GAVeCeLT
Gli Accessi Venosi Centrali a Lungo Termine

Il punto sulla tip navigation: quale è la strategia più costo-efficace?

Mauro Pittiruti

Tip navigation

‘tip navigation’ methods

Methods which may be used during the procedure to help the operator in directing the guidewire and/or the catheter in the right direction.

They do not replace ‘tip location’ methods

Still, they may be useful to reduce the risk of primary malpositions when intra-procedural ‘tip location’ methods are not used.

‘tip navigation’ methods

Visual methods

- **direct**
  - ultrasound
  - fluoroscopy
  - Navigator (Corpak)
- **indirect (projection)**
  - Sherlock (Bard)

Non-visual methods

- **doppler-based** – VPS (Teleflex)
- **pressure-based** – Catfinder (Elcam)
- **ECG-based** – Delta (Romedex)

‘tip navigation’ – visual methods

They provide information about the presumed position of the catheter tip during its trajectory

They help us to identify the ‘wrong’ direction of the tip

- in the ipsilateral internal jugular vein

- in the controlateral veins (brachio-cephalic, subclavian, jugular)

‘tip navigation’ – visual methods

Visual methods

direct (localization)

- ultrasound
- fluoroscopy
- Navigator (Corpak)

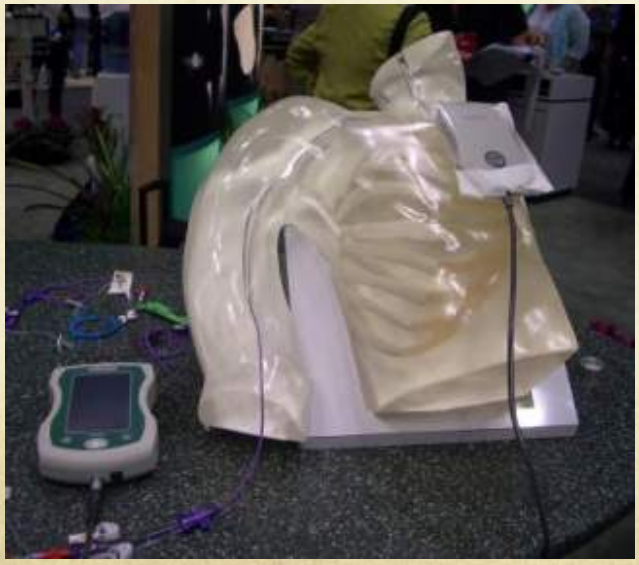
indirect (projection)

- Sherlock (Bard)

Visual methods for tip navigation

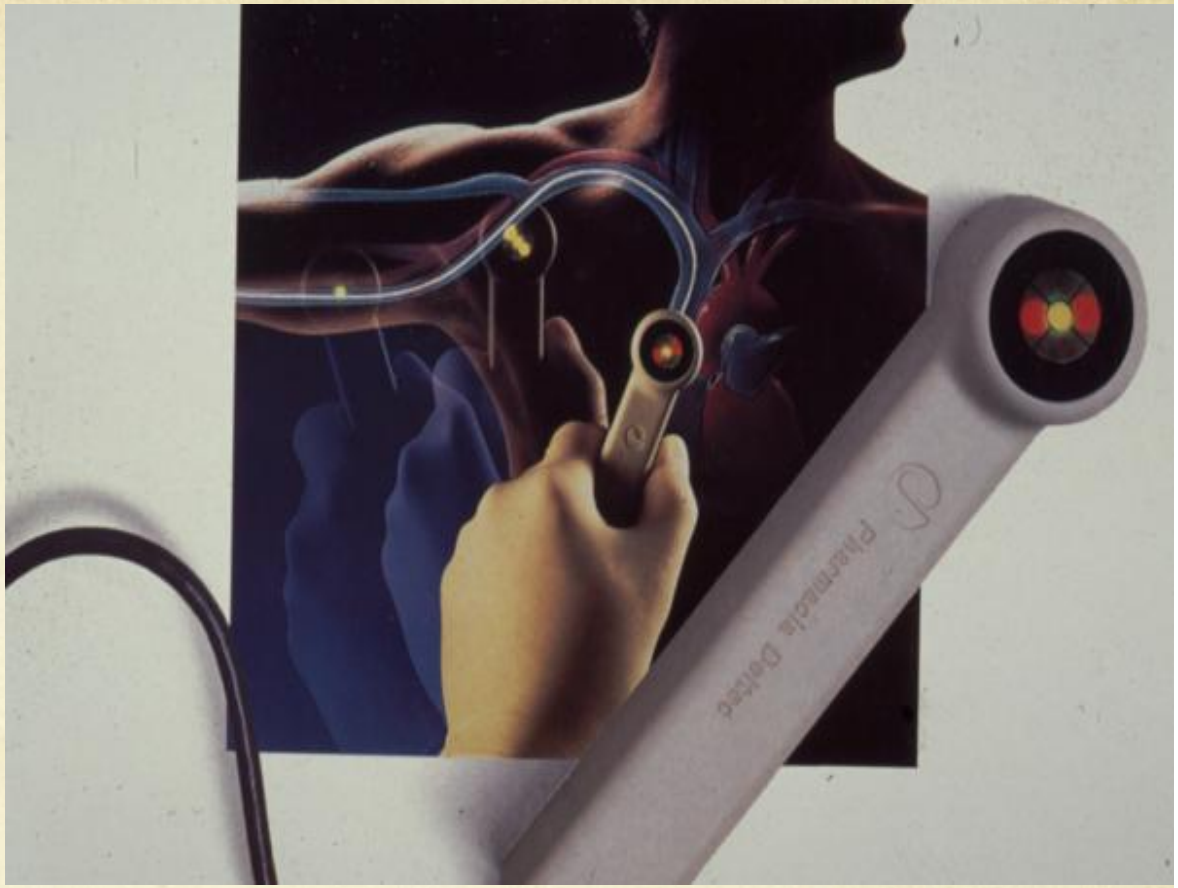
Navigator

Cathfinder



Sherlock

Cath-Finder
(Pharmacia, 1993)

