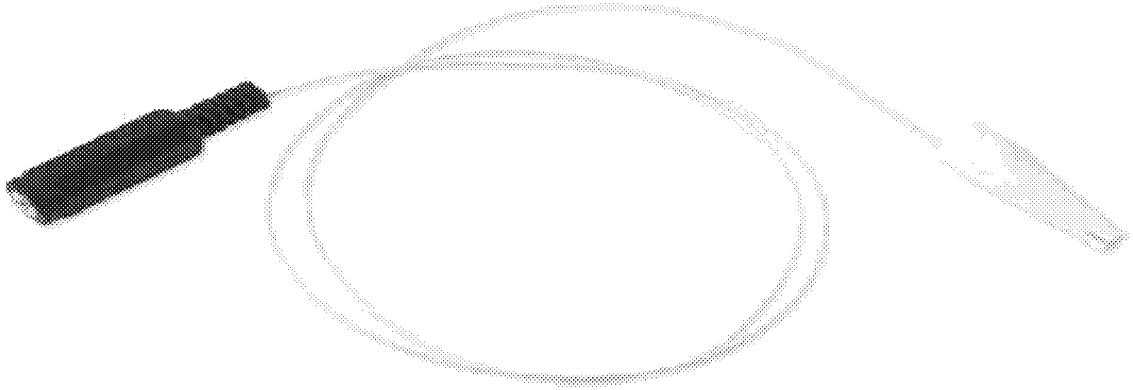
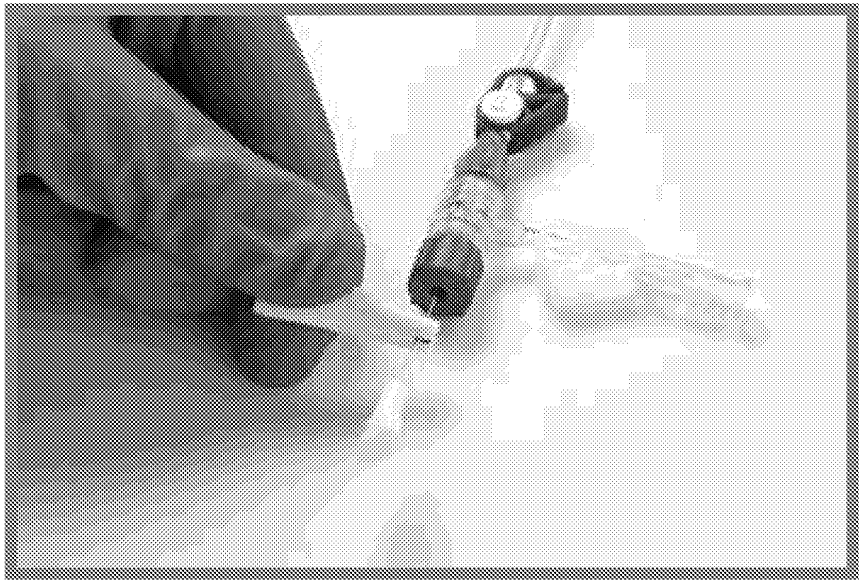
ECG Clip Cable



Secure the ECG clip cable to the proximal end of the stylet



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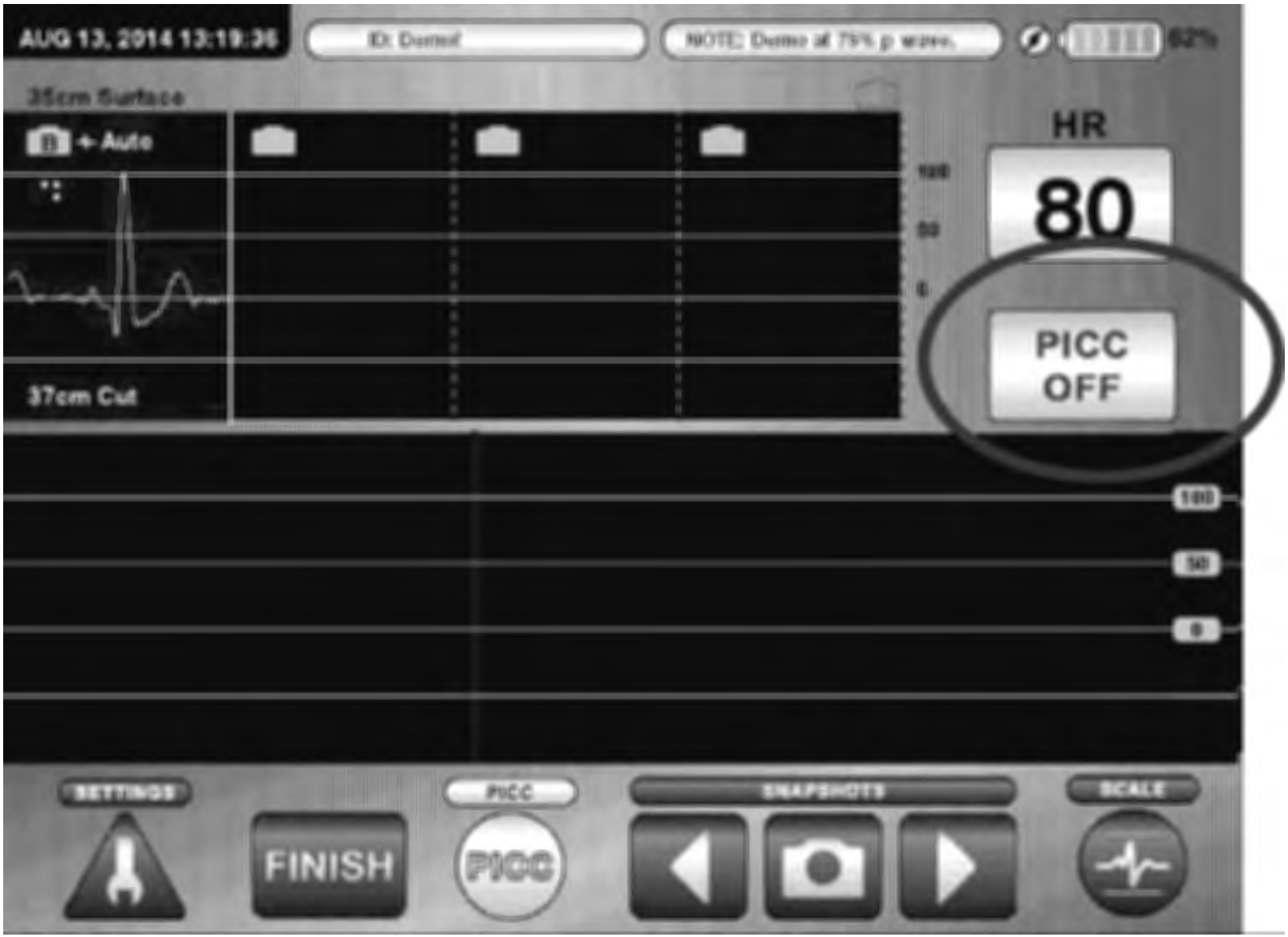
PICC Mode



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PICC Mode

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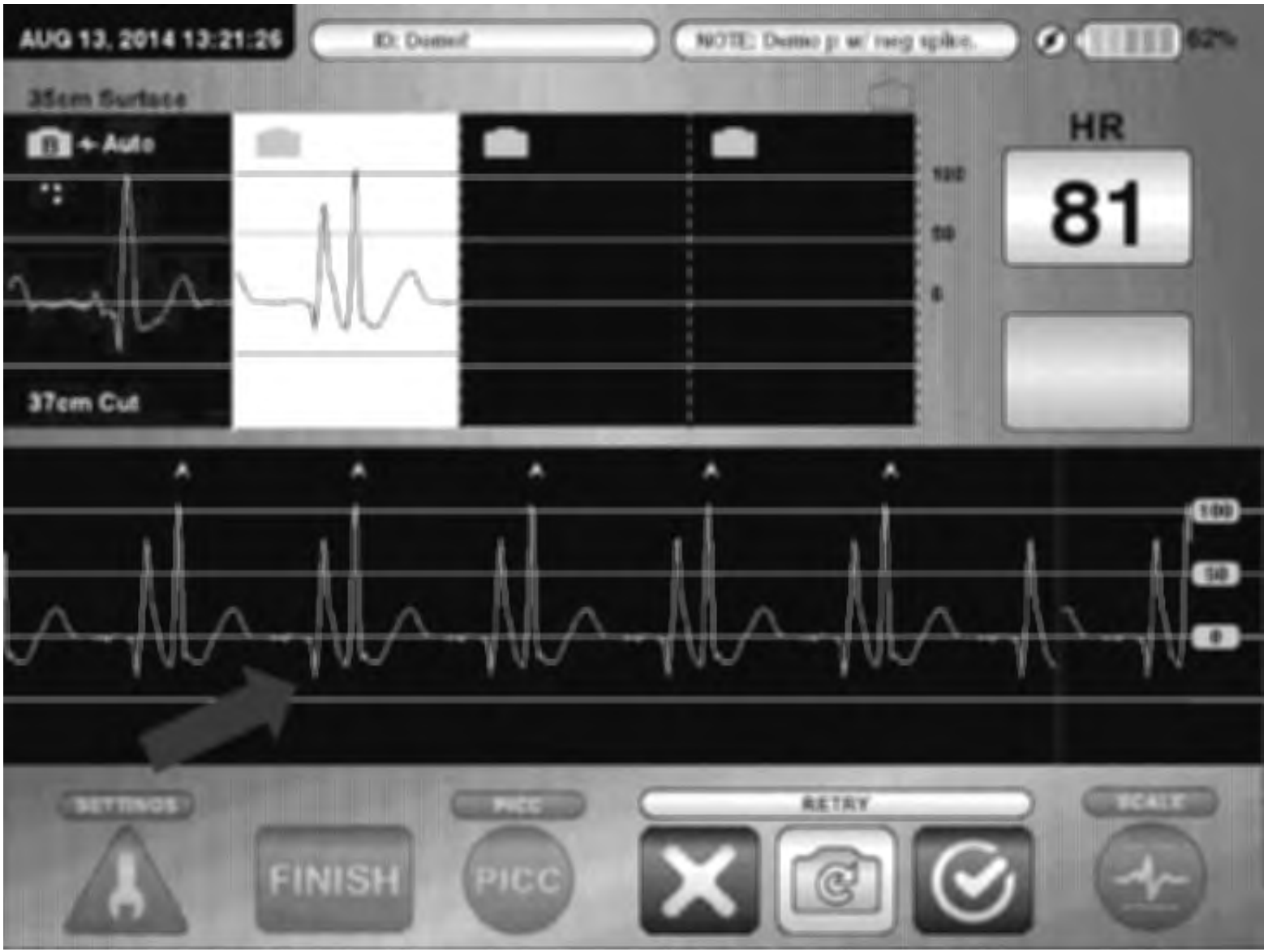
Negative Deflection



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Exposed Catheter Length

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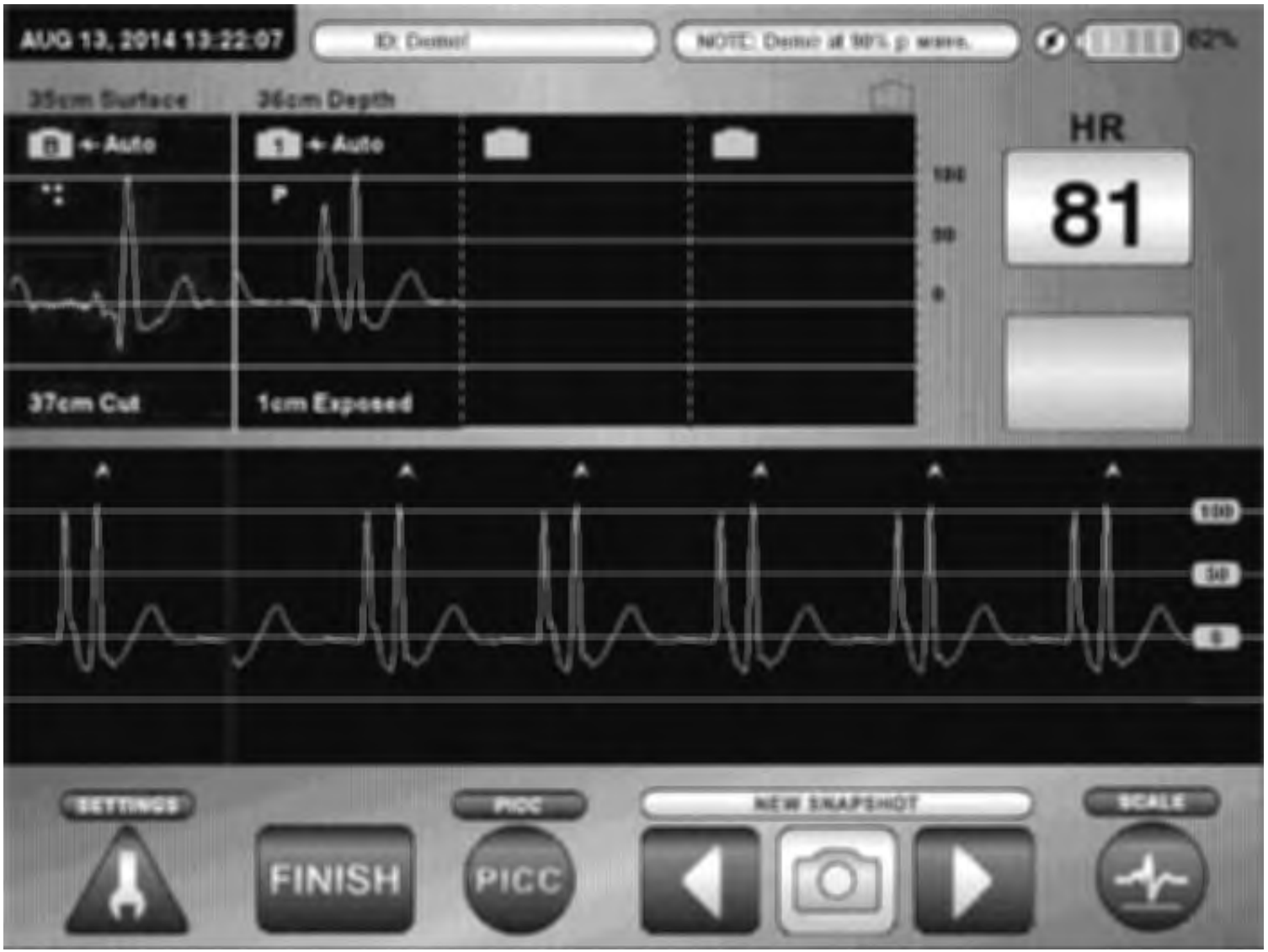
Max P-wave



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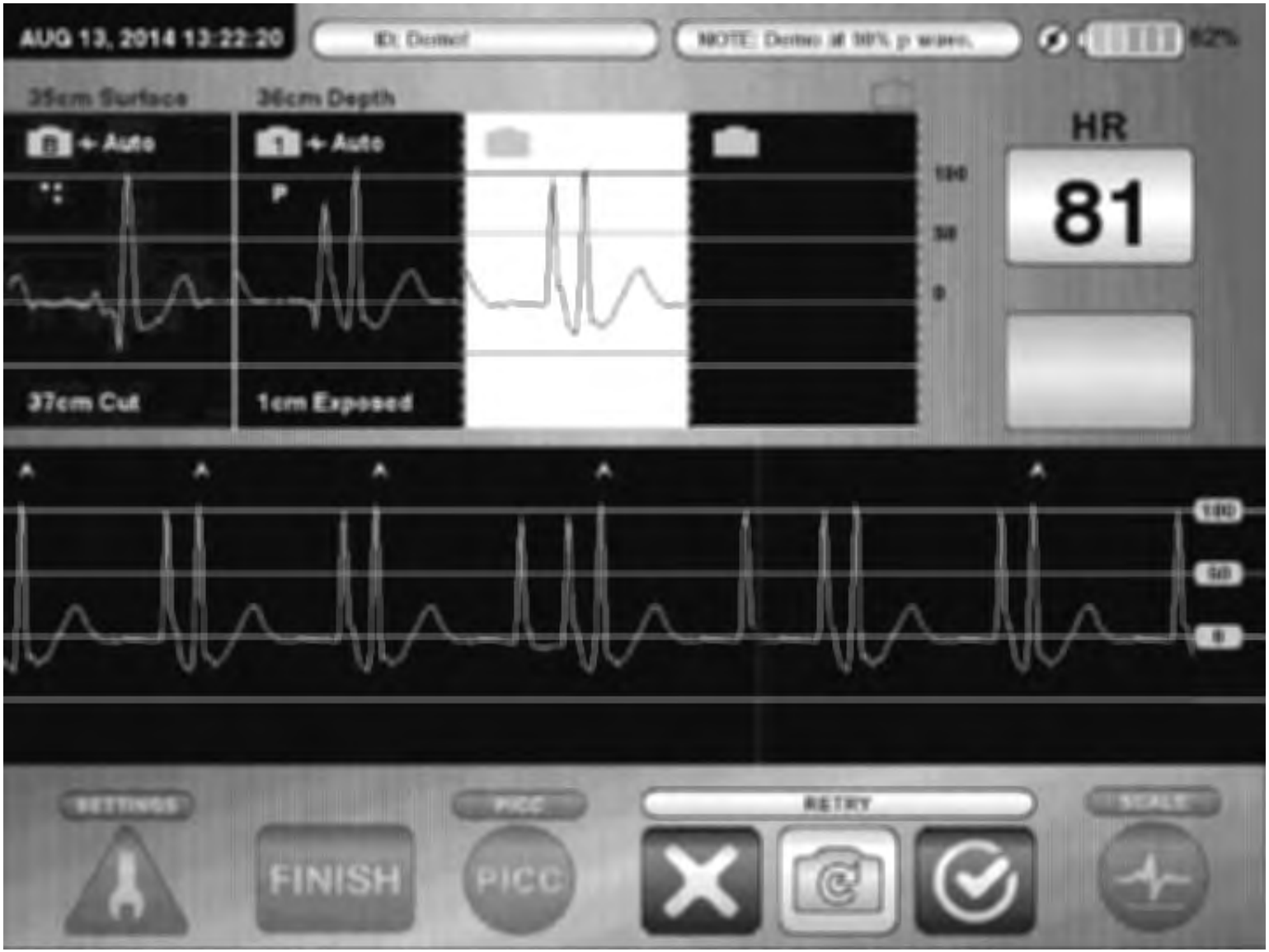
Max P-wave



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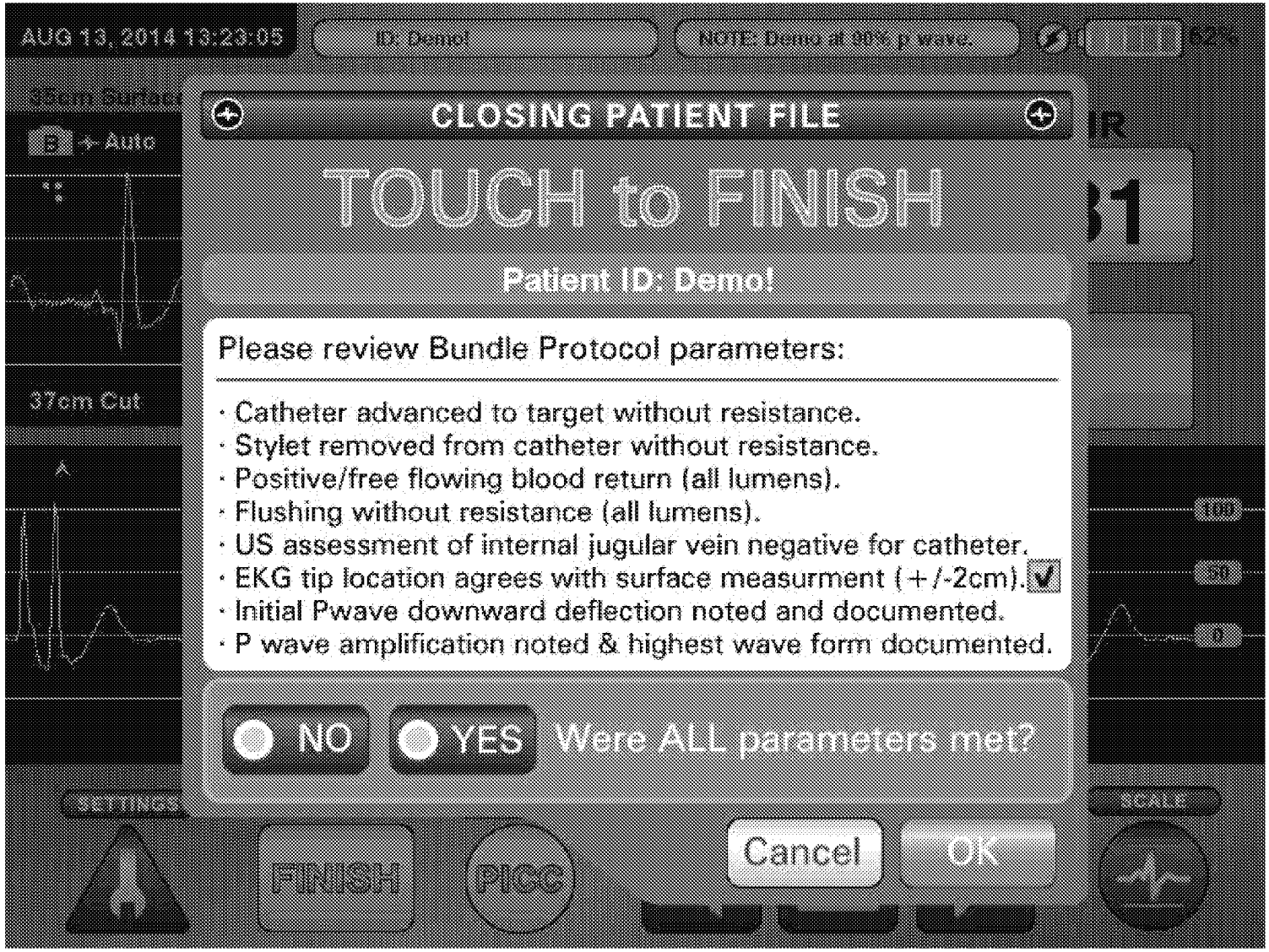
Bundle/Finish screen



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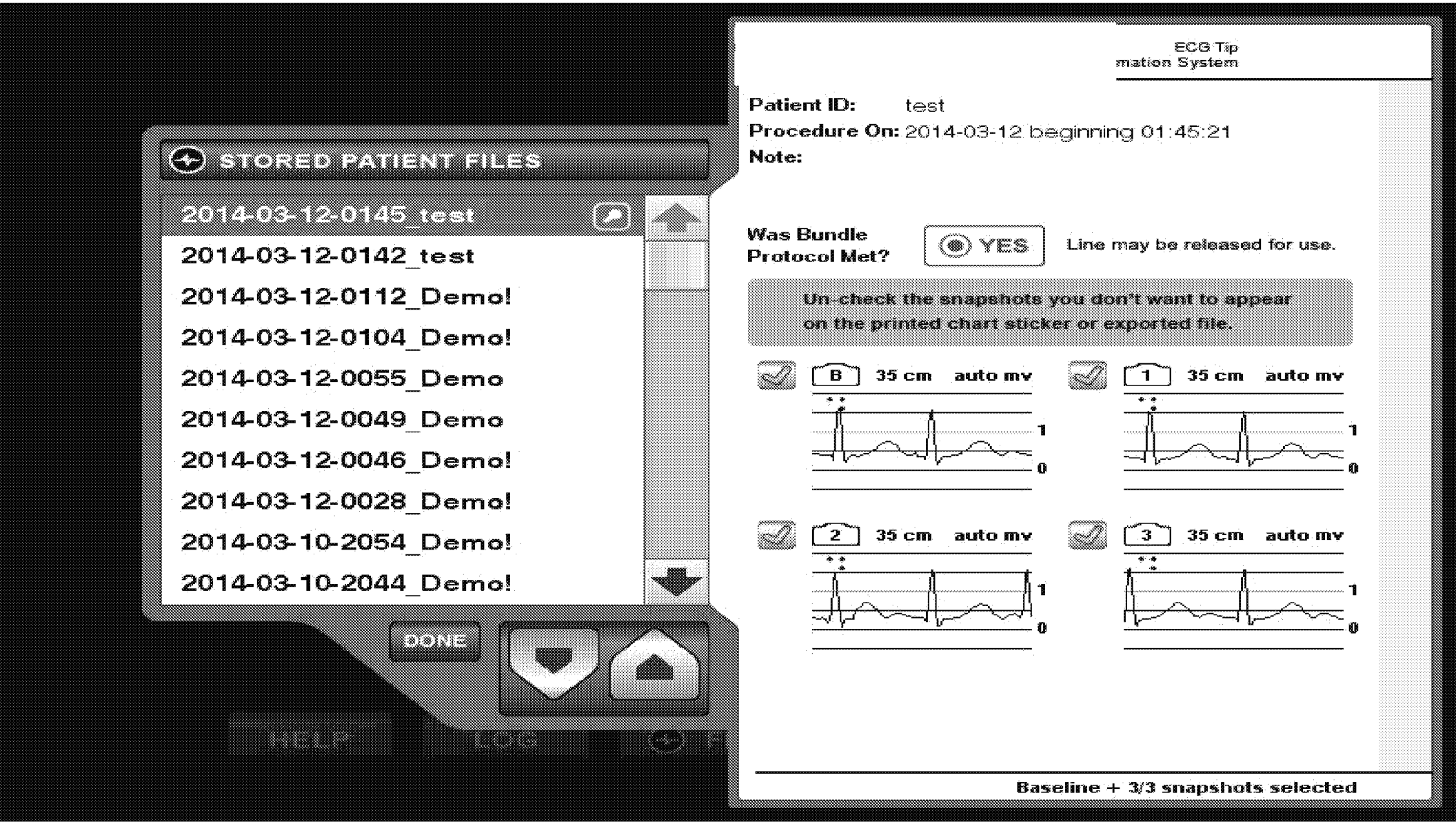
Preview



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Print or Save to USB

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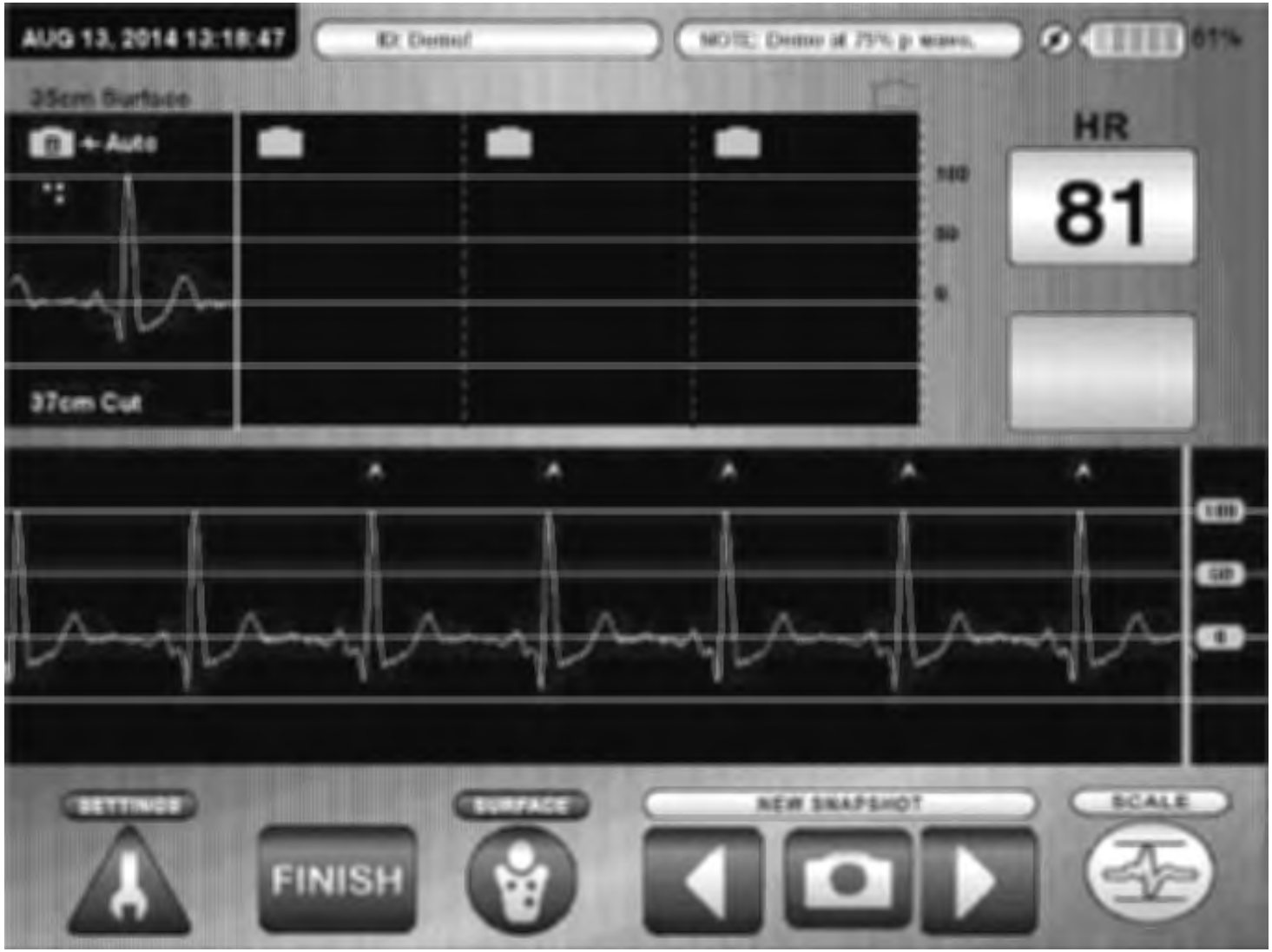
Scale Settings



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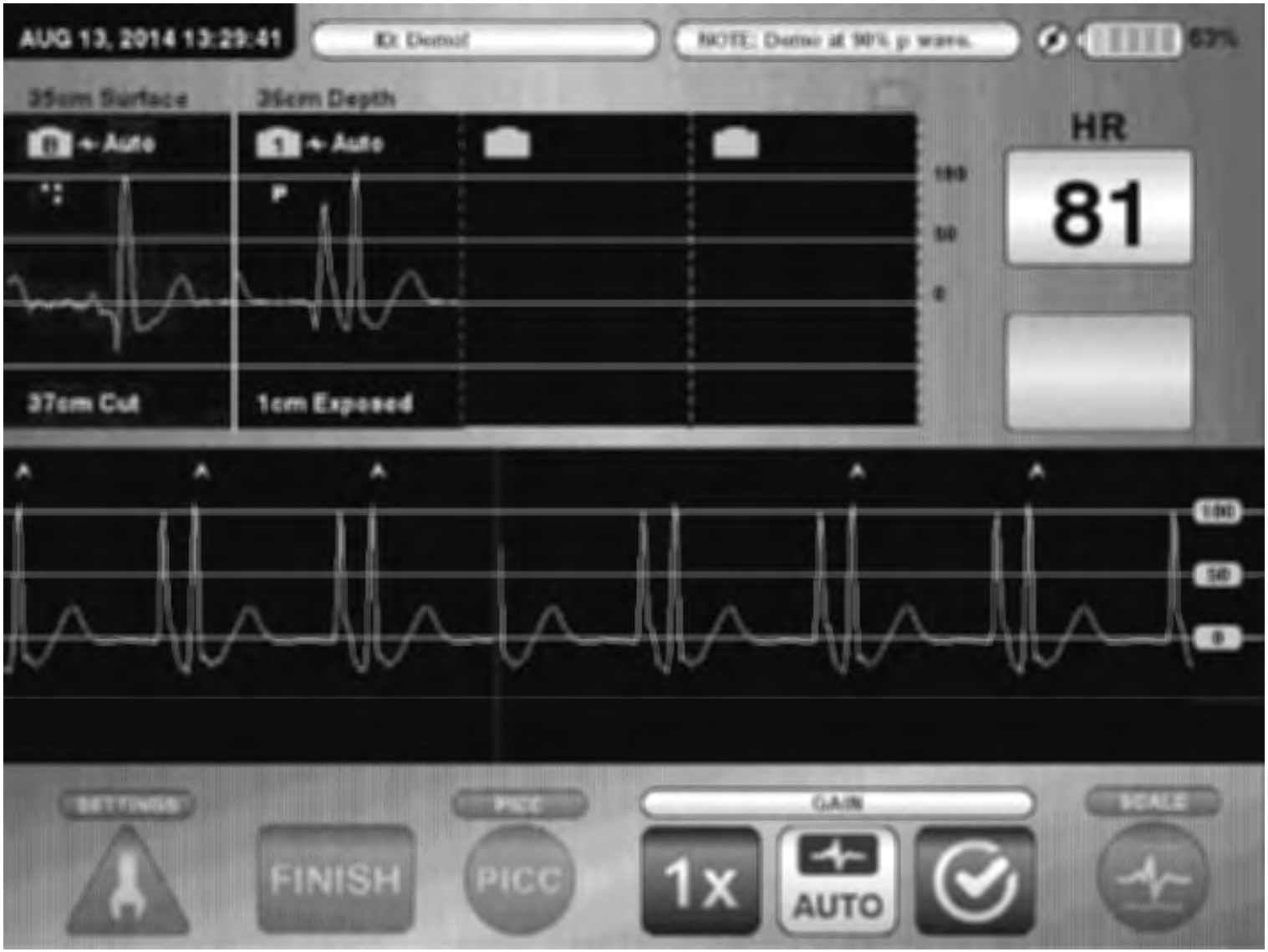
ECG Speed



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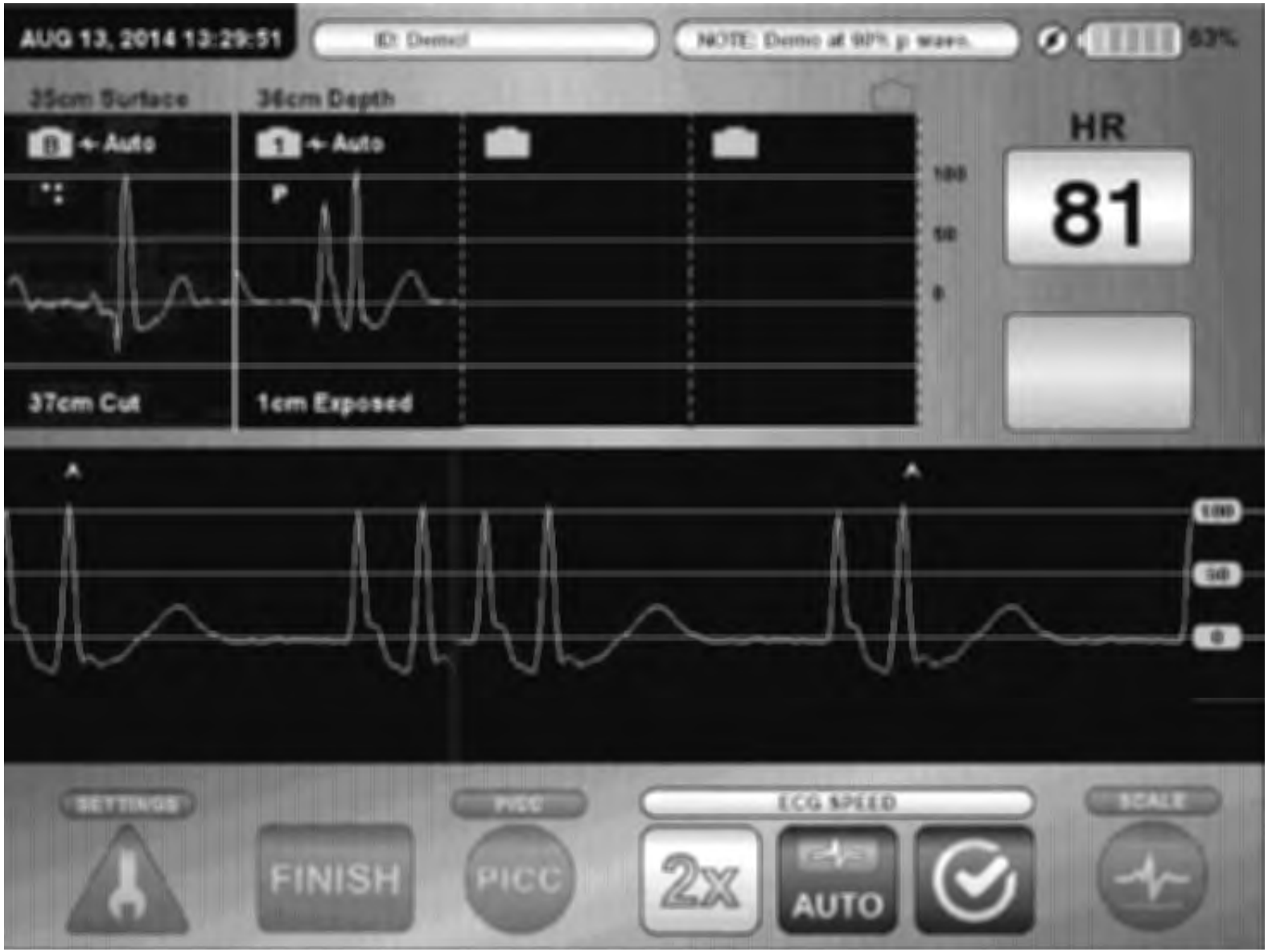

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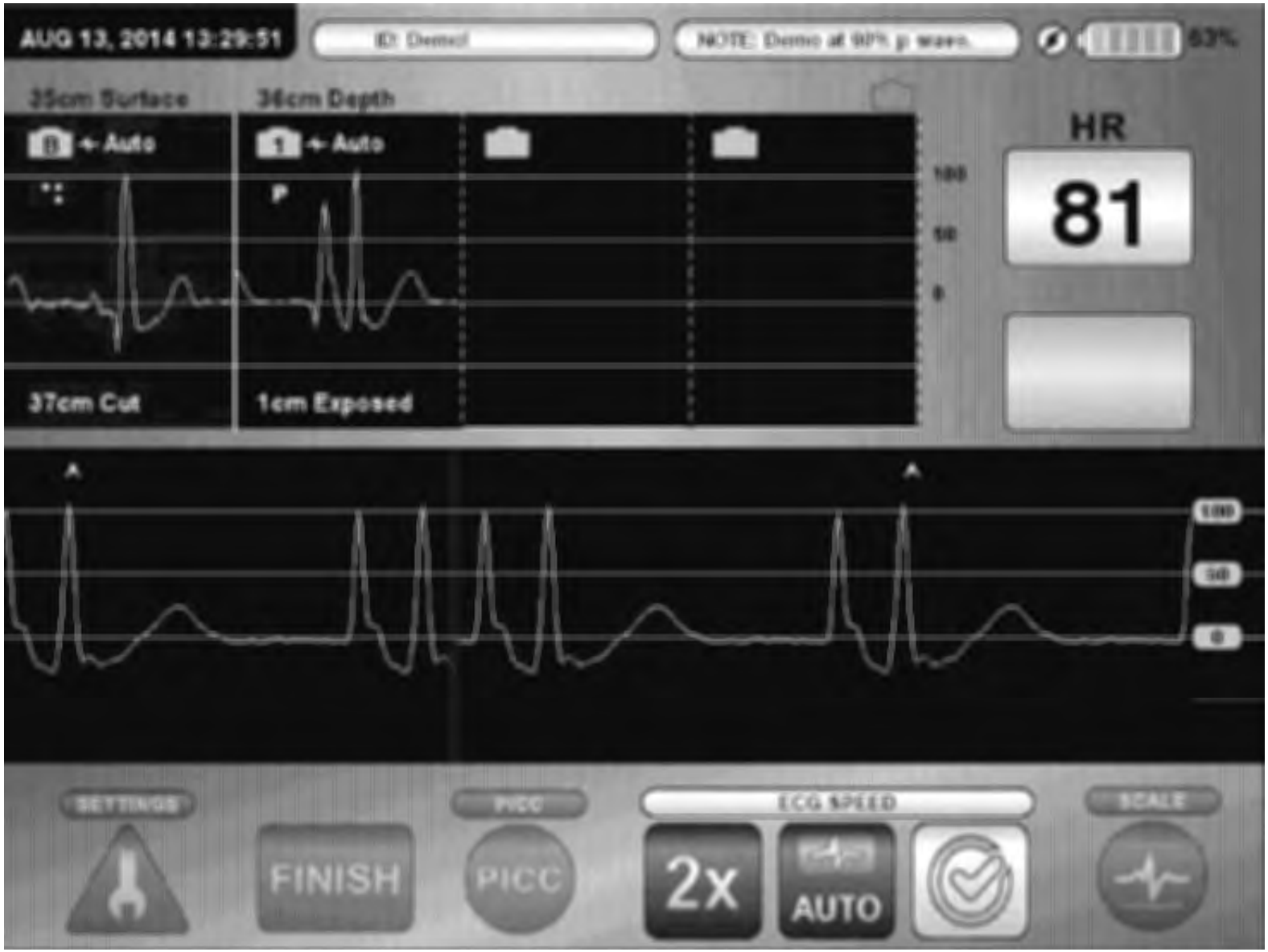
Accept icon



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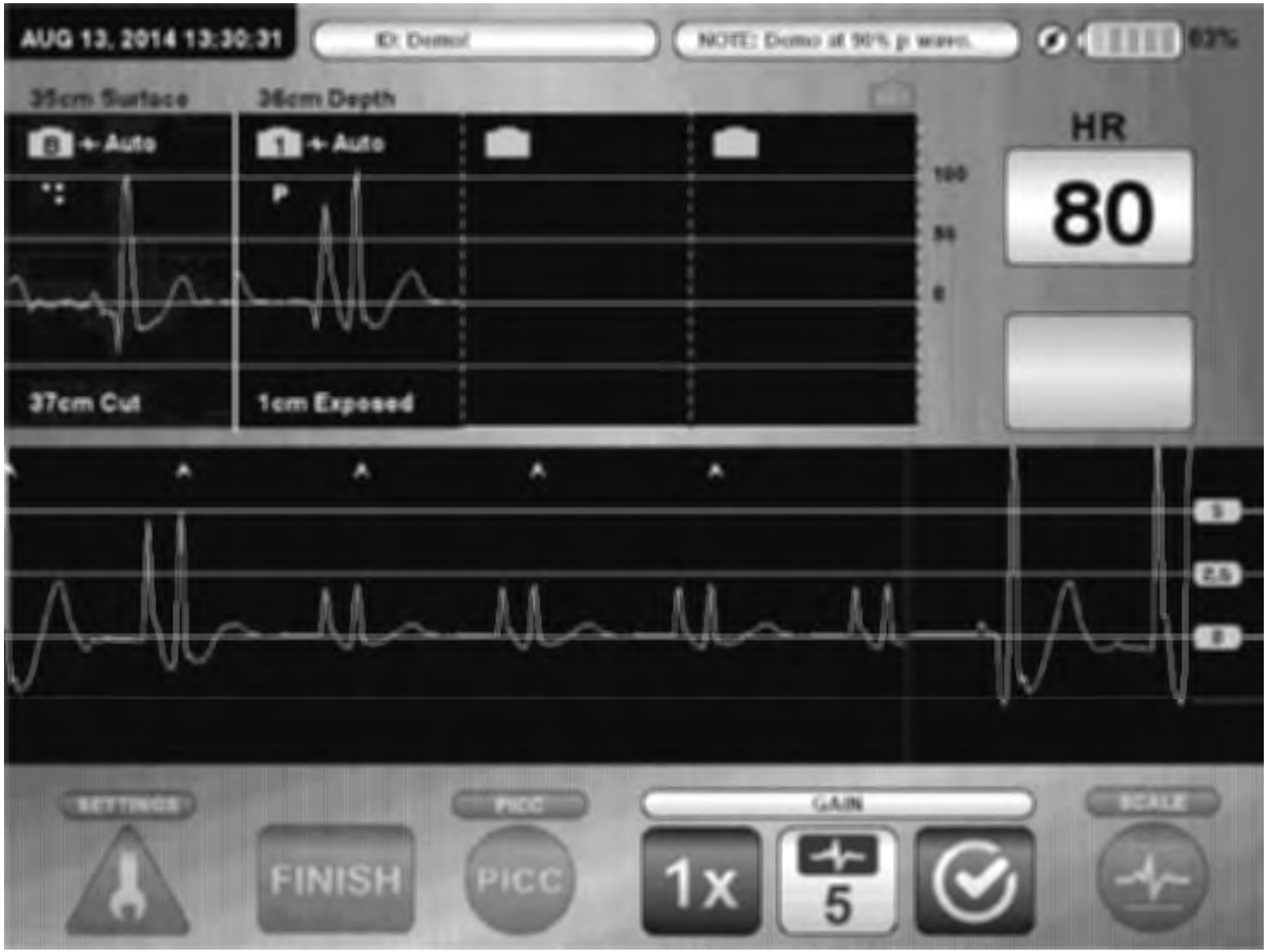
Gain Setting



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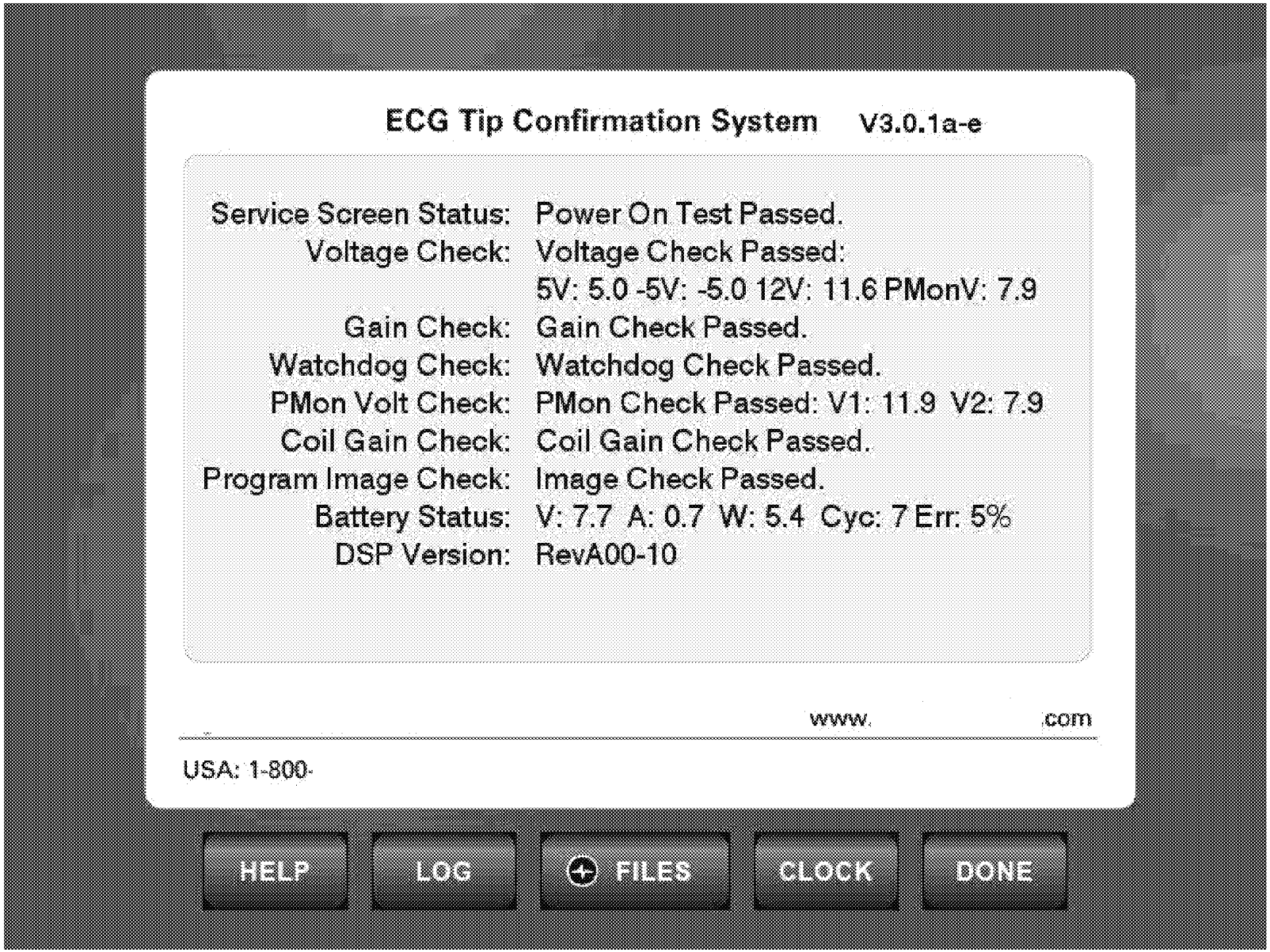
Setting Screen



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Battery

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Battery Warning

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Knowledge Assessment Quiz

First Name Last Name

Phone Facility

1. Proper Peripherally Inserted Central Catheter (PICC) tip location is considered to be…
   - ☐ The Superior Vena Cava.
   - ☐ The Central Venous System.
   - ☐ The upper 1/3 Superior Vena Cava/Innominate junction.
   - ☐ The lower 1/3 Superior Vena Cava/cavo-atrial junction.