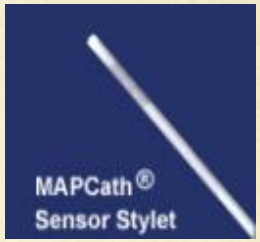


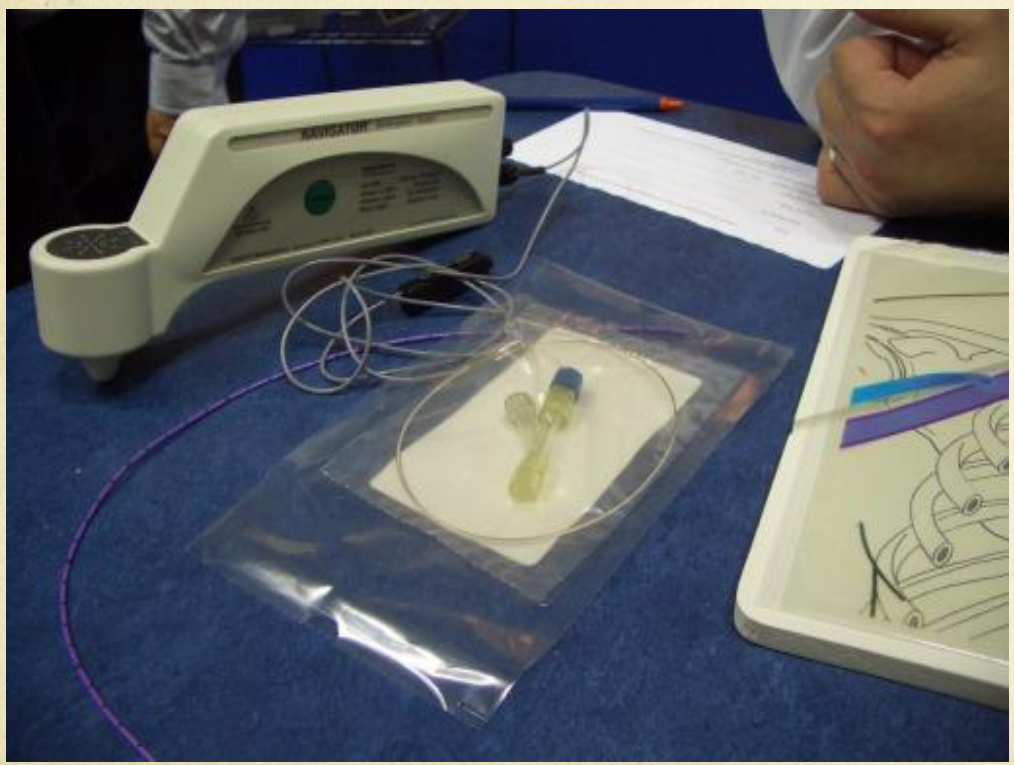
Magnetic stylet in the catheter

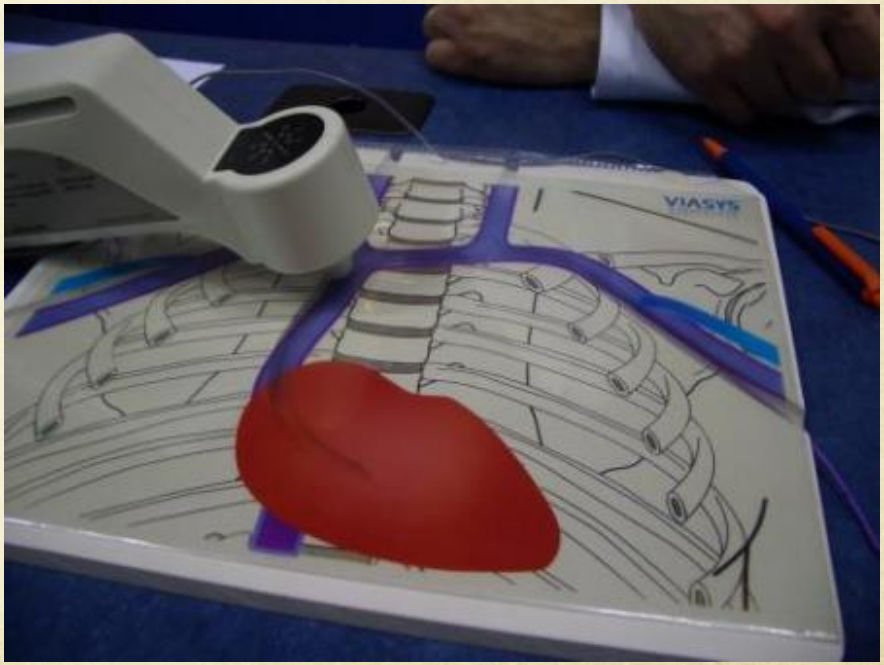
Detector and monitor integrated in a single hand-held device