2. There is a direct link between improper PICC tip location and…
   - ☐ Venous thrombosis.
   - ☐ Post procedural mal positions/catheter dysfunction.
   - ☐ Mechanical/chemical vessel erosion.
   - ☐ All of the above.

3. The Intravenous Nurses Society's standard of practice 2011 has recognized radiography as the only approved technology to determine tip location.
   - ☐ True
   - ☐ False

4. Devices that employ electromagnetic catheter navigation have been proven to be an alternative to radiography for tip location verification.
   - ☐ True
   - ☐ False

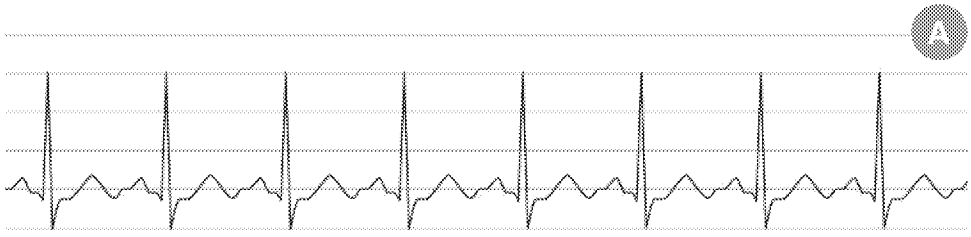
5. ECG tip location devices rely on the detection of faint cardiac arrhythmias that central venous devices normally induce during insertion.
   - ☐ True
   - ☐ False

6. The Sino Atrial Node (SA Node) is considered the heart's primary pace maker.
   - ☐ True
   - ☐ False

7. The SA Node is bundle of cells located…
   - ☐ At the inferior wall of the right ventricle.
   - ☐ At the upper posterior wall of the right atrium
   - ☐ At the lower 1/3 of superior vena cava.
   - ☐ Within the tissue of the tricuspid valve.

8. On a standard electrocardiograph a P wave represents the depolarization of the…
   - ☐ Right atrium.
   - ☐ Left ventricle.
   - ☐ Right bronchus.
   - ☐ Left main coronary artery.

9. Identify cardiac rhythm "A".



   - ☐ Atrial Flutter
   - ☐ Normal Sinus Rhythm
   - ☐ Asystole
   - ☐ Atrial Fibrillation

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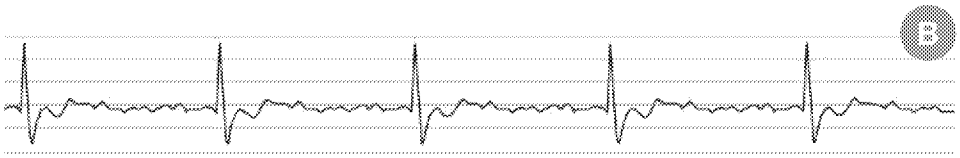
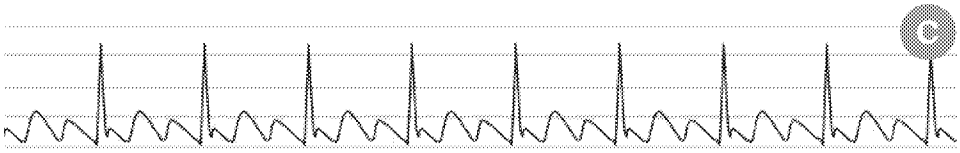
10. Identify cardiac rhythm "B".
- ☐ Atrial Flutter
- ☐ Asystole
- ☐ Normal Sinus Rhythm
- ☐ Atrial Fibrillation

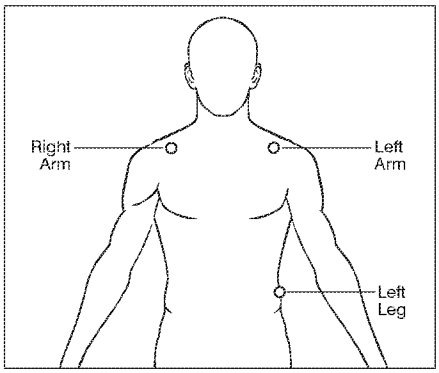


11. Identify cardiac rhythm "C".
- ☐ Normal Sinus Rhythm
- ☐ Atrial Futter
- ☐ Atrial Fibrillation
- ☐ Asystole



12. Match the electrode with correct anatomical location.

	RIGHT ARM	LEFT ARM	LEFT LEG
WHITE			
RED			
BLACK			



13. In three lead mode the ECG Tip Location Device displays…
- ☐ Surface EGG reading.
- ☐ Intracavitary reading.
- ☐ Surface and Intracavitary simultaneously.
- ☐ None of the above.

14. In the PICC mode the ECG Tip Location Device displays…
- ☐ Surface EGG reading.
- ☐ Intracavitary reading.
- ☐ Surface and Intracavitary simultaneously.
- ☐ None of the above.

15. As a central venous access device approaches the Sino Atrial Node (SA Node), the P wave…
- ☐ Becomes irregular.
- ☐ Amplifies.
- ☐ Becomes rapid.
- ☐ No changes occur.

16. No changes in the intracavitary ECG wave form during catheter advancement may indicate catheter malposition.
- ☐ True
- ☐ False

17. Poor or wandering ECG signals may be caused by…
- ☐ Poor electrode contact.
- ☐ Patient movement.
- ☐ Electrical noise.
- ☐ All of the above.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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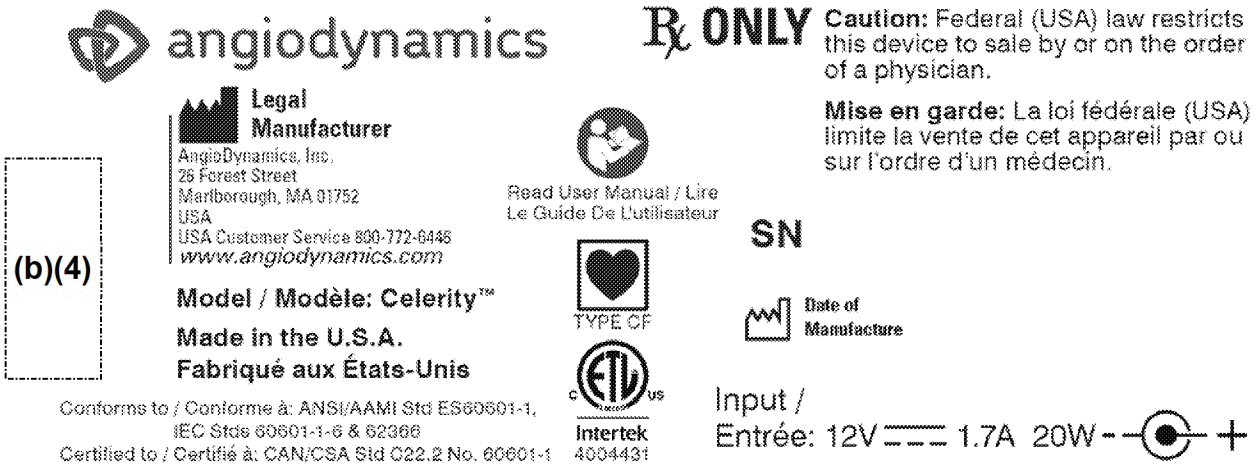
PREDICATE INFORMATION AND LABELING

1. Predicate Celerity Monitor Back Panel Label Predicate



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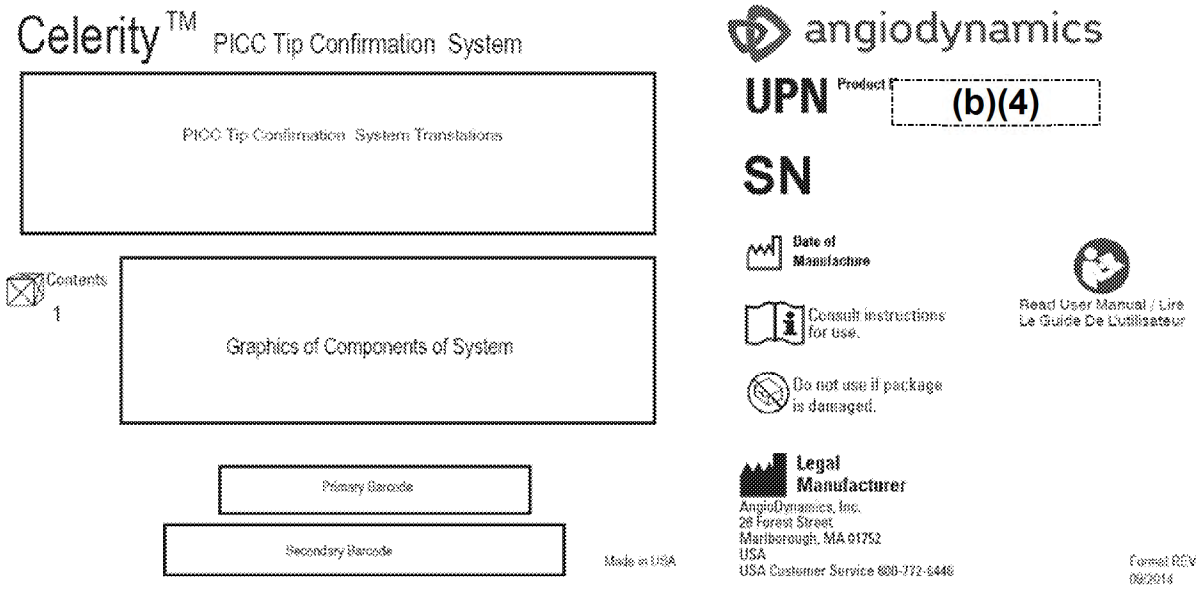
2. Predicate Celerity Monitor Box Label



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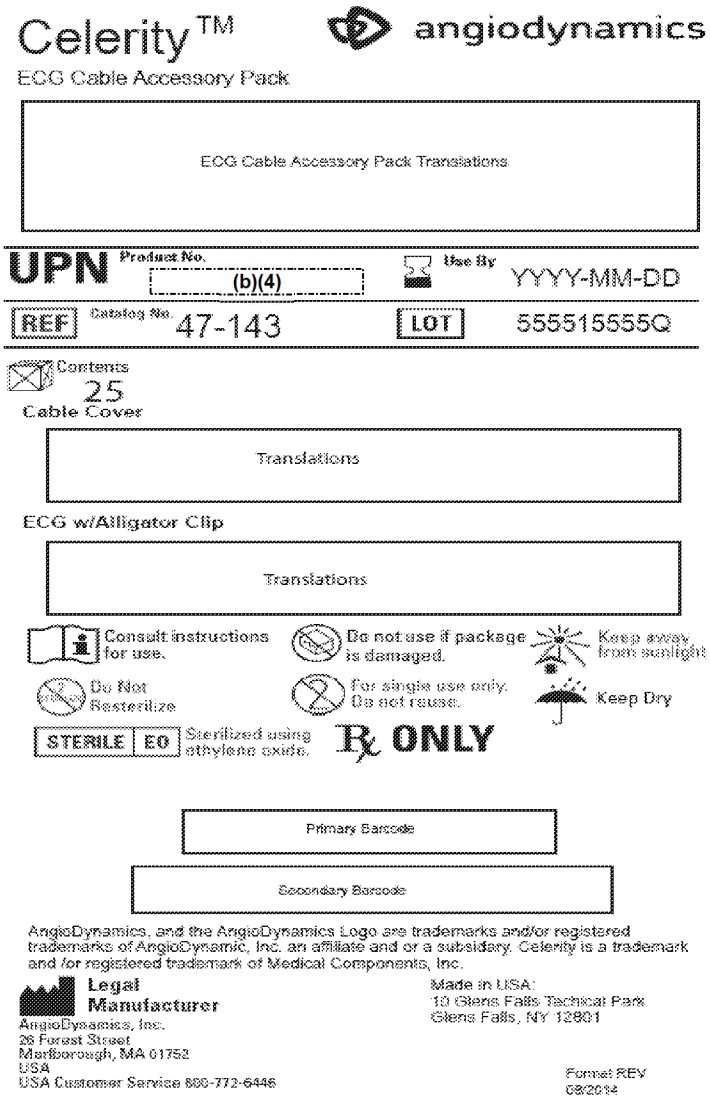
3. Predicate ECG Cable Accessory Pack Box Label



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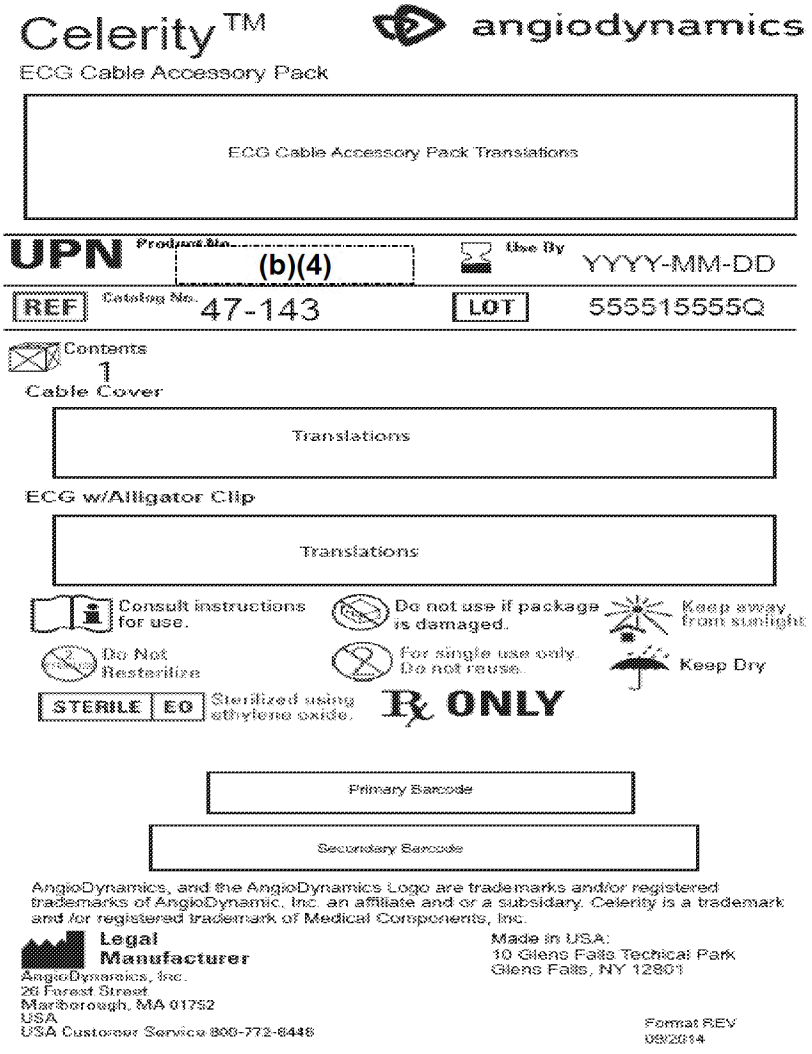
4. Predicate ECG Cable Accessory Pack Pouch Label



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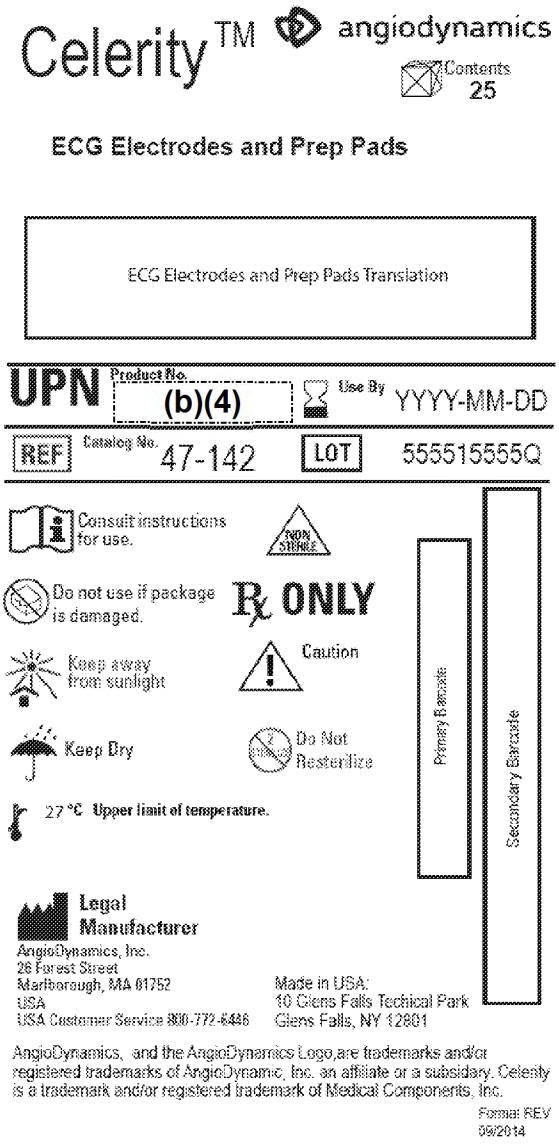
5. Predicate Non Sterile Accessory Kit Box Label



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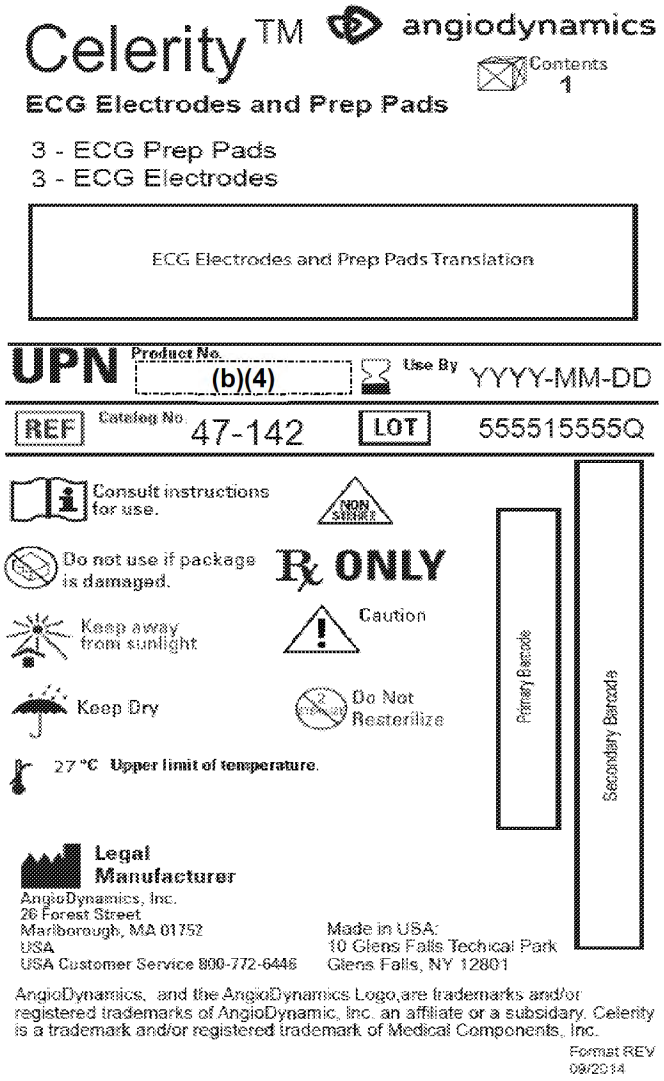
6. Predicate Non Sterile Accessory Kit Pouch Label



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4) Vendor Information

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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8. Predicate Celerity Owners Manual

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Owner's Manual

Celerity PICC Tip Confirmation System

For use with software Version 3.0

16702578-218
2015-01

Celerity

angiodynamics

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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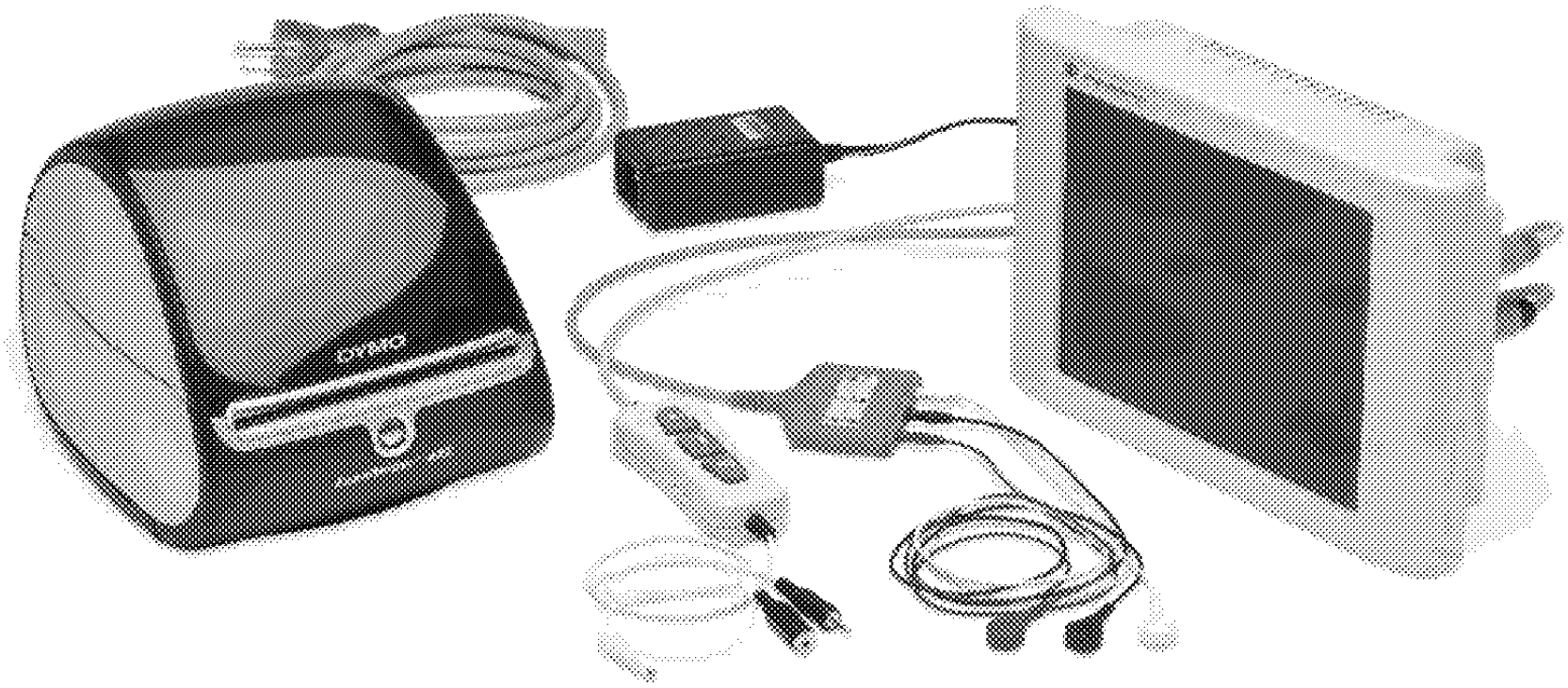
Celerity

PICC Tip Confirmation System



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2022-4717; Released by CDRH on 05-31-2024

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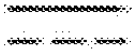
1.SYMBOL TABLE

	On
	Standby
	Read Accompanying Documents for important safety-related information.
	Rated type CF patient protection.
	Date of Manufacture
	Device serial Number
	Separate Collection
	ETL listed mark is proof of product compliance to North American electrical safety standards.
	Legal Manufacturer
	Direct Current
	"ON" for part of equipment
	Left
	Enter

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	Right
	Shipping Conditions
	Storage Conditions
	Operating Conditions
	Temperature Limitation
	Humidity Limitation
	Do not use if package is damaged
	This device emits radiofrequency transmissions
℞ ONLY	RX Only

2. IMPORTANT NOTICES

	Before using this monitor, the operator must thoroughly understand the contents of this manual including all warnings, cautions, contraindications, and intended use.
Warning	This device is only intended for use by qualified and trained medical professionals. Before using this device, the user must be qualified for placement of Peripherally Inserted Central Catheters [PICC] and trained in the proper use of this device.
Caution	Verify the software version of the monitor [shown in power-on screen] agrees with the version listed on this manual – refer to the front page of this manual.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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3. INTRODUCTION

The *Celerity*® system is designed to provide a continuous display of an electrocardiograph [ECG] waveform to be used as a guide in placement of peripherally-inserted central catheters [PICC] in peripheral veins leading to the heart of the patient. The principle for operation of this system uses three ECG leads placed on the patient's chest and generates a third ECG lead by switching from RA to PICC stylet. This system allows the operator to record changes to the ECG waveform as the tip of the catheter approaches the heart. As the PICC catheter approaches the atrium of the heart, the P-wave in the ECG waveform shows substantial changes. This system is designed to aid the visualization of changes in P-wave amplitude.

The Celerity system must only be operated by a skilled nurse, physician, or trained medical professional who has been qualified in placement of PICCs and trained in the proper use of this device.

Warning	Never use a dropped or visibly damaged device. Remove damaged device from service until it can be tested/repaired by a qualified biomedical technician.
Warning	Never submerge the monitor in water or other fluids, serious damage may result, possibly resulting in injury to the user or patient.

4. INDICATIONS FOR USE/INTENDED USE

4.1. Indications for Use

The Celerity System is indicated for positioning of Peripherally Inserted Central Catheters (PICC) in adult patients. It provides real-time catheter tip location information by using the patient's cardiac electrical activity. The Celerity System is indicated for use as an alternative method to chest X-ray or fluoroscopy confirmation of PICC tip placement in adult patients.

Note: In general, devices that utilize ECG technique to observe P-wave are limited, but not contraindicated, for patients where cardiac rhythms may change presentation of the P-wave; including:

- Atrial fibrillation
- Atrial flutter
- Severe tachycardia
- Pacemaker-driven rhythm
- Chronic obstructive pulmonary disease (COPD)

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Such patients are easily identified prior to PICC insertion. Use of an additional confirmation method is necessary to confirm catheter tip location.

4.2. Intended Use

The Celerity System is intended to provide real time tip location information of a central venous catheter by utilization of ECG to observe P-wave changes as the tip approaches the right atrium of the heart via the superior vena cava.

Warning	The Celerity System works with the normal sinus rhythm of the heart. Do not rely on ECG signal detection for catheter tip positioning when interpretation of the external or intravascular ECG P-wave is difficult. For example, when: - P-Wave is not present - P-Wave is not identifiable - P-Wave is intermittent
Warning	This device is not intended for use as a diagnostic ECG device as the system is designed to aid the visualization of changes in P-wave amplitude.
Warning	**DANGER!** Do NOT use this device in the presence of flammable anesthetics, oxygen-enriched atmospheres, or explosive gases.
Warning	This device has not been tested for use near electrosurgical devices. It is not recommended for use in operating rooms.

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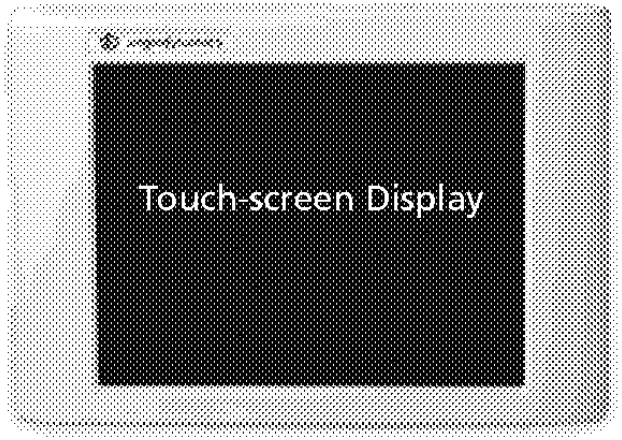
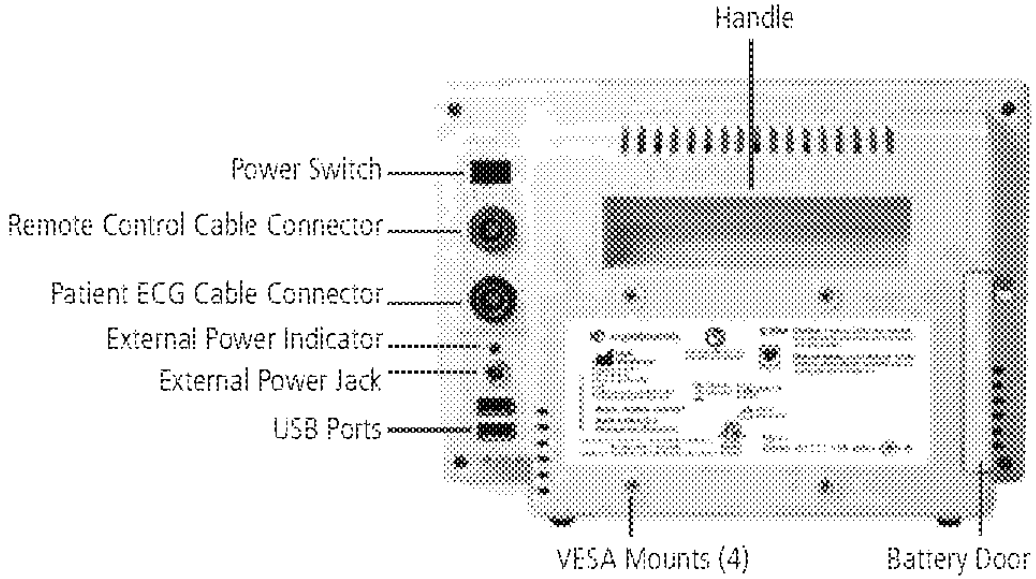
5. FEATURES AND CONTROLS

The Celerity system is composed of a Monitor, a Patient ECG Cable, a Remote Control Cable, ECG Snap Leads, a Battery, a Power Supply and a disposable ECG Clip Cable.

5.1. Monitor





Touch-screen Display	Color graphic display with pressure sensitive touch screen.
Power Switch	On/standby switch. Turns on monitor or places monitor in standby to charge internal battery when external power supply is connected.
Remote Control Cable Connector	Connection for Remote Control Cable. This is a latching connector, pull outside of connector body outward to disconnect.
Patient ECG Cable Connector	Connection for Patient ECG Cable. This is a latching connector, pull outside of connector body outward to disconnect.

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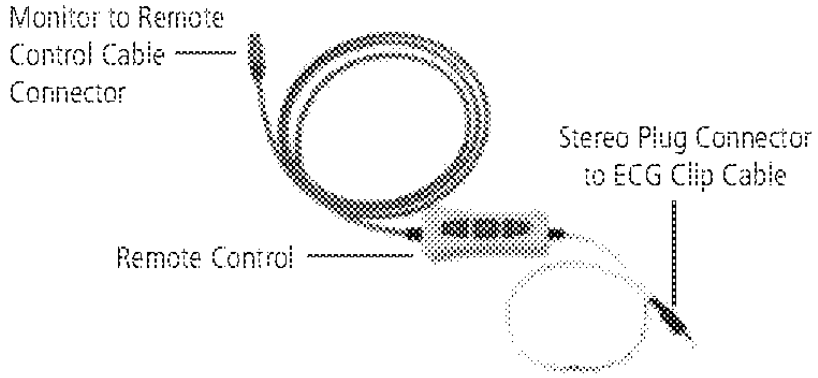
External Power Indicator	Indicator which illuminates when external power is connected to monitor.
External Power Jack	External power jack -- **only** use medical grade power supply provided with the monitor.
USB Ports	Two USB ports provided for connection to an approved printer or flash ["thumb"] drive.
Handle	Carrying handle.
VESA Mounts	Four mounting points in VESA standard 75mm square pattern. Use #6-32 screws.
Battery Door	Battery access door. Allows the user to change battery.

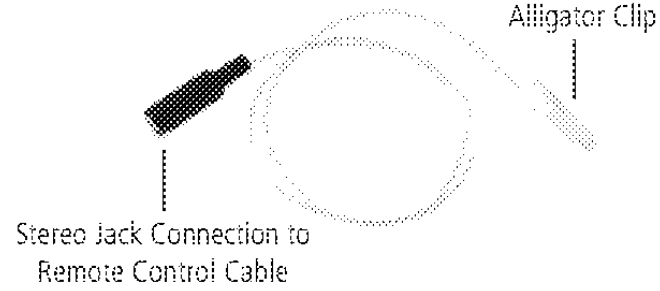
5.2. Remote Control Cable

This Remote Control Cable provides the user the capability to remotely control the monitor and to make a connection to the disposable ECG Clip Cable.



5.3. ECG Clip Cable

This is a sterilized disposable ECG Clip Cable which is part of the disposable kit. This cable makes the ECG connection from the Remote Control Cable to the stylet wire of the PICC catheter. The white alligator clip connects to the stylet, and the jack connector pierces the sterile Cable Cover enclosing the Remote Control Cable.



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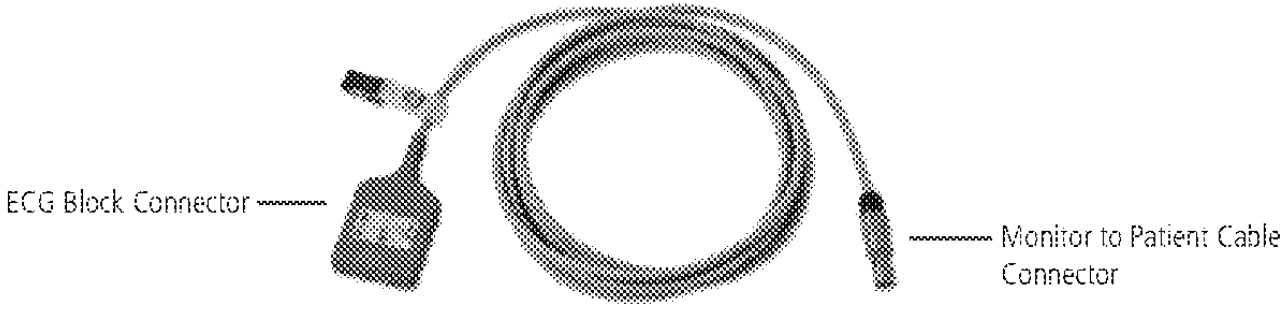
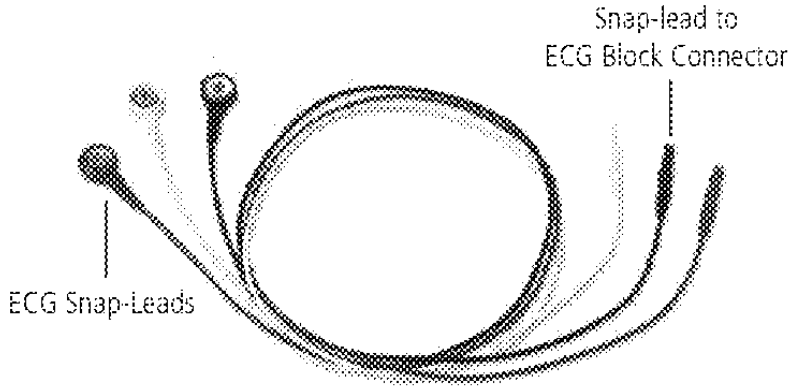
5.4. Patient ECG Cable

This cable allows the user to set up a standard three-lead ECG connection to the patient prior to the start of the PICC location procedure. During the PICC location procedure two leads [red and black] from this cable are used together with the ECG Clip [white] lead on the stylet wire to create the guidance ECG waveform.



5.5. ECG Snap Lead Set

The red, white and black ECG snap-leads plug into the ECG connector block. The snap leads use DIN standard connections into the connector block. The snaps accommodate standard disposable ECG pads.



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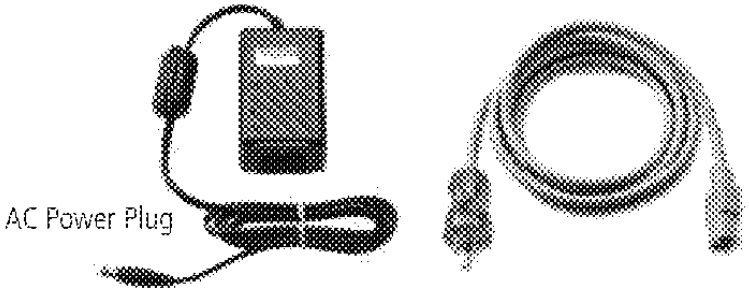
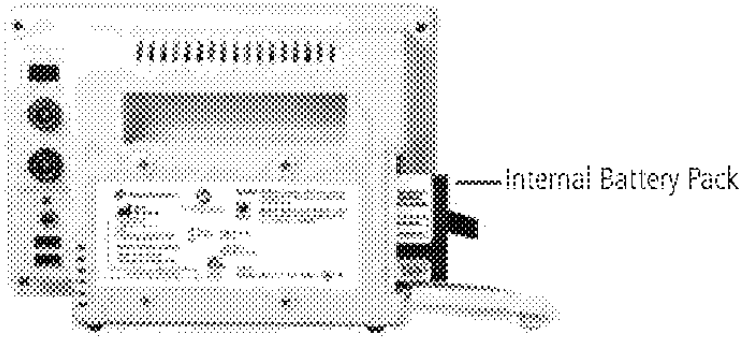
5.6. Medical Grade External Power Supply

This external medical grade power supply [12 VDC 20 watts] may be used to operate the monitor during use on a patient. If the monitor is off [power switch is in stand-by] and this supply is plugged into the monitor then the internal battery will be charging.



5.7. Internal Rechargeable Battery

This user replaceable battery provides for operation of the monitor for at least 4 hours. Follow cautions and warnings listed on the battery for handling and disposal of this battery.



Warning	Do not immerse the external power supply in water or other fluids, as this may create a dangerous shock hazard to the patient and user.
Warning	Only use the Medical Grade Power Adapter provided with the device. Use of unapproved adapter may compromise patient safety or damage the unit.
Warning	Never use a visibly damaged external power supply. Remove damaged supply from service until it can be repaired by a qualified biomedical technician.
Warning	Only use the approved battery provided with this monitor. Use of unapproved battery may compromise patient/user safety or damage the unit.
Warning	To avoid risk of electric shock, this equipment must only be connected to a supply mains with protective earth.

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6. TECHNICAL SPECIFICATIONS

Dimensions [monitor only]	9.5" wide x 6.6" high x 3.1" deep [24 cm x 17 cm x 8 cm]
Weight [monitor only]	3.3 lb [1.5 kg]
Internal Battery Capacity [at 25° C]	Monitor operates at least 4 hours on a fully charged battery. Battery recharges within 8 hours when monitor is in standby.
External Power Supply	Input: 100-240 VAC, 50-60 Hz, 0.5A Output: 12 VDC 1.7A [20 watts]
Normal Operating Conditions	+41° to +104° F [+5° to +40° C] 10 to 90 % non-condensing Relative Humidity No specific relative atmospheric pressure requirement.
Shipping/ Storage [non-operating] Conditions	-22° to +104° F [-30° to +40° C] 10 to 90 % non-condensing Relative Humidity. No specific relative atmospheric pressure requirement.
Monitor Rating	Rated type CF patient protection.
External Power Supply Rating	Class I, medical grade external power supply.

Caution	Do not use sharp objects on touch screen, damage to the monitor may occur.
Caution	Do not operate cell phones or portable radio transmitters near this monitor. These devices may interfere with normal operation of the monitor.
Caution	Never use this device near high intensity magnetic fields, e.g. an MRI scanner. Strong magnetic fields may damage the device.
Caution	If significant interference [noise] is observed in the ECG waveform, then operate the monitor on battery power [disconnect AC adapter] to isolate the monitor from the disruptive environment.
Caution	Federal Law in the United States restricts this device to sale by or on the order of a physician.

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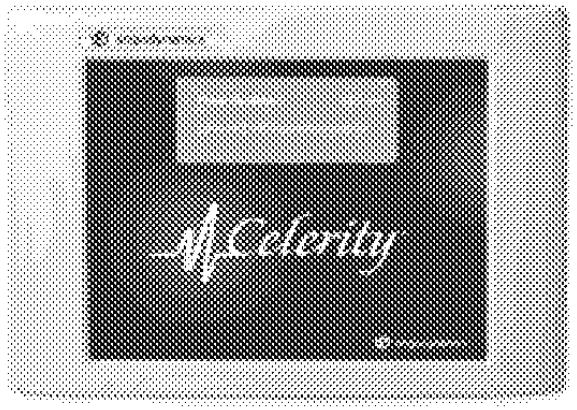
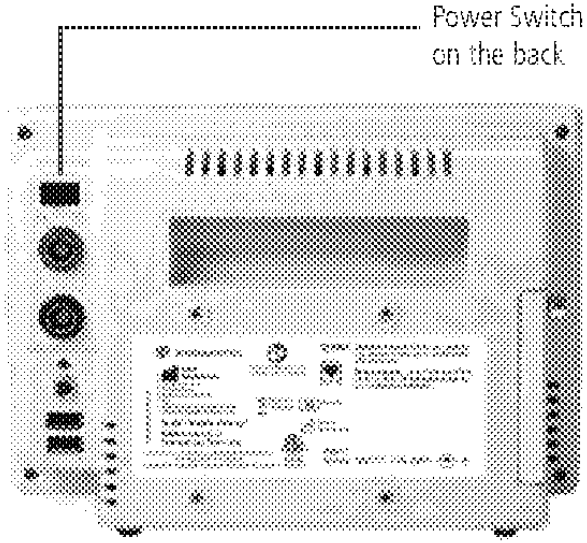
7. MONITOR OPERATION

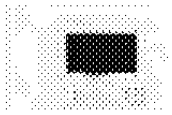
7.1. Monitor Setup

Turn on monitor using power switch on the back.

7.1.1. Power-on Testing



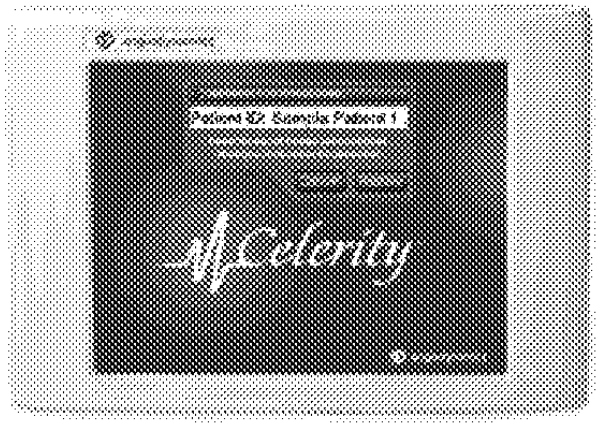




If power-on test failure occurs, then remove the unit from service and have it tested by a trained biomedical technician.

7.1.2. Restart Case [if needed]

If monitor is shut down before the case is finished it is possible to recover settings and data by pressing "Restore" key; otherwise, select "Cancel" to begin a new case.



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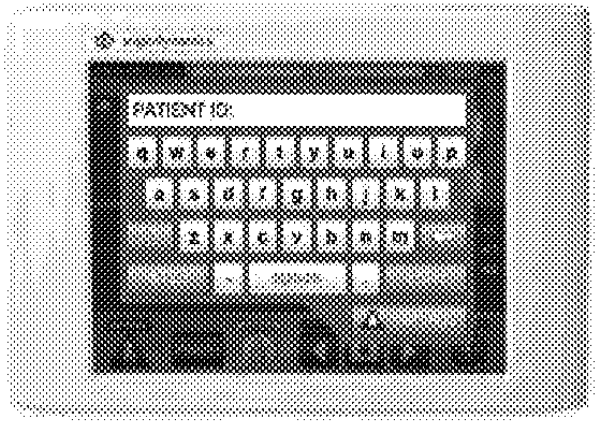
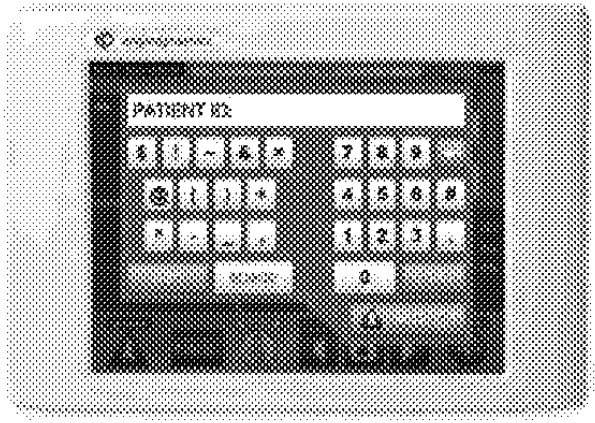
7.1.3. Enter Patient ID

Use touch keypad to enter a patient ID. This is a one line, 32 character max, field used to create a stored patient data record.

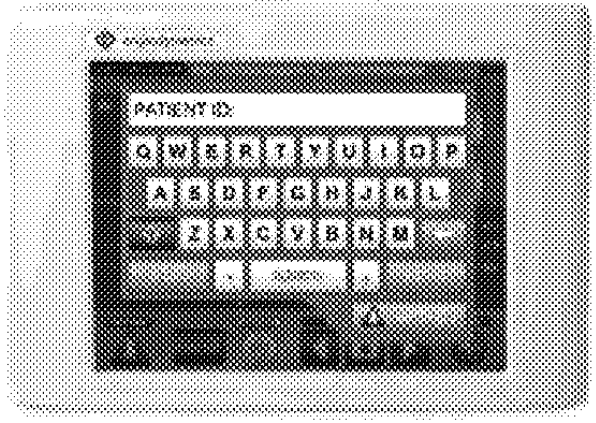
Note: Do not use the patient's name here as this may violate patient privacy rules.



The "Shift" key switches between the lower case and upper case.



The "&123" key brings up the special characters.



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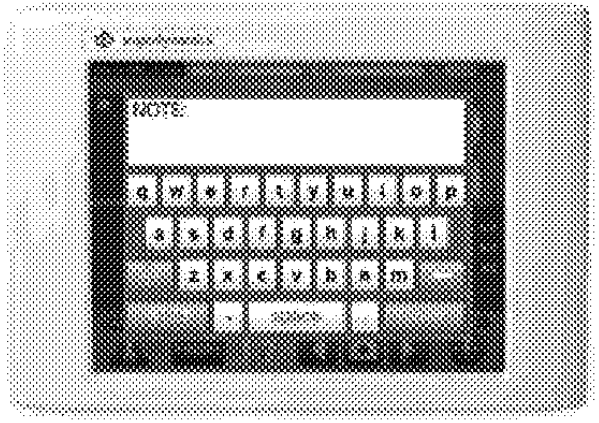
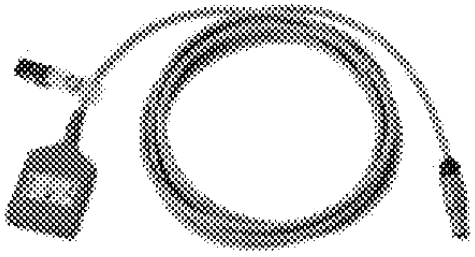
7.1.4. Enter Note

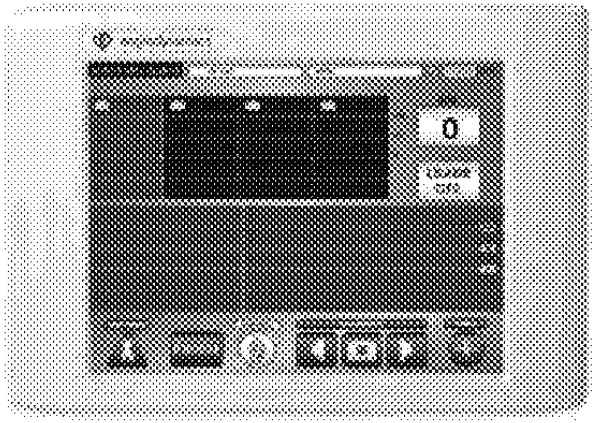
Use touch keypad to enter a patient note [if needed]. This is a three line, 96 character max field, used to enter any other pertinent data which is also stored in the patient record.



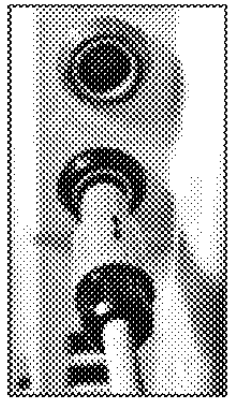
7.1.5. Connect Patient ECG Cable

Plug in the Patient ECG Cable to the monitor. Ensure monitor is in surface mode – "person-icon" shows 3 dots and ECG trace is yellow on a blue background. Verify sufficient battery time remaining or elect to operate with external AC power supply.





Note: Face arrows up to properly insert cable.



Celerity rear-side

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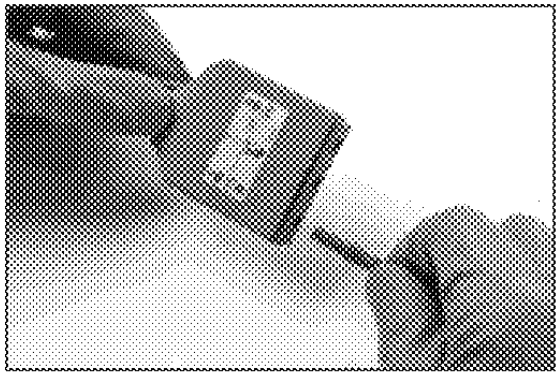
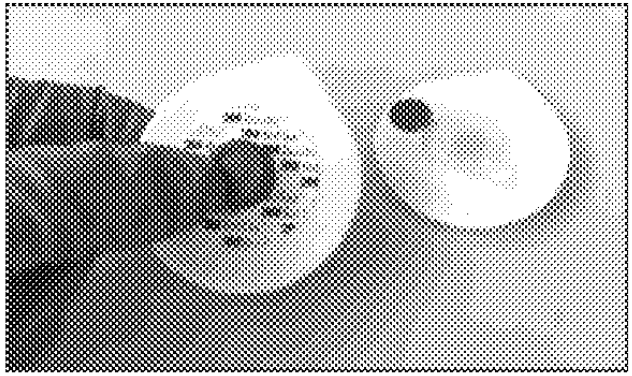
7.1.6. Connect 3 Patient Snap Leads

Connect the ECG Snap Leads to the corresponding color of the Patient ECG Cable. Snap the disposable ECG Adhesive Electrodes from the kit to the ECG snap leads.

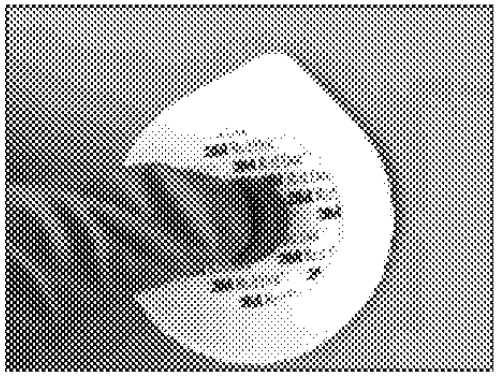


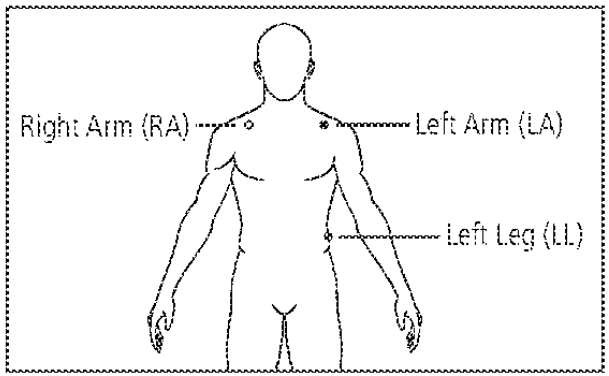


7.1.7. Apply the ECG Adhesive Electrodes to Patients Chest

Clean the patient's skin, remove the ECG Adhesive Electrodes backing and apply the ECG pads to the patient - avoid areas with excessive hair. Follow color codes/lettering on ECG block:

RA (white) = right arm, LA (black) = left arm, and LL (red) = left leg.





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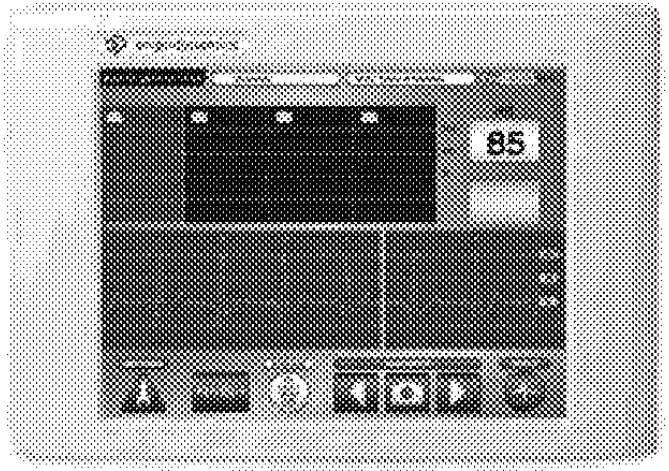
7.1.8. Verify Surface ECG Signal

The "Leads Off" advisory message should be cleared. Verify patient's ECG waveform is acceptable for use in guiding PICC location.

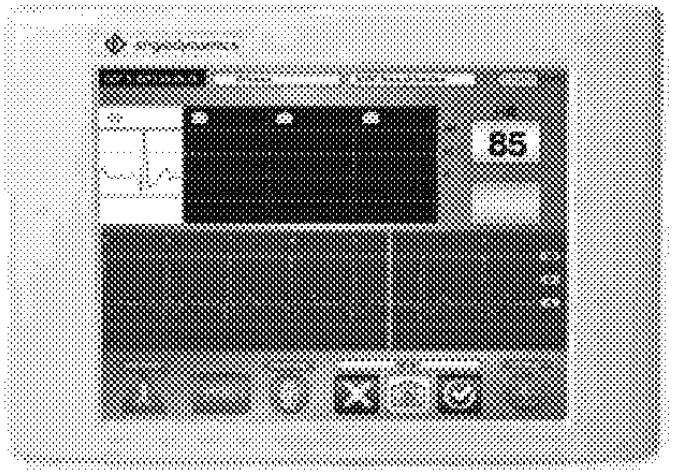


7.1.9. Collect a Baseline ECG Snapshot During 3-Lead Mode

[SNAPSHOT works with both 3-lead and PICC mode.]

Use Remote or touch screen to select "Snapshot" icon. This takes one ECG sample and displays it on top row. Keep patient still while reading the wave forms.

Press retry icon [in green] to retake the snapshot. Scroll left and press "X" to quit without saving. Scroll right and press " ✓ " to save the snapshot into the patient record.



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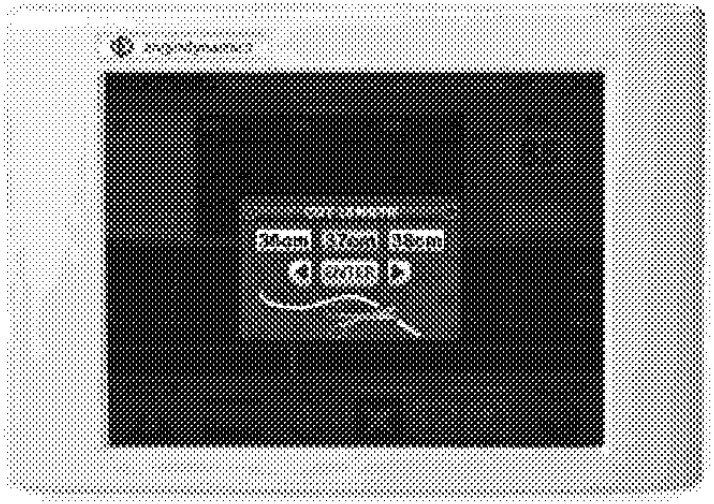
7.1.10. Record Baseline Measurements

Once "✓" is selected a window will pop up allowing the user to mark the surface measurement using the remote or touch screen.

Once surface measurement is entered, a window will pop up allowing the user to input the cut length using the remote or touch screen



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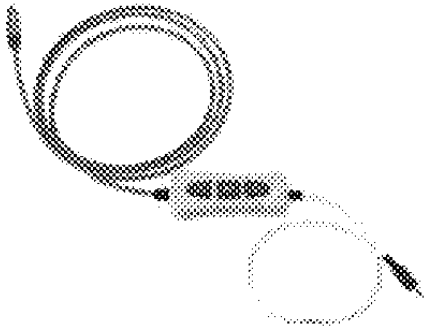
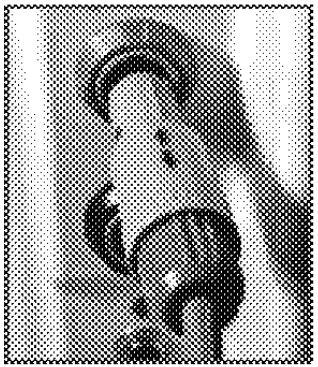
7.1.11. PICC Mode

Plug in the Remote Control Cable to the monitor. Ensure monitor is in "PICC mode" and ECG trace is white on a black background with blue scroll bar. The "NO PICC SIGNAL" advisory message should be present.



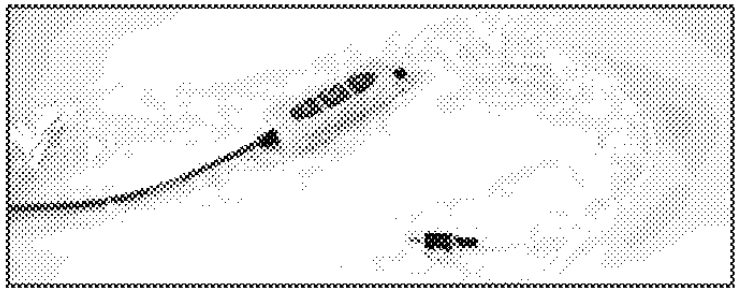
Note: Face arrows up to properly insert cable.



Celerity rear-side

7.1.12. Place Remote Cable in Sterile Cable Cover

Locate Cable Cover and carefully unroll the sterile Cable Cover over the Remote Control Cable.



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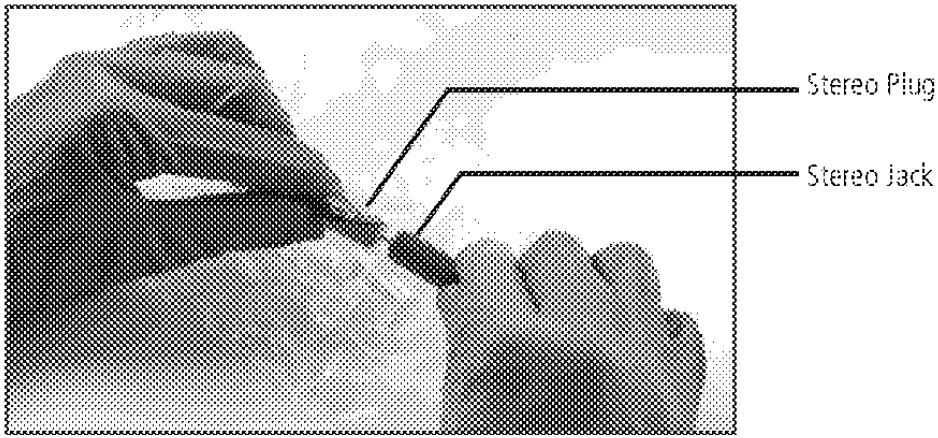
7.1.13. Connect the Disposable ECG Clip Cable

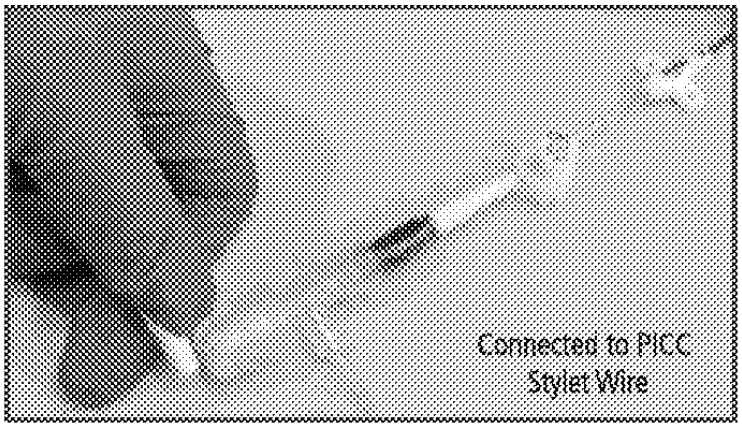
Connect the stereo jack of the Clip cable to stereo plug of Remote Control Cable by carefully piercing the sterile Cable Cover.



7.1.14. Connect the ECG Clip Cable to PICC

Squeeze the alligator clip and place clip over the metal portion of the stylet wire of the PICC catheter. Prepare the PICC catheter per normal procedures.

Note: Only works with conductive [metal] stylet wire.



Note: To Prevent guidewire slippage from the tuohy, use AngioDynamics components. AngioDynamics does not certify the compatibility of other manufacturer products.

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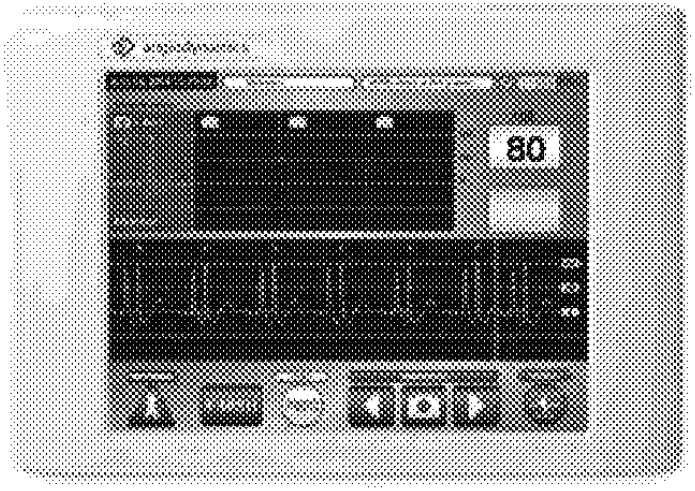
7.1.15. Verify PICC Lead Plus PICC ECG Signal

Advance the PICC catheter as normal into the patient. As the PICC advances a few centimeters past the introducer then an ECG connection is completed to the patient and the "NO PICC SIGNAL" advisory message should be cleared.

Note: For best results of wave image user should keep the PICC and patient still when reading waves.



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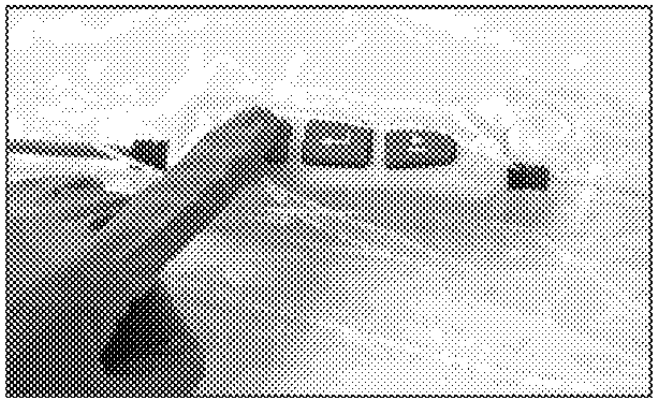
7.2. Monitor Operation

7.2.1. Use Remote Control Cable to Operate Monitor

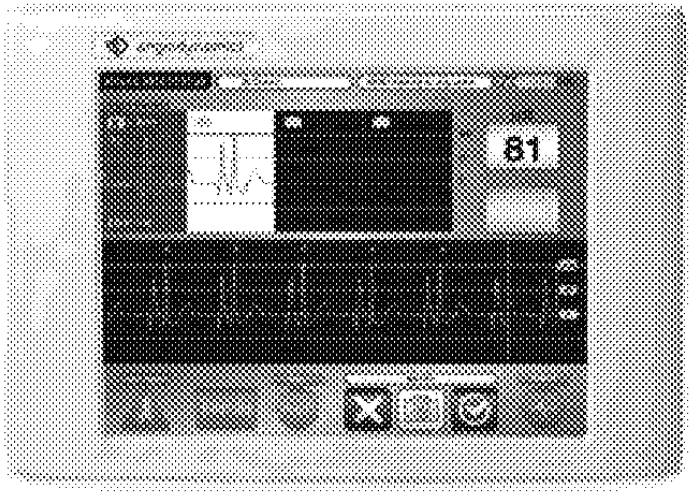
Remote Box has Left, Enter, and Right controls which allow user to control the collection/tagging of ECG data.



7.2.2. Collect ECG Records as the Catheter Advances

Use Remote to select "Snapshot" icon. This takes another ECG sample and displays it.

Press retry icon [in green] to retake the snapshot.
Scroll left and press "X" to quit without saving.
Scroll right and press "✓" to save the snapshot into the patient record.



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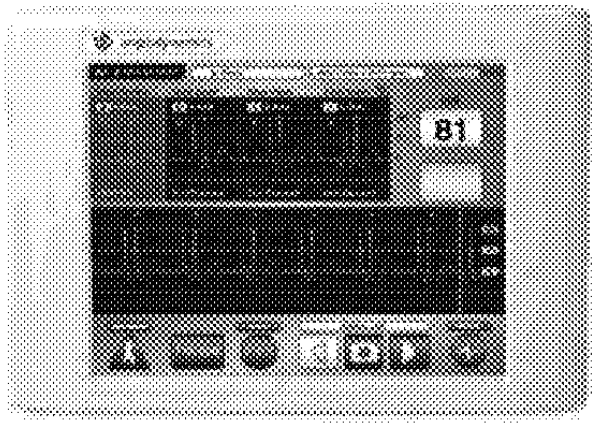
Once "accept" is selected a window will pop up allowing the user to mark the exposed catheter length using the remote. The implanted depth is displayed.



When more than three snapshots are taken, the arrow left and arrow right buttons allow the user to scroll through the snapshots.

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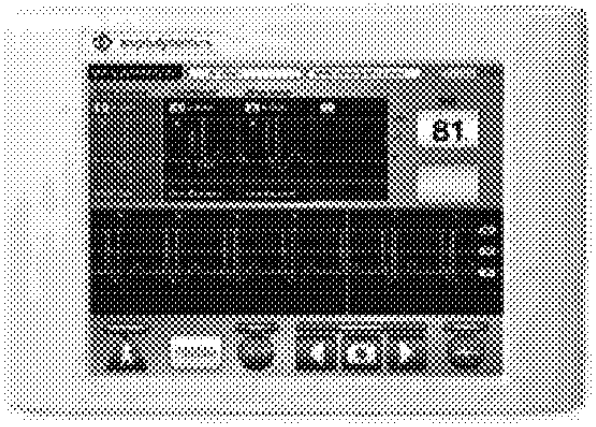
7.2.3. Finish Case When Placement Completed

Use Finish button to complete the case. This screen also provides a path to file management screen.



Upon selecting the option to Finish the case, the bundle protocol is displayed. Use the touch screen to select 'Yes' or 'No' to answer if all bundle protocol parameters were met, then select 'OK'. This saves the information and exits the current case. To return to the current case, use the remote control to select 'Cancel'.

Note: Bundle protocol can be found in Celerity Directions for Use.

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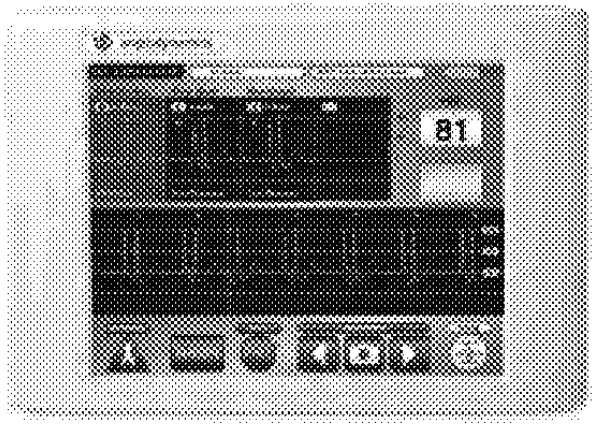
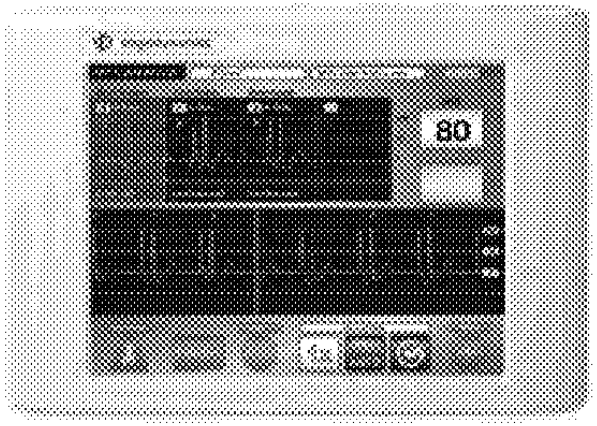
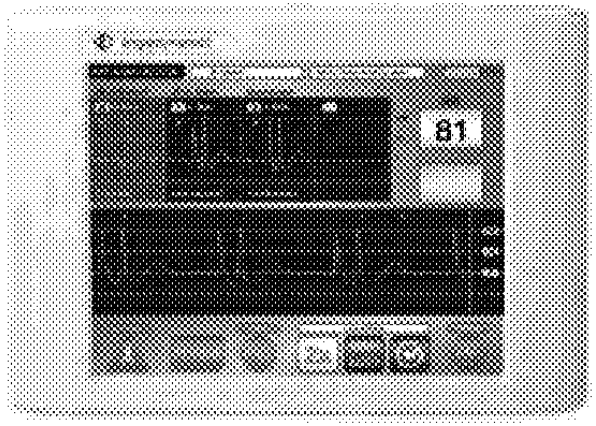
7.3. Additional Monitor Controls

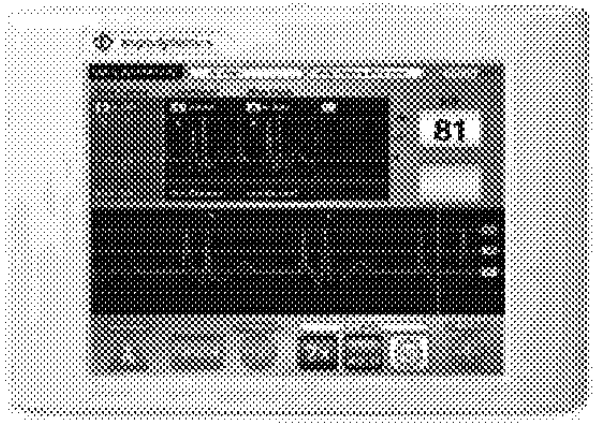
7.3.1. Sweep Speed

Touch or use Remote to select "scale/wave" icon. Then select the "1X" icon. Pressing this changes sweep speed to "2X" for viewing higher heart rates. Then select and press the "✓" icon to save changes.









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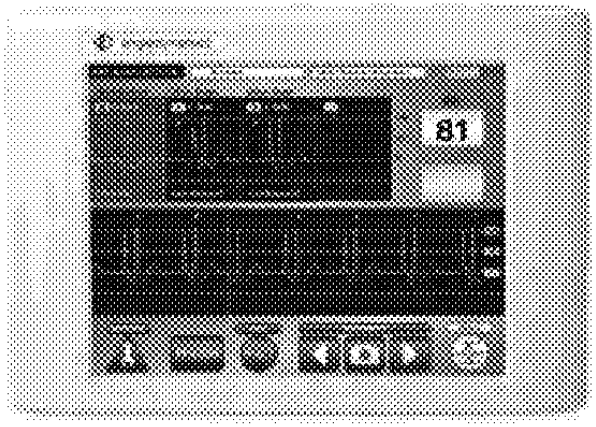
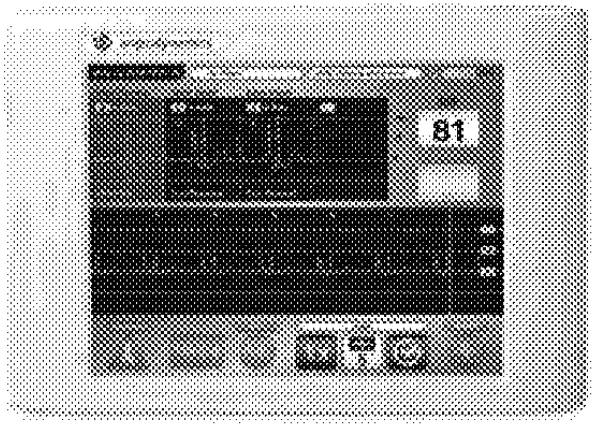
7.3.2. Selecting Fixed ECG Waveform Scale

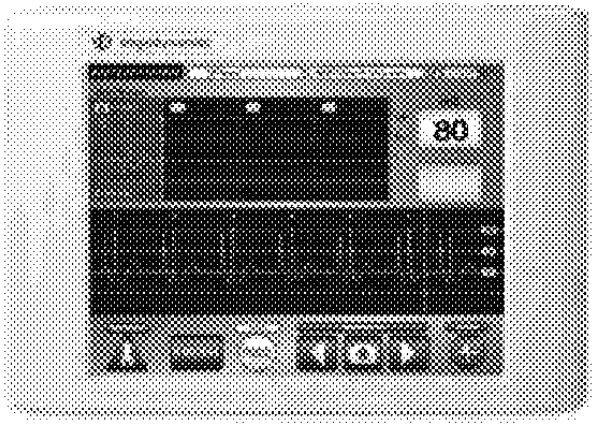
Touch or use Remote to select "scale" then select AUTO which changes to a fixed 1 mv scale, and select button again to change to 2, 5, etc until you select the best millivolt scale to view the ECG waveform. Accept and lock this scale setting by pressing "✓" and return to the previous screen.





7.3.3. Surface or PICC-Lead

User can select Surface to check the normal chest-leads ECG waveform - a yellow trace with blue background. Then press again to select PICC lead for viewing the PICC-based ECG waveform - a white trace with black background. The button icon reflects the current waveform being displayed.



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7.4. Service Screen

Use the touch screen to select the Settings button to access the service screen. The service screen cannot be entered using the remote control. It is only used in setup or at end of case.

The service screen permits user to set date and time or access special service/diagnostic functions.

7.4.1. Set Clock

Press Clock on service screen to set the system clock and calendar. Use "+" or "-" arrows to increase or decrease selected date/time value. Use left and right arrow to change selected value. [seconds are not needed].

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7.5. Copy or Print Patient Files

Selecting Files button on the service screen brings up the file management screen. Do not copy or print files when operating the monitor on a patient.

Insert USB "thumb" flash drive into either USB port on the back of the monitor. Select the Files button and the following screen appears.

Note: This message indicates flash drive or printer not connected.

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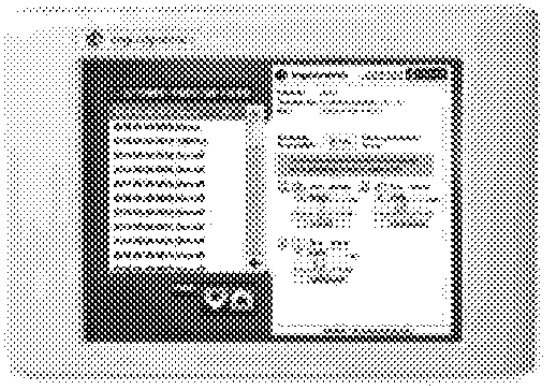
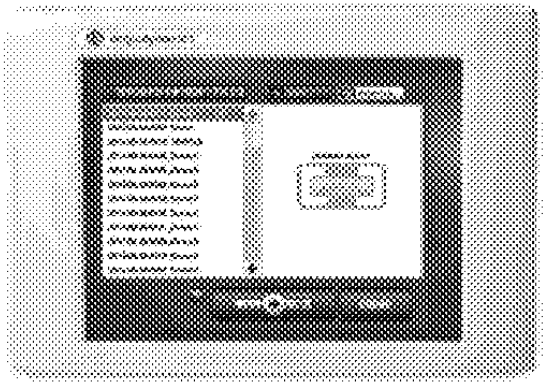
7.5.1. Preview Snapshots

Highlight file, then select the magnifying glass on the right side of file. While in preview mode you can deselect any image you don't want to print or save to thumb drive by deselecting the "check" mark.

Insert USB of approved printer. Select printer icon. Select the file you wish to print. Press the move files (arrow) button.

Touch the files in the left column that you wish to copy. Press the move files [arrow] button which copies files to flash, moving them from the left column to the right column. Use Done button to exit.





Caution	If using specified Dymo printer then do not print while in the patient's room.
Caution	Do not connect any device to USB port except a printer with supplied cable or compact flash devices which are approved in this manual or other user instructions.
Caution	Do NOT connect an external hard drive or CD/DVD drive to the USB ports. This may result in excessive radio interference from monitor causing disruption of surrounding equipment.

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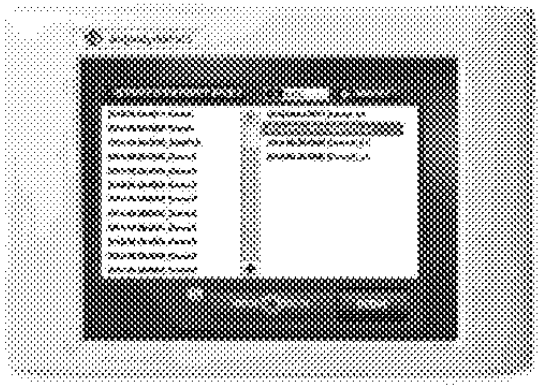
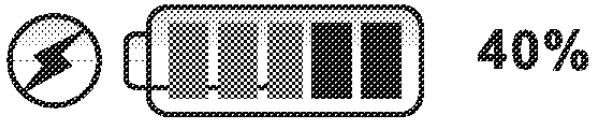
7.5.2. Deleting Files

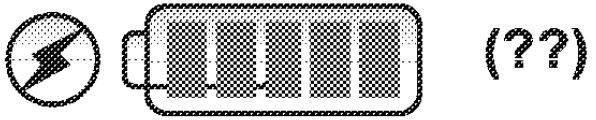
Select the file you want to delete, then select the "X" and then select OK to confirm deletion. Either patient or copied files may be deleted. Once deleted files can NOT be recovered.



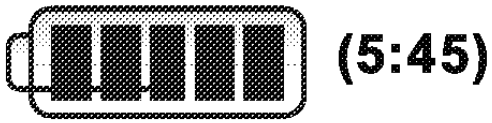
7.6. Battery Power and External AC Power Operation



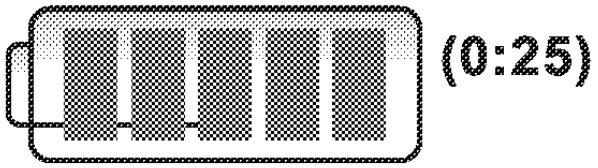
The AC plug indicates unit is running off external AC power with the percentage of battery charge displayed.



When battery is removed or has failed and the unit is running on AC power, two question marks appear.



The battery icon without AC plug indicates unit is running off battery power with the remaining run time displayed in hours and minutes.



When battery capacity drops to 10%, the battery icon appears larger and begins to flash.

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When the battery capacity drops below 1% a caution screen appears to advise that power failure will occur within a few minutes unless the monitor is plugged into external AC power.

Note: Battery will only accept a charge when the monitor is in normal operating temperature range: +41° to +104° F [+5° to +40° C].

7.7. Warning Screen

This warning screen appears when the monitor software detects an internal failure in the system. User controls may operate - depending upon severity of the failure - to assist in saving patient data.

Warning	If you see this screen, the monitor is not operating correctly. Remove this device from use for repair by a qualified biomedical engineer.

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8. CLEANING

The monitor and associated cables [excluding disposables] may be cleaned with the following using your institutions guidelines or disinfectant manufacturer's recommendations.

- Mild detergent and water.
- Bleach 10% solution with water.
- Isoproply Alcohol 70% solution.
- Surface disinfectants compatible with plastic materials.

For best results use cleaning solution on a soft cloth to wipe the monitor and cables.

Caution	Never use organic solvents [acetone, kerosene, strong acids, or strong bases] to clean monitor or cables as this will damage the monitor.
Caution	Never steam sterilize or autoclave the monitor or cables as severe damage will result.

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9. PARTS AND ACCESSORIES

9.1. Parts

Description

- ECG Accessory Pack [ECG Clip & Cable Cover; 25-box]
- Remote Cable
- ECG Snap Leads Set
- Patient Cable
- Battery, 7.2V, 63W-hr, Li-ion
- Power Cord

9.2. Accessories

- Sony Medical Grade USB Printer [Approved for patient bedside use.]
- Dymo USB Printer [Office use only. NOT for patient beside use.]

9.3. Applied Parts

- Tape Measure
- Catheter
- Stylet/Guidewire
- Touhy/Y-Adapter
- Sheath
- Securement Device
- ECG Adhesive Electrodes
- ECG Snap Leads
- ECG Clip Cable

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10. TROUBLESHOOTING GUIDE

10.1. Alarms, Alerts & Informational Messages

Alarm	Priority	Description	Corrective Action
System Failure Alarm [power-on self-test] "Power Supply Failure" "I2C Communication Failure" "Watchdog Failure" "Software Image Failure"	High [Red]	System self-test failure detected at power-on.	Remove monitor from service for repair by qualified biomedical engineer. [**Note**: button is provided to enter service screen which allows user to recover patient files.]
System Failure Alarm [while operating] "Power Supply Failure" "I2C Communication Failure"	High [Red]	System failure detected while running.	Remove monitor from service for repair by qualified biomedical engineer. [**Note**: button is provided to enter service screen which allows user to recover patient files.]
Battery Warning: "Extremely Low Battery"	High [Red]	Internal Battery is almost fully depleted.	Plug monitor into AC power and continue use. Alarm may be cleared by pressing enter on remote control or by touching "OK" on the screen.
Alert Message: "NO PICC SIGNAL"	Moderate [Yellow]	Patient Lead is disconnected.	Check ECG Alligator Clip and connection to Remote Cable.

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10.1. Alarms, Alerts & Informational Messages cont...

Alarm	Priority	Description	Corrective Action
Alert Message: "RA Off" "LL Off" "LA Off" "Leads Off"	Moderate [Yellow]	Patient Lead shows poor electrical connection.	Check connections from patient cable to ECG pads on patient. Consider replacing ECG pad if excessive noise or wander in ECG waveform.
Informational Message: "...confirm entry..."	Low [Grey]	Confirm selected action, such as "Finish Case", or "Delete File".	None.

Note: High priority alarms can be reviewed from settings/service screen by pressing the "LOG" button on the settings service screen. This displays the system log file [with date/time stamp] which shows the results of all power-up tests and high priority alarms.

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11. ELECTROMAGNETIC COMPATIBILITY DECLARATION

Table 1

Guidance and manufacturer's declaration – electromagnetic emissions		
Celerity monitor is intended for use in the electromagnetic environment specified below. The user of the Celerity should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The Celerity uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The Celerity is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes. The Celerity should be set up and used per instructions in this manual to insure electromagnetic emissions are at acceptable levels.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

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Table 2

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
Celerity monitor is intended for use in the electromagnetic environment specified below. The user of the Celerity should assure that it is used in such an environment.			
IMMUNITY Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment – Guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/ burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 s	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 s	Mains power quality should be that of a typical commercial or hospital environment.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: U_T is the a.c. mains voltage prior to application of the test level.			

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Table 3

Guidance and manufacturer's declaration – electromagnetic immunity			
The Celerity monitor is intended for use in the electromagnetic environment specified below. The user of the Celerity should assure that it is used in such an environment.			
IMMUNITY Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment – Guidance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz outside ISM bands[a]	3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the Celerity , including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1{,}2\sqrt{P}$ $d = 1{,}2\sqrt{P}$ 80 MHz to 800 MHz $d = 2{,}3\sqrt{P}$ 800 MHz to 2,5 GHz
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m).[b] Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[c] should be less than the compliance level in each frequency range.[d] Interference may occur in the vicinity of equipment marked with the following symbol: 

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Guidance and manufacturer's declaration – electromagnetic immunity
NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies. **NOTE 2**: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.
a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Celerity is used exceeds the applicable RF compliance level above, the Celerity should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Celerity. b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

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Table 4

Recommended separation distances between portable and mobile RF communications equipment and the Celerity monitor.			
The Celerity monitor is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The user of the monitor can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the monitor as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter (W)	**Separation distance according to frequency of transmitter (m)**		
	150 kHz to 80 MHz $d = 1{,}2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1{,}2\sqrt{P}$	**800 MHz to 2,5 GHz** $d = 2{,}3\sqrt{P}$
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. **NOTE 1**: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. **NOTE 2**: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

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12. MAINTENANCE AND SERVICE REQUIREMENTS

12.1. Periodic Maintenance

The monitor together with the external power supply should be tested at least annually by a trained biomedical engineer to verify electrical safety. Testing should be performed immediately if the monitor has been dropped or visibly damaged.

12.2. Service Assistance

Contact the Technical Service Department for assistance: AngioDynamics, Inc.
Phone: +1 866-883-8820

When calling please have the following information available:
Model of unit, serial number, date of purchase, and description of problem.

12.3. Training

Contact your local sales representative to schedule training.

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12.4. Returning Unit for Repair

Contact the Technical Service Department. If it becomes necessary to return a unit for repair, then you will be issued a Return Authorization [RA] number.

Clean and decontaminate monitor and cables prior to returning these items for repair.

Package monitor carefully for return and mark the RA number on the outside of the box.

Monitors will not be accepted for service without an RA number.

Ship monitor to USA service at:

AngioDynamics, Inc
603 Queensbury Ave.
Queensbury, NY 12804, USA

Phone: +1 866-883-8820

Warning	Users should never disassemble the monitor. Refer servicing to qualified biomedical engineer for repair.
Warning	Only a trained biomedical engineer may service this device. Service personnel should disconnect the AC power adapter and remove the battery before servicing the device.
Warning	Never perform unauthorized modifications to the monitor hardware or software. This could result in serious injury to the patient or the user.

12.5. Disposal of Unit

Follow labeling instructions on battery for its disposal. The monitor does not contain any lead products and does not present a hazard for disposal.