Plastic disposable stylet with a magnetic tip

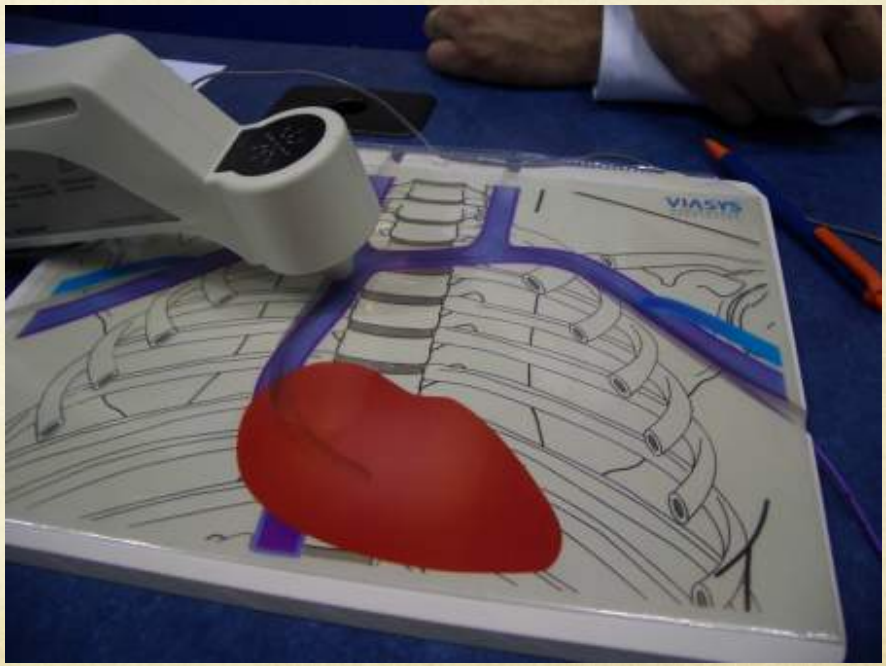
Navigator (Corpak)





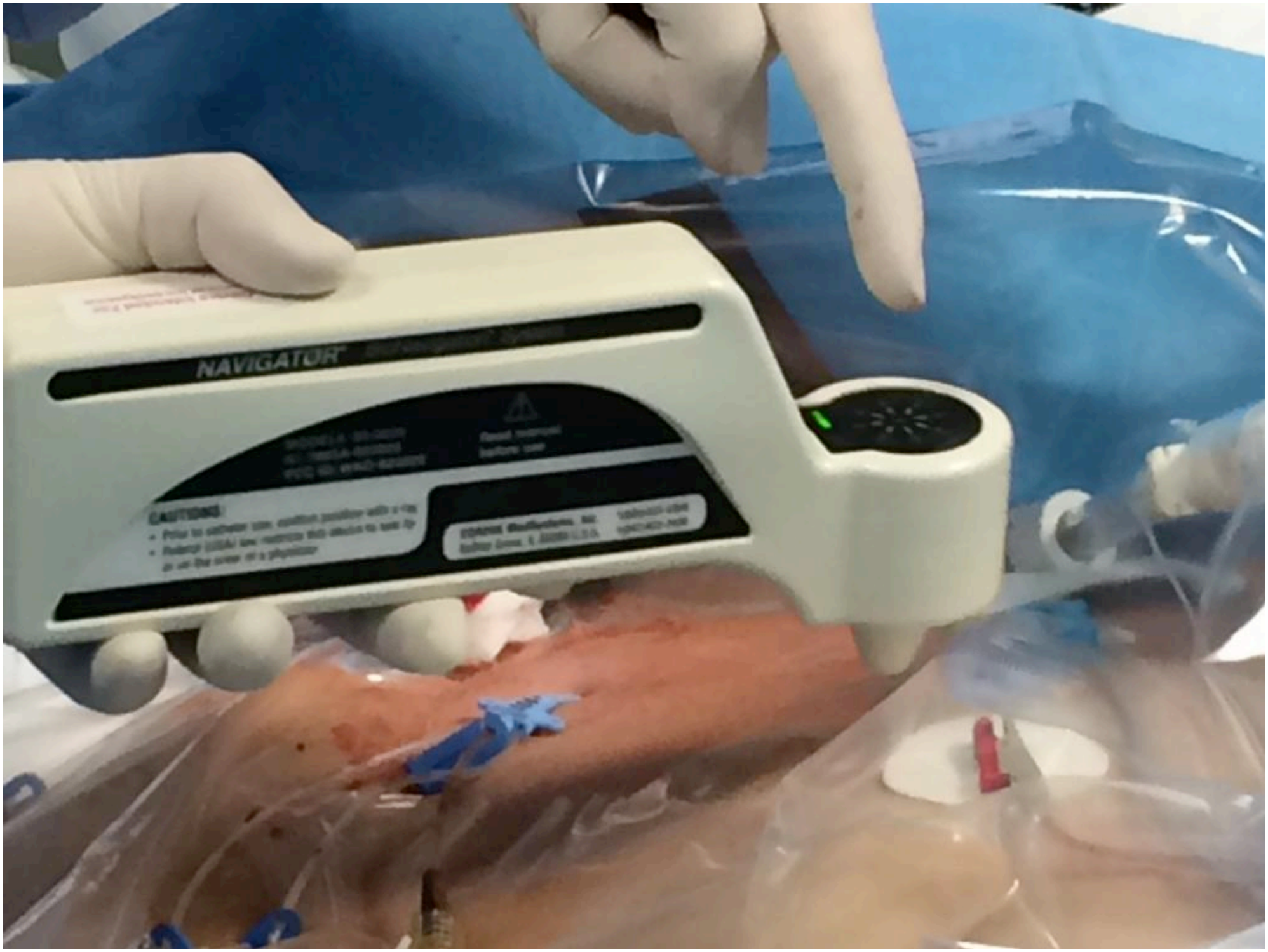


Navigator



Naylor, JAVA 2007

Viasys/CORPAK MedSystems, Inc.