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13. WARRANTY

AngioDynamics, Inc. warrants that reasonable care has been used in the design and manufacture of this instrument. **This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether express or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness for a particular purpose.** Handling, storage, cleaning and sterilization of this instrument as well as other factors relating to the patient, diagnosis, treatment, surgical procedures and other matters beyond AngioDynamics' control directly affect the instrument and the results obtained from its use. AngioDynamics' obligation under this warranty is limited to the repair or replacement of this instrument and AngioDynamics shall not be liable for any incidental or consequential loss, damage or expense directly or indirectly arising from the use of this instrument. AngioDynamics neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this instrument. **AngioDynamics assumes no liability with respect to instruments reused, reprocessed, resterilized, modified or altered in any way, and makes no warranties, express or implied, including but not limited to merchantability or fitness for a particular purpose, with respect to such instruments.**

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Legal Manufacturer

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www.angiodynamics.com

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9. Predicate Sterile Kit IFU

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10. Predicate ECG Technique and Training Materials

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AngioDynamics ECG Education

SECTION 1—CATHETER TIP LOCATION

The Relevance of Catheter Tip Location

There is overwhelming evidence that improper tip location negatively impacts clinical outcomes. A direct link has been observed between central vascular access catheter tips located outside of the optimal position and venous thrombosis, chemical and mechanical vessel erosion, fibrin sleeves, spontaneous malpositions, and catheter dysfunction including persistent withdraw occlusions.

The Guidelines Regarding Catheter Tip Location

In 1998, the National Association of Vascular Access Networks (NAVAN now AVA) issued a position statement recommending that the optimal location for the tip of peripherally inserted central catheter (PICC) is the lower one-third of the superior vena cava (SVC), close to the junction of the SVC and the right atrium. The Intravenous Nurses Society (INS) shares this recommendation in their Infusion Nursing Standards of Practice 2011 stating "central venous access devices (CVADs) shall have the tip dwelling within the superior vena cava (SVC) near it's junction with the right atrium."

Other Organizations with Recommendations on Tip Location Include:

- Oncology Nurses Society—Access Device Guidelines 2010: Distal third of the superior vena cava.
- Society of Interventional Radiologists—Quality Improvement Guidelines 2010: cavo atrial region.

Why The Lower 1/3 Superior Vena Cava/Right Atrial Junction?

- Large vein diameter.
- High velocity blood flow.
- Improved infusate distribution and dilution.
- Position offers the least amount of interference with vein intima.

The Vascular Access Specialist Challenge

- Reduce time to therapy.
- Achieve consistent and accurate catheter placements.
- Reduce catheter malpositions. (Rates documented to be as high as 30%)
- Reduce patient radiation exposure.
- Improve patient satisfaction.
- Improve clinician workflow and efficiency.

SECTION 2—PICC PLACEMENT TECHNOLOGIES

The Intravenous Nurses Society Standards of Practice 2011; 35.8 –"Tip location of CVAD shall be determined radiographically or by other approved technologies prior to initiation of infusion therapy." The traditional practices to ensure proper tip location for peripherally inserted central catheter (PICC) placement has included pre-procedure landmark and anthropometric (surface) measurements followed by post-procedural chest radiography (X-ray). The challenge has been in the inherent inefficiency of radiography and the known inconsistency of the interpretation of the PICC tip position via radiographic image. Considering the clinical significance and the position of peer groups such as AVA and INS regarding proper tip placement, it is not only best practice, but also should be the professional standard of practice to ensure proper central tip placement is achieved. Consequently, clinicians should consider more accurate and efficient technologies to reach this goal.

Navigation vs. Tip Location Technology

Navigation refers to a technology that ascertains information regarding general directionality of a vascular access device. Tip Location refers to a technology that ascertains a precise location of the distal tip of a vascular access device within the superior vena cava (SVC).

1. Electromagnetic Catheter Navigation—Technologies that utilize electro-magnetic field detection to illustrate audibly or visually catheter direction and general position. These systems measure the relationship between the catheter stylet and its external sensor (chest plate or hand held wand). These devices require a custom stylet wire inserted within the catheter. These devices are effective in reducing catheter malpositions, however they do not provide detailed information regarding the catheter's tip location with respect to the heart.
2. Electrocardiograpic (ECG) Tip Location—Technologies that employ a saline column or stylet as an intracavitary electrode to monitor ECG waveform changes as the vascular access device approaches final tip position.

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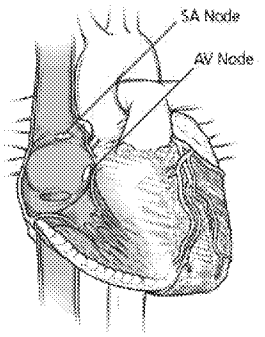
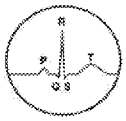
SECTION 3—ELECTROCARDIOGRAPHIC (ECG) TIP LOCATION

Electrophysiology of the Heart



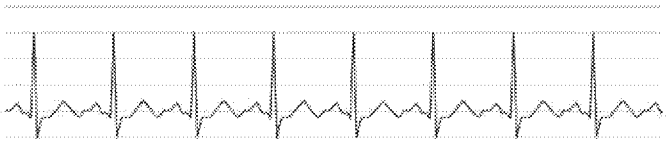
The heart is composed of four chambers: right atrium, right ventricle, left atrium, and left ventricle. These chambers are electrically stimulated to contract in specific timed and paced fashion. The heart's primary pace maker is a bundle of cells, known as the sinoatrial node (SA node), located upper posterior wall of the right atrium. While at rest, the myocardial muscle is negatively charged or polarized. The stimulation, called depolarization, causes these muscles to become positively charged and contract. This depolarization is immediately followed by repolarization. Both depolarization and repolarization are electrical phenomena and can be detected by sensors on the skin. These signals are represented by the deflections we see on an ECG strip. Electrical signals from the brain arrive at the SA node to stimulate a heartbeat. The depolarization spreads from the SA node across the atrium causing the atrial muscle to contract while generating the P-wave. This stimulation reaches the atrioventricular node (AV node) and passes through a set of fibers out to the ventricles. This depolarization then spreads across the ventricles causing the ventricles to contract while generating the QRS wave. The repolarization of the ventricles generates the T-wave as the ventricular muscles relax.

The height or amplitude of the deflection is a measure of voltage. Positive deflections are upward on an ECG, negative deflections are downward. ECG analysis examines the shape, consistency, and the time between waveforms elements (deflections) to assess the functionality of the hearts conduction system.

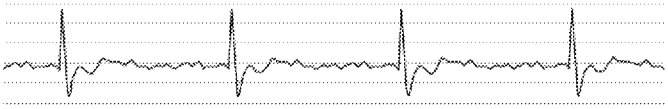


ECG Examples

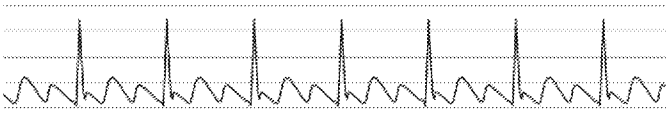
Normal Sinus Rhythm (NSR): Sinus rhythms are a class of rhythms which originate at the SA node. Sinus rhythms generally travel through the heart's entire conduction system without inhibition.
NOTE: NSR is required for reliable ECG tip location.



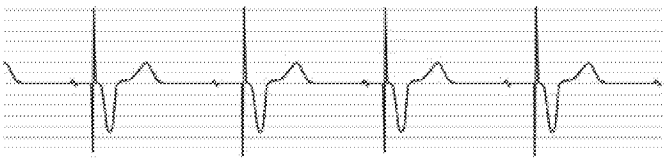
Atrial Fibrillation (A-Fib): Atrial Fibrillation is most common sustained arrhythmia. It affects as many as 10% of patients over 75 yrs. A-Fib is characterized by small, rapid, erratic spikes that may appear like a wavy baseline. A-Fib is caused by an unorganized depolarization of the atrial foci.
NOTE: A-Fib will not allow accurate interpretation of the P-wave response for ECG tip location.



Atrial Flutter (A-Flutter): A-Flutter is recognized by the distinct "saw tooth" pattern of P-waves. It is characterized by a series of identical "flutter" waves in back to back succession.
NOTE: A-Flutter will not allow accurate interpretation of the P-wave response for ECG tip location.



Artificial Pacemaker: With SA node pace failure, an artificial pacemaker may be implanted as a permanent pace making source. The demand feature engages when the inherent rate of the SA node is insufficient.
NOTE: An artificially atrial paced heart will not allow accurate interpretation of the P-wave response for ECG tip location.



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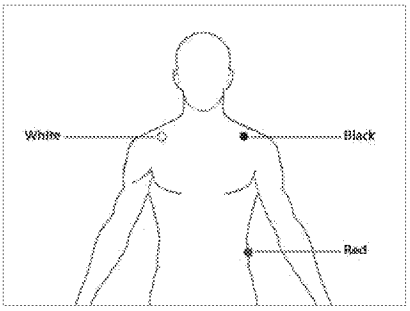
Assessing P-Waves:

1. Are they present?
2. Do they look alike?
3. Do they occur at a regular rate?
4. Is there one P-wave for each QRS?
5. Are they upright?

ECG Tip Location Applied:

Electrodes Defined—Electrodes are placed on the skin surface to detect the faint electrical activity of the heart. ECG tip location generally utilizes 3 electrodes. These electrodes are placed on the body in what is known as Einthoven's Triangle; right arm (RA), left arm (LA), left leg (LL). The three electrodes are colored white (RA), black (LA), and red (LL) in accordance with the American Heart Association (AHA) standards.



NOTE: These color standards are not universal. The International Electrotechnical Commission (IEC) has different color standards, red (RA), yellow (LA), and green (LL). Place electrodes only on clean, dry skin and in areas of minimal muscle activity.

ELECTRODE PLACEMENT MNEMONICS:

"White to the right. Red to the ribs. Black on top."
"White to the right. Smoke (black) over fire (red)."

ECG Tip Location Explained

In ECG tip location, the catheter itself becomes an intracavitary traveling electrode. As the catheter advances toward the SA node the electrical activity is monitored. This activity appears on ECG as a progressively larger P-wave. As the catheter enters the superior vena cava (SVC) the P-wave response will reflect the catheters proximity to the SA node within the upper right atrium. In this fashion, we can identify an anatomical landmark (the SA node), from which to base our catheter tip location.

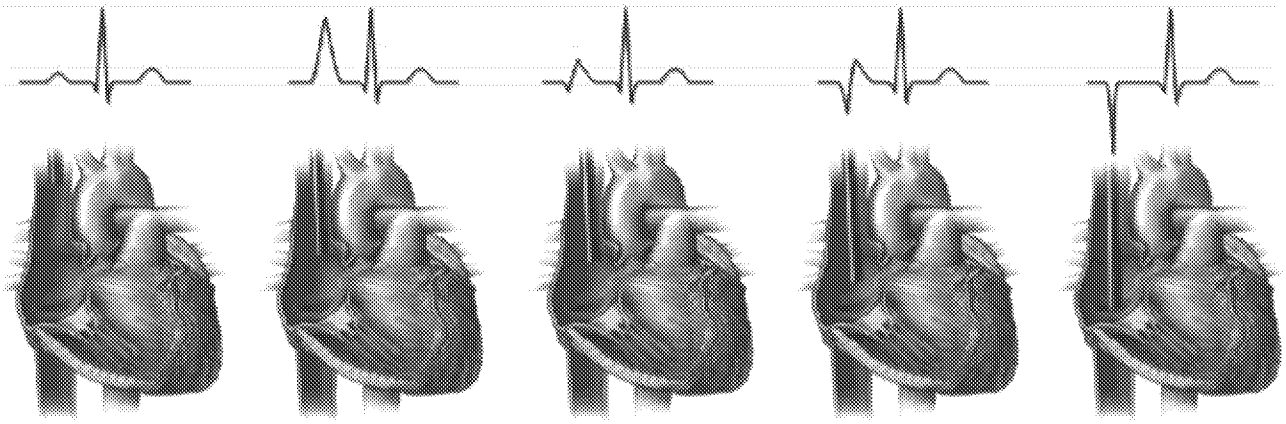


Figure 1
No evident P-wave changes indicates a catheter is not in acceptable position.

Figure 2
A P-wave at its maximum height will indicate the catheter is in the lower 1/3 of superior vena cava/ right atrial junction.

Figure 3
A downward deflection on the leading edge of the P-wave indicates the catheter entering the right atrium.

Figure 4
A biphasic P-wave indicates the catheter is within the right atrium.

Figure 5
An inverted P-wave indicates a catheter is approaching the right ventricle.

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Leads Defined

Two electrodes form a bipolar lead. Lead I is a lateral view from the RA to LA electrodes. Lead II is an inferior view from the RA to the LL electrodes. In ECG tip location it is generally lead I or Lead II that is monitored. For the purposes of central line placement lead I or lead II is generally monitored. Lead I monitoring implies the electrical activity is measured from right arm to left arm. Lead II ECG monitoring implies that the electrical activity is measured from the right arm to the left leg.

ECG Connection Techniques

Guidewire Technique—In this method the metal guidewire or stylet within the catheter is used as our conductive material to receive the electronic signals from the heart (SA node). In this technique the wire must not advance beyond the tip of the catheter being placed.

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Introduction to ECG Tip Location

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Introduction to Tip Location [1,2]

The correct position of a central venous access catheter tip is just above the level of the right atrium, in the lower (distal) third of the SVC.

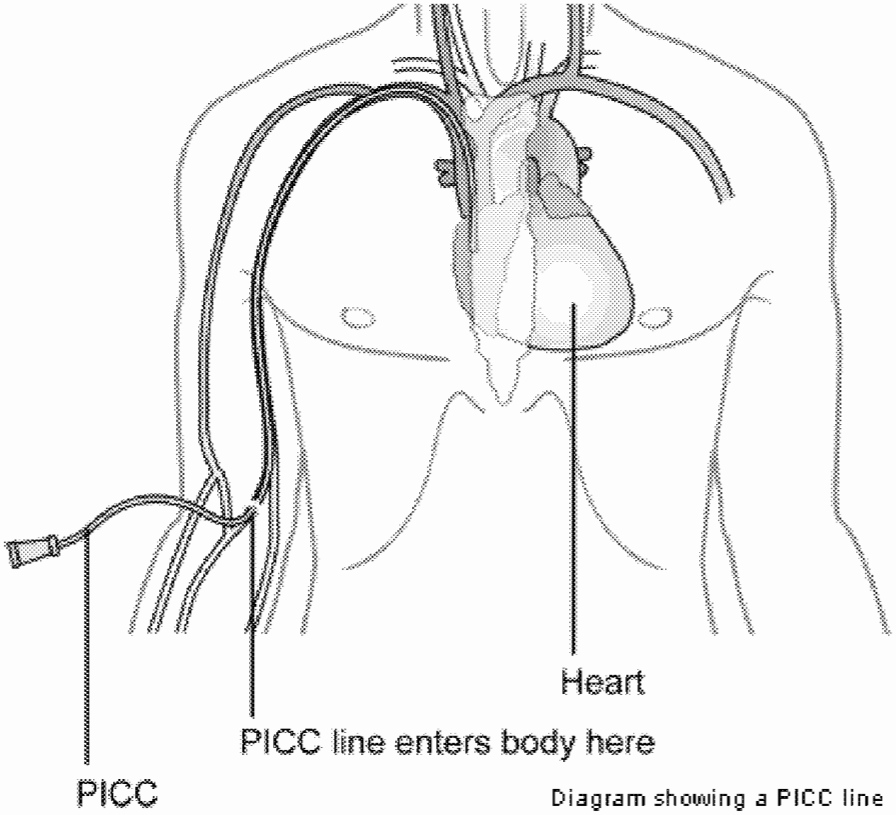
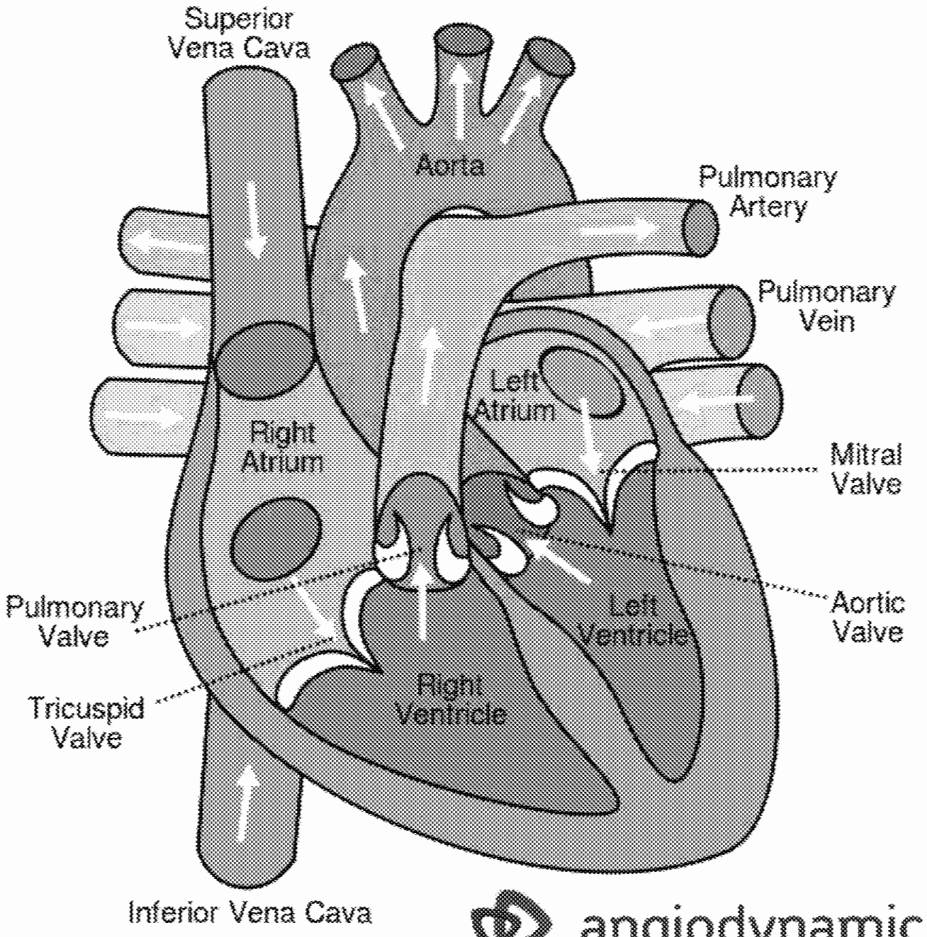


Diagram showing a PICC line



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Guidelines Regarding Catheter Tip Location [1,2,3,4]

Organization	Recommendation
The Association for Vascular Access (1998)	Lower one-third of the superior vena cava (SVC), close to the junction of the SVC and the right atrium
Infusion Nurses Society (2011)	Central venous access devices (CVAD) shall have the tip dwelling within the SVC near its junction with the right atrium.
Oncology Nurses Society (2010)	Distal third of the SVC
Society of Interventional Radiologists (2010)	Cavoatrial region

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Locating the Cavo-Atrial Junction [1,3,4]

The cavo-atrial junction (CAJ) is the point at which the superior vena cava meets the right atrium. This area of high blood volume (hemodilution) and turbulence creates a favorable location for delivery of IV medication.

- Catheter tip is too short (proximal SVC or in the innominate veins)
  - 10% to 50% increased risk of venous thrombosis , fibrin sleeve, vein erosion, catheter dysfunction
  - Spontaneous malposition (up into IJ)
- Catheter tip is too long (in the lower portion of the RA, RV, or beyond)
  - increased risk of arrhythmia, tricuspid valve dysfunction, atrial thrombosis, myocardial erosion (cardiac tamponade)

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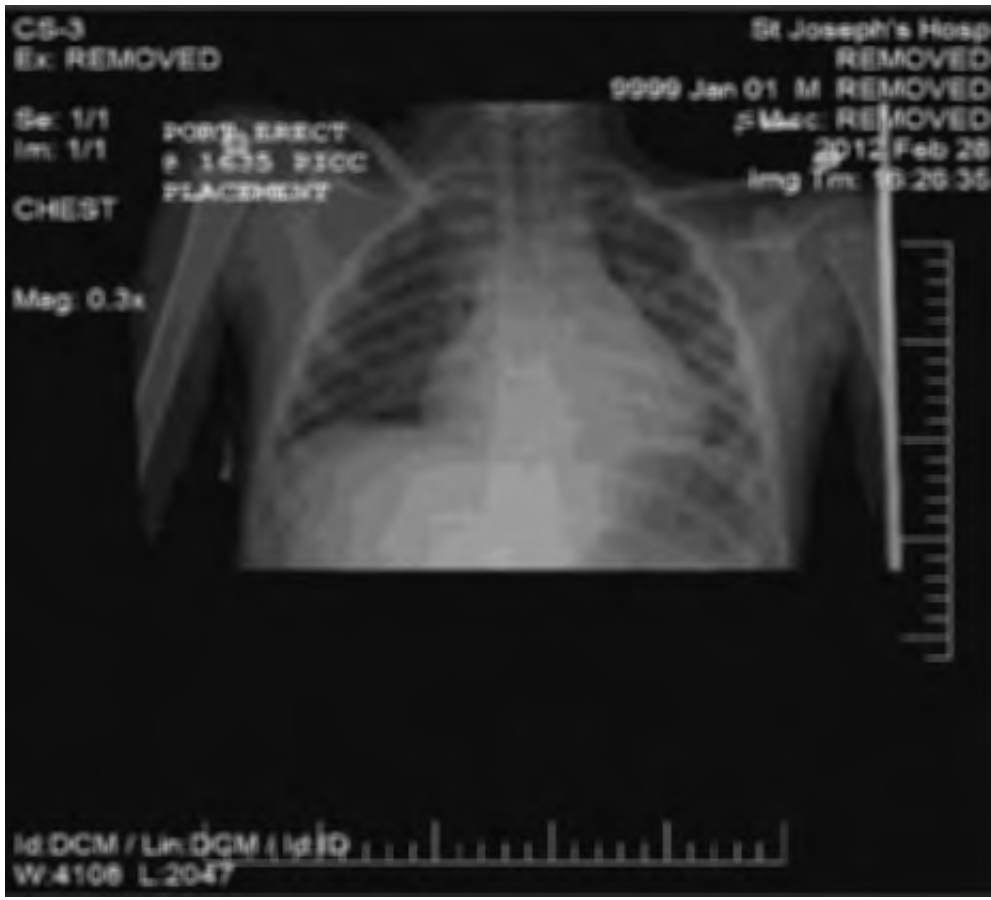
PICC Tip Positioning without ECG [2,3,7,8]

Traditional practices- included procedure landmark and anthropometric measurements followed by post-procedural chest radiography (x-ray).



Challenges with this practice include:

- Inefficient placement (malpositions) requiring repeat x-rays
- Inconsistency in required post-procedure x-ray interpretation by MDs
- Delays in clearing the PICC for use

Tip location of central venous access devices shall be determined radiographically or by other approved technologies prior to the initiation of infusion therapy. *(Infusion Nurses Society, 2011)*

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Navigation vs. Tip Location [3,4,7,8]

- **Navigation**
  - Refers to technology that ascertains information regarding general directionality of a vascular access device.
  - Utilizes electro-magnetic detection to illustrate audibly or visually catheter direction and general direction.
  - Require a custom stylet wire to be inserted within the catheter
  - Are effective in reducing catheter malpositions; however they **DO NOT** provide information regarding the catheter's tip location with respect to the heart
- **Tip Location**
  - Utilizes technology based on ECG to determine a catheters tip position in relation to the location of the heart
  - Rely on a stylet to serve as an intracavitary electrode to detect P-wave changes as the catheter nears the sinoatrial node
  - Approved tip location devices are used as an alternative or supplement to chest x-ray or fluoroscopy for PICC catheter line clearance.

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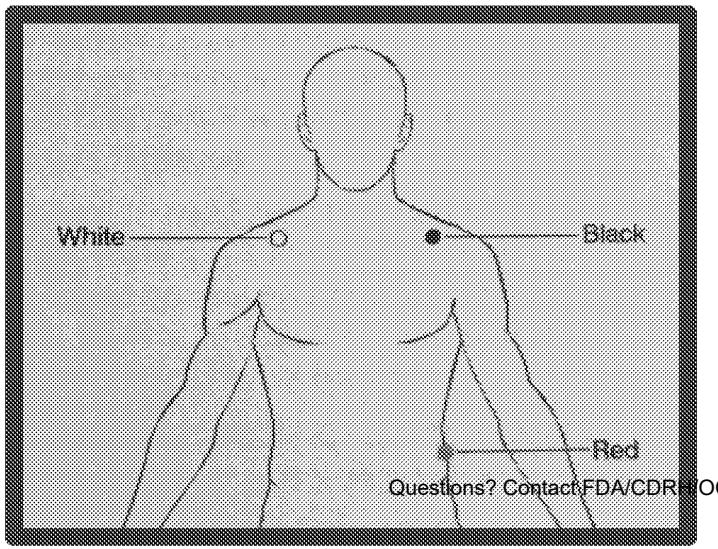
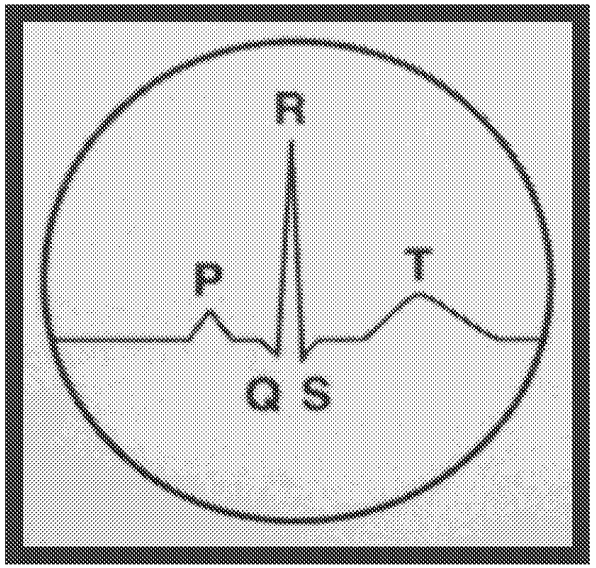
Electrocardiogram (ECG) Guidance [3,4,7,8]

- The catheter tip location is verified by observing the ECG
- An intra-cavitary electrode connected to the PICC (stylet, guidewire, or saline column) and three surface electrodes are placed on the patient's skin.
- The voltage across the electrodes indicates changes in the p wave as the catheter approaches the SA node (primary pacemaker of the heart)

"White on the right, smoke over fire"





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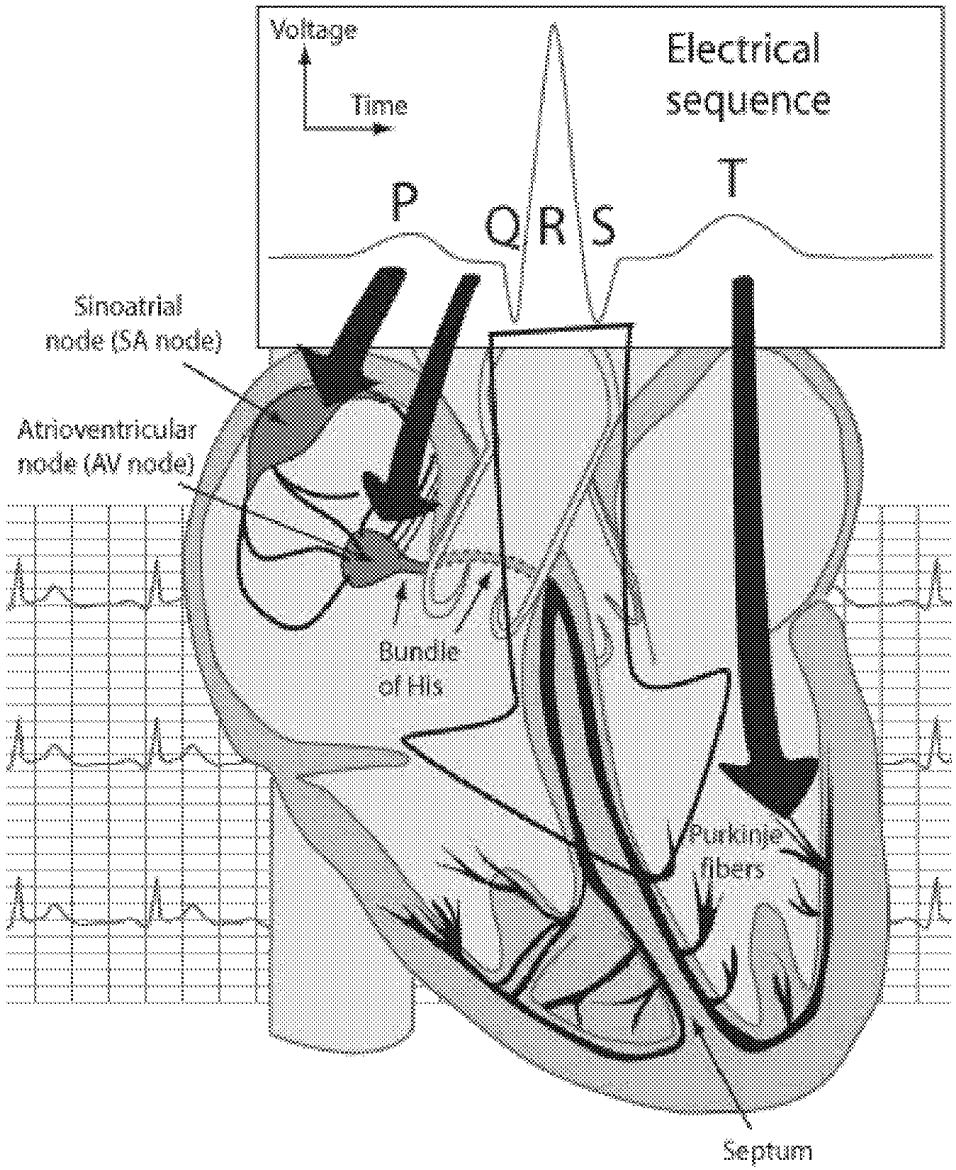
How ECG tip verification works [4,8,9]

- The PICC is advanced while monitoring the p wave and observing changes in amplitude
- The heart's **primary pacemaker** is a bundle of cells, known as the sinoatrial node or **SA node** and is located in the upper posterior wall of the right atrium.
- As PICC nears the SA node the exact catheter position can be determined by these changes
- When the p wave is at its maximum amplitude just prior to downward deflection the tip is at the CAJ



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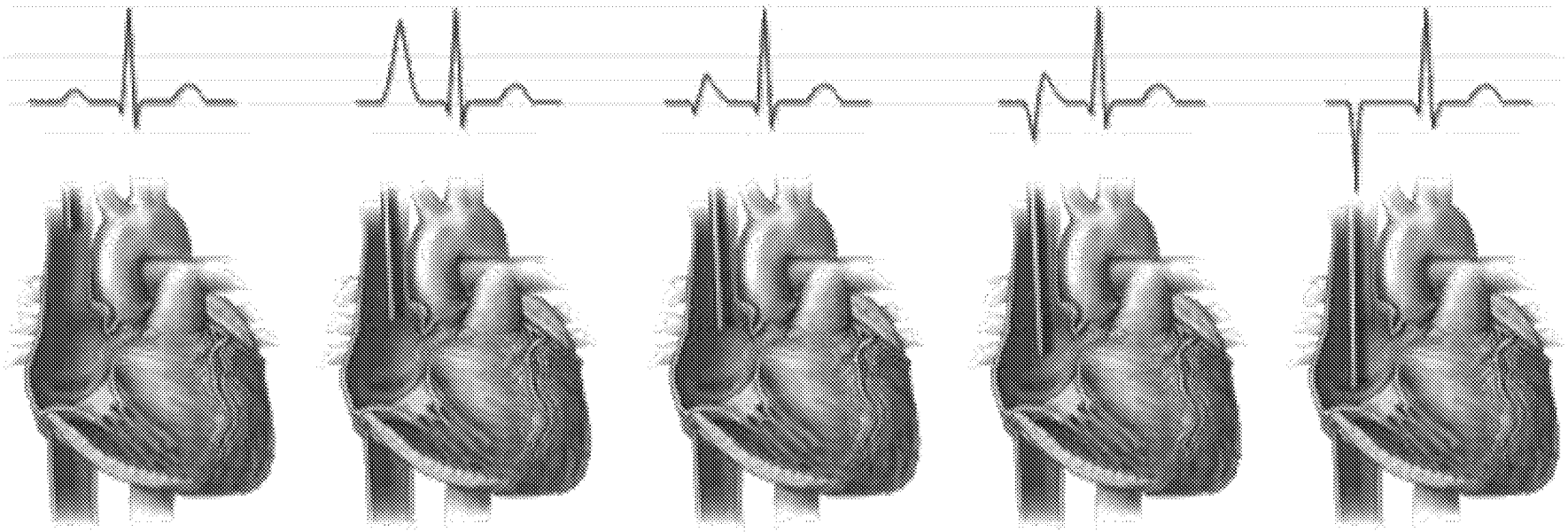
P-Wave Correlates to Catheter Proximity [4,8]



No evident P wave changes indicates a catheter is not in acceptable position.

A P wave at its max height will indicate the catheter is in the lower 1/3 of SVC

A downward defection edge of P wave indicates the catheter entering the right atrium

A biphasic P wave indicates the catheter is within the right atrium.

An inverted P wave indicates a catheter is approaching the right ventricle

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Limitations

Limiting, but not contraindicated, situations for this technique are patients where cardiac rhythms may change presentation of the P-wave:

- Atrial fibrillation
- Atrial flutter
- Severe tachycardia
- Pacemaker-driven rhythm
- Chronic obstructive pulmonary disease (COPD)

Such patients are easily identified prior to PICC insertion

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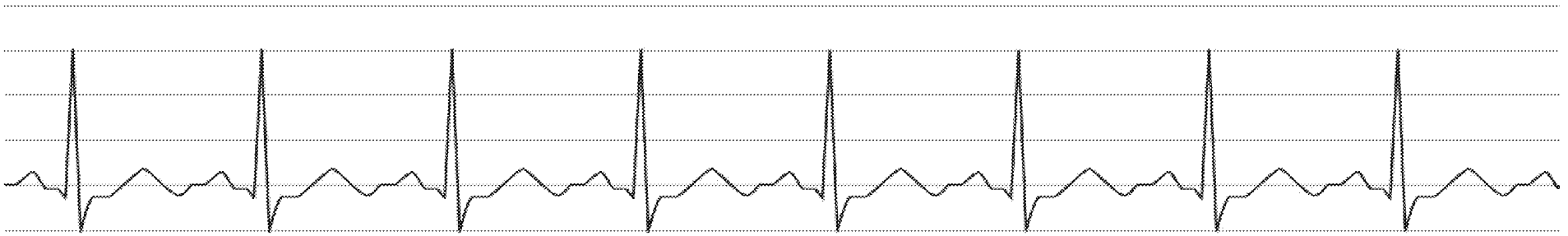
Assessing P Wave [9]

- Are P waves present?
- Do they look alike?
- Do they occur at a regular rate?
- Is there one P wave for each QRS?
- Are they upright?



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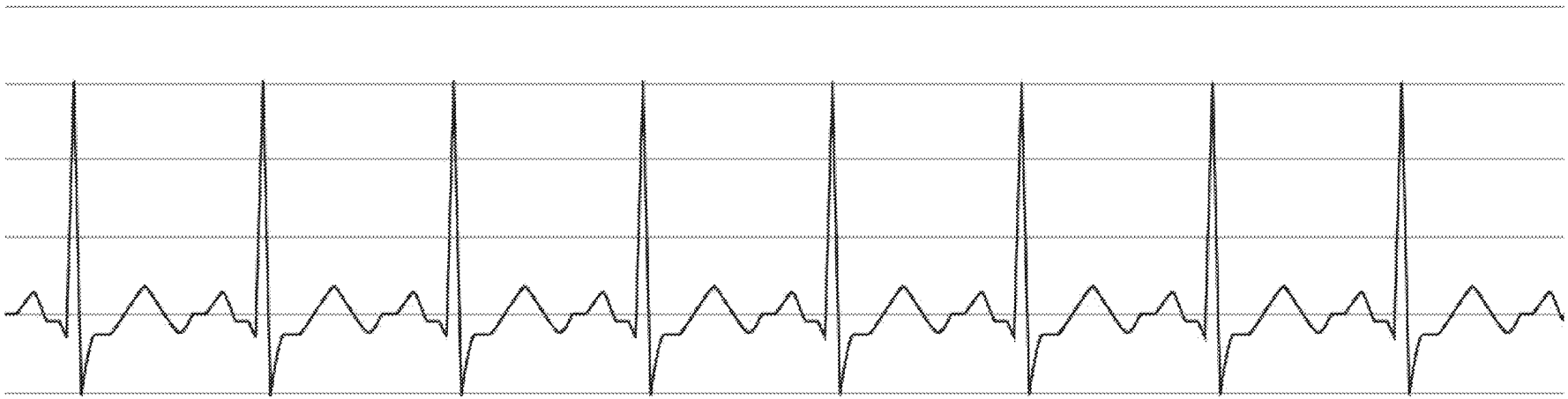
Normal Sinus Rhythm [9]

- Sinus rhythms originate at the SA node & generally travel through the heart's entire conduction system without inhibition. This is a "normal" rhythm.
- Rate 60-100 beats per minute*



* Sinus bradycardia looks similar but with rate less than 60
Sinus tachycardia likewise but with rate greater than 100

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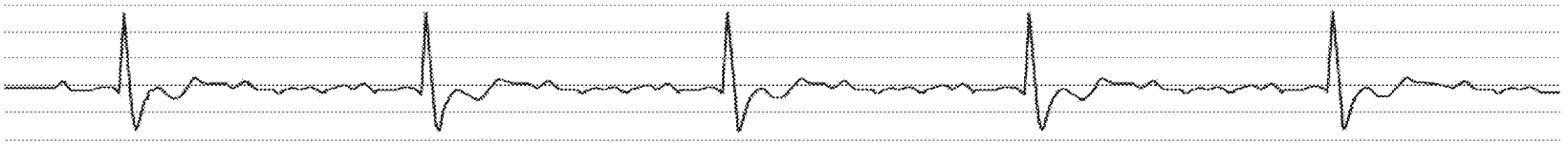
Atrial Fibrillation [9]

- Atrial fibrillation is the most common sustained arrhythmia. It affects as many as 10% of patients over age 75.
- A multitude of foci initiate impulses causing a chaotic irregular atrial rhythm having no pattern or shape
- Atrial rate can exceed 400 beats per minute but most are blocked by the AV node and considered under control by medication when heart rate is between 60-100 beats per minute
- Mistaken for Atrial Tachycardia but AT has p waves with multiple shapes that vary and a rate 120-150

A-Fib will not allow accurate P wave interpretation for ECG tip location



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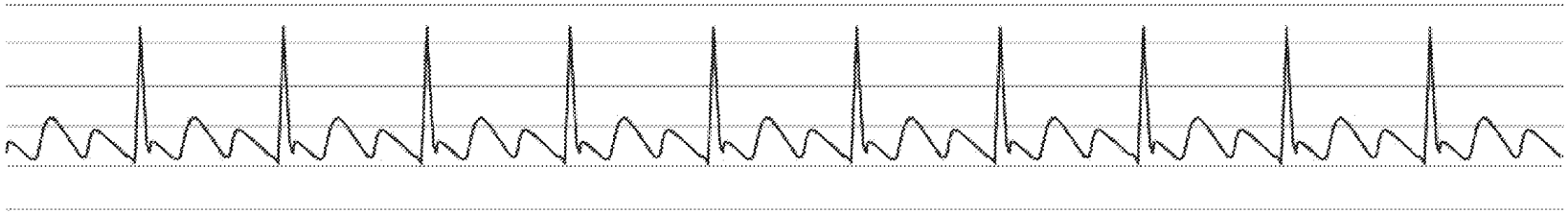
Atrial Flutter [9]

- Atrial flutter is recognized by P-waves with a “saw-tooth” pattern or resemble a “picket fence”
- Characterized by a series of identical flutter waves in a rapid, repetitive fashion
- Atrial rate is between 250-400 but most impulses are blocked by the AV node.

A-Flutter will not allow accurate P wave interpretation for ECG tip location



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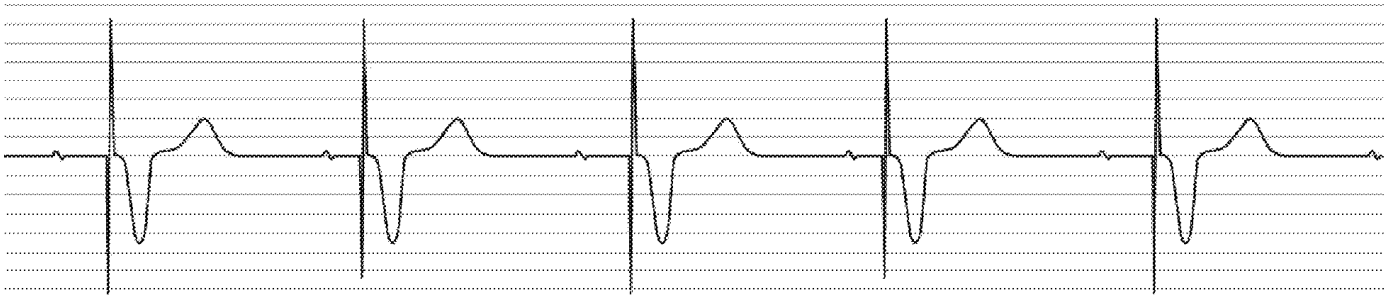
Artificial Pacemaker [9]

- With SA node pace failure, an artificial pacemaker may be implanted as a permanent pace making source. The demand feature engages when the inherent rate of the SA node is insufficient (too slow)

An artificially atrial paced heart will not allow accurate interpretation of the P wave response for ECG tip location.



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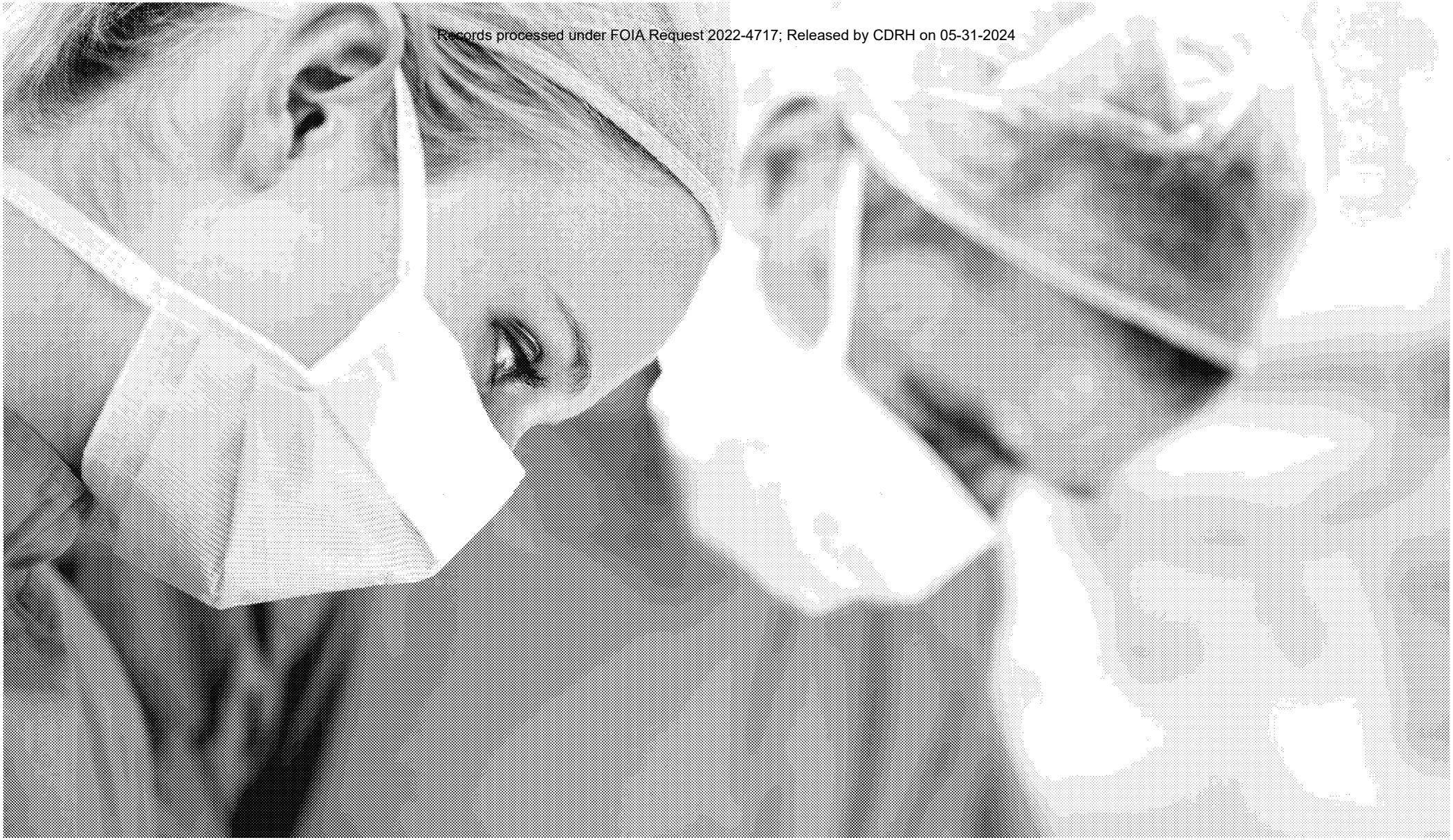

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Celerity

ECG-Based PICC Tip Confirmation System

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Indications for Use

The Celerity System is indicated for use as a supplemental aid in positioning for Peripherally Inserted Central Catheters (PICC) in adult patients.

It provides real-time catheter tip location information by using the patients cardiac electrical activity. Confirmation of tip placement should be verified according to clinical judgment and established hospital protocol (e.g. chest x-ray, fluoroscopy).

Note: Limiting but no contraindicated, situations for this technique are patients where cardiac rhythms may change presentation of the P-wave: Atrial fibrillation, Atrial flutter, Severe tachycardia, Pacemaker-driven rhythm and COPD. Such patients are easily identified prior to PICC insertion. Use of an additional confirmation method is necessary to confirm catheter tip location.

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Intended Use

- The CELERITY system is intended to provide real time tip location information of a central venous catheter
- Utilizes ECG to observe P-wave changes as the tip approaches the right atrium of the heart via the superior vena cava

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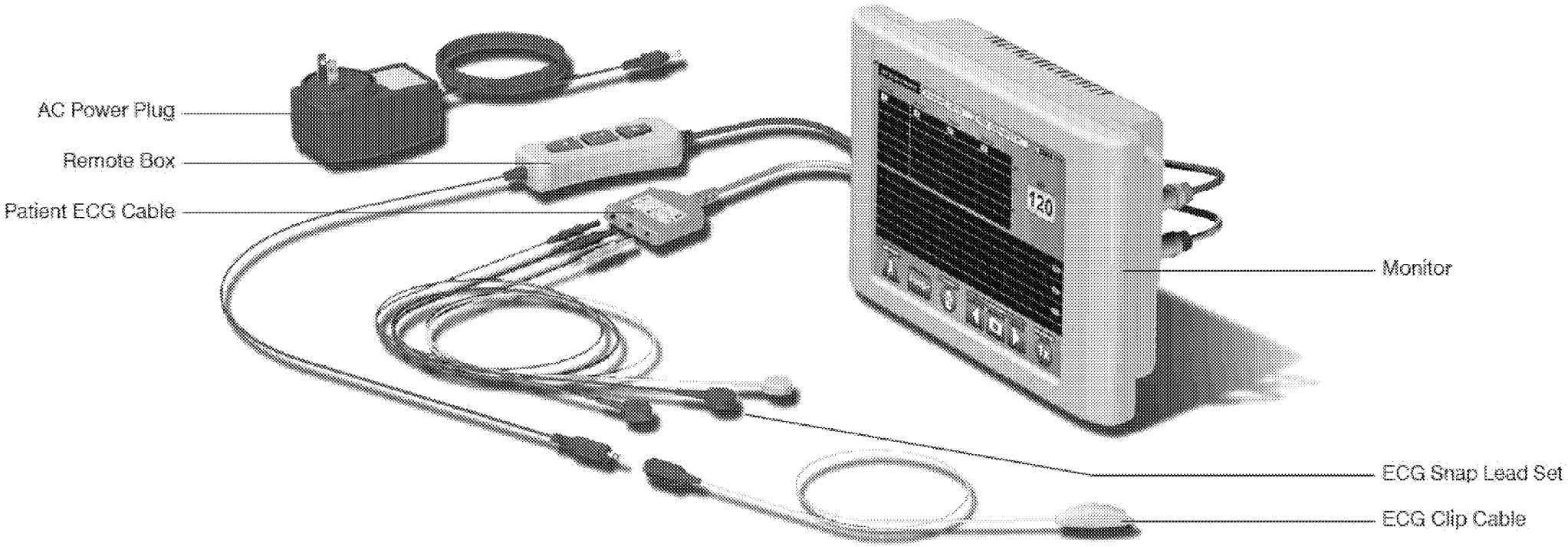
CELERITY SYSTEM



- Monitor
- Patient ECG Cable
- Remote Box
- ECG Clip Cable

- AC Power Plug
- ECG Snap Lead Set
  Disposable ECG Clip Cable

* Also will offer Dymo label printer and CELERITY stand depending on customer needs

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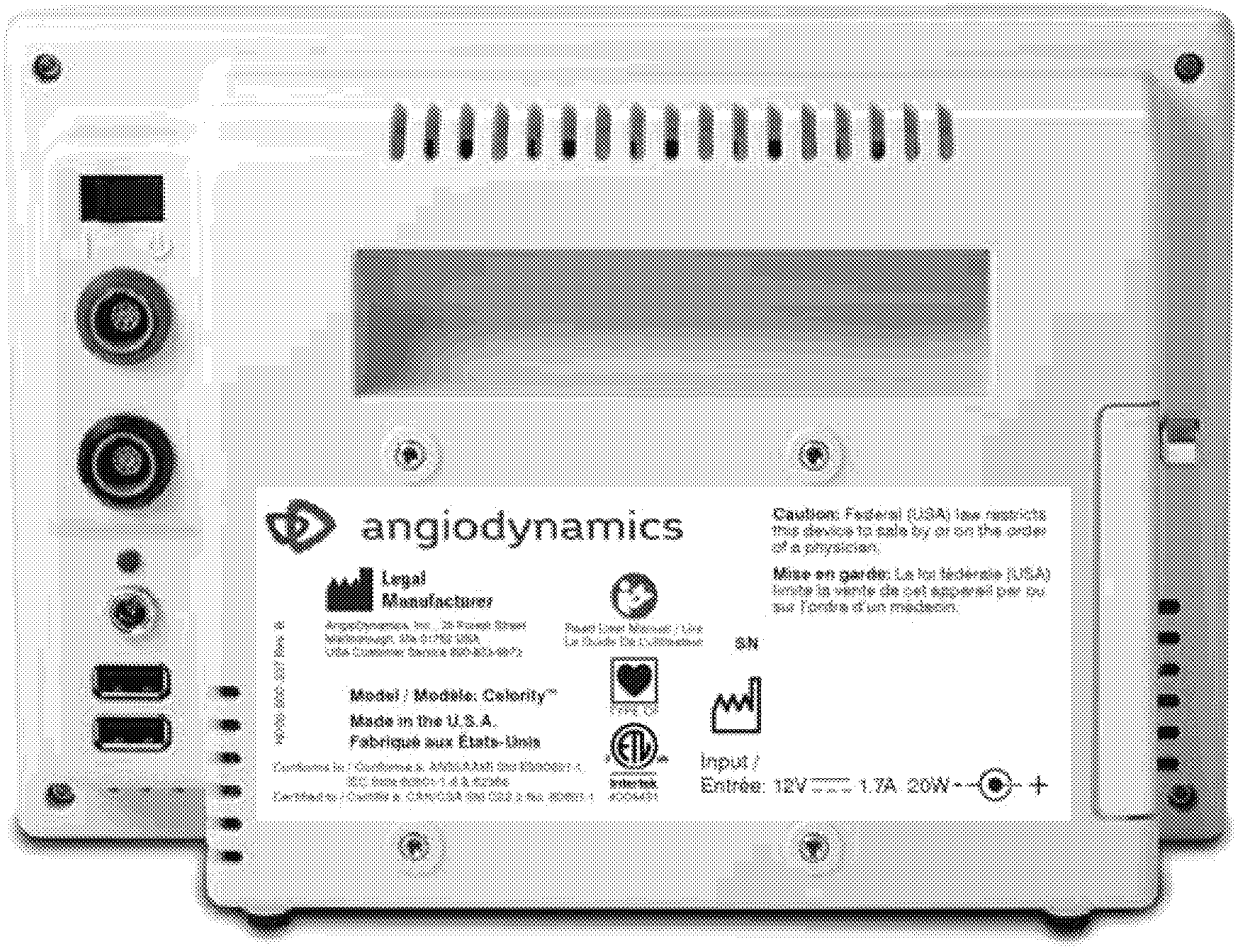
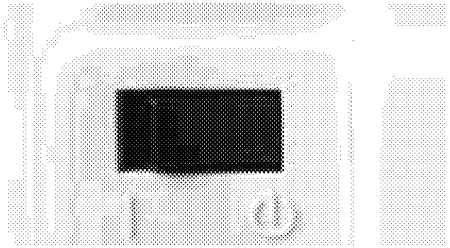
Power it on





Refer to Celerity Owner's Manual,

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Patient ID

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ECG Screen

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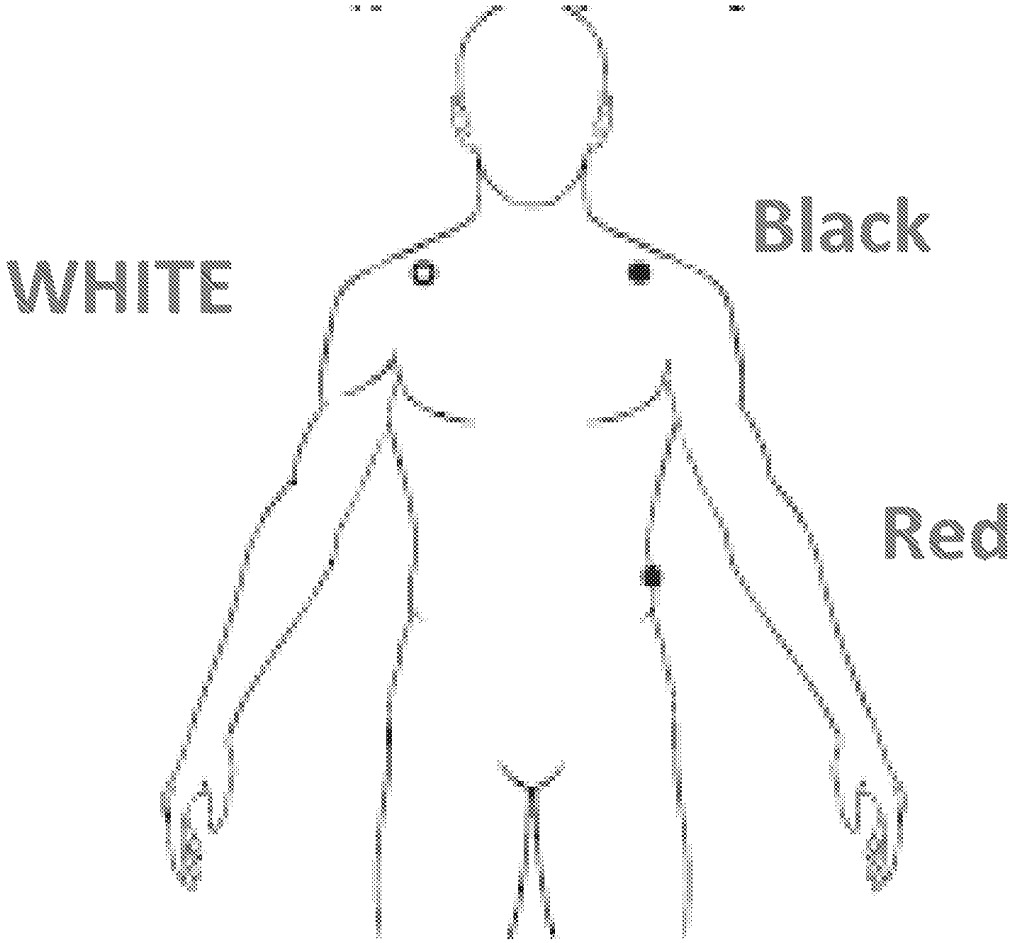
Connect Surface Leads



"White on the right, smoke over fire"

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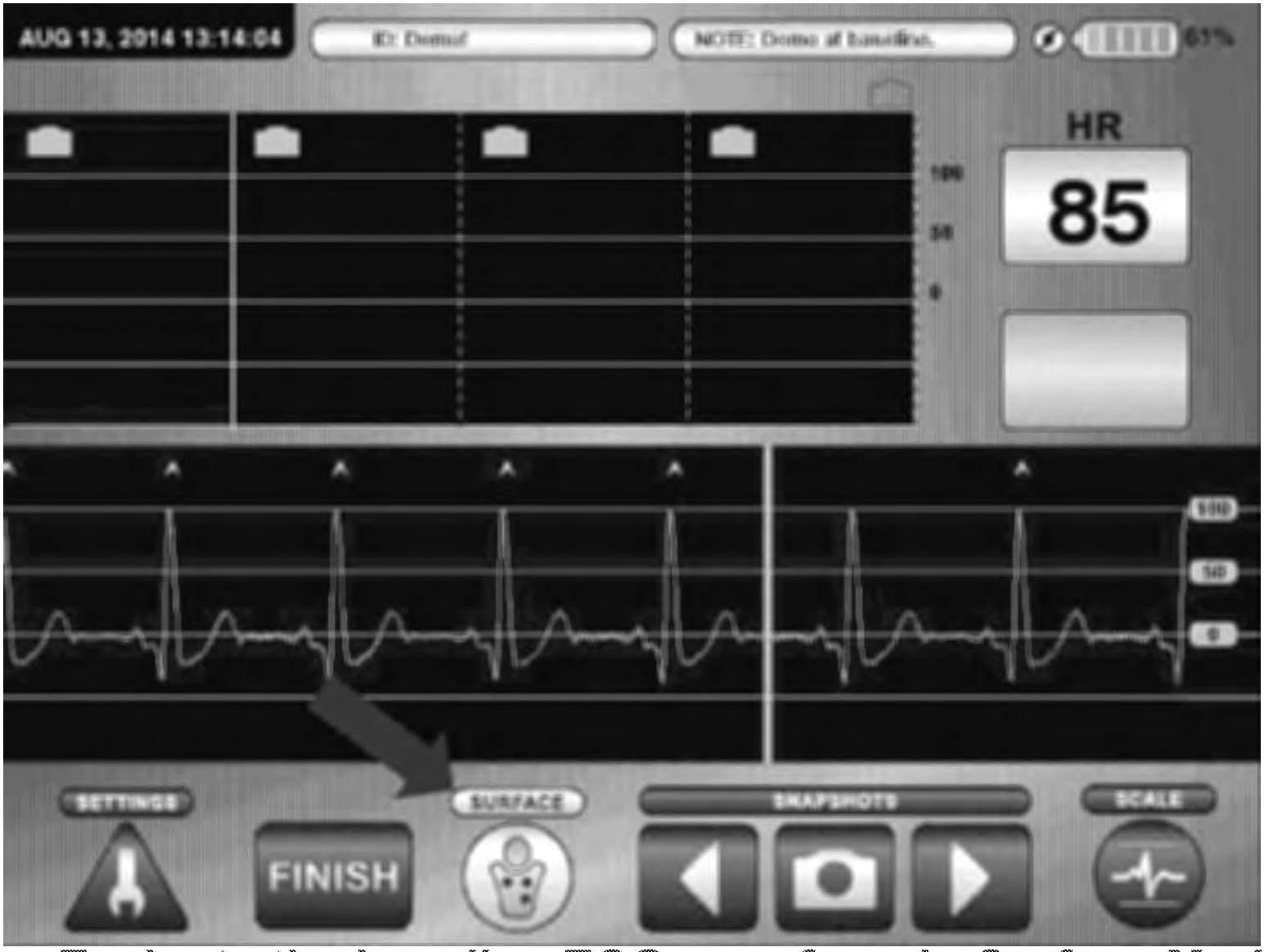
Surface ECG



Evaluate the baseline ECG waveform in Surface Mode

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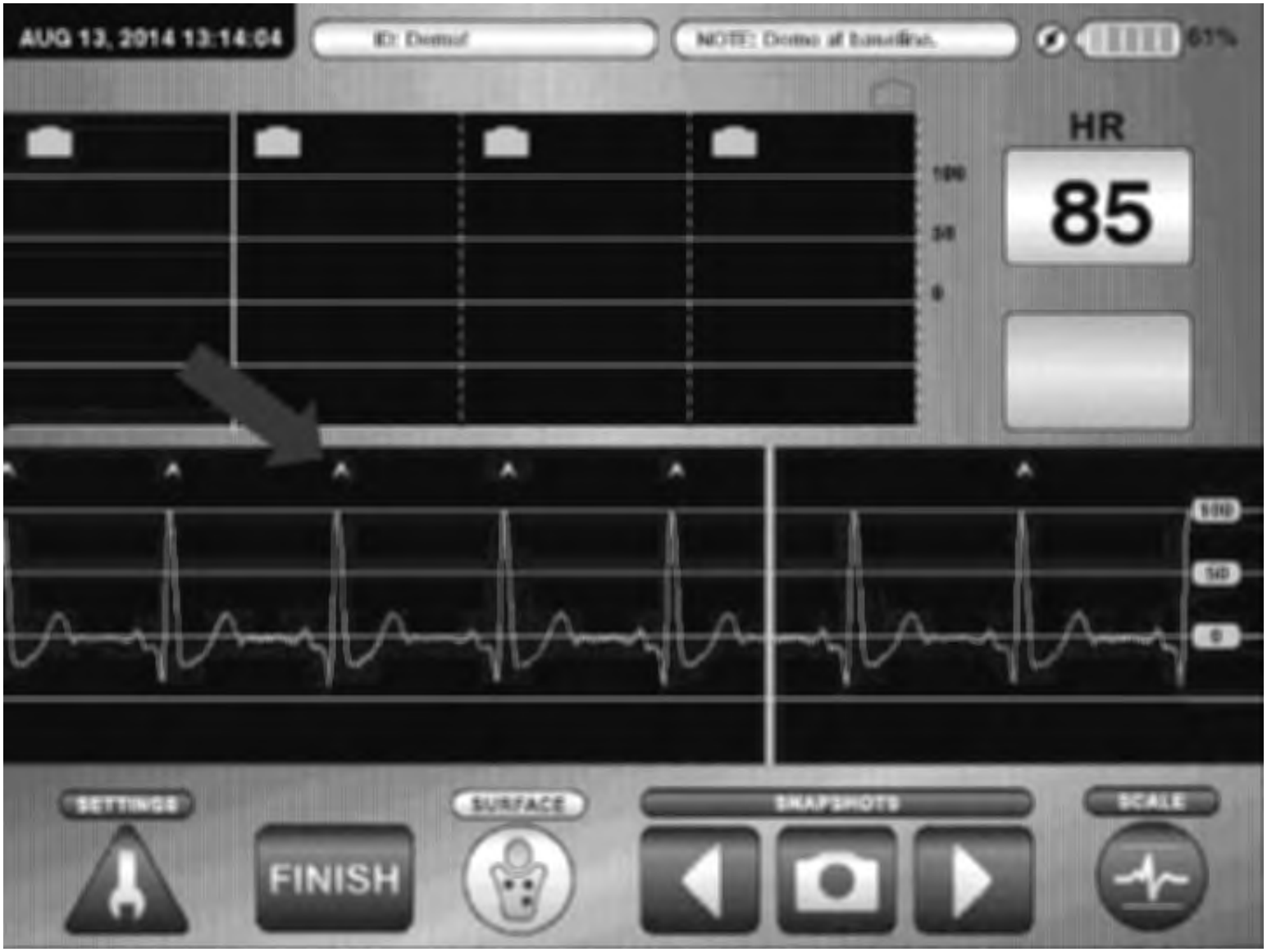
Normal Sinus Rhythm



Use the snapshot icon to obtain an image of the baseline ECG

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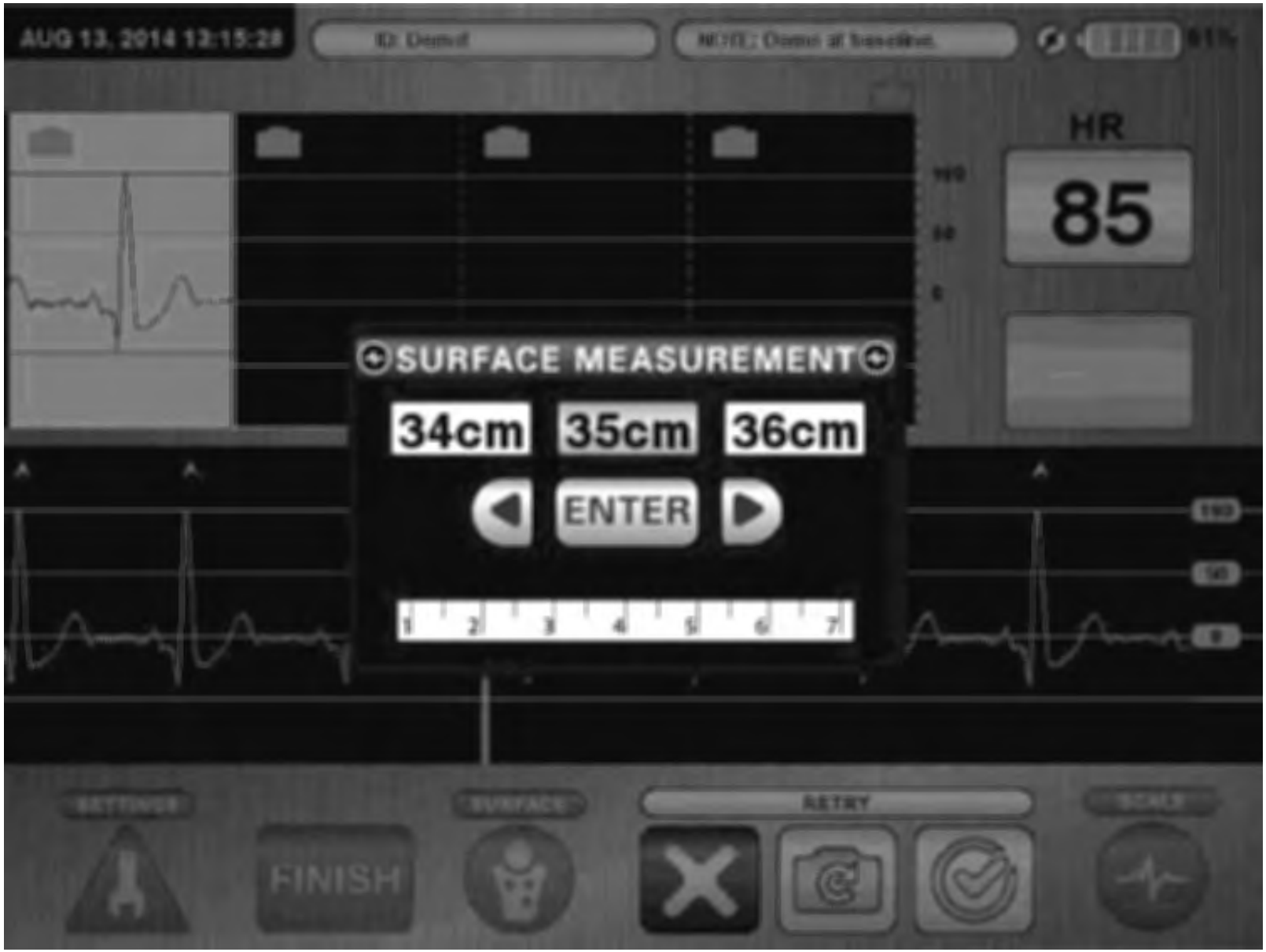
Surface Measurement



Enter the surface measurement

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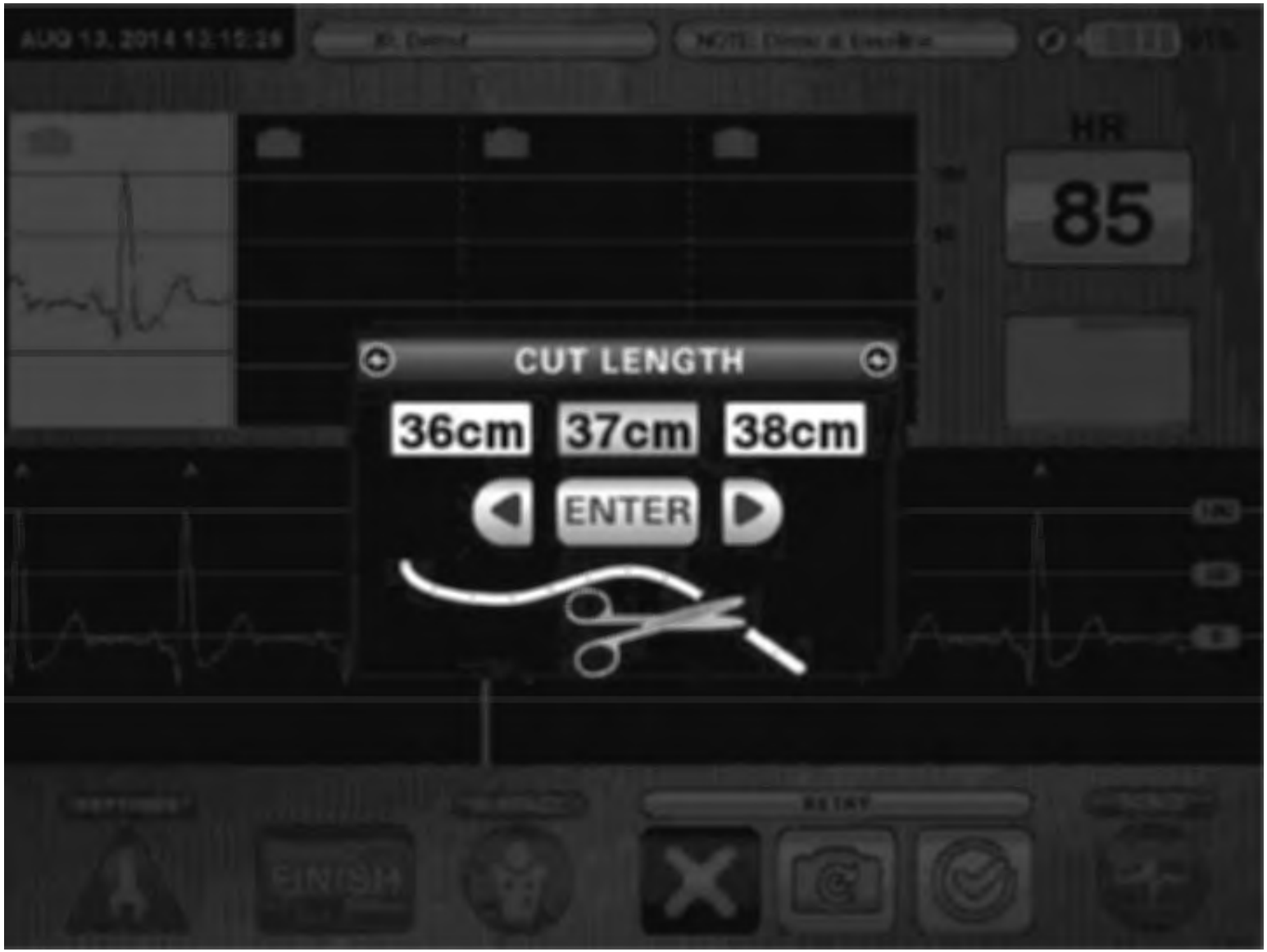
Cut Length



Enter the surface measurement

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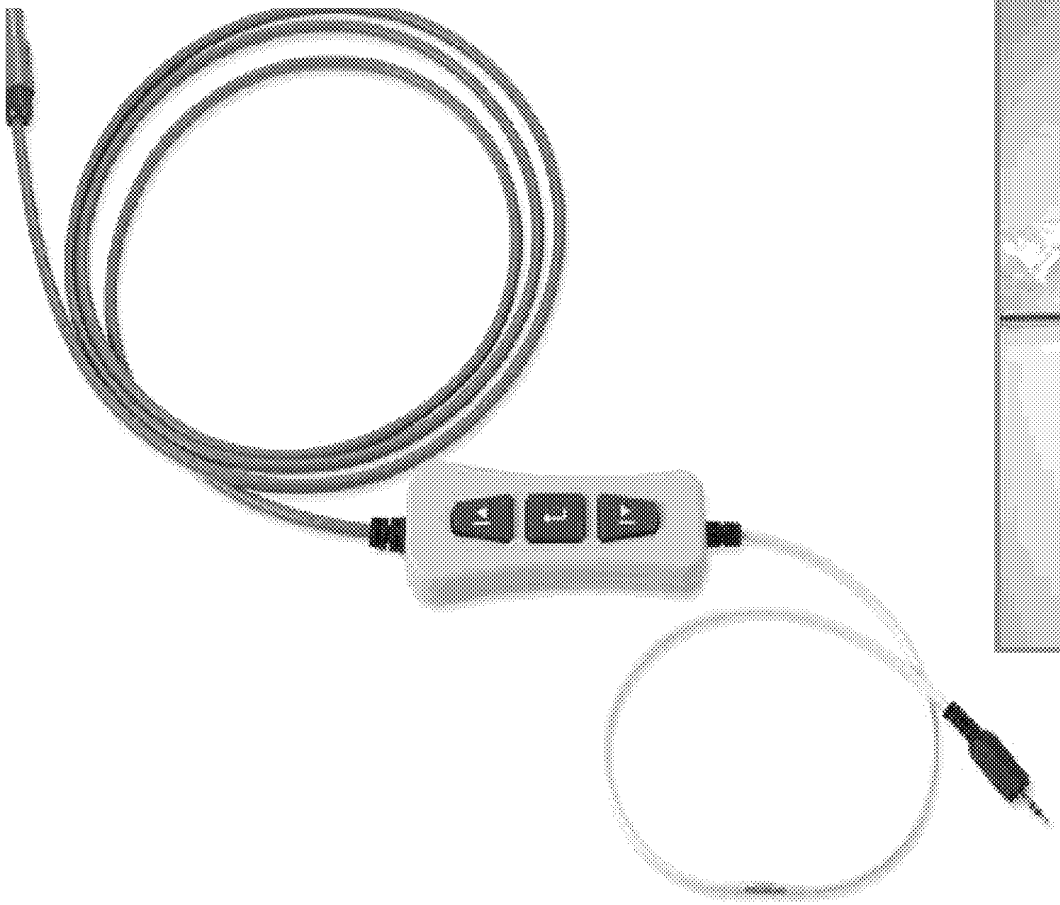
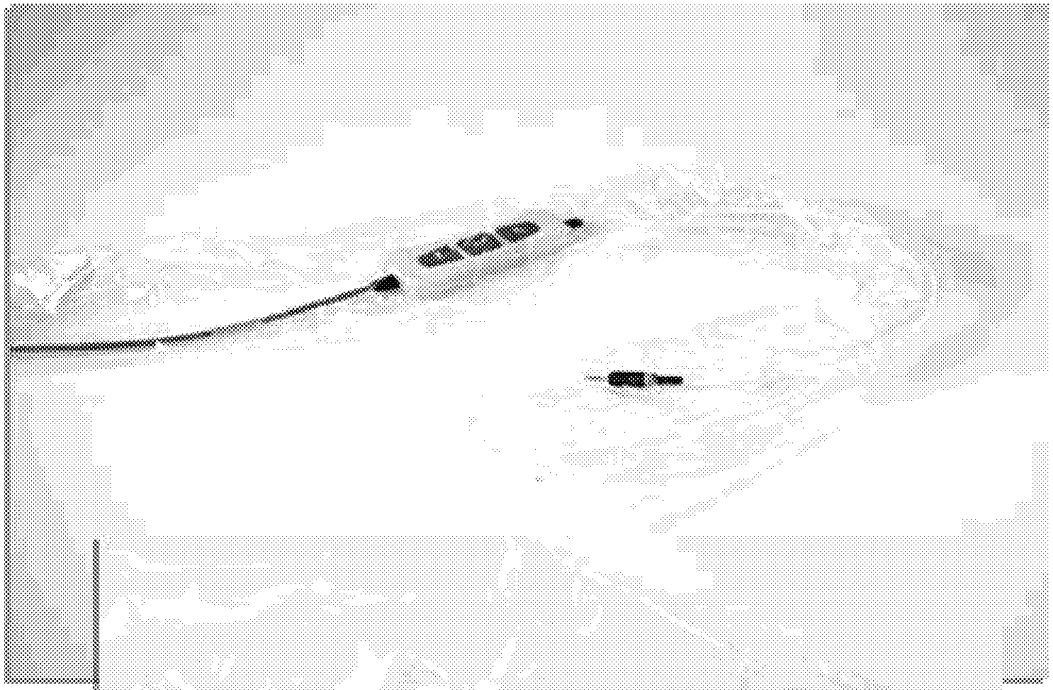
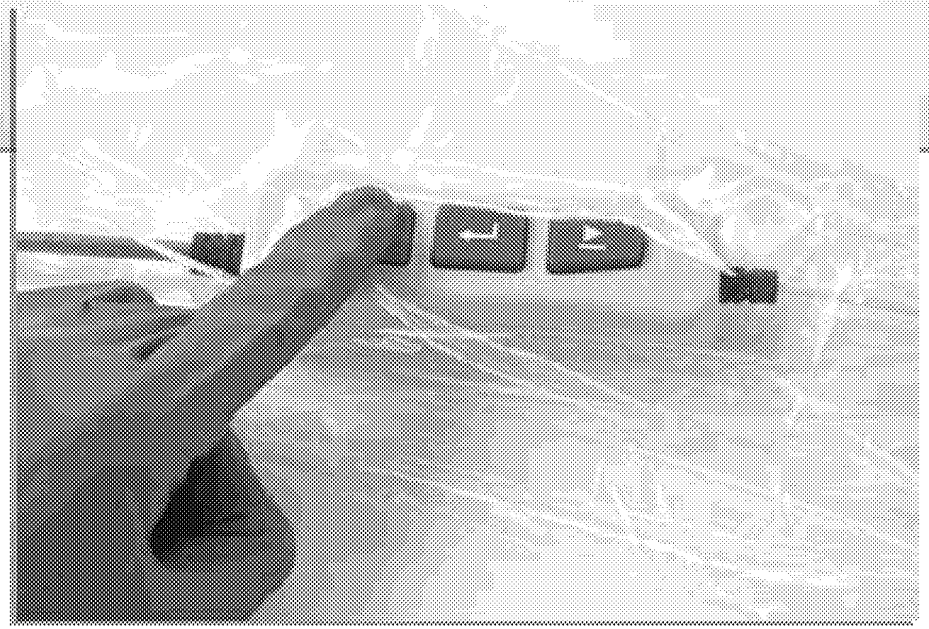
Remote Cable







Cover the remote cable with the sterile cable

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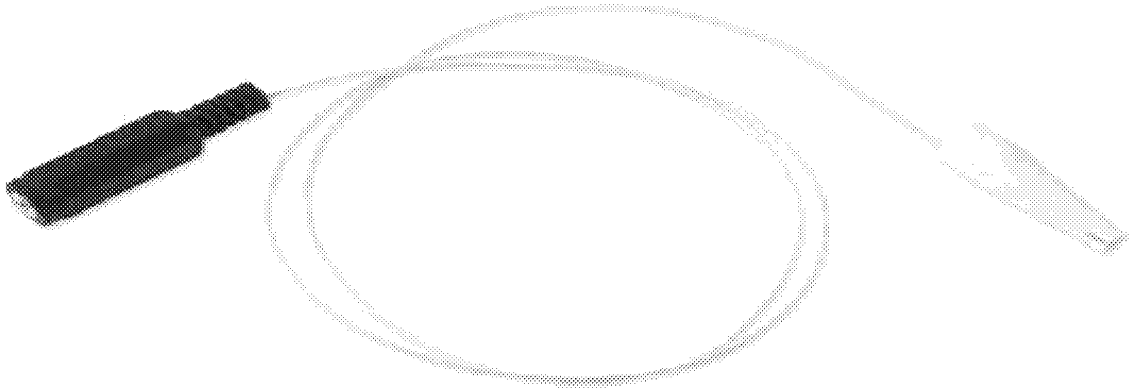
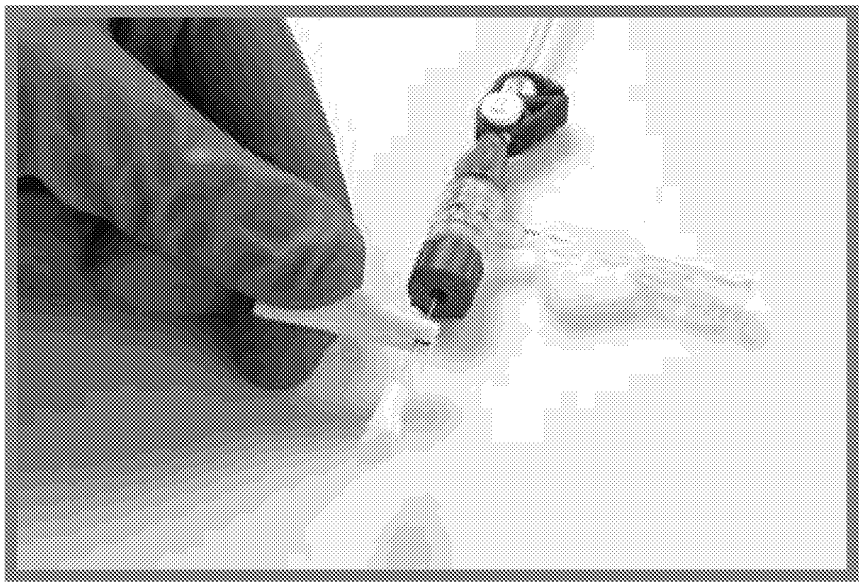
ECG Clip Cable



Secure the ECG clip cable to the proximal end of the stylet



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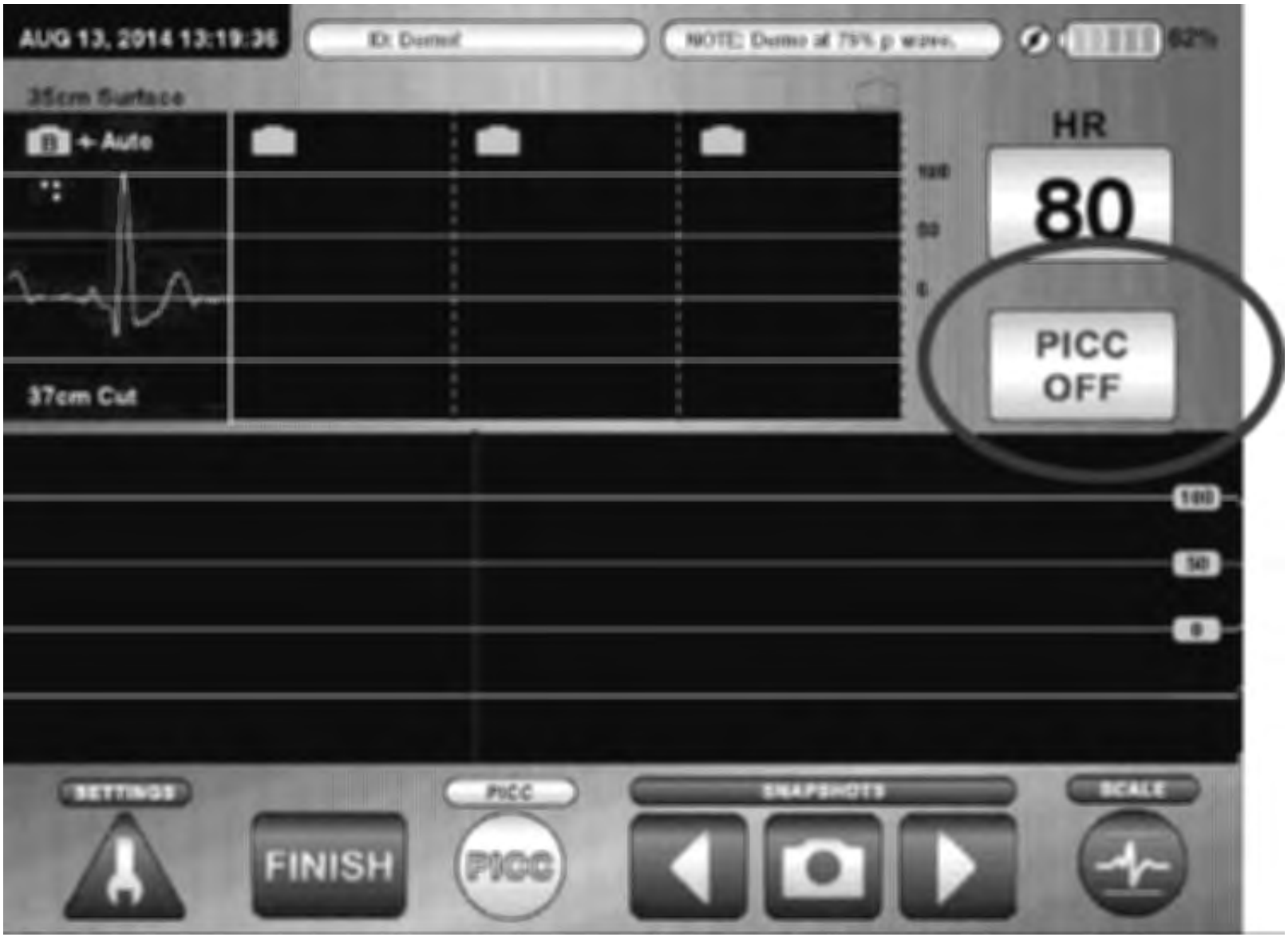
PICC Mode



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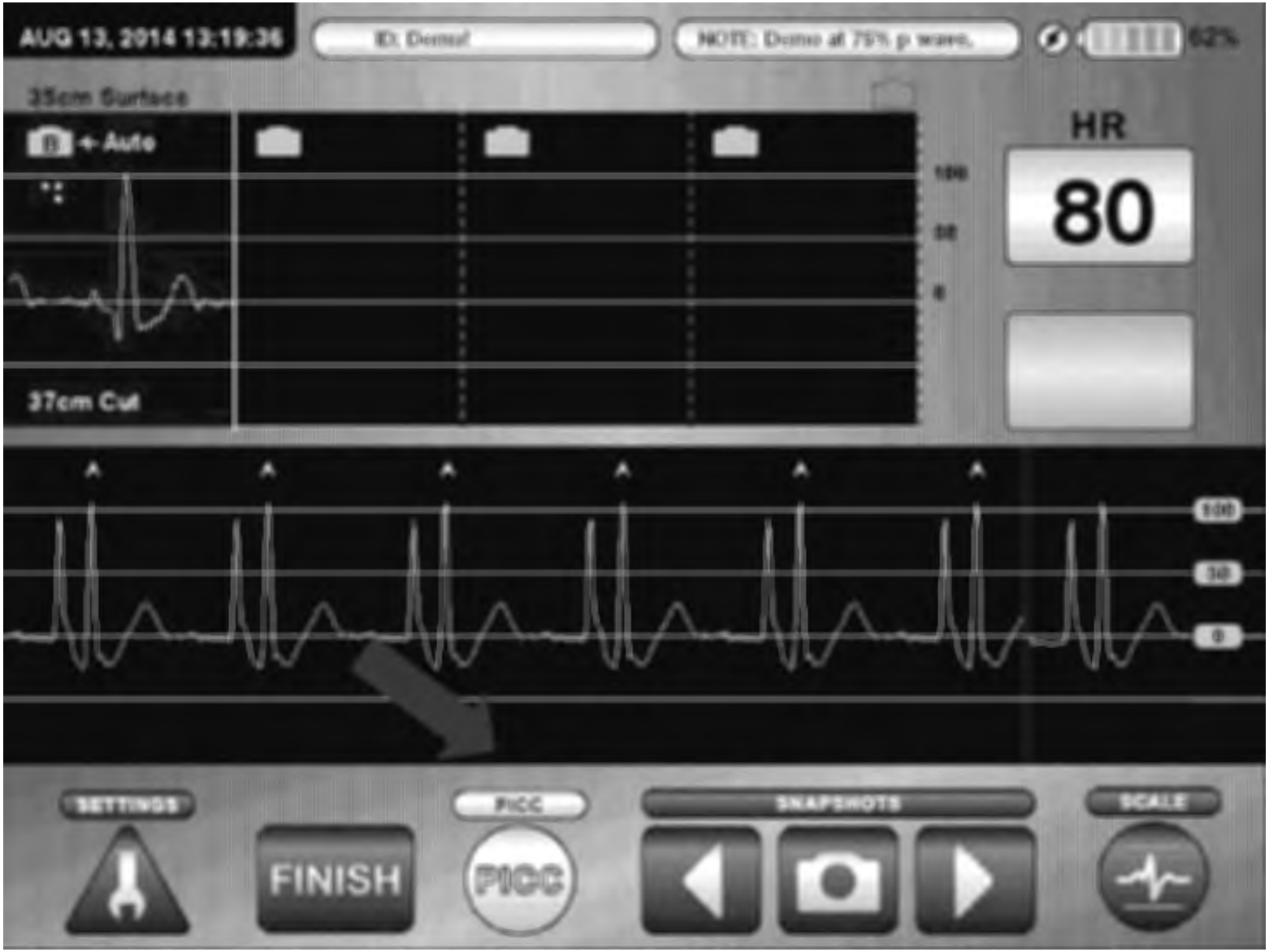
PICC Mode