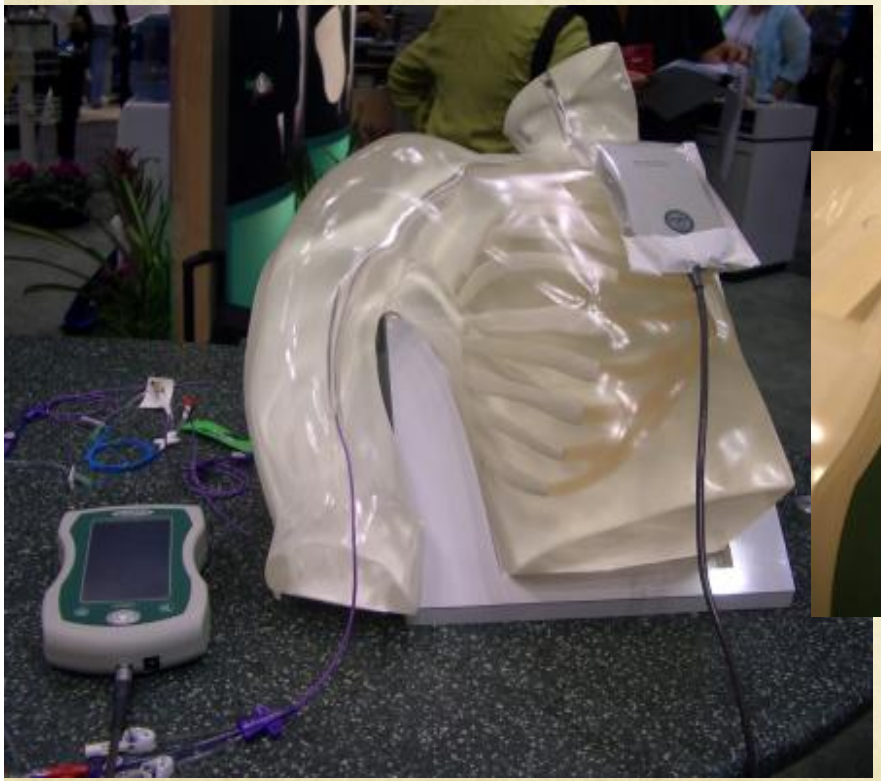

NAVIGATOR

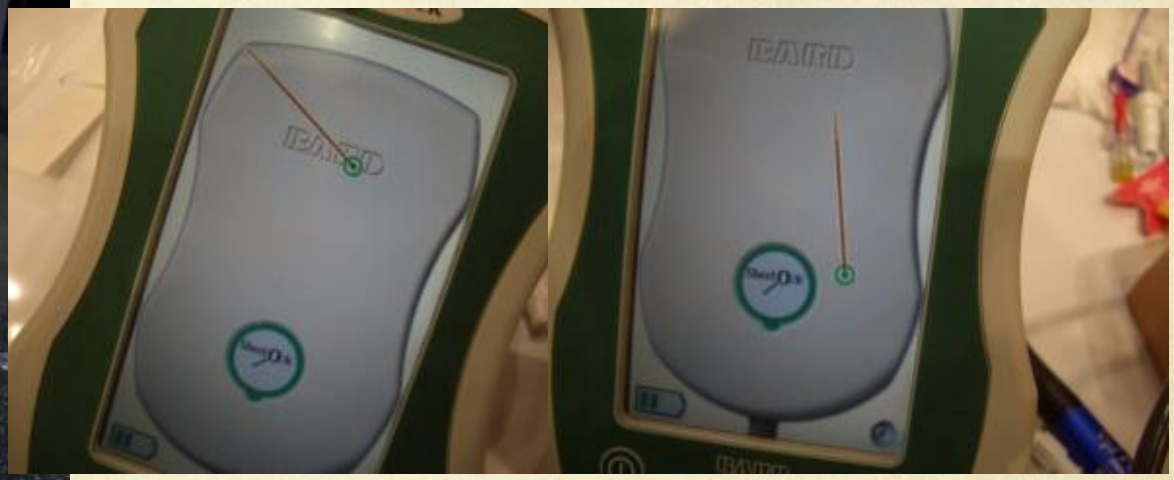

NAVIGATOR
CAUTIONS:

Magnetic "Tracking"

Sherlock (Bard)