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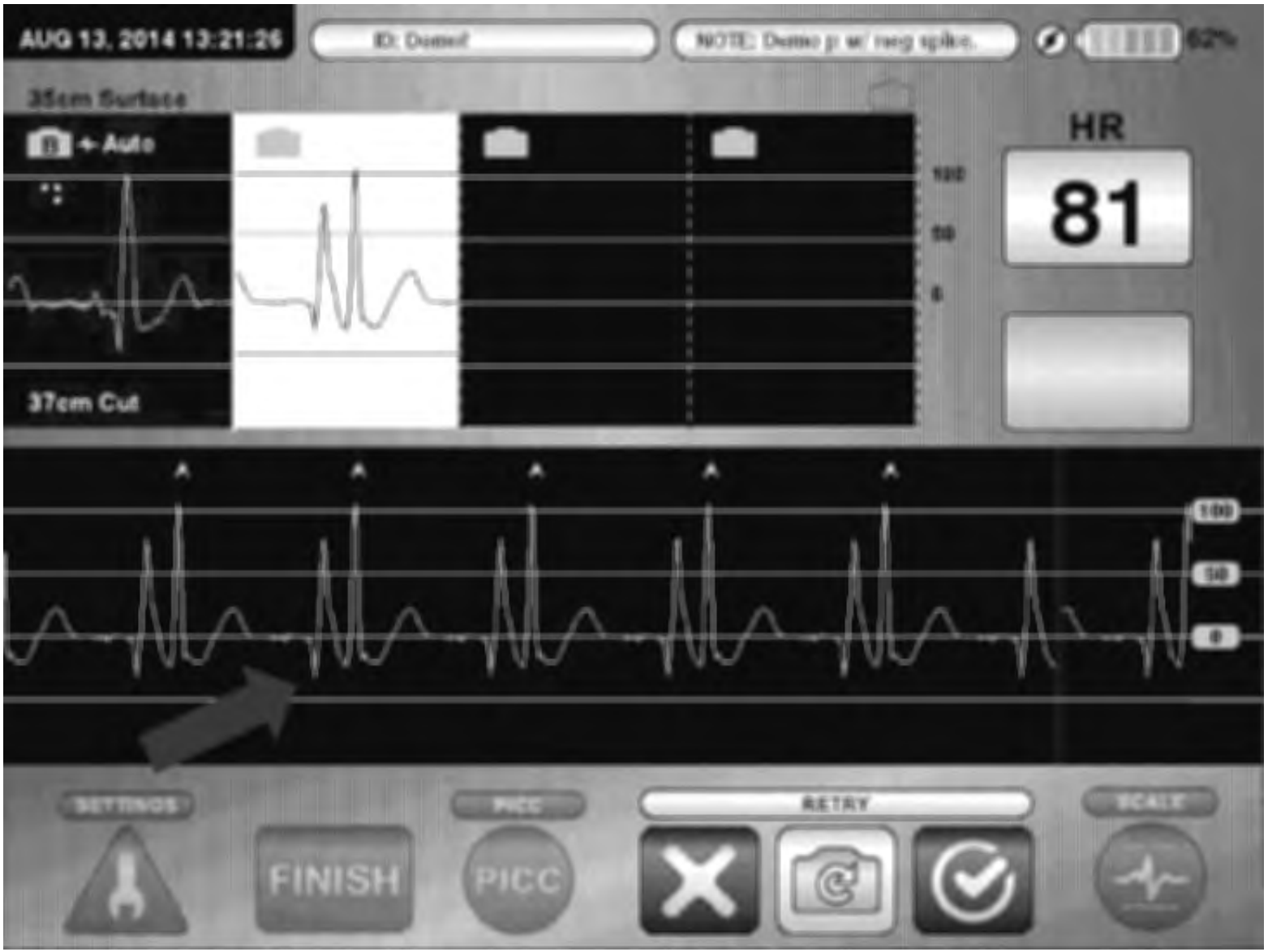
Negative Deflection



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Exposed Catheter Length

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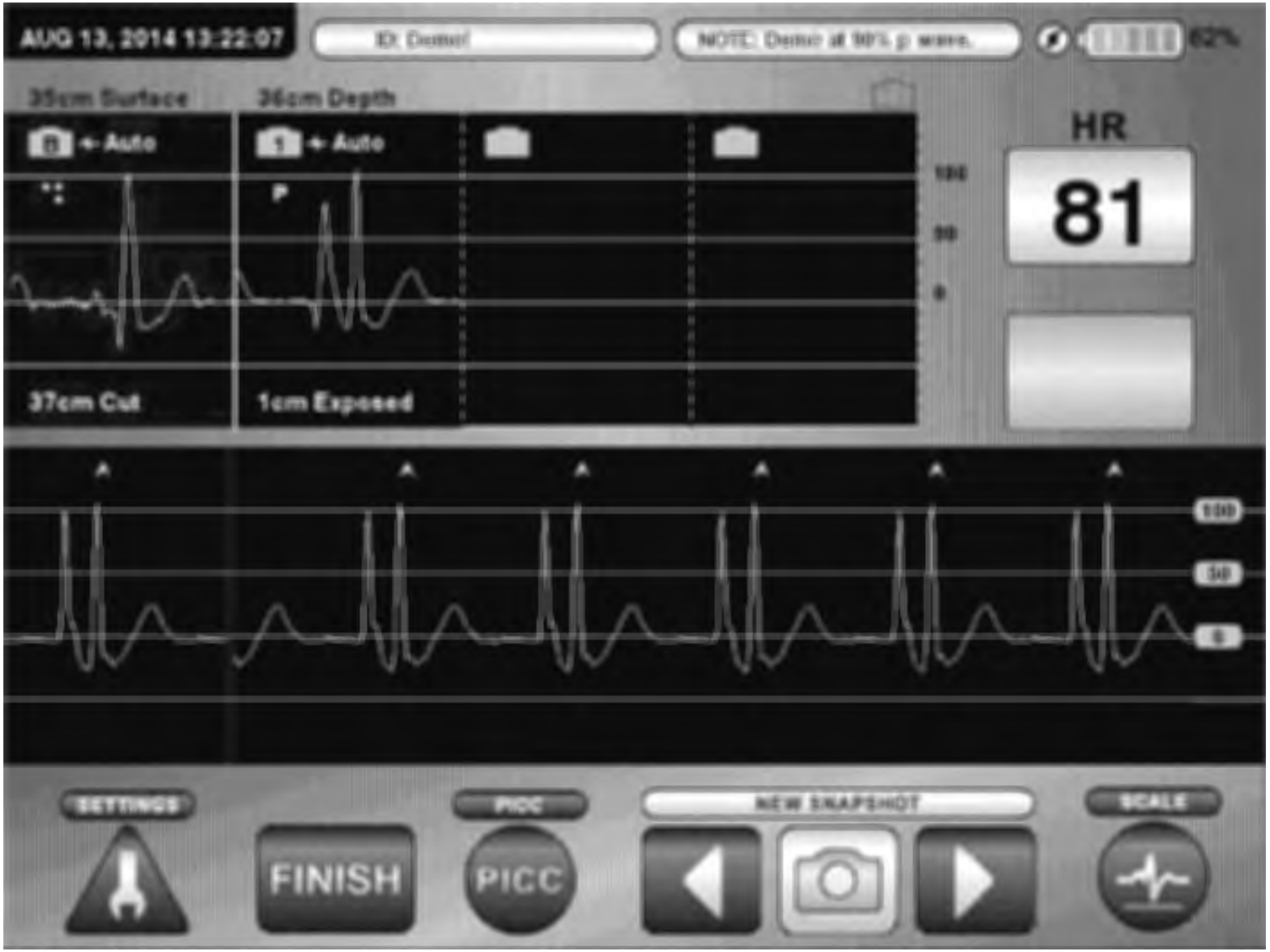
Max P-wave



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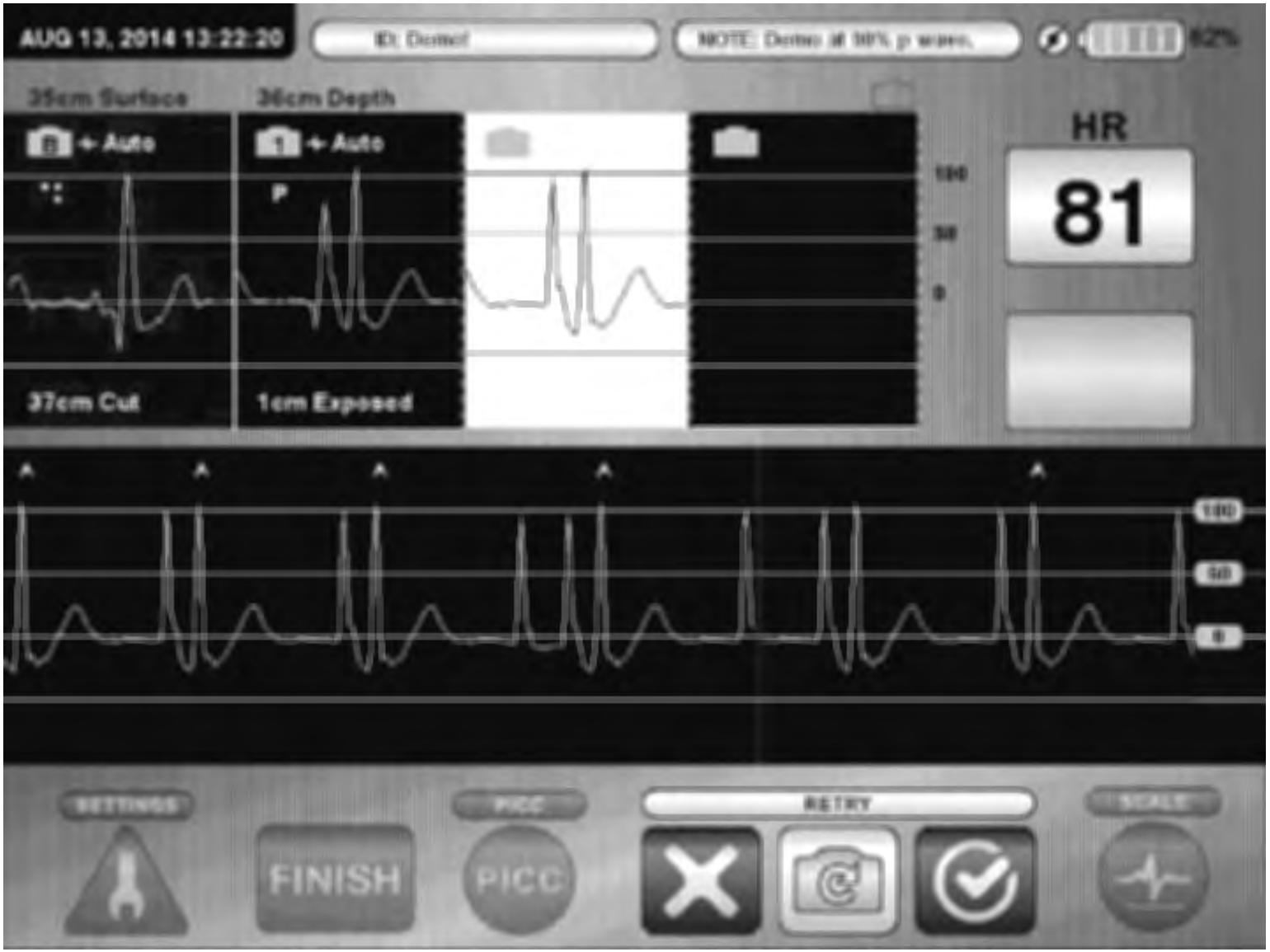
Max P-wave



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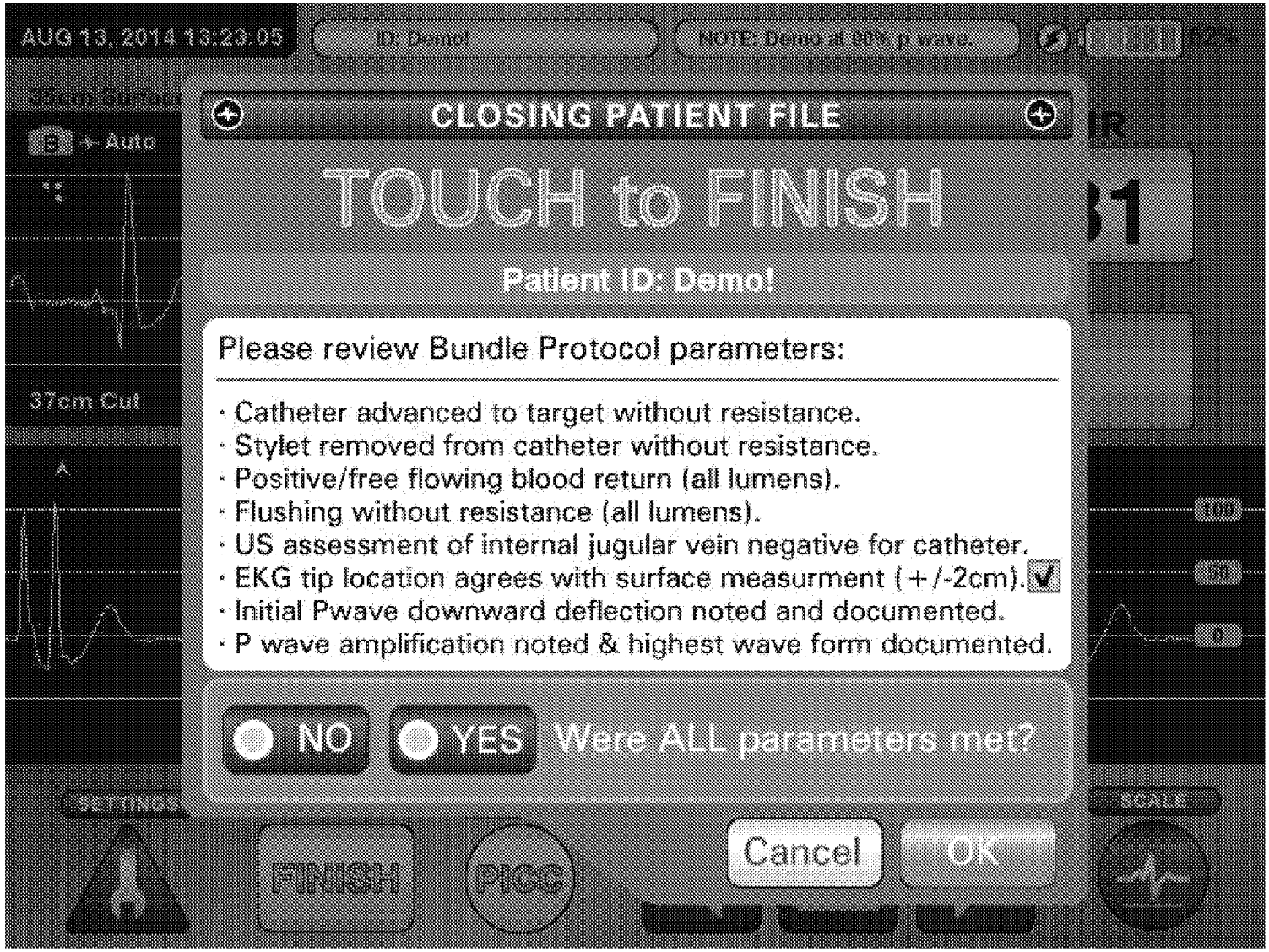
Bundle/Finish screen



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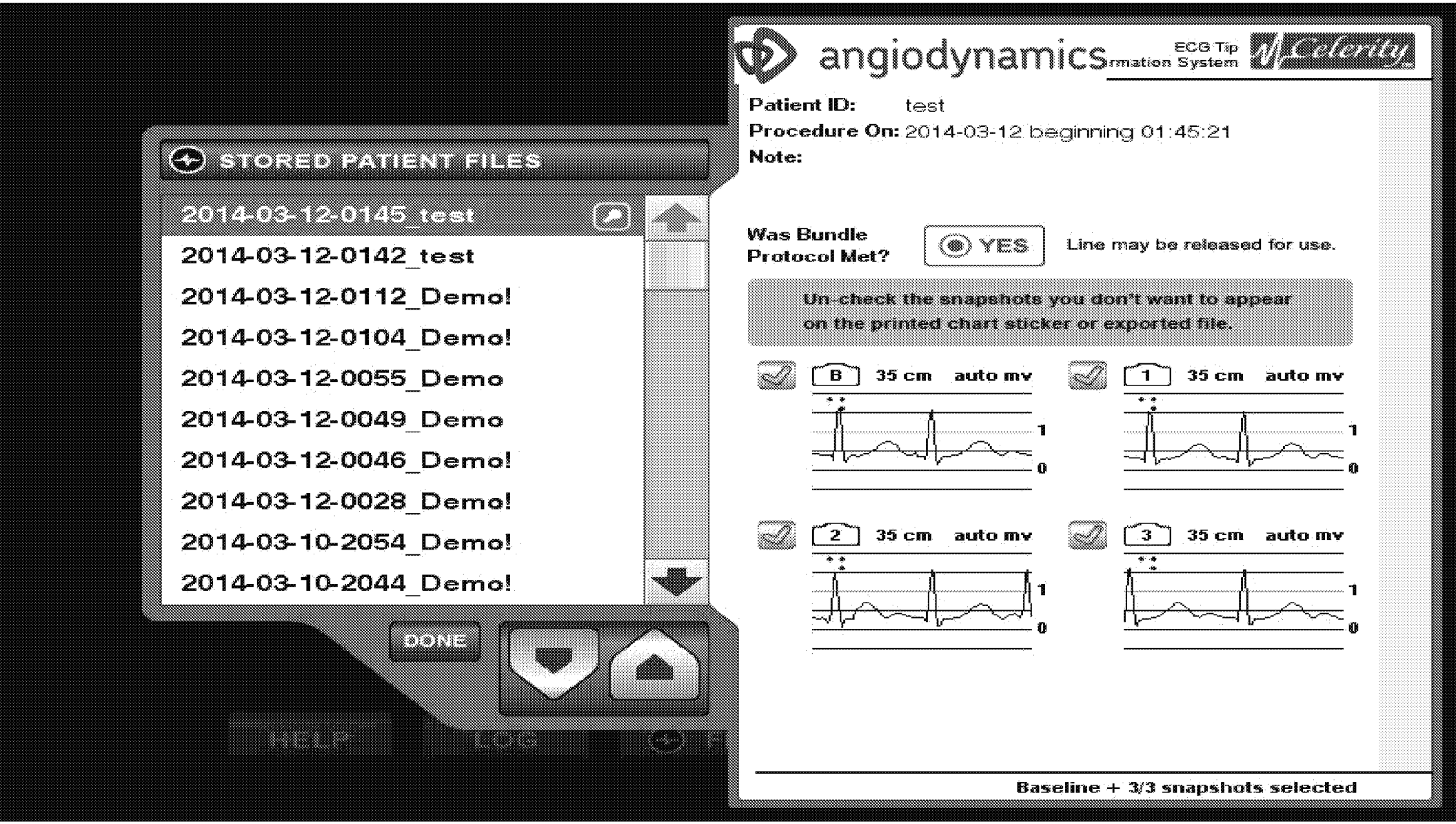
Preview



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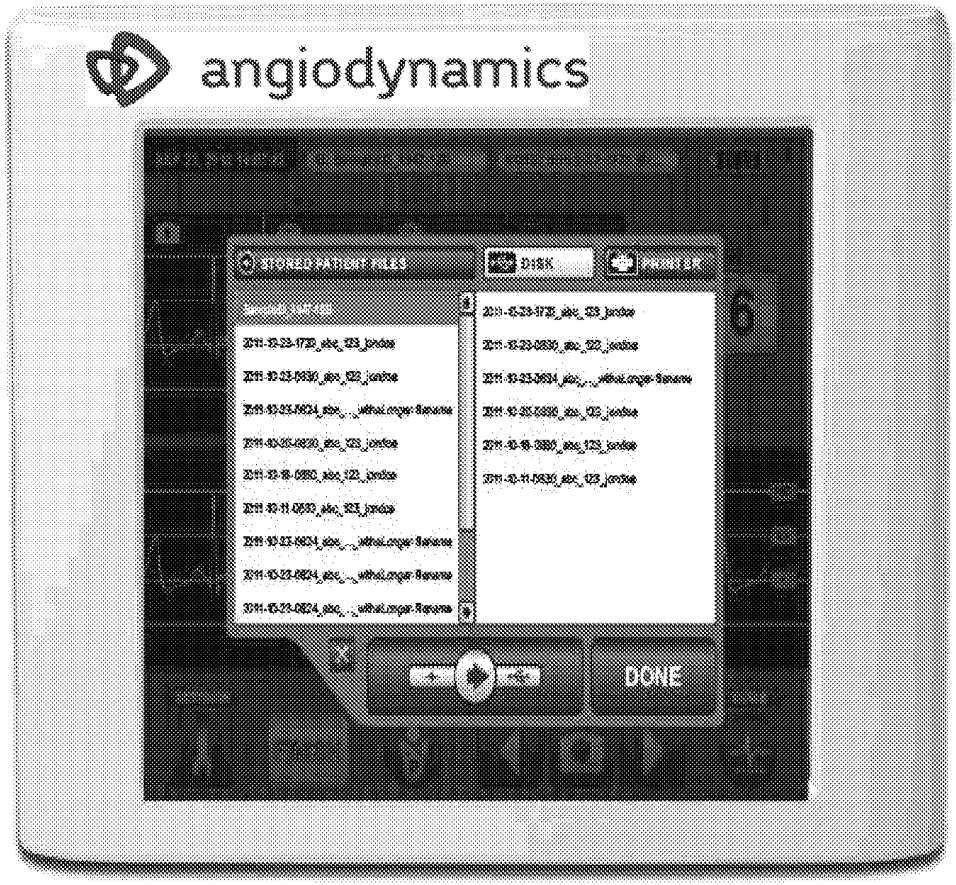
Print or Save to USB



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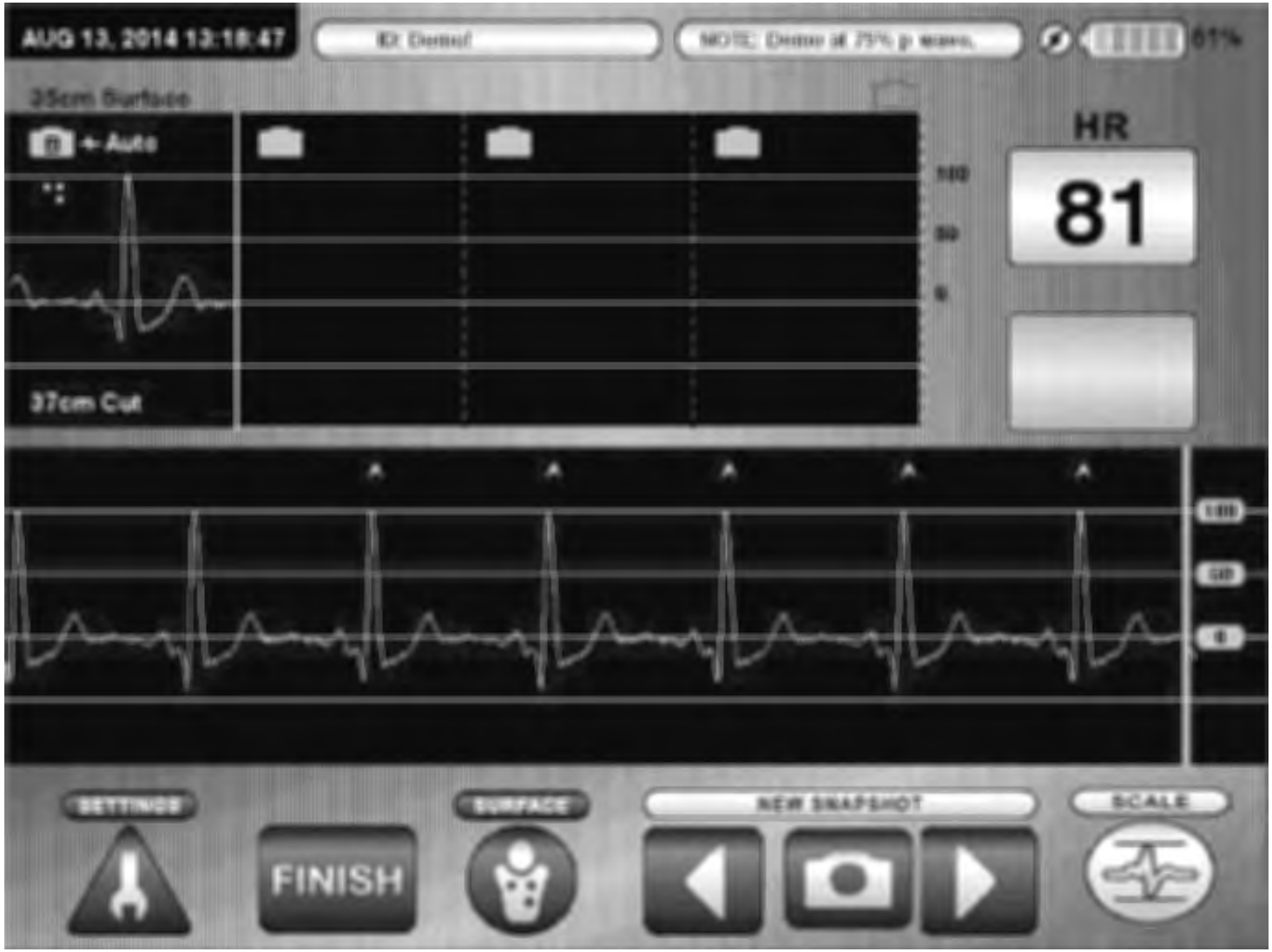
Scale Settings



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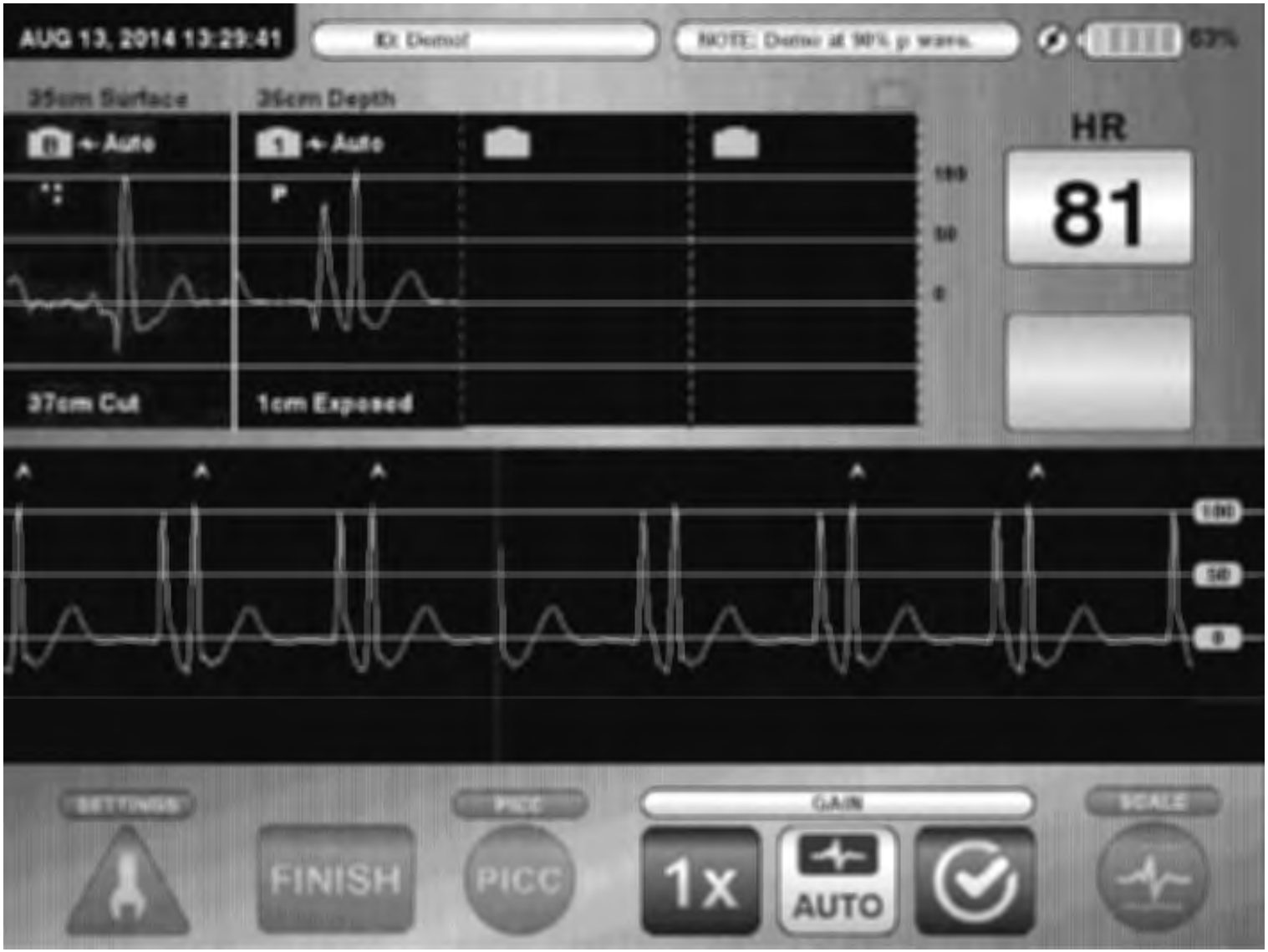
ECG Speed



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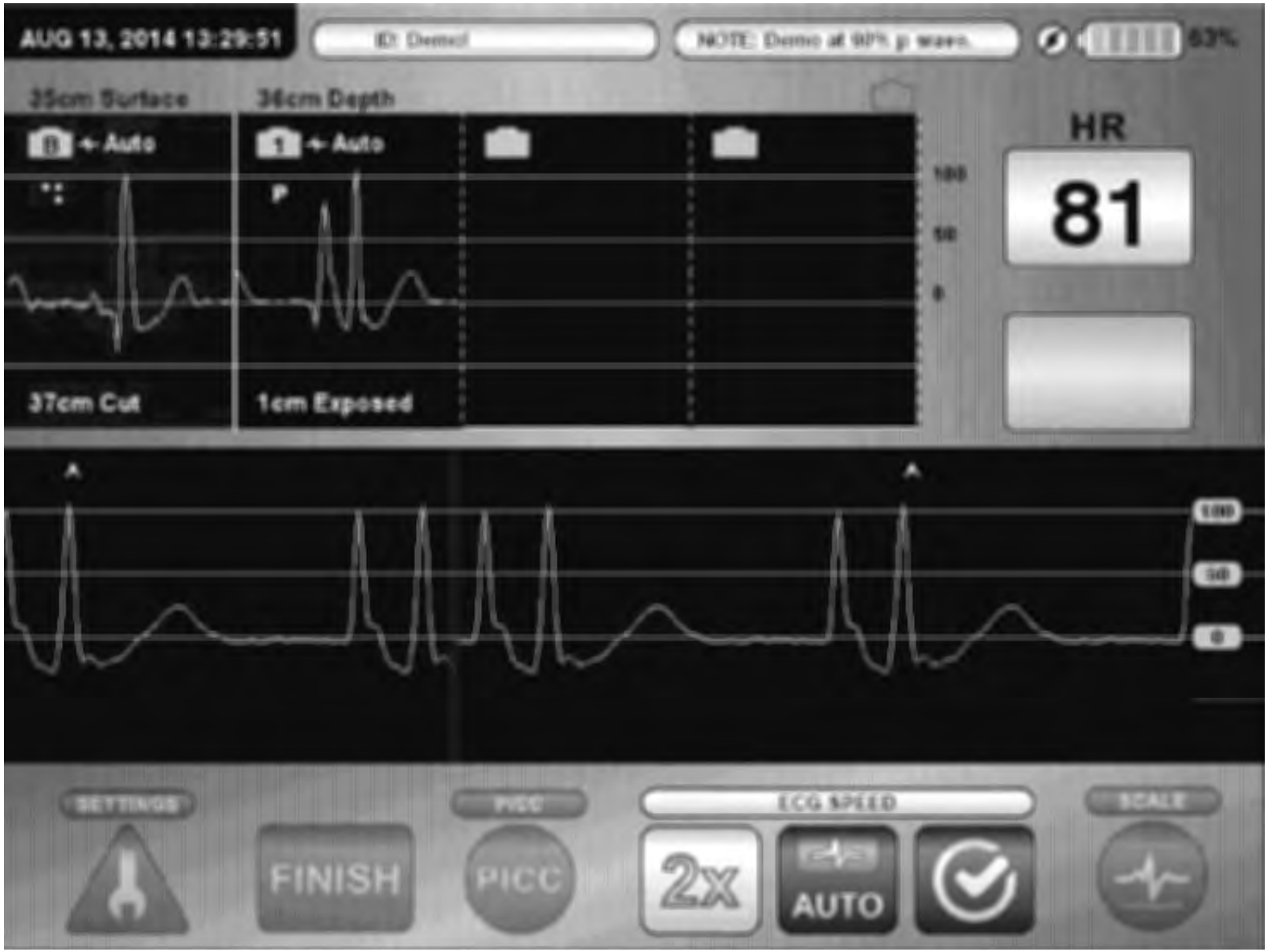
ECG Speed



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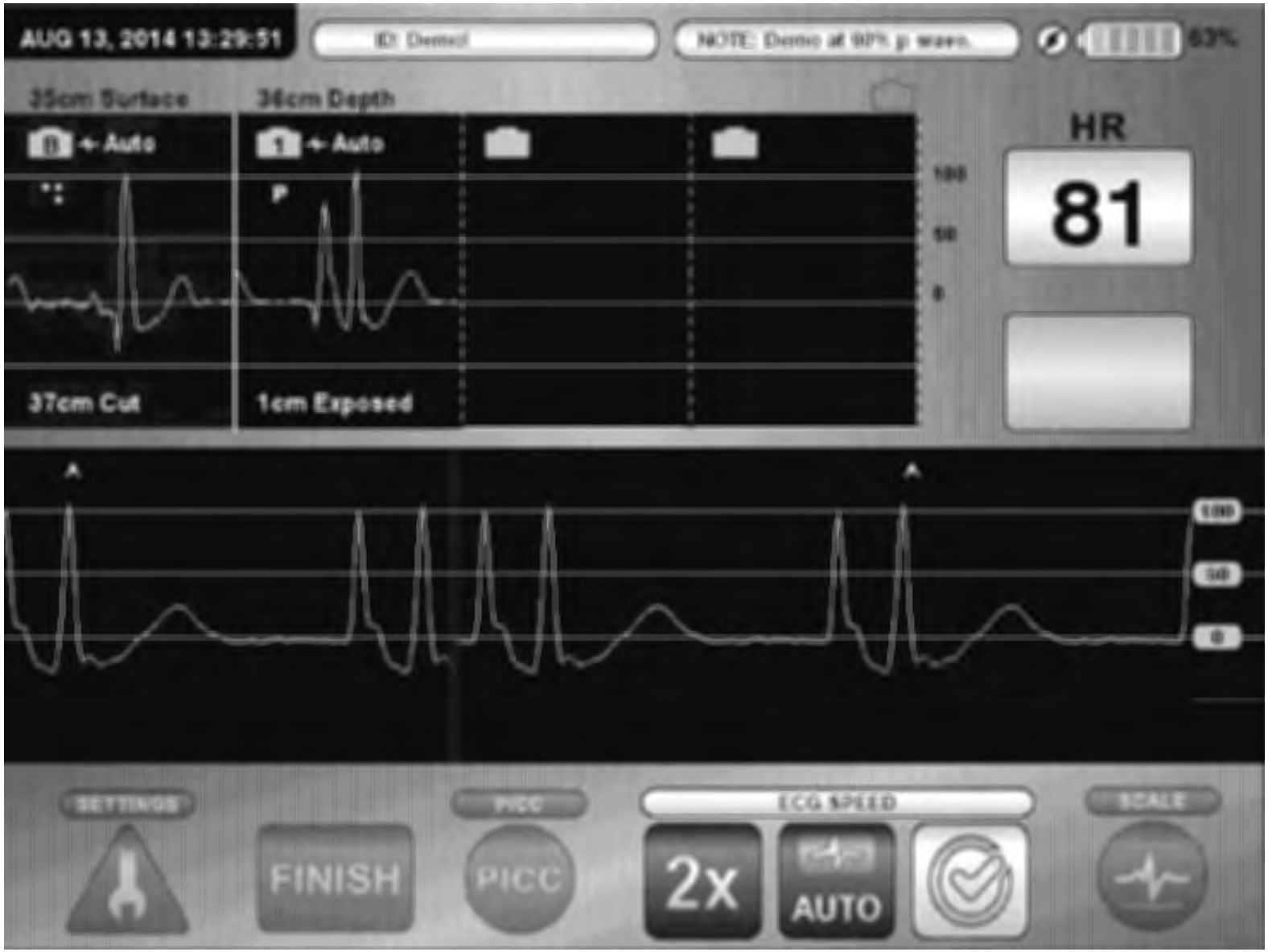
Accept icon



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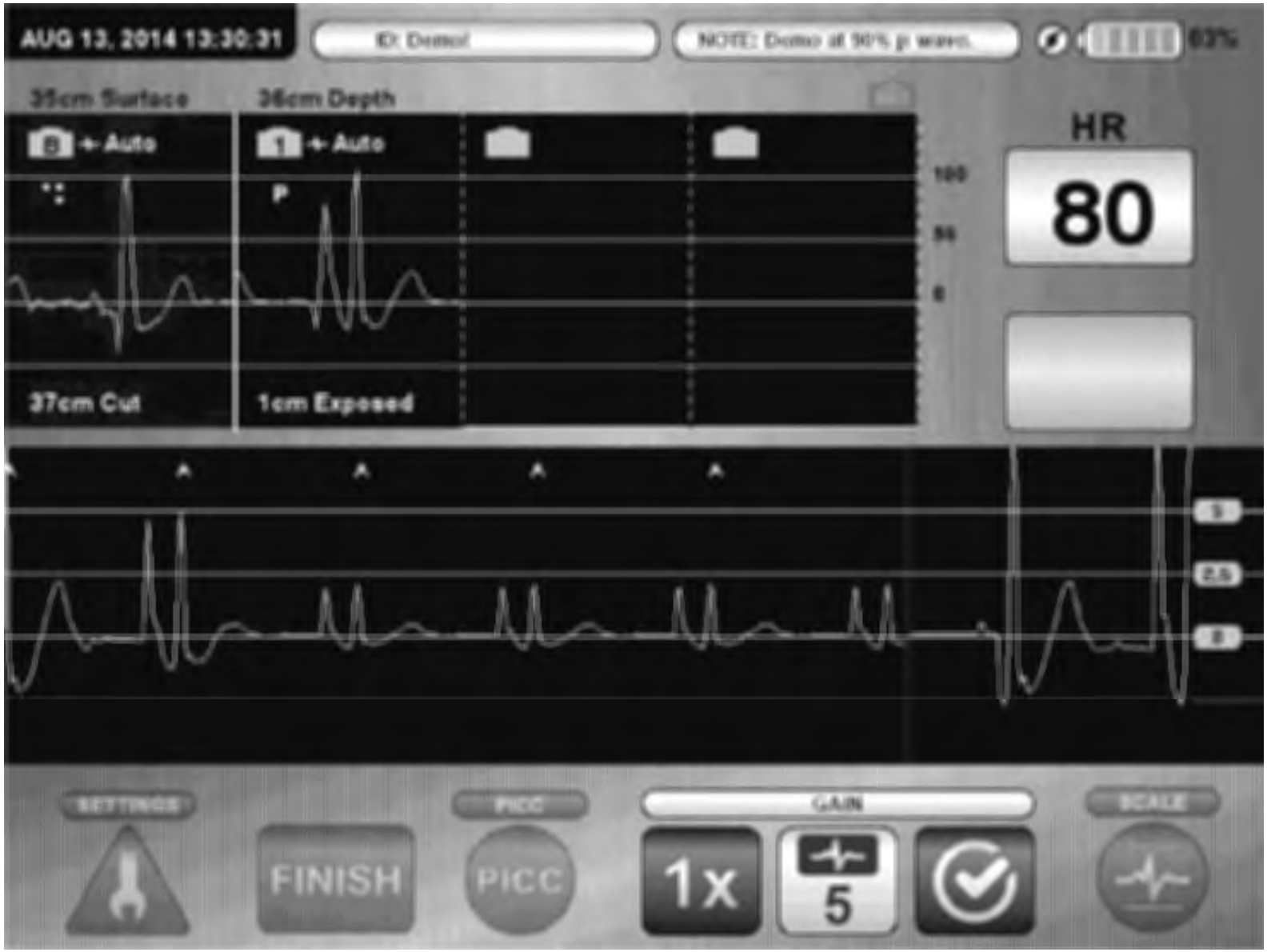
Gain Setting



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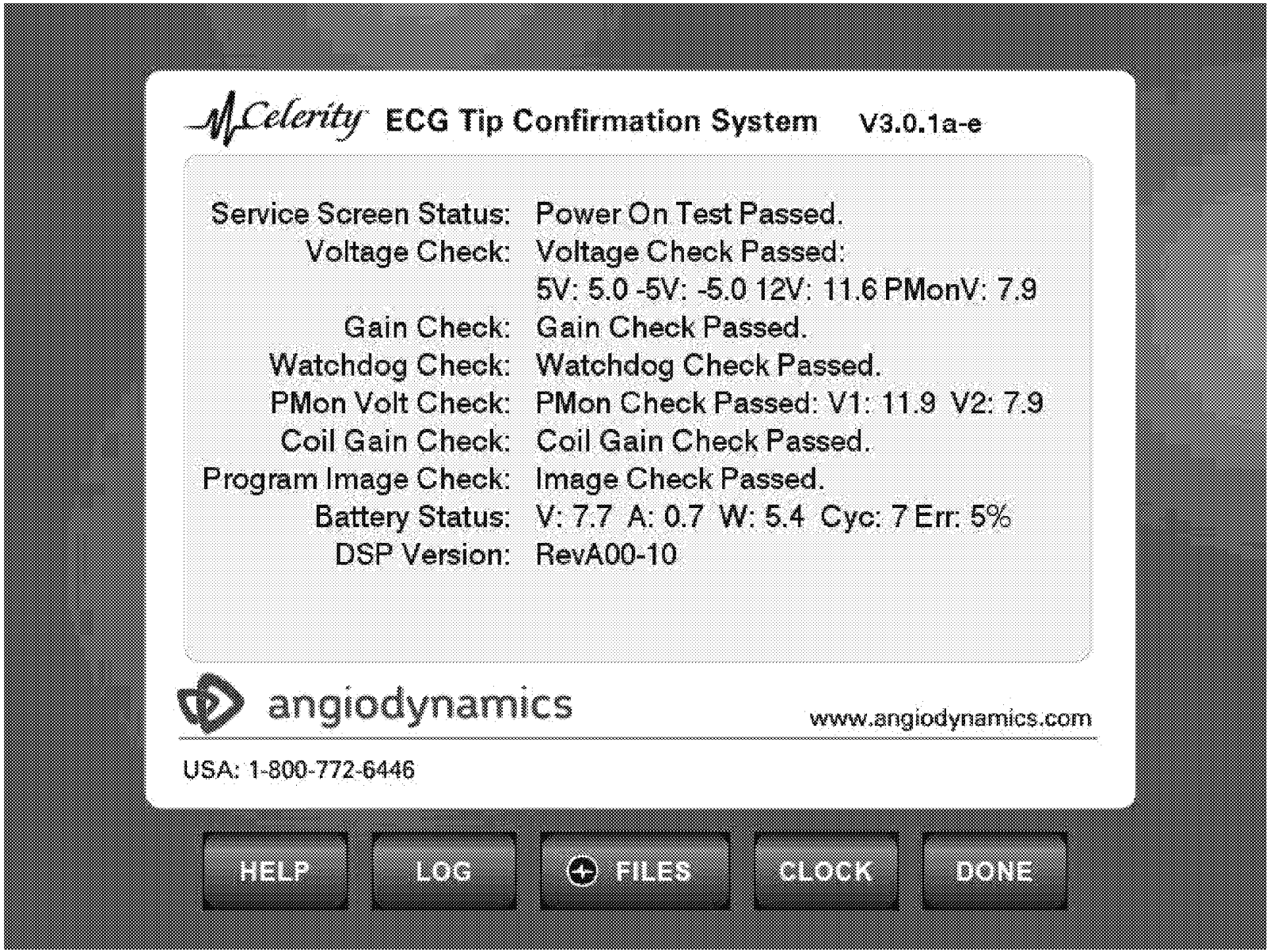
Setting Screen



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Battery

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Battery Warning

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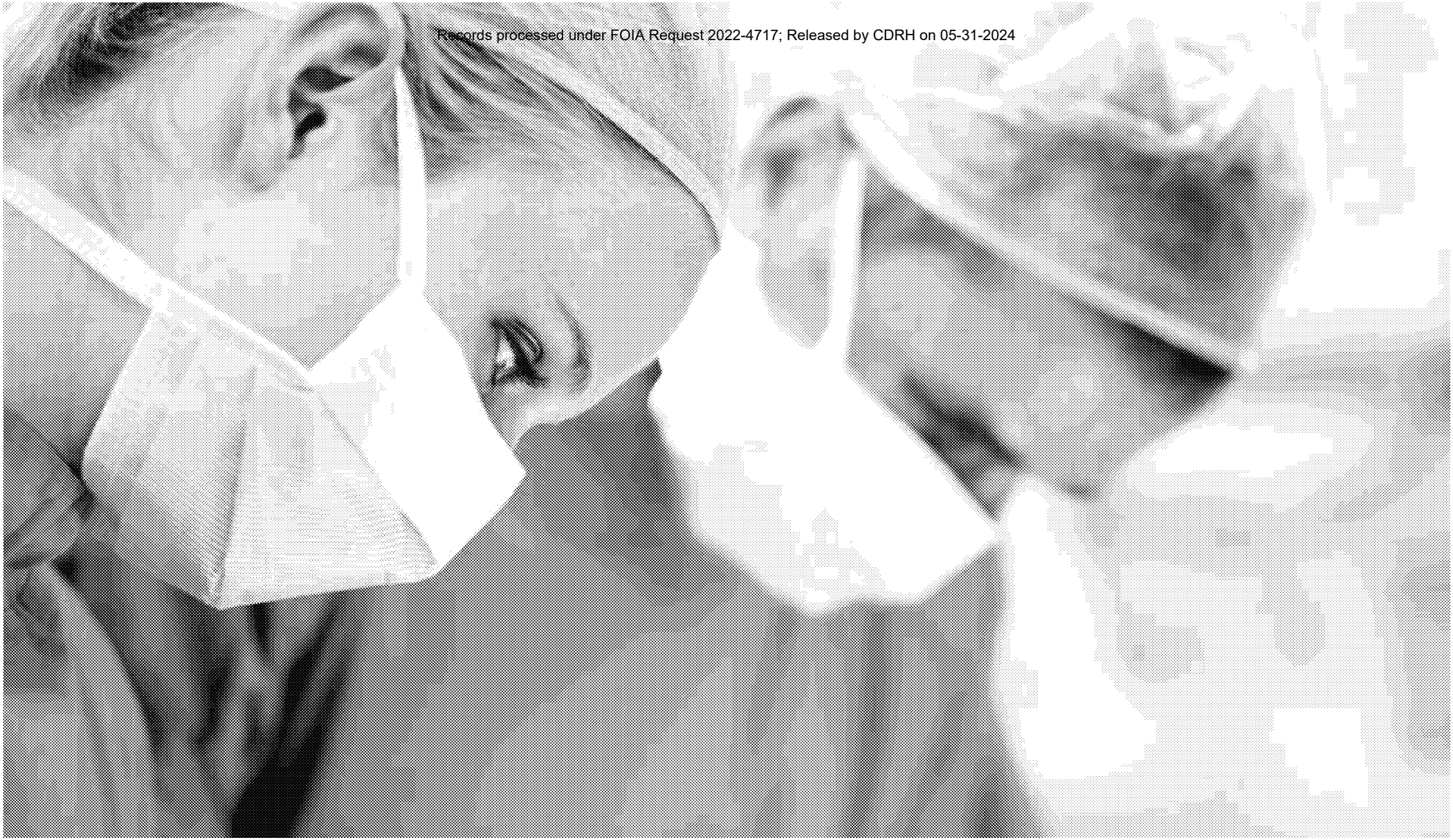

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Knowledge Assessment Quiz

First Name Last Name

Phone Facility

1. Proper Peripherally Inserted Central Catheter (PICC) tip location is considered to be…
   - ☐ The Superior Vena Cava.
   - ☐ The Central Venous System.
   - ☐ The upper 1/3 Superior Vena Cava/Innominate junction.
   - ☐ The lower 1/3 Superior Vena Cava/cavo-atrial junction.