Magnetic stylet



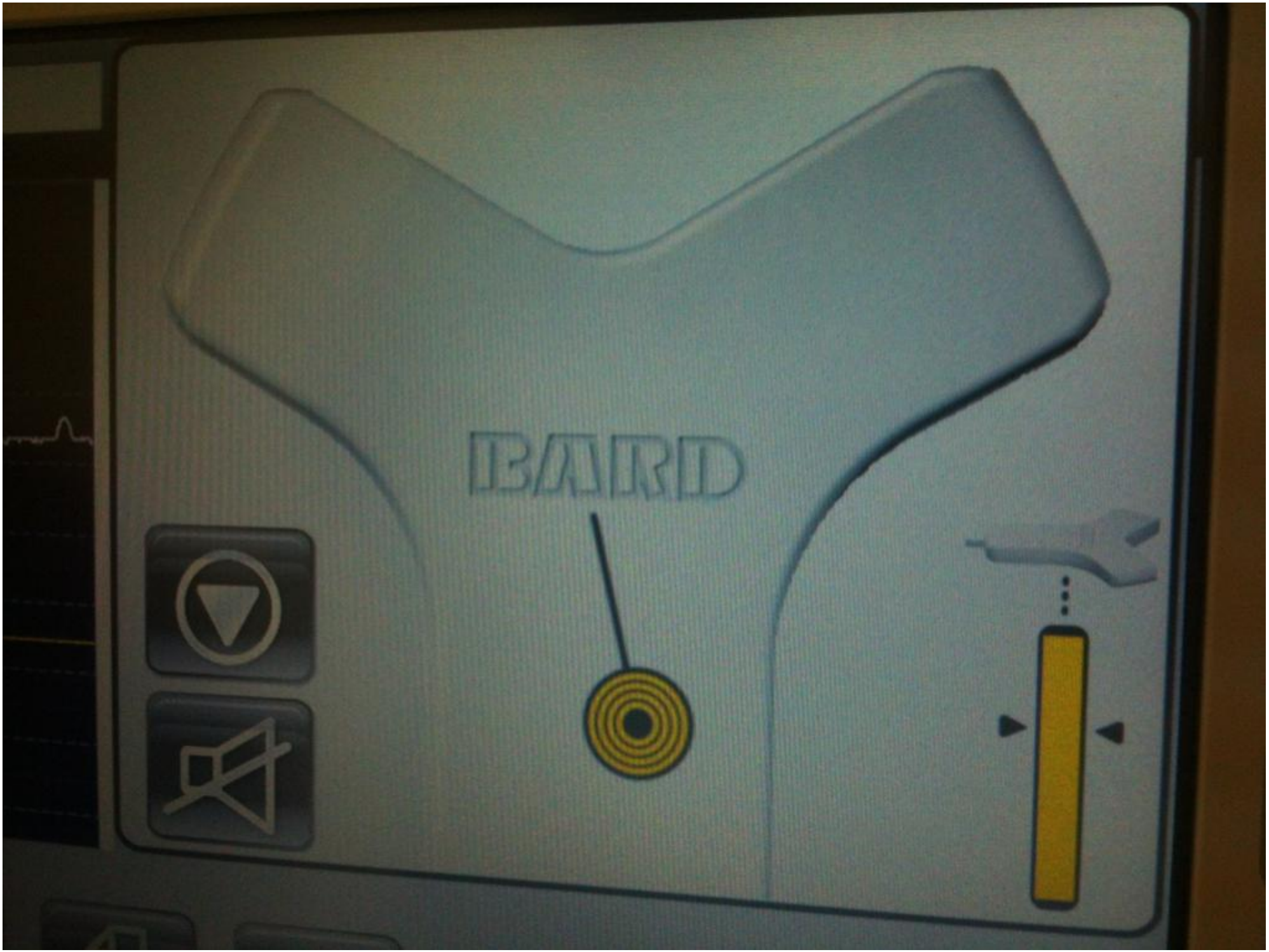


hands-free monitor

BARD - Sherlock II Tip Location System

Sherlock* II TLS Sensor

The sensor detects magnetic fields generated by the Sherlock* stylet. The Sherlock* II TLS sensor is placed as high up on the chest as possible, right at the base of the neck or as recommended by facility protocols. ***An external measurement can never exactly duplicate the internal venous anatomy.***


BARD

2013

Clin Imaging. 2013 Sep-Oct;37(5):917-21. doi: 10.1016/j.clinimag.2013.04.009. Epub 2013 Jul 15.

Analysis of the Sherlock II tip location system for inserting peripherally inserted central venous catheters.

Lelkes V[1], Kumar A, Shukla PA, Contractor S, Rutan T.

⊕ Author information

Abstract

Peripherally inserted central catheters (PICCs) are frequently placed at the bedside. The purpose of our study was to evaluate the efficacy of the Sherlock II tip location system (Bard Access Systems, Salt Lake City, UT), which offers electromagnetic detection of the PICC tip to assist the operator in guiding the tip to a desired location. We performed a retrospective review of patients who had a bedside PICC using the Sherlock II tip location system. Three hundred seventy-five of 384 patients (97.7%) had the catheter tip positioned appropriately. Our results suggest that the Sherlock II tip location system is an efficacious system for bedside PICC placement.

Published by Elsevier Inc.

Clin Imaging. 2013 Sep-Oct;37(5):917-21. doi: 10.1016/j.clinimag.2013.04.009. Epub 2013 Jul 15.

Analysis of the Sherlock II tip location system for inserting peripherally inserted central venous catheters.

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Epub 2013 Jul 15.

Analysis of the Sherlock II tip location system for inserting peripherally inserted central venous catheters.

Lelkes V, Kumar A, Shukla PA, Contractor S, Rutan T.

University of Medicine and Dentistry of New Jersey, Newark, NJ 07101, USA.

IT IS NOT 'TIP LOCATION'.....!

LumenVue

LumenVue

Founders – Greg Schears, MD (Mayo Clinic) and David Wilson, PhD (U Penn)

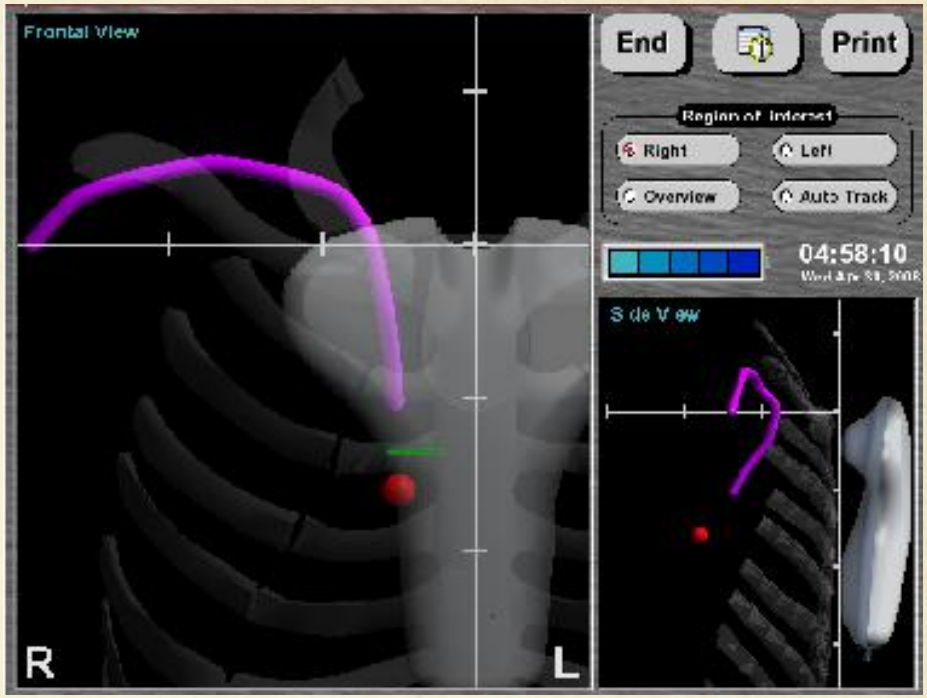
Technology uses near-infrared, optical fiber combined with a guidewire, and a camera that detects and displays the light