2. There is a direct link between improper PICC tip location and…
   - ☐ Venous thrombosis.
   - ☐ Post procedural mal positions/catheter dysfunction.
   - ☐ Mechanical/chemical vessel erosion.
   - ☐ All of the above.

3. The Intravenous Nurses Society's standard of practice 2011 has recognized radiography as the only approved technology to determine tip location.
   - ☐ True
   - ☐ False

4. Devices that employ electromagnetic catheter navigation have been proven to be an alternative to radiography for tip location verification.
   - ☐ True
   - ☐ False

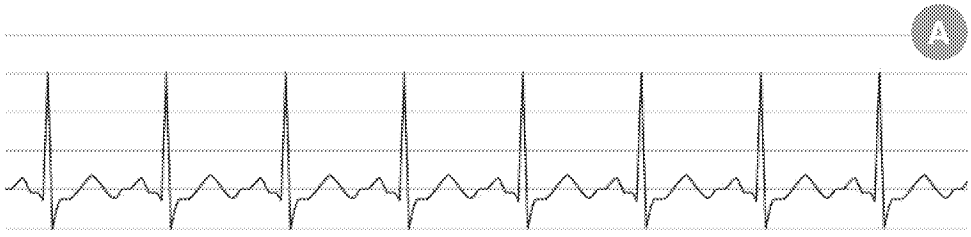
5. ECG tip location devices rely on the detection of faint cardiac arrhythmias that central venous devices normally induce during insertion.
   - ☐ True
   - ☐ False

6. The Sino Atrial Node (SA Node) is considered the heart's primary pace maker.
   - ☐ True
   - ☐ False

7. The SA Node is bundle of cells located…
   - ☐ At the inferior wall of the right ventricle.
   - ☐ At the upper posterior wall of the right atrium
   - ☐ At the lower 1/3 of superior vena cava.
   - ☐ Within the tissue of the tricuspid valve.

8. On a standard electrocardiograph a P wave represents the depolarization of the…
   - ☐ Right atrium.
   - ☐ Left ventricle.
   - ☐ Right bronchus.
   - ☐ Left main coronary artery.

9. Identify cardiac rhythm "A".



   - ☐ Atrial Flutter
   - ☐ Normal Sinus Rhythm
   - ☐ Asystole
   - ☐ Atrial Fibrillation

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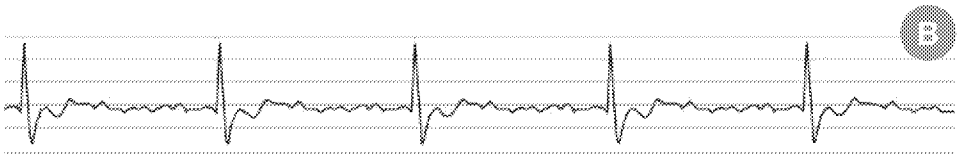
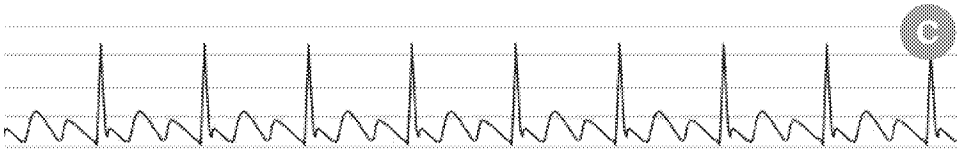
10. Identify cardiac rhythm "B".
- ☐ Atrial Flutter
- ☐ Asystole
- ☐ Normal Sinus Rhythm
- ☐ Atrial Fibrillation

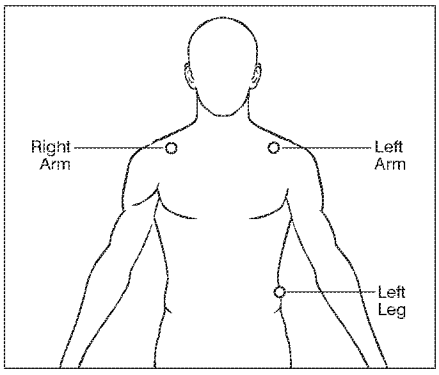


11. Identify cardiac rhythm "C".
- ☐ Normal Sinus Rhythm
- ☐ Atrial Futter
- ☐ Atrial Fibrillation
- ☐ Asystole



12. Match the electrode with correct anatomical location.

	RIGHT ARM	LEFT ARM	LEFT LEG
WHITE			
RED			
BLACK			



13. In three lead mode the Celerity ECG Tip Location Device displays…
- ☐ Surface EGG reading.
- ☐ Intracavitary reading.
- ☐ Surface and Intracavitary simultaneously.
- ☐ None of the above.

14. In the PICC mode the Celerity ECG Tip Location Device displays…
- ☐ Surface EGG reading.
- ☐ Intracavitary reading.
- ☐ Surface and Intracavitary simultaneously.
- ☐ None of the above.

15. As a central venous access device approaches the Sino Atrial Node (SA Node), the P wave…
- ☐ Becomes irregular.
- ☐ Amplifies.
- ☐ Becomes rapid.
- ☐ No changes occur.

16. No changes in the intracavitary ECG wave form during catheter advancement may indicate catheter malposition.
- ☐ True
- ☐ False

17. Poor or wandering ECG signals may be caused by…
- ☐ Poor electrode contact.
- ☐ Patient movement.
- ☐ Electrical noise.
- ☐ All of the above.

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SECTION 14 STERILIZATION & SHELF LIFE

While two of the components are meant to be sterilized as part of an ECG Accessory Kit, Nostix has nothing to do with the packaging and sterilization. Thus, sterilization discussions are not applicable to this submission. (b)(4)

(b)(4)

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SECTION 2 CDRH PREMARKET REVIEW SUBMISSION COVER SHEET (FORM FDA 3514)

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number *(if known)*
7 August 2015	(b)(4)	

SECTION A TYPE OF SUBMISSION

PMA	PMA & HDE Supplement	PDP	510(k)	Request for Feedback
☐ Original Submission	☐ Regular (180 day)	☐ Original PDP	☒ Original Submission:	☐ Pre-Submission
☐ Premarket Report	☐ Special	☐ Notice of Completion	☒ Traditional	☐ Informational Meeting
☐ Modular Submission	☐ Panel Track (PMA Only)	☐ Amendment to PDP	☐ Special	☐ Submision Issue Meeting
☐ Amendment	☐ 30-day Supplement		☐ Abbreviated (Complete section I, Page 5)	☐ Day 100 Meeting
☐ Report	☐ 30-day Notice		☐ Additional Information	☐ Agreement Meeting
☐ Report Amendment	☐ 135-day Supplement		☐ Third Party	☐ Determination Meeting
☐ Licensing Agreement	☐ Real-time Review			☐ Study Risk Determination
	☐ Amendment to PMA & HDE Supplement			☐ Other *(specify):*
	☐ Other			

IDE	Humanitarian Device Exemption (HDE)	Class II Exemption Petition	Evaluation of Automatic Class III Designation (De Novo)	Other Submission
☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ 513(g)
☐ Amendment	☐ Amendment	☐ Additional Information	☐ Additional Information	☐ Other *(describe submission):*
☐ Supplement	☐ Supplement			
	☐ Report			
	☐ Report Amendment			

Have you used or cited Standards in your submission? ☒ Yes ☐ No *(If Yes, please complete Section I, Page 5)*

SECTION B SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name	Establishment Registration Number *(if known)*		
Nostix LLC			
Division Name *(if applicable)*	**Phone Number *(including area code)***		
	303 245 8895		
Street Address	**FAX Number *(including area code)***		
5541 Central Av Suite 170	303 245 8909		
City	**State / Province**	**ZIP/Postal Code**	**Country**
Boulder	CO	80301	USA
Contact Name			
Peter Nelson			
Contact Title	**Contact E-mail Address**		
Director of Engineering	petenelson@nostix.com		

SECTION C APPLICATION CORRESPONDENT (e.g., consultant, if different from above)

Company / Institution Name			
Salus Ventures LLC			
Division Name *(if applicable)*	**Phone Number *(including area code)***		
	303 945 5675		
Street Address	**FAX Number *(including area code)***		
5335 Holmes Place			
City	**State / Province**	**ZIP Code**	**Country**
Boulder	CO	80303	USA
Contact Name			
Jim Lewis			
Contact Title	**Contact E-mail Address**		
Executive Consultant	salusventures@aol.com		

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SECTION D1 REASON FOR APPLICATION - PMA, PDP, OR IDE

- ☐ New Device
- ☐ Withdrawal
- ☐ Additional or Expanded Indications
- ☐ Request for Extension
- ☐ Post-approval Study Protocol
- ☐ Request for Applicant Hold
- ☐ Request for Removal of Applicant Hold
- ☐ Request to Remove or Add Manufacturing Site

- ☐ Change in design, component, or specification:
  - ☐ Software / Hardware
  - ☐ Color Additive
  - ☐ Material
  - ☐ Specifications
  - ☐ Other *(specify below)*

- ☐ Location change:
  - ☐ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager

- ☐ Process change:
  - ☐ Manufacturing ☐ Packaging
  - ☐ Sterilization
  - ☐ Other *(specify below)*

- ☐ Labeling change:
  - ☐ Indications
  - ☐ Instructions
  - ☐ Performance Characteristics
  - ☐ Shelf Life
  - ☐ Trade Name
  - ☐ Other *(specify below)*

- ☐ Report Submission:
  - ☐ Annual or Periodic
  - ☐ Post-approval Study
  - ☐ Adverse Reaction
  - ☐ Device Defect
  - ☐ Amendment

- ☐ Response to FDA correspondence:

- ☐ Change in Ownership
- ☐ Change in Correspondent
- ☐ Change of Applicant Address

- ☐ Other Reason *(specify)*:

SECTION D2 REASON FOR APPLICATION - IDE

- ☐ New Device
- ☐ New Indication
- ☐ Addition of Institution
- ☐ Expansion / Extension of Study
- ☐ IRB Certification
- ☐ Termination of Study
- ☐ Withdrawal of Application
- ☐ Unanticipated Adverse Effect
- ☐ Notification of Emergency Use
- ☐ Compassionate Use Request
- ☐ Treatment IDE
- ☐ Continued Access

- ☐ Change in:
  - ☐ Correspondent / Applicant
  - ☐ Design / Device
  - ☐ Informed Consent
  - ☐ Manufacturer
  - ☐ Manufacturing Process
  - ☐ Protocol - Feasibility
  - ☐ Protocol - Other
  - ☐ Sponsor

- ☐ Report submission:
  - ☐ Current Investigator
  - ☐ Annual Progress Report
  - ☐ Site Waiver Report
  - ☐ Final

- ☐ Response to FDA Letter Concerning:
  - ☐ Conditional Approval
  - ☐ Deemed Approved
  - ☐ Deficient Final Report
  - ☐ Deficient Progress Report
  - ☐ Deficient Investigator Report
  - ☐ Disapproval
  - ☐ Request Extension of Time to Respond to FDA
  - ☐ Request Meeting
  - ☐ Request Hearing

- ☐ Other Reason *(specify)*:

SECTION D3 REASON FOR SUBMISSION - 510(k)

- ☐ New Device
- ☐ Additional or Expanded Indications
- ☐ Change in Technology

- ☒ Other Reason *(specify)*:

Additional marketer of device

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	LJS	2		3		4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

☒ 510 (k) summary attached
☐ 510 (k) statement

Information on devices to which substantial equivalence is claimed *(if known)*

	510(k) Number	Trade or Proprietary or Model Name	Manufacturer
1	K142889	Celerity PICC Tip Confirmation System	AngioDynamics, Inc., Marlborough MA
2			
3			
4			
5			
6			

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification name

PICC placement accessory

	Trade or Proprietary or Model Name for This Device	Model Number
1	PICC Tip Positioning Aid	
2		
3		
4		
5		

FDA document numbers of all prior related submissions *(regardless of outcome)*

1 K142889	2 (b)(4)	4	5	6	
7	8	9	10	11	12

Data Included in Submission

☐ Laboratory Testing ☐ Animal Trials ☐ Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code	C.F.R. Section *(if applicable)*	Device Class
LJS	880.5970	☐ Class I ☒ Class II ☐ Class III ☐ Unclassified

Classification Panel

General Hospital

Indications *(from labeling)*

The PICC Tip Positioning Aid is indicated for the positioning of Peripherally Inserted Central Catheters (PICC) in adult patients. It provides real-time catheter tip location information by using the patient's cardiac electrical activity. The PICC Tip Positioning Aid is indicated for use as an alternative method to chest x-ray or fluoroscopy confirmation of PICC tip placement in adult patients.

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Note: Submission of the information entered in Section H does not affect the need to submit device establishment registration.	FDA Document Number (if known)

SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

☒ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☒ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager / Relabeler
Company / Institution Name: Nostix LLC		Establishment Registration Number	
Division Name *(if applicable)*		Phone Number *(including area code)*: 303-345-8895	
Street Address: 5541 Central Av, Suite 170		FAX Number *(including area code)*	
City: Boulder	State / Province: CO	ZIP Code: 80301	Country: USA
Contact Name: Charles Henry	Contact Title: CEO	Contact E-mail Address: cwh@nostix.com	

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager / Relabeler
Company / Institution Name		Establishment Registration Number	
Division Name *(if applicable)*		Phone Number *(including area code)*	
Street Address		FAX Number *(including area code)*	
City	State / Province	ZIP Code	Country
Contact Name	Contact Title	Contact E-mail Address	

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager / Relabeler
Company / Institution Name		Establishment Registration Number	
Division Name *(if applicable)*		Phone Number *(including area code)*	
Street Address		FAX Number *(including area code)*	
City	State / Province	ZIP Code	Country
Contact Name	Contact Title	Contact E-mail Address	

SECTION I UTILIZATION OF STANDARDS

Note: Complete this section if your application or submission cites standards or includes a *"Declaration of Conformity to a Recognized Standard"* statement.

	Standards No.	Standards Organization	Standards Title	Version	Date
1	HE 75	AAMI	Human factors engineering---Design of medical devices	9 ed.	'2009
2	60601-1	IEC	Medical electrical equipment---Part 1: general requirements for basic safety and essential performance	3 ed.	'2005
3	60601-1-2	IEC	Medical electrical equipment---Part 1-2: general requirements for safety---collateral standard: electromagnetic compatibility---requirements and tests	3 ed.	"2005
4	10993-1	ISO	Biological evaluation of medical devices---Part 1:evaluation and testing within a risk management process	4 ed.	'2009
5					
6					
7					

Please include any additional standards to be cited on a separate page.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF ADDRESS BELOW.

The burden time for this collection of information is estimated to average 0.5 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
1350 Piccard Drive, Room 400
Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

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Keith,

(b)(4) Deficiencies

Thanks,

Peter

From: Marin, Keith [mailto:Keith.Marin@fda.hhs.gov]
Sent: Monday, September 21, 2015 9:05 AM
To: Peter Nelson
Cc: Chapman, Richard; K152261@docs.fda.gov; 'Charles Henry';
salusventures@aol.com
Subject: RE: additional questions -- (b)(4) Deficiencies attached
Importance: High

Peter,

(b)(4) Deficiencies

Keith

From: Peter Nelson [mailto:petenelson@nostix.com]
Sent: Friday, September 04, 2015 11:34 AM
To: Marin, Keith
Cc: Chapman, Richard; K152261@docs.fda.gov; 'Charles Henry';
salusventures@aol.com
Subject: RE: additional questions -- (b)(4) Deficiencies attached

Keith,

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4) Deficiencies

Thanks,

Peter

Peter Nelson
R&D Manager
Nostix
5541 Central Ave, Suite 170
Boulder, CO 80301
Ph: 303-245-8895 ext. 3#
Fax: 303-245-8909

From: Marin, Keith [mailto:Keith.Marin@fda.hhs.gov]
Sent: Thursday, September 03, 2015 9:39 AM
To: Peter Nelson
Cc: Chapman, Richard; K152261@docs.fda.gov
Subject: additional questions

Peter,

(b)(4) Deficiencies

Thanks.

Keith

From: Peter Nelson [mailto:petenelson@nostix.com]
Sent: Monday, August 17, 2015 12:54 PM
To: Marin, Keith
Cc: K152261@docs.fda.gov; Chapman, Richard; 'Charles Henry';

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2022-4717; Released by CDRH on 05-31-2024

salusventures@aol.com

Subject: RE: Letter of authorization -- attached

Keith,

(b)(4) Deficiencies

Thanks,

Peter

Peter Nelson

Director of Engineering

Nostix

5541 Central Ave, Suite 170

Boulder, CO 80301

Ph: 303-245-8895 ext. 3#

Fax: 303-245-8909

From: Marin, Keith [mailto:Keith.Marin@fda.hhs.gov]

Sent: Monday, August 17, 2015 10:01 AM

To: petenelson@nostix.com

Cc: K152261@docs.fda.gov; Chapman, Richard

Subject: **(b)(4) Deficiencies**

Mr. Nelson,

(b)(4) Deficiencies

Thanks.

Keith Marin

Keith Marin, RN, MS, MBA, OCN, RAC

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Lieutenant Commander, United States Public Health Service

General Hospital Devices Combination Product Team Lead / Nurse Consultant

FDA/CDRH/ODE/DAGRID/GHDB

10903 New Hampshire Avenue, WO66-2567

Silver Spring, MD, 20993-0002

Telephone: (301) 796-2462, Fax: (301) 847-8109

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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SECTION 12 SUBSTANTIAL EQUIVALENCE DISCUSSION

SUMMARY OF SIMILARITIES AND DIFFERENCES

The proposed PICC Tip Positioning Aid is substantially equivalent to the predicate Celerity™ System (K142889) because it is the same device in terms of intended use, operating principle/ technology, safety and performance, built to the same Device Master Record by the same suppliers.

SUBSTANTIAL EQUIVALENCE TREE

The 510(k) "Substantial Equivalence" Decision-Making Flowchart, as outlined in FDA's Guidance Document entitled, The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)] dated July 28, 2014, was used to determine substantial equivalence of the proposed device to the predicate devices. The decision tree from the FDA guidance document is presented at the end of this section as Table 12.1. The answers to the following questions lead to a determination that the proposed Celerity System is substantially equivalent to the predicate device.

1. **Is the predicate device legally marketed?**

   Yes. The predicate Celerity System (K142889, cleared February 5, 2015) is a legally marketed device.

2. **Do the devices have the same intended use?**

   Yes. Both the proposed PICC Tip Positioning Aid and predicate (K142889) are intended to provide real time tip location information of a central venous catheter by utilization of ECG to observe P-wave changes as the tip approaches the right atrium of the heart via the superior vena cava.

3. **Do the devices have the same technological characteristics, e.g. design, materials, etc.?**

   Yes. Identical, both predicate and proposed device utilizes ECG to observe P-wave changes in real time catheter tip location **information** by using the patient's cardiac electrical activity. Both devices are driven by software using the same algorithms displaying patient waveforms on a monitor to aid in venous catheter tip placement, ECG connectors and leads.

4. **Do the different technological characteristics of the devices raise different questions of safety and effectiveness?**

   No. The predicate (K142889) and proposed device have the same intended use; i.e., to provide real time tip location information of a central venous catheter by utilization of ECG to observe P-wave changes as the tip approaches the right atrium of the heart via the superior vena cava).

5.a. Are the methods acceptable?

Yes. Test results are unchanged between the two designs.

5.b Do the data demonstrate equivalence?

Data not applicable as unit design and construction are identical.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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SUMMARY OF SUBSTANTIAL EQUIVALENCE STATEMENT

The following points summarize the statement of substantial equivalence for the proposed PICC Tip Positioning Aid:

- The intended use/indications for use, operating principle/technology, safety and performance of the proposed PICC Tip Positioning Aid are identical to those of predicate device.

Conclusion: The comparison of similarities and differences including intended use and indications for use statements; as well as answers to questions raised via the FDA's 510(k) Decision Making Flowchart and narrative support a determination of "substantially equivalent" to the predicate Celerity™ System (K142889).

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Table 12.1 – Comparison of Key Similarities and Differences
Proposed: PICC Tip Positioning Aid**; Predicate** Celerity System

Device Characteristic	**Proposed Device** PICC Tip Positioning Aid	**Predicate Device** Celerity System K142889	**Equivalence**
Indications for Use	The Positioning Aid is indicated for the positioning of Peripherally Inserted Central Catheters (PICC) in adult patients. It provides real-time catheter tip location information by using the patient's cardiac electrical activity. The Celerity System is indicated for use as an alternative method to chest x-ray or fluoroscopy confirmation of PICC tip placement in adult patients. Note: In general, devices that utilize ECG technique to observe P-wave are limited, but not contraindicated, for patients where cardiac rhythms may change presentation of the P-Wave; including -Atrial fibrillation -Atrial flutter -Severe tachycardia -Pacemaker-drive rhythm -COPD Such patients are easily identified prior to PICC insertion. Use of an additional confirmation method is necessary to confirm catheter tip location.	The Celerity System is indicated for the positioning of Peripherally Inserted Central Catheters (PICC) in adult patients. It provides real-time catheter tip location information by using the patient's cardiac electrical activity. The Celerity System is indicated for use as an alternative method to chest x-ray or fluoroscopy confirmation of PICC tip placement in adult patients. Note: In general, devices that utilize ECG technique to observe P-wave are limited, but not contraindicated, for patients where cardiac rhythms may change presentation of the P-Wave; including -Atrial fibrillation -Atrial flutter -Severe tachycardia -Pacemaker-drive rhythm -COPD Such patients are easily identified prior to PICC insertion. Use of an additional confirmation method is necessary to confirm catheter tip location.	Identical

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2022-4717; Released by CDRH on 05-31-2024

Table 12.1 – Comparison of Key Similarities and Differences
Proposed: PICC Tip Positioning Aid; **Predicate** Celerity System

Device Characteristic	**Proposed Device** PICC Tip Positioning Aid	**Predicate Device** Celerity System K142889	**Equivalence**
Intended Use	To provide real time tip location information of a central venous catheter by utilization of ECG to observe P-wave changes as the tip approaches the right atrium of the heart via the superior vena	To provide real time tip location information of a central venous catheter by utilization of ECG to observe P-wave changes as the tip approaches the right atrium of the heart via the superior vena	Identical
Operating Principle/Technology	Displays surface ECG via 3 electrode leads and the intravascular ECG connected to a catheter's stylet; P-wave amplitude indicates tip position to sino-atrial node	Displays surface ECG via 3 electrode leads and the intravascular ECG connected to a catheter's stylet; P-wave amplitude indicates tip position to sino-atrial node	Identical
System and Components	*Monitor*: Dedicated monitor to display ECG waveforms via proprietary software *ECG Sensor*: Integral to monitor, connected via ECG Patient Cable and stylet lead using built-in circuitry with digital conversion for analysis and display *ECG Clip Cable*: Insulated copper-wire lead with stainless-steel alligator clip	*Monitor*: Dedicated monitor to display ECG waveforms via proprietary software *ECG Sensor*: Integral to monitor, connected via ECG Patient Cable and stylet lead using built-in circuitry with digital conversion for analysis and display *ECG Clip Cable*: Insulated copper-wire lead with stainless-steel alligator clip	Identical
Commercially available accessories (may include)	ECG snap leads, ECG surface electrodes and prep pads	ECG snap leads, ECG surface electrodes and prep pads	Identical
Energy Source	Mains power (battery backed)	Mains power (battery backed)	Identical
Performance	Displays ECG waveforms in real time	Displays ECG waveforms in real time	Identical

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2022-4717; Released by CDRH on 05-31-2024

Table 12.1 – Comparison of Key Similarities and Differences
Proposed: PICC Tip Positioning Aid; **Predicate** Celerity System

Device Characteristic	**Proposed Device** PICC Tip Positioning Aid	**Predicate Device** Celerity System K142889	**Equivalence**
EMC and Electrical Safety	IEC 60601 3rd Edition	IEC 60601 3rd Edition	Identical

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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SECTION 5 510(k) SUMMARY

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Nostix

510(k) Summary

Prepared: 25 September 2015

Submitter

Company	Nostix LLC 5541 Central Av, Suite 170 Boulder, CO 80301
Tel	303 245 8895
Fax	303 245 8909
Contact	Pete Nelson Director of Engineering petenelson@nostix.com

Device

Trade Name	PICC Tip Positioning Aid
Common Name	PICC placement accessory
Class Name	Percutaneous, implanted, long-term intravascular catheter
Product Code	LJS
Regulation	21 CFR 880.5970
Class	2

Predicate

Trade Name	Celerity System
Clearance	K142889, 27 January 2015
Common Name	PICC placement accessory
Class Name	Percutaneous, implanted, long-term intravascular catheter
Product Code	LJS
Regulation	21 CFR 880.5970
Class	2

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Device Description

The PICC Tip Positioning Aid includes a standalone Monitor containing software, battery and power cord accompanied by an ECG Patient Cable, a Remote Control Cable, probe cover and ECG Clip Cable.

Other procedural accessories; including ECG Snap Leads, ECG Surface Electrodes, Cable Cover, Gloves and Prep Pads; may be provided as a convenience for the clinician but are not in the scope of this submission.

Intended Use

The PICC Tip Positioning Aid is intended to provide real time tip location information of a central venous catheter by utilization of ECG to observe P-wave changes as the tip approaches the right atrium of the heart via the superior vena cava.

Indications for Use

The PICC Tip Positioning Aid is indicated for the positioning of Peripherally Inserted Central Catheters (PICC) in adult patients. It provides real-time catheter tip location information by using the patient's cardiac electrical activity. The PICC Tip Positioning Aid is indicated for use as an alternative method to chest x-ray or fluoroscopy confirmation of PICC tip placement in adult patients.

Note: In general, devices that utilize ECG technique to observe P-Wave arc limited, but not contraindicated, for patients where cardiac rhythms may change presentation of the P-Wave; including

- Atrial fibrillation
- Atrial flutter
- Severe tachycardia
- Pacemaker-driven rhythm
- Chronic obstructive pulmonary disease (COPD)

Such patients are easily identified prior to PICC insertion. Use of an additional confirmation method is necessary to confirm catheter tip location.

Technological Characteristics

Technological Characteristics of the subject PICC Tip Positioning Aid are identical to the predicate device. The name and address changes on the labels between the predicate and proposed devices do not raise new technological questions.

Performance Data

As the only differences between the device and its predicate are names, logos, and addresses in the labeling, the following recognized standards from the IEC 60601 (3rd Edition) series continue to be satisfied.

IEC 60601-1-1	Medical electrical equipment—Part 1-1: General requirements for safety—Collateral standard: Safety requirements for medical electrical systems

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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IEC 60601-1-2 Medical electrical equipment—Part 1-2: General requirements for basic safety and essential performance—Collateral standard: Electromagnetic compatibility – Requirements and tests

Human Factors Evaluation - Simulated Use Testing alternate to chest x-ray and fluoroscopy:

Simulated Use / Human Factors Testing has been conducted to evaluate the application of the PICC Tip Placement Aid as embodied in the predicate Celerity System when used to confirm PICC tip position as an alternative method to chest X-ray or fluoroscopy confirmation. The use related events noted in the studies have been adequately reviewed and addressed in order to ensure the appropriate use of the device as an alternate to x-ray techniques for confirmation of tip location of PICC.

Based on the content of the proposed PICC Tip Positioning Aid's Risk Analysis / Use and Design FMEAs, and the content of the Instructions for Use, the PICC Tip Positioning Aid has demonstrated its suitability for its intended purpose.

Substantial Equivalence Conclusion

As this device design and manufacturing are the same as the predicate except for name changes to the device and the manufacturer, the device is clearly equivalent to its predicate.

The proposed device is clearly substantially equivalent to the predicate device based on identical:

- Intended Use
- Indications for Use
- Design
- Production
- Operating principles, characteristics, and user interface
- Technology and specifications
- Labeling

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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SECTION 17 ELECTROMAGNETIC COMPATIBILITY & SAFETY

No changes have been made to the design of the proposed device from predicate to proposed device.

All data and qualifications from the submission for the predicate device apply to this submission.

Please refer to the letter attached to the cover letter of this 510(k) from the owner of the Predicate Device, Angiodynamics, acknowledging their support of this submission with all data and certification from the predicate submission.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2022-4117; Released by CDRH on 05-31-2024

(b)(4)

Via Email only (cwh@nostix.com)

August 19, 2015

Nostix, LLC
5541 Central Avenue, Suite 170
Boulder, Colorado 80301
Attention: Charles W. Henry, President and CEO

Re: Development and Supply Agreement ("Agreement") between Nostix, LLC and (b)(4)

Dear Mr. Henry:

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2022-4717; Released by CDRH on 05-31-2024

<font color='black' size='2' face='Arial, Helvetica, sans-serif'>Mr. Marin

(b)(4) Deficiencies

Thank you.

--

Jim Lewis

--

For Nosix LLC, Boulder, Colorado, USA

303 945 5675; salusventures@aol.com

-----Original Message-----

From: Marin, Keith <Keith.Marin@fda.hhs.gov>

To: Peter Nelson <petenelson@nostix.com>

Cc: K152261 <K152261@docs.fda.gov>; Chapman, Richard <Richard.Chapman@fda.hhs.gov>; 'Charles Henry' <cwh@nostix.com>; salusventures <salusventures@aol.com>; McCabe-Janicki, Margaret <Margaret.McCabe@fda.hhs.gov>

Sent: Mon, Aug 17, 2015 11:50 am

Subject: **(b)(4) Deficiencies**

<style scoped="">#AOLMsgPart_2_ab807a3d-527e-4c81-ae4f-839b4cbceff6 td{color: black;} @font-face {font-family:Wingdings; panose-1:5 0 0 0 0 0 0 0 0 0;} @font-face {font-family:Wingdings; panose-1:5 0 0 0 0 0 0 0 0 0;} @font-face {font-family:Calibri; panose-1:2 15 5 2 2 2 4 3 2 4;} @font-face {font-family:Tahoma; panose-1:2 11 6 4 3 5 4 4 2 4;} .aolReplacedBody p.MsoNormal,.aolReplacedBody li.MsoNormal,.aolReplacedBody div.MsoNormal {margin:0in; margin-bottom:.0001pt; font-size:11.0pt; font-family:"Calibri","sans-serif";} .aolReplacedBody a:link,.aolReplacedBody span.MsoHyperlink {mso-style-priority:99; color:blue; text-

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2022-4717; Released by CDRH on 05-31-2024

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span.MsoHyperlinkFollowed {mso-style-priority:99; color:purple; text-
decoration:underline;} .aolReplacedBody p.MsoAcetate,.aolReplacedBody
li.MsoAcetate,.aolReplacedBody div.MsoAcetate {mso-style-priority:99; mso-style-
link:"Balloon Text Char"; margin:0in; margin-bottom:.0001pt; font-size:8.0pt;
font-family:"Tahoma","sans-serif";} .aolReplacedBody p.Mso
span.EmailStyle17 {mso-style-type:personal; font-family:"Calibri","sans-
serif"; color:windowtext;} .aolReplacedBody span.EmailStyle18 {mso-style-
type:personal; font-family:"Calibri","sans-serif"; color:#1F497D;}
.aolReplacedBody span.EmailStyle19 {mso-style-type:personal; font-
family:"Calibri","sans-serif"; color:#1F497D;} .aolReplacedBody
span.EmailStyle20 {mso-style-type:personal-reply; font-
family:"Calibri","sans-serif"; color:#1F497D;} .aolReplacedBody
span.BalloonTextChar {mso-style-name:"Balloon Text Char"; mso-style-
priority:99; mso-style-link:"Balloon Text"; font-
family:"Tahoma","sans-serif";} .aolReplacedBody .MsoChpDefault
{mso-style-type:export-only; font-size:10.0pt;} @page WordSection1 {size:8.5in 11.0in;
margin:1.0in 1.0in 1.0in 1.0in;} .aolReplacedBody div.WordSection1 {page:WordSection1;}
@ @ @ @ @ @ @ @ @ ol {margin-bottom:0in;} .aolReplacedBody ul {margin-
bottom:0in;}</style>

Mr. Nelson,

(b)(4) Deficiencies

Please provide this information by
Wednesday August 19, 2015.

Thanks.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2022-4717; Released by CDRH on 05-31-2024

```
Keith</span></div>


<div>

<div style="border:none;border-top:solid #B5C4DF 1.0pt;padding:3.0pt 0in 0in 0in">

<div class="MsoNormal"><b><span style="font-size:10.0pt;font-
family:&quot;Tahoma&quot;,&quot;sans-serif&quot;">From:</span></b><span style="font-
size:10.0pt;font-family:&quot;Tahoma&quot;,&quot;sans-serif&quot;"> Peter Nelson [<a
removedlink__feffd2d8-bbac-45cd-be13-
4c5d50e69b30__href="mailto:petenelson@nostix.com?">mailto:petenelson@nostix.com</a>]
<br>

<b>Sent:</b> Monday, August 17, 2015 12:54 PM<br>

<b>To:</b> Marin, Keith<br>

<b>Cc:</b> <a removedlink__feffd2d8-bbac-45cd-be13-
4c5d50e69b30__href="mailto:K152261@docs.fda.gov">K152261@docs.fda.gov</a>; Chapman,
Richard; 'Charles Henry'; <a removedlink__feffd2d8-bbac-45cd-be13-
4c5d50e69b30__href="mailto:salusventures@aol.com">salusventures@aol.com</a><br>

<b>Subject:</b> RE: (b)(4) Deficiencies -- attached</span></div>

</div>

</div>


<div class="MsoNormal"> </div>


<div class="MsoNormal"><span style="color:#1F497D">Keith,</span></div>
```

(b)(4) Deficiencies

```
<div class="MsoNormal"><span style="color:#1F497D">Thanks,</span></div>


<div class="MsoNormal"><span style="color:#1F497D">Peter</span></div>


<div class="MsoNormal"><span style="color:#1F497D"> </span></div>


<div class="MsoNormal" style="margin-bottom:12.0pt"><b><span style="font-
size:10.0pt;font-family:&quot;Tahoma&quot;,&quot;sans-serif&quot;;color:black">Peter
Nelson <br>

Director of Engineering <br>

Nostix <br>

5541 Central Ave, Suite 170 <br>

Boulder, CO 80301 <br>

Ph: 303-245-8895 ext. 3#<br>

Fax: 303-245-8909 </span></b><span style="color:#1F497D"></span></div>
```

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2022-4717; Released by CDRH on 05-31-2024

From: Marin, Keith [mailto:Keith.Marin@fda.hhs.gov]

Sent: Monday, August 17, 2015 10:01 AM

To: petenelson@nostix.com

Cc: K152261@docs.fda.gov; Chapman, Richard

Subject: (b)(4) Deficiencies /span>

(b)(4) Deficiencies

Mr. Nelson,

Thanks.

Keith Marin

Keith Marin, RN, MS, MBA, OCN, RAC

Lieutenant Commander, United States Public Health Service

General Hospital Devices Combination Product Team Lead / Nurse Consultant

<span

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2022-4717; Released by CDRH on 05-31-2024

```
style="font-size:10.0pt;font-family:&quot;Arial&quot;,&quot;sans-
serif&quot;;color:black">FDA/CDRH/ODE/DAGRID/GHDB<br>

10903 New Hampshire Avenue, WO66-2567<br>

Silver Spring, MD, 20993-0002 <br>

Telephone: (301) 796-2462, Fax: (301) 847-8109 </span></div>


<div class="MsoNormal"> </div>

</div>

</div>

</div>



</div>

</div>

</font>
```

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2022-4717; Released by CDRH on 05-31-2024

K152261 / A001

Nostix
5541 Central Avenue
Suite 170
Boulder, CO 80301 USA
Tel: 303-245-8895
Fax: 303-245-8909

19 August 2015

FDA/CDRH/DCC
AUG 25 2015
RECEIVED

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (WO66-G609)
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Reference: K152261S1: Supplemental Information

Dear Madam/Sir:

Nostix LLC of Boulder, Colorado, submits this paper copy of Supplemental Information to 510(k) submission K152261 (b)(4)

(b)(4)

If you have any questions, the contact person for this application is Jim Lewis, reachable directly at 303-945-5675.

Respectfully submitted,

(b)(6)

James W. Lewis

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2022-4717; Released by CDRH on 05-31-2024

(b)(4)

Via Email only (cwh@nostix.com)

August 19, 2015

Nostix, LLC
5541 Central Avenue, Suite 170
Boulder, Colorado 80301
Attention: Charles W. Henry, President and CEO

Re: Development and Supply Agreement ("Agreement") between Nostix, LLC and (b)(4)

Dear Mr. Henry:

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2022-4717; Released by CDRH on 05-31-2024

From: Jim Lewis <salusventures@aol.com>
To: Keith.Marin <Keith.Marin@fda.hhs.gov>; petenelson <petenelson@nostix.com>
Cc: K152261 <K152261@docs.fda.gov>; Richard.Chapman <Richard.Chapman@fda.hhs.gov>; cwh <cwh@nostix.com>; Margaret.McCabe <Margaret.McCabe@fda.hhs.gov>
Subject: Re: K152261S1 Right of Reference to K142889 and K140799
Date: Wed, Aug 19, 2015 1:54 pm
Attachments: (b)(4) Deficiencies

Mr. Marin

(b)(4) Deficiencies

Thank you.
--
Jim Lewis

--
For Nosix LLC, Boulder, Colorado, USA
303 945 5675; salusventures@aol.com

-----Original Message-----
From: Marin, Keith <Keith.Marin@fda.hhs.gov>
To: Peter Nelson <petenelson@nostix.com>
Cc: K152261 <K152261@docs.fda.gov>; Chapman, Richard <Richard.Chapman@fda.hhs.gov>; 'Charles Henry' <cwh@nostix.com>; salusventures <salusventures@aol.com>; McCabe-Janicki, Margaret <Margaret.McCabe@fda.hhs.gov>
Sent: Mon, Aug 17, 2015 11:50 am
Subject: (b)(4) Deficiencies

Mr. Nelson,

(b)(4) Deficiencies

Please provide this information by Wednesday August 19, 2015.

Thanks.

Keith

From: Peter Nelson [mailto:petenelson@nostix.com]
Sent: Monday, August 17, 2015 12:54 PM
To: Marin, Keith
Cc: K152261@docs.fda.gov; Chapman, Richard; 'Charles Henry'; salusventures@aol.com
Subject: RE: (b)(4) Deficiencies -- attached

Keith,

(b)(4) Deficiencies

Thanks,

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2022-4717; Released by CDRH on 05-31-2024

Peter

Peter Nelson
Director of Engineering
Nostix
5541 Central Ave, Suite 170
Boulder, CO 80301
Ph: 303-245-8895 ext. 3#
Fax: 303-245-8909

From: Marin, Keith [mailto:Keith.Marin@fda.hhs.gov]
Sent: Monday, August 17, 2015 10:01 AM
To: petenelson@nostix.com
Cc: K152261@docs.fda.gov; Chapman, Richard
Subject: Letter of authorization

Mr. Nelson,

(b)(4) Deficiencies

Thanks.

Keith Marin

Keith Marin, RN, MS, MBA, OCN, RAC
Lieutenant Commander, United States Public Health Service
General Hospital Devices Combination Product Team Lead / Nurse Consultant
FDA/CDRH/ODE/DAGRID/GHDB
10903 New Hampshire Avenue, WO66-2567
Silver Spring, MD, 20993-0002
Telephone: (301) 796-2462, Fax: (301) 847-8109

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2022-4717; Released by CDRH on 05-31-2024

Nostix

510(k) Summary

Prepared: 25 September 2015

Submitter

Company	Nostix LLC 5541 Central Av, Suite 170 Boulder, CO 80301
Tel	303 245 8895
Fax	303 245 8909
Contact	Pete Nelson Director of Engineering petenelson@nostix.com

Device

Trade Name	PICC Tip Positioning Aid
Common Name	PICC placement accessory
Class Name	Percutaneous, implanted, long-term intravascular catheter
Product Code	LJS
Regulation	21 CFR 880.5970
Class	2

Predicate

Trade Name	Celerity System
Clearance	K142889, 27 January 2015
Common Name	PICC placement accessory
Class Name	Percutaneous, implanted, long-term intravascular catheter
Product Code	LJS
Regulation	21 CFR 880.5970
Class	2

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2022-4717; Released by CDRH on 05-31-2024

Device Description

The PICC Tip Positioning Aid includes a standalone Monitor containing software, battery and power cord accompanied by an ECG Patient Cable, a Remote Control Cable, probe cover and ECG Clip Cable.

Other procedural accessories; including ECG Snap Leads, ECG Surface Electrodes, Cable Cover, Gloves and Prep Pads; may be provided as a convenience for the clinician but are not in the scope of this submission.

Intended Use

The PICC Tip Positioning Aid is intended to provide real time tip location information of a central venous catheter by utilization of ECG to observe P-wave changes as the tip approaches the right atrium of the heart via the superior vena cava.

Indications for Use

The PICC Tip Positioning Aid is indicated for the positioning of Peripherally Inserted Central Catheters (PICC) in adult patients. It provides real-time catheter tip location information by using the patient's cardiac electrical activity. The PICC Tip Positioning Aid is indicated for use as an alternative method to chest x-ray or fluoroscopy confirmation of PICC tip placement in adult patients.

Note: In general, devices that utilize ECG technique to observe P-Wave arc limited, but not contraindicated, for patients where cardiac rhythms may change presentation of the P-Wave; including

- Atrial fibrillation
- Atrial flutter
- Severe tachycardia
- Pacemaker-driven rhythm
- Chronic obstructive pulmonary disease (COPD)

Such patients are easily identified prior to PICC insertion. Use of an additional confirmation method is necessary to confirm catheter tip location.

Technological Characteristics

Technological Characteristics of the subject PICC Tip Positioning Aid are identical to the predicate device. The name and address changes on the labels between the predicate and proposed devices do not raise new technological questions.

Performance Data

As the only differences between the device and its predicate are names, logos, and addresses in the labeling, the following recognized standards from the IEC 60601 (3rd Edition) series continue to be satisfied.

IEC 60601-1-1	Medical electrical equipment—Part 1-1: General requirements for safety—Collateral standard: Safety requirements for medical electrical systems

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2022-4717; Released by CDRH on 05-31-2024

IEC 60601-1-2 Medical electrical equipment—Part 1-2: General requirements for basic safety and essential performance—Collateral standard: Electromagnetic compatibility – Requirements and tests

Human Factors Evaluation - Simulated Use Testing alternate to chest x-ray and fluoroscopy:

Simulated Use / Human Factors Testing has been conducted to evaluate the application of the PICC Tip Placement Aid as embodied in the predicate Celerity System when used to confirm PICC tip position as an alternative method to chest X-ray or fluoroscopy confirmation. The use related events noted in the studies have been adequately reviewed and addressed in order to ensure the appropriate use of the device as an alternate to x-ray techniques for confirmation of tip location of PICC.

Based on the content of the proposed PICC Tip Positioning Aid's Risk Analysis / Use and Design FMEAs, and the content of the Instructions for Use, the PICC Tip Positioning Aid has demonstrated its suitability for its intended purpose.

Substantial Equivalence Conclusion

As this device design and manufacturing are the same as the predicate except for name changes to the device and the manufacturer, the device is clearly equivalent to its predicate.

The proposed device is clearly substantially equivalent to the predicate device based on identical:

- Intended Use
- Indications for Use
- Design
- Production
- Operating principles, characteristics, and user interface
- Technology and specifications
- Labeling

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2022-4717; Released by CDRH on 05-31-2024

Mr. Nelson,

(b)(4) Deficiencies

Please provide this information by Wednesday August 19, 2015.

Thanks.

Keith

From: Peter Nelson [mailto:petenelson@nostix.com]

Sent: Monday, August 17, 2015 12:54 PM

To: Marin, Keith

Cc: K152261@docs.fda.gov; Chapman, Richard; 'Charles Henry'; salusventures@aol.com

Subject: RE: (b)(4) Deficiencies -- attached

Keith,

(b)(4) Deficiencies

Thanks,

Peter

Peter Nelson

Director of Engineering

Nostix

5541 Central Ave, Suite 170

Boulder, CO 80301

Ph: 303-245-8895 ext. 3#

Fax: 303-245-8909

From: Marin, Keith [mailto:Keith.Marin@fda.hhs.gov]

Sent: Monday, August 17, 2015 10:01 AM

To: petenelson@nostix.com<mailto:petenelson@nostix.com>

Cc: K152261@docs.fda.gov<mailto:K152261@docs.fda.gov>; Chapman, Richard

Subject: (b)(4) Deficiencies

Mr. Nelson,

(b)(4) Deficiencies

Questions? Contact FDA/CDRH/OCE/DIDSI at CDRH-FOIASTAFF@fda.hhs.gov or 301-796-9115

Records processed under FOIA Request 2022-4717; Released by CDRH on 05-31-2024

(b)(4) Deficiencies

Thanks.

Keith Marin

Keith Marin, RN, MS, MBA, OCN, RAC
Lieutenant Commander, United States Public Health Service
General Hospital Devices Combination Product Team Lead / Nurse Consultant
FDA/CDRH/ODE/DAGRID/GHDB
10903 New Hampshire Avenue, WO66-2567
Silver Spring, MD, 20993-0002
Telephone: (301) 796-2462, Fax: (301) 847-8109

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2022-4717; Released by CDRH on 05-31-2024

From: Le, Ponleiy * [Ponleiy.Le@fda.hhs.gov]
Sent: 8/25/2015 3:00:08 PM
To: salusventures@aol.com
CC: DCCLetters [DCCLetters@fda.hhs.gov]
Subject: K152261/A001 ACK LETTER
Attachments: Acknowledgment%20Letter.pdf

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2022-4717; Released by CDRH on 05-31-2024

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Acknowledgment Letter

08/25/2015

Jim Lewis
Executive Consultant
Salus Ventures LLC
5335 Holmes Place
Boulder, CO 80303
United States

Dear Jim Lewis:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has received your submission. This submission has been assigned the unique document control number below. Please refer prominently to this number in all future correspondence that relates to this submission. Failure to do so may result in processing delays. If the 'Applicant' identified below is incorrect, please notify the 510(k) Staff immediately at (301) 796-5640.

Submission Number: K152261/A001
Received: 08/25/2015
Applicant: NOSTIX LLC
Device: PICC Tip Positioning Aid

We will notify you when the processing of your 510(k) has been completed or if any additional information is required. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

If any additional information is required, we will notify you via an Acceptance Review communication, Additional Information (AI) request, and/or Interactive Review communication. For additional information on these types of communication and their effect on the FDA Review Clock (if any), please refer to the following guidance documents:

"FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Goals" at http://www.fda.gov/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm089735.htm.

"Refuse to Accept Policy for 510(k)s" at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM315014.pdf.

"Types of Communication During the Review of Medical Device Submissions" at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm341918.htm.

When responding to an information request that stops the FDA Review Clock (e.g., an AI request or refuse to accept (RTA) decision), you must submit your complete response with valid electronic copy (eCopy) to the Document Control Center (DCC) at the above address. An incomplete response or a response sent any other way (e.g., to another address or via email) will **not** be considered an official response and will not restart the FDA Review Clock. For more information about FDA's eCopy program, including the new technical standards for an eCopy, refer to the guidance document, "eCopy Program for Medical Device Submissions" at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM313794.pdf

Record processed under FOIA Request 2022-4737, Released by CDRH on 05-31-2024

To learn more about the overall 510(k) submission process, please refer to our website at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/default.htm.

If you have any procedural or policy questions, please refer to our website at http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm or contact the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041, (301) 796-7100, or *DICE@fda.hhs.gov*.

Sincerely yours,

Marjorie Shulman
Director, 510(k) Program
Premarket Notification (510(k)) Staff
Office of Device Evaluation
Center for Devices and Radiological Health

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2022-4717; Released by CDRH on 05-31-2024

Keith,

(b)(4) Deficiencies

Thanks,

Peter

Peter Nelson
R&D Manager
Nostix
5541 Central Ave, Suite 170
Boulder, CO 80301
Ph: 303-245-8895 ext. 3#
Fax: 303-245-8909

From: Marin, Keith [mailto:Keith.Marin@fda.hhs.gov]
Sent: Thursday, September 03, 2015 9:39 AM
To: Peter Nelson
Cc: Chapman, Richard; K152261@docs.fda.gov
Subject: additional questions

Peter,

(b)(4) Deficiencies

Thanks.

Keith

From: Peter Nelson [mailto:petenelson@nostix.com]
Sent: Monday, August 17, 2015 12:54 PM

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2022-4717; Released by CDRH on 05-31-2024

To: Marin, Keith

Cc: K152261@docs.fda.gov; Chapman, Richard; 'Charles Henry';

salusventures@aol.com

Subject: RE: (b)(4) Deficiencies -- attached

Keith,

(b)(4) Deficiencies

Thanks,

Peter

Peter Nelson

Director of Engineering

Nostix

5541 Central Ave, Suite 170

Boulder, CO 80301

Ph: 303-245-8895 ext. 3#

Fax: 303-245-8909

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Sent: Monday, August 17, 2015 10:01 AM

To: petenelson@nostix.com

Cc: K152261@docs.fda.gov; Chapman, Richard

Subject: (b)(4) Deficiencies

Mr. Nelson,

(b)(4) Deficiencies

Thanks.

Keith Marin

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Keith Marin, RN, MS, MBA, OCN, RAC

Lieutenant Commander, United States Public Health Service

General Hospital Devices Combination Product Team Lead / Nurse Consultant

FDA/CDRH/ODE/DAGRID/GHDB

10903 New Hampshire Avenue, WO66-2567

Silver Spring, MD, 20993-0002

Telephone: (301) 796-2462, Fax: (301) 847-8109

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Peter,

(b)(4) Deficiencies

Thanks.

Keith

From: Peter Nelson [mailto:petenelson@nostix.com]

Sent: Monday, September 21, 2015 4:58 PM

To: Marin, Keith

Cc: Chapman, Richard; K152261@docs.fda.gov; 'Charles Henry'; salusventures@aol.com

Subject: RE: additional questions -- (b)(4) Deficiencies attached

Keith,

(b)(4) Deficiencies

Thanks,

Peter

From: Marin, Keith [mailto:Keith.Marin@fda.hhs.gov]

Sent: Monday, September 21, 2015 9:05 AM

To: Peter Nelson

Cc: Chapman, Richard; K152261@docs.fda.gov<mailto:K152261@docs.fda.gov>; 'Charles Henry'; salusventures@aol.com<mailto:salusventures@aol.com>

Subject: RE: additional questions -- (b)(4) Deficiencies attached

Importance: High

Peter,

(b)(4) Deficiencies

Keith

From: Peter Nelson [mailto:petenelson@nostix.com]

Sent: Friday, September 04, 2015 11:34 AM

To: Marin, Keith

Cc: Chapman, Richard; K152261@docs.fda.gov<mailto:K152261@docs.fda.gov>; 'Charles Henry'; salusventures@aol.com<mailto:salusventures@aol.com>

Subject: RE: additional questions -- (b)(4) Deficiencies attached

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(b)(4) Deficiencies

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Peter

Peter Nelson

R&D Manager

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Boulder, CO 80301

Ph: 303-245-8895 ext. 3#

Fax: 303-245-8909

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Sent: Thursday, September 03, 2015 9:39 AM

To: Peter Nelson

Cc: Chapman, Richard; K152261@docs.fda.gov<mailto:K152261@docs.fda.gov>

Subject: additional questions

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(b)(4) Deficiencies

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Sent: Monday, August 17, 2015 12:54 PM

To: Marin, Keith

Cc: K152261@docs.fda.gov<mailto:K152261@docs.fda.gov>; Chapman, Richard; 'Charles Henry'; salusventures@aol.com<mailto:salusventures@aol.com>

Subject: RE: (b)(4) Deficiencies -- attached

Keith,

(b)(4) Deficiencies

Thanks,

Peter

Peter Nelson

Director of Engineering

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Nostix

5541 Central Ave, Suite 170

Boulder, CO 80301

Ph: 303-245-8895 ext. 3#

Fax: 303-245-8909

From: Marin, Keith [mailto:Keith.Marin@fda.hhs.gov]

Sent: Monday, August 17, 2015 10:01 AM

To: petenelson@nostix.com<mailto:petenelson@nostix.com>

Cc: K152261@docs.fda.gov<mailto:K152261@docs.fda.gov>; Chapman, Richard

Subject: **(b)(4) Deficiencies**

Mr. Nelson,

(b)(4) Deficiencies

Thanks.

Keith Marin

Keith Marin, RN, MS, MBA, OCN, RAC

Lieutenant Commander, United States Public Health Service

General Hospital Devices Combination Product Team Lead / Nurse Consultant

FDA/CDRH/ODE/DAGRID/GHDB

10903 New Hampshire Avenue, WO66-2567

Silver Spring, MD, 20993-0002

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

October 21, 2015

Nostix LLC
c/o Mr. Jim Lewis
Salus Ventures LLC
5335 Holmes Place
Boulder, Colorado, 80303

Re: K152261
Trade/Device Name: PICC Tip Positioning Aid
Regulation Number: 21 CFR 880.5970
Regulation Name: Percutaneous, implanted, long-term intravascular catheter
Regulatory Class: II
Product Code: LJS
Dated: August 7, 2015
Received: August 11, 2015

Dear Mr. Lewis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K152261

Device Name

PICC Tip Positioning Aid

Indications for Use *(Describe)*

The PICC Tip Positioning Aid is indicated for the positioning of Peripherally Inserted Central Catheters (PICC) in adult patients. It provides real-time catheter tip location information by using the patient's cardiac electrical activity. The PICC Tip Positioning Aid is indicated for use as an alternative method to chest x-ray or fluoroscopy confirmation of PICC tip placement in adult patients.

Note: In general, devices that utilize ECG technique to observe P-Wave are limited, but not contraindicated, for patients where cardiac rhythms may change presentation of the P-Wave; including
- Atrial fibrillation
- Atrial flutter
- Severe tachycardia
- Pacemaker-driven rhythm
- Chronic obstructive pulmonary disease (COPD)

Such patients are easily identified prior to PICC insertion. Use of an additional confirmation method is necessary to confirm catheter tip location.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Nostix

510(k) Summary

Prepared: 25 September 2015

Submitter

Company	Nostix LLC 5541 Central Av, Suite 170 Boulder, CO 80301
Tel	303 245 8895
Fax	303 245 8909
Contact	Pete Nelson Director of Engineering petenelson@nostix.com

Device

Trade Name	PICC Tip Positioning Aid
Common Name	PICC placement accessory
Class Name	Percutaneous, implanted, long-term intravascular catheter
Product Code	LJS
Regulation	21 CFR 880.5970
Class	2

Predicate

Trade Name	Celerity System
Clearance	K142889, 27 January 2015
Common Name	PICC placement accessory
Class Name	Percutaneous, implanted, long-term intravascular catheter
Product Code	LJS
Regulation	21 CFR 880.5970
Class	2

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Device Description

The PICC Tip Positioning Aid includes a standalone Monitor containing software, battery and power cord accompanied by an ECG Patient Cable, a Remote Control Cable, probe cover and ECG Clip Cable.

Other procedural accessories; including ECG Snap Leads, ECG Surface Electrodes, Cable Cover, Gloves and Prep Pads; may be provided as a convenience for the clinician but are not in the scope of this submission.

Intended Use

The PICC Tip Positioning Aid is intended to provide real time tip location information of a central venous catheter by utilization of ECG to observe P-wave changes as the tip approaches the right atrium of the heart via the superior vena cava.

Indications for Use

The PICC Tip Positioning Aid is indicated for the positioning of Peripherally Inserted Central Catheters (PICC) in adult patients. It provides real-time catheter tip location information by using the patient's cardiac electrical activity. The PICC Tip Positioning Aid is indicated for use as an alternative method to chest x-ray or fluoroscopy confirmation of PICC tip placement in adult patients.

Note: In general, devices that utilize ECG technique to observe P-Wave arc limited, but not contraindicated, for patients where cardiac rhythms may change presentation of the P-Wave; including

- Atrial fibrillation
- Atrial flutter
- Severe tachycardia
- Pacemaker-driven rhythm
- Chronic obstructive pulmonary disease (COPD)

Such patients are easily identified prior to PICC insertion. Use of an additional confirmation method is necessary to confirm catheter tip location.

Technological Characteristics

Technological Characteristics of the subject PICC Tip Positioning Aid are identical to the predicate device. The name and address changes on the labels between the predicate and proposed devices do not raise new technological questions.

Performance Data

As the only differences between the device and its predicate are names, logos, and addresses in the labeling, the following recognized standards from the IEC 60601 (3rd Edition) series continue to be satisfied.

IEC 60601-1-1	Medical electrical equipment—Part 1-1: General requirements for safety—Collateral standard: Safety requirements for medical electrical systems

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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IEC 60601-1-2 Medical electrical equipment—Part 1-2: General requirements for basic safety and essential performance—Collateral standard: Electromagnetic compatibility – Requirements and tests

Human Factors Evaluation - Simulated Use Testing alternate to chest x-ray and fluoroscopy:

Simulated Use / Human Factors Testing has been conducted to evaluate the application of the PICC Tip Placement Aid as embodied in the predicate Celerity System when used to confirm PICC tip position as an alternative method to chest X-ray or fluoroscopy confirmation. The use related events noted in the studies have been adequately reviewed and addressed in order to ensure the appropriate use of the device as an alternate to x-ray techniques for confirmation of tip location of PICC.

Based on the content of the proposed PICC Tip Positioning Aid's Risk Analysis / Use and Design FMEAs, and the content of the Instructions for Use, the PICC Tip Positioning Aid has demonstrated its suitability for its intended purpose.

Substantial Equivalence Conclusion

As this device design and manufacturing are the same as the predicate except for name changes to the device and the manufacturer, the device is clearly equivalent to its predicate.

The proposed device is clearly substantially equivalent to the predicate device based on identical:

- Intended Use
- Indications for Use
- Design
- Production
- Operating principles, characteristics, and user interface
- Technology and specifications
- Labeling

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Keith,

(b)(4) Deficiencies

Thanks,

Peter

Peter Nelson
Director of Engineering
Nostix
5541 Central Ave, Suite 170
Boulder, CO 80301
Ph: 303-245-8895 ext. 3#
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Mr. Nelson,

(b)(4) Deficiencies

Thanks.

Keith Marin

Keith Marin, RN, MS, MBA, OCN, RAC
Lieutenant Commander, United States Public Health Service
General Hospital Devices Combination Product Team Lead / Nurse Consultant

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INTRODUCTORY INFORMATION

TRADITIONAL 510(k) ACCEPTANCE CHECKLIST

Completed and Created by Nostix to aide reviewers
Based on CDRH *Refuse to Accept Policy for 510(k)s – Guidance for Industry and Food and Drug Administration Staff, 31 Dec. 2012*

		Y	N/A	N
	Preliminary Questions			
1.	Is the product a device (per section 201(h) of the FD&S Act) or a combination product (per 21 CFR 3.2 (e)) with a device constituent part subject to review in a 510(k)?	✓		
	Comment: See Section 2 --CDRH Premarket Review Submission Cover Sheet (Section G)			
2.	Is the application with the appropriate Center?	✓		
	Comment: See Section 2 --CDRH Premarket Review Submission Cover Sheet (Section G)			
3.	If a Request for Designation (RFD) was a submitted for the device or combination product with a device constituent part and assigned to your center, identify the RFD# and confirm the following: a) Is the device or combination the same (e.g., design, formulation) as the predicate in the RFD submission? b) Are there indications for use for the device or combination product identified in the 510(k) the same as those identified in the RFD submission?		✓	
	Comment: Not Applicable			
4.	Is the device type eligible for a 510(k) submission?	✓		
	Comment: See Section 2 --CDRH Premarket Review Submission Cover Sheet (Section G)			
5.	Is there a pending PMA for the same device with the same indications for use?			✓
	Comment: Not a PMA Device			
6.	If clinical studies have been submitted, is the submitter the subject of an Application Integrity Policy (AIP)?			✓
	Comment: No Clinical Studies conducted in support of this 510(k)			
	Organizational Elements			
	a. Submission contains Table of Contents	✓		
	b. Each section is labeled	✓		
	c. All pages of the submission are numbered	✓		
	d. Type of 510(k) is identified– traditional, abbreviated, or special	✓		
	Comment: See Table of Contents; Section 2: CDRH Premarket Review Submission Cover Sheet Section 3: Cover Letter			
	Elements of a Complete Submission (21 CFR 807.87 unless otherwise indicated)			
A.	**Administrative**			
1.	All content used to support the submission is written in English	✓		
	Comment: Submission is in English			
2.	Submission identifies the following (such as in CDRH Premarket Review Submission Cover Sheet (Form 3514) or in 510(k) cover letter):			
	a. Device trade name or proprietary name	✓		
	b. Device common name	✓		
	c. Device class and panel or Classification regulation or Statement that device has not been classified with rationale for that conclusion	✓		
	Comment: See Section 2: CDRH Premarket Review Submission Cover Sheet; See Section 3: Cover Letter			

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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		Y	N/A	N
3.	Submission contains Indications for Use Statement with Rx and/or OTC designated (see also and 801.109)	✓		
	Comment: See Section 4: Indications for Use Statement			
4.	Submission contains 510(k) Summary or 510(k) Statement	✓		
	a. Summary contains all elements per 21 CFR 807.92	✓		
	b. Statement contains all elements per 21 CFR 807.93		✓	
	Comment: See Section 5: 510(k) Summary			
5.	Submission contains signed Truthful and Accuracy Statement per 21 CFR 807.87(k)	✓		
	Comment: See Section 6: Truthful and Accuracy Certification Statement			
6.	Submission contains signed Class III Summary and Certification		✓	
	Comment: See Section 7 - Device is Class II			
7.	Submission contains clinical data		✓	
	a. Submission includes completed Financial Certification (FDA Form 3454) or Disclosure (FDA Form 3455) information for each clinical study included in the submission.		✓	
	b. Submission includes completed Certification of Compliance with requirements of ClinicalTrials.gov Data bank (FDA Form 3674) (42 U.S.C. 282(j)(5)(B)) for each applicable device clinical trial included in the submission.		✓	
	Comment: No Clinical Studies conducted in support of this 510(k)			
8.	If submission references use of a national or international standard as part of demonstration of substantial equivalence, submission contains Standards Data Report for 510(k)s (FDA Form 3654)		✓	
	Comment: While standards mentioned, they are not used to demonstrate substantial equivalence			
9.	The submission identifies prior submissions for the same device which FDA provided feedback related to the data or information needed to support substantial equivalence (e.g., submission numbers for Pre- Submission, IDE, prior not substantially equivalent (NSE) determination, prior 510(k) that was deleted or withdrawn) or states that there were no prior submissions for the subject device.	✓		
	a. If there were prior submissions, the submitter has identified where in the current submission any issues related to a determination of substantial equivalence outlined in prior communications are addressed.	✓		
	Comment: See CDRH Premarket Review Submission Cover Sheet Section F; K142889			
B.	**Device Description**			
10.	a. If there are requirements regarding the device description, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes device description information to establish that the submitter has followed the device-specific requirement.		✓	
	b. If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes device description information to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach.		✓	
	Comment: No device specific requirements or guidance			

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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		Y	N/A	N
11.	Descriptive information is present and consistent within the submission (e.g., the device description section is consistent with the device description in the labeling), including:			
	a. A description of the principle of operation and mechanism of action for achieving the intended effect.	✓		
	b. A description of proposed conditions of use, such as surgical technique for implants; anatomical location of use; user interface; how the device interacts with other devices; and/or how the device interacts with the patient.	✓		
	c. A list and description of each device for which clearance is requested.	✓		
	Comment: See Section 11: Device Description			
12.	Submission contains representative engineering drawing(s), schematics, illustrations and/or figures of the device that are clear, legible, labeled, and include dimensions.	✓		
	Comment: See Section 11: Device Description			
13.	If device is intended to be marketed with multiple components, accessories, and/or as part of a system			
	a. Submission includes a list of all components and accessories to be marketed with the subject device.	✓		
	b. Submission includes a description (as detailed in item #11.a. and b. and 12 above) of each component or accessory.	✓		
	c. A 510(k) number is provided for each component or accessory that received a prior 510(k) clearance.	✓		
	Comment: See Section 11- Device Description			
C.	**Substantial Equivalence Discussion**			
14.	Submitter has identified a predicate(s) device	✓		
	a. Predicate's 510(k) number, trade name, and model number (if applicable) provided. For predicates that are preamendment devices, information is provided to document preamendment status.	✓		
	b. The identified predicate(s) is consistent throughout the submission (i.e., the predicate(s) identified in the Substantial Equivalence section is the same as that listed in the 510(k) Summary (if applicable) and that used in comparative performance testing).	✓		
	Comment: See Section 2: CDRH Premarket Review Submission Cover Sheet (Section E)			
15.	Submission includes a comparison of the following for the predicate(s) and subject device			
	a. Indications for use	✓		
	b. Technology, including features, materials, and principles of operation	✓		
	Comment: See Section 12: Substantial Equivalence Discussion			
16.	Submission includes an analysis of why any differences between the subject device and predicate(s) do not render the device NSE (e.g., do not constitute a new intended use, and any differences in technological characteristics are accompanied by information that demonstrates the device is as safe and effective as the predicate and do not raise different questions of safety and effectiveness than the predicate) affect safety or effectiveness, or raise different questions of safety and effectiveness) (see section 513(i)(l)(A) of the FD&C Act)	✓		
	Comment: See Section 12: Substantial Equivalence Discussion			

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		Y	N/A	N
D.	**Proposed Labeling (see also 21 CFR part 801)**			
	If a vitro diagnostic (IVD) device, criteria 17, 18, and 19 may be omitted			
17.	Submission includes proposed package labels and labeling (e.g., instructions for use, package insert, operator's manual) that include a description of the device, its intended use, and directions for use.	✓		
	a. Indications for use are stated in the labeling and are identical to Indications for Use form and 510(k) summary (if 510(k) Summary provided.)	✓		
	b. Submission includes directions for use that - Include statements of all conditions, purposes or uses for which the device is intended (e.g., hazards, warnings, precautions, contraindications) (21 CFR 801.5) AND - Includes directions for layperson (see 21CFR 801.5) OR submission states that the device qualifies for exemption 21 21 CFR 801 Subpart D	✓		
	Comment: See Section 13: Proposed Labeling			
18.	If indicated for prescription us, labeling includes the prescription use statement (see 21 CFR 801.109(b)(1)) or "Rx only" symbol	✓		
	Comment: See Section 13: Proposed Labeling			
19.	General labeling provisions			
	a. Labeling includes name and place of business of the manufacturer, packer, or distributor (21 CFR 801.1)	✓		
	b. Labeling includes device common or usual name (21 CFR 801.61)	✓		
	Comment: See Section 13: Proposed Labeling			
20.	a. If there are requirements regarding labeling, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes labeling to establish that the submitter has followed the device-specific requirement.		✓	
	b. If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes labeling to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach.		✓	
	c. If there is a special controls document applicable to the device, the submission includes labeling to establish that the submitter has complied with the particular mitigation measures set for in the special controls document or uses alternative mitigation measures but provides a rationale to demonstrate that those alternative measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness.		✓	
	Comment: No device specific requirements or guidance			
21.	If the device is an in vitro diagnostic device, provided labeling includes all applicable information required per 21 CFR 809.10.		✓	
E.	**Sterilization**			
	If in vitro diagnostic (IVD) device, select N/A. The criteria in the section will be omitted from the checklist if N/A is selected.			
	Submission states that the device and/or accessories are (one of the below must be checked) ☒ provided sterile **(ECG Accessory Kit)** ☐ provided non-sterile but sterilized by the end user ☒ non-sterile when used **(Capital Equipment)**			
	Comment: See Section 14: Sterilization and Shelf Life			

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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		Y	N/A	N
22.	Assessment of the need for sterilization information			
	a. Identification of device, and/or accessories, and/or components that are provided sterile.	✓		
	b. Identification of device, and/or accessories, and/or components that are end user sterilized.		✓	
	c. Identification of device, and/or accessories, and/or components that are reusable and cleaning/disinfection instructions are provided.	✓		
	Comment: See Section 13: Device Labeling; and 14:Sterilization and Shelf Life			
23.	If the device, and/or accessory, and/or component is provided sterile:		✓	
	a. Sterilization method is stated for each component (including parameters such as dry time for steam sterilization, radiation dose, etc.)			
	b. A description of the method to validate the sterilization parameters (e.g., half-cycle method and full citation of FDA-recognized standard, including date) is provided for each proposed sterilization method.			
	c. For devices sterilized using chemical sterilants such as ethylene oxide (EO) and hydrogen peroxide, submission states maximum levels of sterilant residuals remaining on the device and sterilant residual limits.			
	d. Submission includes description of packaging and packaging contents (e.g., if multiple devices are included within the same package, Tyvek packaging, etc.)			
	e. Sterility Assurance Level (SAL) stated			
	Comment: See Section 14: Sterilization and Shelf Life (Sterility not subject of this submission)			
24.	If the device, and/or accessory, and/or component is end user sterilized:		✓	
	a. Sterilization method is stated for each component (including parameters such as dry time for steam sterilization, radiation dose, etc.)			
	b. A description of the method to validate the sterilization parameters (e.g., half-cycle method and full citation of FDA-recognized standard, including date) is provided for each proposed sterilization method.			
	c. Submission includes description of packaging and packaging contents (e.g., if multiple devices are included within the same package, Tyvek packaging, etc.)			
	d. Submission includes sterilization instructions for end user			
25.	a. If there are requirements regarding sterility controls, in a device-specific regulation that are applicable to the device, the submission includes sterility information to establish that the submitter has followed the device-specific requirement.		✓	
	b. If there is a device-specific guidance other than a special controls guidance document applicable to the device, the submission includes sterility information to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach.		✓	
	c. If there is a special controls guidance document applicable to the device, the submission includes sterility information to establish that the submitter has complied with the particular mitigation measures set forth in the special controls document uses alternative mitigation measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness.		✓	
	Comment: No device specific requirements or guidance			

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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		Y	N/A	N
F.	**Shelf Life**			
26.	Proposed shelf life/expiration date stated	✓		
	Comment: See Section 14: Sterilization and Shelf Life			
27.	For sterile device, submission included summary of methods used to establish that device sterility will remain substantially equivalent to that of the predicate through the proposed shelf life, or a rationale for why testing to establish shelf life is not applicable.		✓	
	Comment: See Section 14: Sterilization and Shelf Life			
28.	Submission includes summary of methods used to establish that device performance is not adversely affected by aging and therefore device performance will remain substantially equivalent to that of the predicate, or includes a rationale for why the storage conditions are not expected to affect device safety or effectiveness.	✓		
	Comment: See Section 14: Sterilization and Shelf Life			
G.	**Biocompatibility**			
	If an in-vitro diagnostic (IVD) device, select N/A. The criteria in the section will be omitted from the checklist if N/A is selected.		✓	
	Submission states that there: ☐ are ☒ are not direct or indirect (e.g., through infusion) patient-contacting components.			
29.	Submission includes a list of patient-contacting device components and associated materials of construction, including identification of color additives, if present		✓	
	Comment: Proposed Device has no patient contact			
30.	Submission identifies contact classification (e.g., surface-contacting, less than 24 hour duration)		✓	
	Comment: Proposed Device has no patient contact			
31.	Biocompatibility assessment of patient-contacting components Submission includes: Test protocol (including identification and description of test article), methods, pass/fail criteria. And results provided for each completed test, OR A statement that the biocompatibility testing is not needed with a rationale (e.g., materials and manufacturing/processing are identical to the predicate).		✓	
	Comment: Proposed Device has no patient contact			
H.	**Software**			
	Submission states that the device: ☒ does ☐ does not contain software/firmware.			
32.	Submission includes a statement of software level of concern and rationale for the software level of concern.	✓		
33.	All applicable software documentation provided based on the level of concern identified by the submitter, as described in Guidance for the Content of premarket Submissions for Software Contained in Medical Devices, or the submission includes information to establish that the submitter has otherwise met the applicable statutory or regulatory criteria through an alternative approach (i.e., the submitter has identified an alternate approach with a rationale).	✓		

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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		Y	N/A	N
I.	**EMC and Electrical Safety**			
	Submission states that the device: ☒ does ☐ does not require EMC and Electrical Safety evaluation			
34.	Submission includes evaluation of electrical safety (e.g., per IEC 60601-1, or equivalent FDA-recognized standard, and if applicable, the device-specific standard), OR submission includes electrical safety evaluation using methods or standards that are not FDA-recognized and submission includes information to establish that the submitter has otherwise met the applicable statutory or regulatory criteria through this alternative approach (i.e., the submitter has identified alternate methods or standards with a rationale).	✓		
35.	Submission includes evaluation of electromagnetic compatibility (e.g., per IEC 60601-1-2 or equivalent FDA-recognized standard and if applicable, the device-specific standard) OR submission includes electromagnetic compatibility evaluation using methods or standards that are not FDA-recognized and submission includes information to establish that the submitter has otherwise met the applicable statutory or regulatory criteria through this alternative approach (i.e., the submitter has identified alternate methods or standards with a rationale).	✓		
J.	**Performance Data – General** **If in vitro diagnostic (IVD) device, select "N/A." The criteria in this section will be omitted from the checklist if "N/A" is selected. Performance data criteria relating to IVD devices will be addressed in Section K.**			
36.	Full test report is provided for each completed test. A full test report includes: objective of the test, description of the test methods and procedures, study endpoint(s), pre- defined pass/fail criteria, results summary, conclusions, and an explanation of how the data generated from the test supports a finding of substantial equivalence.		✓	
	Comment: See Section 18: Performance Testing for rationale			
37.	a. If there are requirements regarding performance data, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes performance data to establish that the submitter has followed the device-specific requirement.		✓	
	b. If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes performance data to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach		✓	
	c. If there is a special controls document applicable to the device, the submission includes performance data to establish that the submitter has complied with the particular mitigation measures set forth in the special controls document or uses alternative mitigation measures but provides a rationale to demonstrate that those alternative measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness.		✓	
	Comment: No device specific requirements or guidance			

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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		Y	N/A	N
38.	If literature is referenced in the submission, submission includes:		✓	
	a. Legible reprints or a summary table of each article			
	b. Discussion of how each article is applicable to support substantial equivalence of the subject device to the predicate. Comment: See Section 12			
	Comment: No reference to literature in submission			
39.	For each completed nonclinical (i.e., animal) study conducted		✓	
	a. Submission includes a study protocol which includes all elements as outlined in 21 CFR 58.120			
	b. Submission includes final study report which includes all elements outlined in 21 CFR 58.185			
	c. Submission contains a statement that the study was conducted in compliance with applicable requirements in the GLP regulation (21 CFR Part 58), or, if the study was not conducted in compliance with the GLP regulation, the submission explains why the noncompliance would not impact the validity of the study data provided to support a substantial equivalence determination.			
	Comment: No Non-Clinical (Animal Studies) conducted is support of this submission			
K.	**Performance Characteristics – In Vitro Diagnostic Devices Only (see also 21 CFR 809.10(b)(12))**			
	Submission states that the device: ☐ is ☒ is not an in vitro diagnostic device (IVD)		✓	
40.	Submission includes the following studies, as appropriate for the device type, including associated protocol descriptions, study results and line data:			
	a. Precision/reproducibility		✓	
	b. Accuracy (includes as appropriate linearity; calibrator or assay traceability; calibrator and/or assay stability protocol and acceptance criteria; assay cut-off; method comparison or comparison to clinical outcome; matrix comparison; and clinical reference range or cutoff.		✓	
	c. Sensitivity (detection limits, LoB, LoD, LoQ where relevant for the device type).		✓	
	d. Analytical specificity		✓	
41.	1. If there are requirements regarding performance data, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes performance data to establish that the submitter has followed the device-specific requirement.		✓	
	2. If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes performance data to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach.		✓	
	3. If there is a special controls document applicable to the device, the submission includes performance data to establish that the submitter has complied with the particular mitigation measures set forth in the special controls document or uses alternative mitigation measures but provides a rationale to demonstrate that those alternative measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness.		✓	

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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SECTION 6 TRUTHFUL AND ACCURACY CERTIFICATION STATEMENT

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Premarket Notification
Truthful and Accurate Statement

[As Required by 21 CFR 807.87(k)]

I certify that, in my capacity as Director of Engineering of Nostix LLC, I believe, to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

(b)(6)

Pete Nelson
Director of Engineering
Nostix LLC

8/6/15

Date

Premarket Notification [510(k)] Number

Must be signed by a responsible person of the firm required to submit the premarket notification [e.g., not a consultant for the 510(k) submitter].

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2022-4717; Released by CDRH on 05-31-2024

Nostix
5541 Central Avenue
Suite 170
Boulder, CO 80301 USA
Tel: 303-245-8895
Fax: 303-245-8909

FDA CDRH DMC
AUG 11 2015
Received

7 August 2015

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (WO66-G609)
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

K152261

Reference: Traditional 510(k): **PICC Tip Positioning Aid**
Classification Panel: General Hospital and Personal Use Devices

Dear Madam/Sir:

Nostix LLC of Boulder, Colorado, submits this **Traditional 510(k)** notification per 21 CFR 807.90 to indicate its intent to market an standalone, electronic **PICC Tip Positioning Aid,** which uses ECG wave changes as an alternative approach to chest x-ray or fluoroscopy for the positioning of PICC Catheters in adult patients.

Device names and classification

Device name	**PICC Tip Positioning Aid**
Common name	**PICC placement accessory**
Regulation	**21 CFR 880.5970**
Classification name	**Percutaneous, implanted, long-term intravascular catheter**
Product code	**LJS**
Device class	**2**
Panel	**General Hospital and Personal Use**

Purpose of submission

(b)(4)

Continued on next page

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2022-4717; Released by CDRH on 05-31-2024

Design and Use of Device

The device provides electrocardiographic (ECG) information, which indicates the tip location for central venous catheters in real time. A competent operator can use P-wave changes in the patient's ECG waveform to confirm positioning of the catheter tip as the catheter approaches the right atrium of the heart via the superior vena cava.

Table. Design and Use of Device.

Device intended for prescription use (21 CFR 801 Subpart D)	yes
Device intended for over-the-counter use (21 CFR 807 Subpart C)	no
Does device contain components derived from biologic source	no
Device provided sterile	no
Device intended for single use	no
Device a reprocessed single use device	no
Device contain a drug	no
Device contain a biologic	no
Device uses software	yes
Submission include clinical information	no
Device implanted	no

Type of 510(k)

Traditional 510(k) for a new medical device.

Company

Information about Nostix LLC, including contact information, is listed in the *CDRH Premarket Review Submission Cover Sheet* (Section 2).

Confidentiality

Nostix considers its intent to market this device as confidential commercial information. As such, the company takes precautions to protect the confidentiality of this information and requests that FDA do so, also.

Electronic copy

Per CDRH policy announced on its website, two copies of this premarket notification are provided: one paper copy and one electronic copy (eCopy). Paper copies of signed documents are included with the eCopy. The eCopy is an exact duplicate of the paper copy.

If you have any questions, the contact person for this application is Jim Lewis, reachable directly at 303-945-5675.

Thank you in advance for your consideration of our application.

Sincerely,

(b)(6)

Peter Nelson
Director of Engineering

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2022-4717; Released by CDRH on 05-31-2024

SECTION 3 510(K) COVER LETTER

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2022-4717; Released by CDRH on 05-31-2024

Nostix
5541 Central Avenue
Suite 170
Boulder, CO 80301 USA
Tel: 303-245-8895
Fax: 303-245-8909

7 August 2015

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (WO66-G609)
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Reference: Traditional 510(k): **PICC Tip Positioning Aid**
Classification Panel: General Hospital and Personal Use Devices

Dear Madam/Sir:

Nostix LLC of Boulder, Colorado, submits this **Traditional 510(k)** notification per 21 CFR 807.90 to indicate its intent to market an standalone, electronic **PICC Tip Positioning Aid,** which uses ECG wave changes as an alternative approach to chest x-ray or fluoroscopy for the positioning of PICC Catheters in adult patients.

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Product code	**LJS**
Device class	**2**
Panel	**General Hospital and Personal Use**

Purpose of submission

(b)(4)

Continued on next page

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2022-4717; Released by CDRH on 05-31-2024

Design and Use of Device

The device provides electrocardiographic (ECG) information, which indicates the tip location for central venous catheters in real time. A competent operator can use P-wave changes in the patient's ECG waveform to confirm positioning of the catheter tip as the catheter approaches the right atrium of the heart via the superior vena cava.

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Submission include clinical information	no
Device implanted	no

Type of 510(k)

Traditional 510(k) for a new medical device.

Company

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Confidentiality

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Electronic copy

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If you have any questions, the contact person for this application is Jim Lewis, reachable directly at 303-945-5675.

Thank you in advance for your consideration of our application.

Sincerely,

(b)(6)

Peter Nelson
Director of Engineering

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2022-4117; Released by CDRH on 05-31-2024

(b)(4)

Via Email only (cwh@nostix.com)

July 21, 2015

Nostix, LLC
5541 Central Avenue, Suite 170
Boulder, Colorado 80301
Attention: Charles W. Henry, President and CEO

Re: Development and Supply Agreement ("Agreement") between Nostix, LLC ("Nostix") and (b)(4)

Dear Charlie:

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2022-4717; Released by CDRH on 05-31-2024

Keith,

(b)(4) Deficiencies

--

Jim

--

For Nostix LLC, Boulder, Colorado, USA

303 945 5675; salusventures@aol.com

-----Original Message-----

From: Marin, Keith <Keith.Marin@fda.hhs.gov>

To: Peter Nelson <petenelson@nostix.com>

Cc: Chapman, Richard <Richard.Chapman@fda.hhs.gov>; K152261 <K152261@docs.fda.gov>; 'Charles Henry' <cwh@nostix.com>; salusventures <salusventures@aol.com>

Sent: Fri, Sep 25, 2015 12:33 pm

Subject: RE: additional questions -- (b)(4) Deficiencies attached

Peter,

(b)(4) Deficiencies

Thanks.

Keith

From: Peter Nelson [mailto:petenelson@nostix.com]

Sent: Monday, September 21, 2015 4:58 PM

To: Marin, Keith

Cc: Chapman, Richard; K152261@docs.fda.gov; 'Charles Henry'; salusventures@aol.com

Subject: RE: additional questions -- (b)(4) Deficiencies attached

Keith,

(b)(4) Deficiencies

Thanks,

Peter

From: Marin, Keith [mailto:Keith.Marin@fda.hhs.gov]

Sent: Monday, September 21, 2015 9:05 AM

To: Peter Nelson

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2022-4717; Released by CDRH on 05-31-2024

Cc: Chapman, Richard; K152261@docs.fda.gov; 'Charles Henry';salusventures@aol.com

Subject: RE: additional questions -- (b)(4) Deficiencies attached

Importance: High

Peter,

(b)(4) Deficiencies

Keith

From: Peter Nelson [mailto:petenelson@nostix.com]

Sent: Friday, September 04, 2015 11:34 AM

To: Marin, Keith

Cc: Chapman, Richard; K152261@docs.fda.gov; 'Charles Henry';salusventures@aol.com

Subject: RE: additional questions -- (b)(4) Deficiencies attached

Keith,

(b)(4) Deficiencies

Thanks,

Peter

Peter Nelson

R&D Manager

Nostix

5541 Central Ave, Suite 170

Boulder, CO 80301

Ph: 303-245-8895 ext. 3#

Fax: 303-245-8909

From: Marin, Keith [mailto:Keith.Marin@fda.hhs.gov]

Sent: Thursday, September 03, 2015 9:39 AM

To: Peter Nelson

Cc: Chapman, Richard; K152261@docs.fda.gov

Subject: additional questions

Peter,

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2022-4717; Released by CDRH on 05-31-2024

(b)(4) Deficiencies

Thanks.

Keith

From: Peter Nelson [mailto:petenelson@nostix.com]

Sent: Monday, August 17, 2015 12:54 PM

To: Marin, Keith

Cc: K152261@docs.fda.gov; Chapman, Richard; 'Charles Henry';salusventures@aol.com

Subject: RE: (b)(4) Deficiencies -- attached

Keith,

(b)(4) Deficiencies

Thanks,

Peter

Peter Nelson

Director of Engineering

Nostix

5541 Central Ave, Suite 170

Boulder, CO 80301

Ph: 303-245-8895 ext. 3#

Fax: 303-245-8909

From: Marin, Keith [mailto:Keith.Marin@fda.hhs.gov]

Sent: Monday, August 17, 2015 10:01 AM

To: petenelson@nostix.com

Cc: K152261@docs.fda.gov; Chapman, Richard

Subject: (b)(4) Deficiencies

Mr. Nelson,

(b)(4) Deficiencies

Thanks.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Keith Marin

Keith Marin, RN, MS, MBA, OCN, RAC

Lieutenant Commander, United States Public Health Service

General Hospital Devices Combination Product Team Lead / Nurse Consultant

FDA/CDRH/ODE/DAGRID/GHDB

10903 New Hampshire Avenue, WO66-2567

Silver Spring, MD, 20993-0002

Telephone: (301) 796-2462, Fax: (301) 847-8109

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2022-4717; Released by CDRH on 05-31-2024

Keith,

(b)(4) Deficiencies

Thanks,
Peter

Peter Nelson
Director of Engineering
Nostix
5541 Central Ave, Suite 170
Boulder, CO 80301
Ph: 303-245-8895 ext. 3#
Fax: 303-245-8909

From: Marin, Keith [mailto:Keith.Marin@fda.hhs.gov]
Sent: Monday, August 17, 2015 10:01 AM
To: petenelson@nostix.com
Cc: K152261@docs.fda.gov; Chapman, Richard
Subject (b)(4) Deficiencies

Mr. Nelson,

(b)(4) Deficiencies

Thanks.

Keith Marin

Keith Marin, RN, MS, MBA, OCN, RAC
Lieutenant Commander, United States Public Health Service
General Hospital Devices Combination Product Team Lead / Nurse Consultant
FDA/CDRH/ODE/DAGRID/GHDB
10903 New Hampshire Avenue, WO66-2567
Silver Spring, MD, 20993-0002
Telephone: (301) 796-2462, Fax: (301) 847-8109

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118