SonoSite acquired LumenVu – July 2007


Invetech
micronix
micronix

Micronix/MedComp

In fase sperimentale
Abbandonato



CathRite™

A key point of difference with the Micronix technology is that the "transmitter" is placed in the catheter tip and the "receiver" is outside of the body.

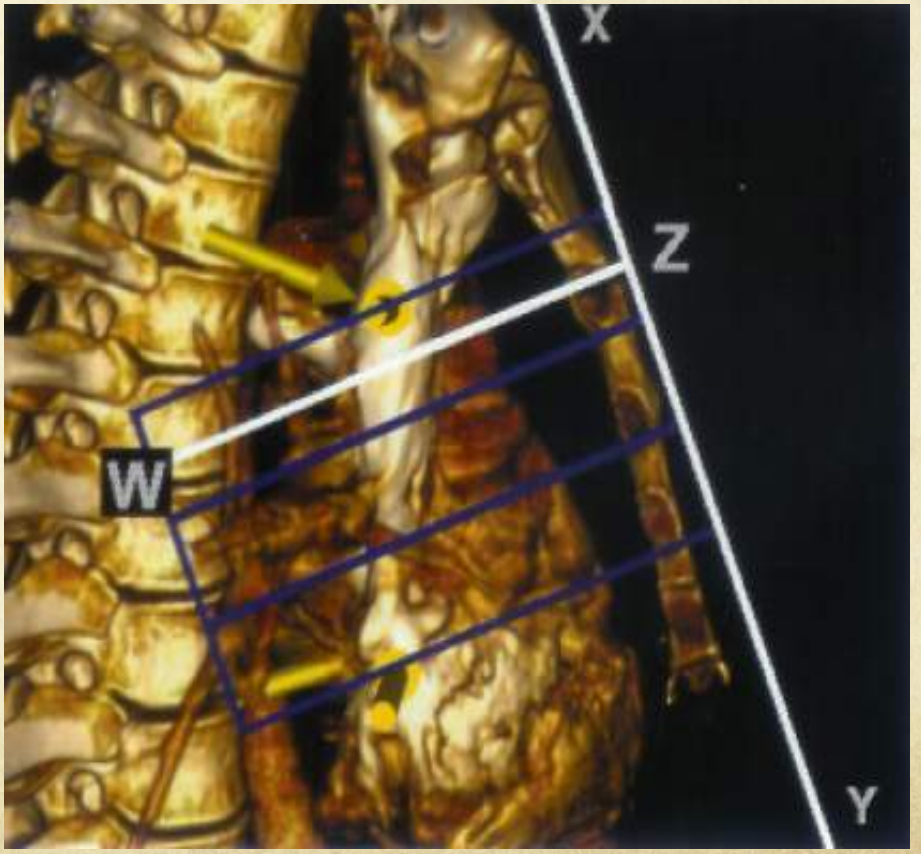
Visual methods for tip navigation

- Imprecise (projection of the position of the tip on the skin surface)

A Study of the Relationship of the Superior Vena Cava to the Bony Landmarks of the Sternum in the Supine Adult: Implications for Magnetic Guidance Systems

Antonia A. Claasz, BSc (Hons), PhD, and Don P. Chorley

JAVA | Vol 12 No 3 | 2007



‘tip navigation’ – non-visual methods

They tell us whether the tip is directed in the right direction (following blood flow) or in the wrong direction (against blood flow)

doppler-based – VPS (Teleflex)

pressure-based – Catfinder (Elcam)

ECG-based – Delta (Romedex)

ALL INTEGRATED WITH TIP LOCATION

Conductance guidewire (CGW)

J Vasc Surg Venous Lymphat Disord. 2013 Apr;1(2):202-208.e1. doi: 10.1016/j.jvsv.2012.10.065. Epub 2013 Mar 14.

Accurate nonfluoroscopic guidance and tip location of peripherally inserted central catheters using a conductance guidewire system.

Svendsen MC[1], Birrer D[1], Jansen B[1], Teague SD[2], Combs B[1], Schears GJ[3], Kassab GS[4].

⊕ **Author information**

Abstract

BACKGROUND: Bedside placement of peripherally inserted central catheters (PICCs) may result in navigation to undesirable locations, such as the contralateral innominate or jugular vein, instead of the superior vena cava or right atrium. Although some guidance and tip location tools exist, they have inherent limitations because of reliance on physiological measures (eg, chest landmarks, electrocardiogram, etc), instead of anatomical assessment (ie, geometric changes in the vasculature). In this study, an accurate, anatomically based, non-X-ray guidance tool placed on a novel 0.035" conductance guidewire (CGW) is validated for PICC navigation and tip location.

METHODS: The CGW system uses electrical conductance recordings to assess changes in vessel cross-sectional area to guide navigation of the PICC tip. Conductance rises and oscillates when going in the correct direction to the superior vena cava/right atrium, but drops when going in the incorrect direction away from the heart. Bench and in vivo studies in six swine were used to confirm the accuracy and repeatability of the PICC placement at various anatomical locations. The PICC tip location was confirmed by direct visualization vs the desired location.

RESULTS: CGW PICC guidance was highly accurate and repeatable with virtually no difference between actual and desired catheter tip location. The difference between the CGW PICC location vs the desired target was -0.07 ± 0.07 cm (6.6% error) on the bench and 0.04 ± 0.10 cm (5% error) in vivo. No complications or adverse events occurred during CGW usage.

CONCLUSIONS: The CGW provides an anatomically based, reproducible, and clinically significant method for PICC navigation and tip location that can improve accuracy, decrease the wait time prior to therapy delivery, decrease cost, and minimize the need for X-ray. These findings warrant clinical evaluation of this navigation tool for PICC line placement.

Fluoroscopy for tip navigation

Fluoroscopy ?

- You should not use fluoroscopy for tip navigation (or tip location)
  - Is not safe
  - Is not accurate
  - Is not cost-effective

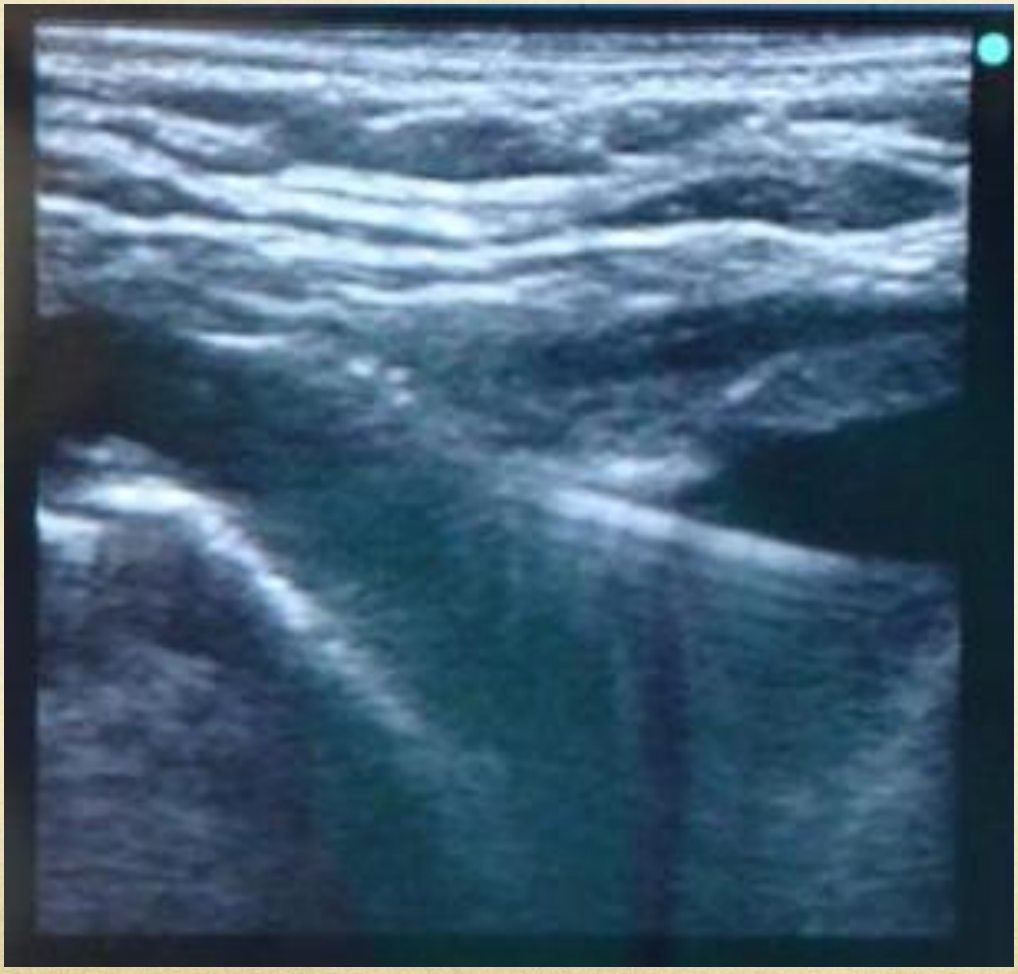
See recommendations of AHRQ 2013, INS 2016, etc.

Ultrasound for tip navigation

Ultrasound detection of guidewire position during central venous catheterization

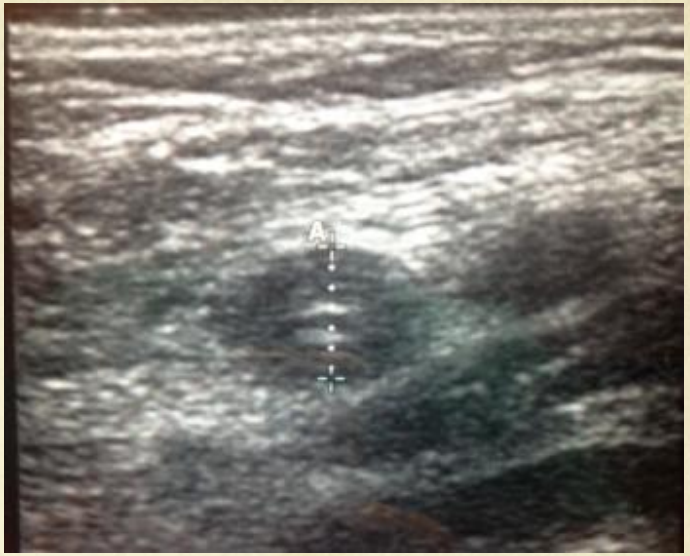
Michael B. Stone MD, RDMS[a,*], Arun Nagdev MD[b], Michael C. Murphy MD[b], Craig A. Sisson MD[b]

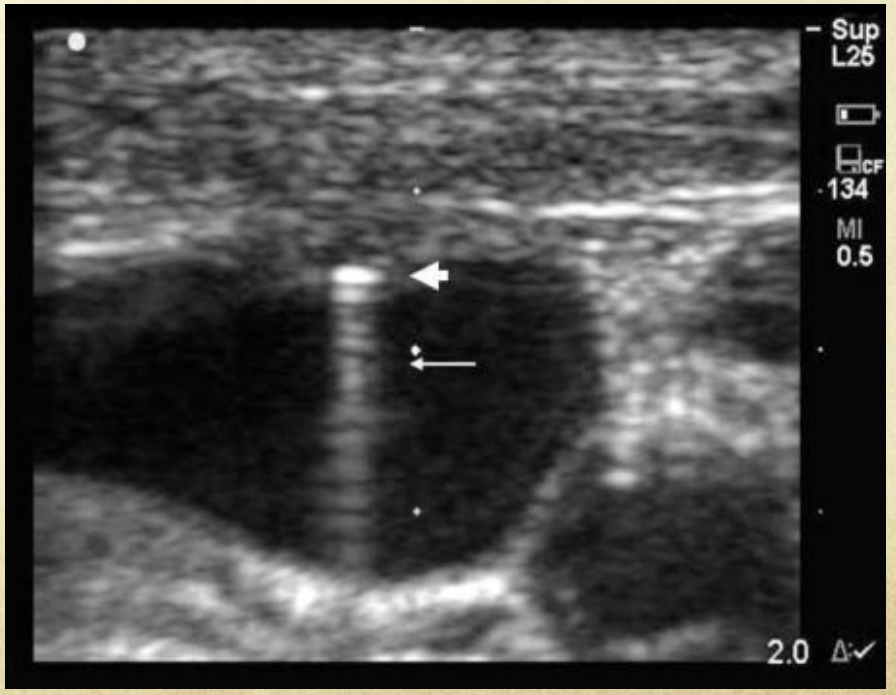
The American Journal of Emergency Medicine



Ultrasound for tip navigation

Negative Assessment

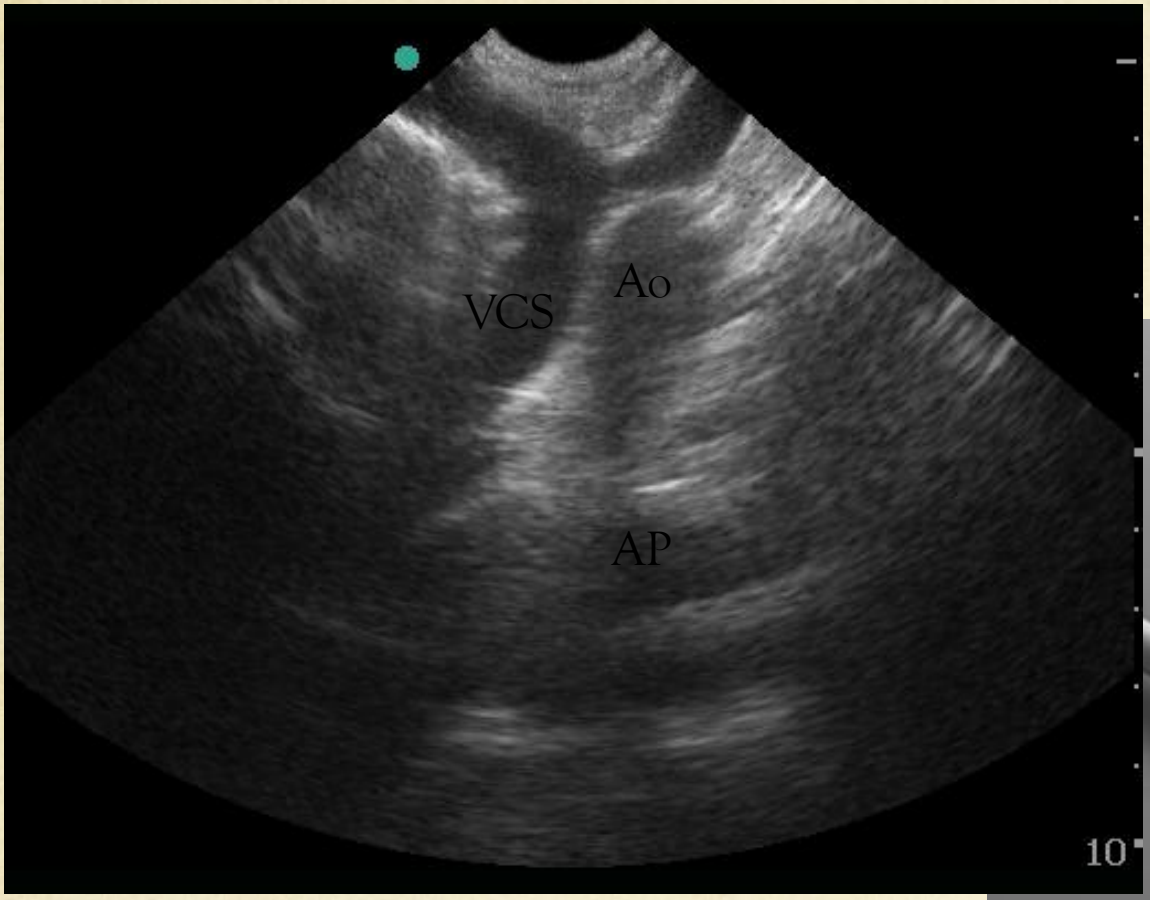


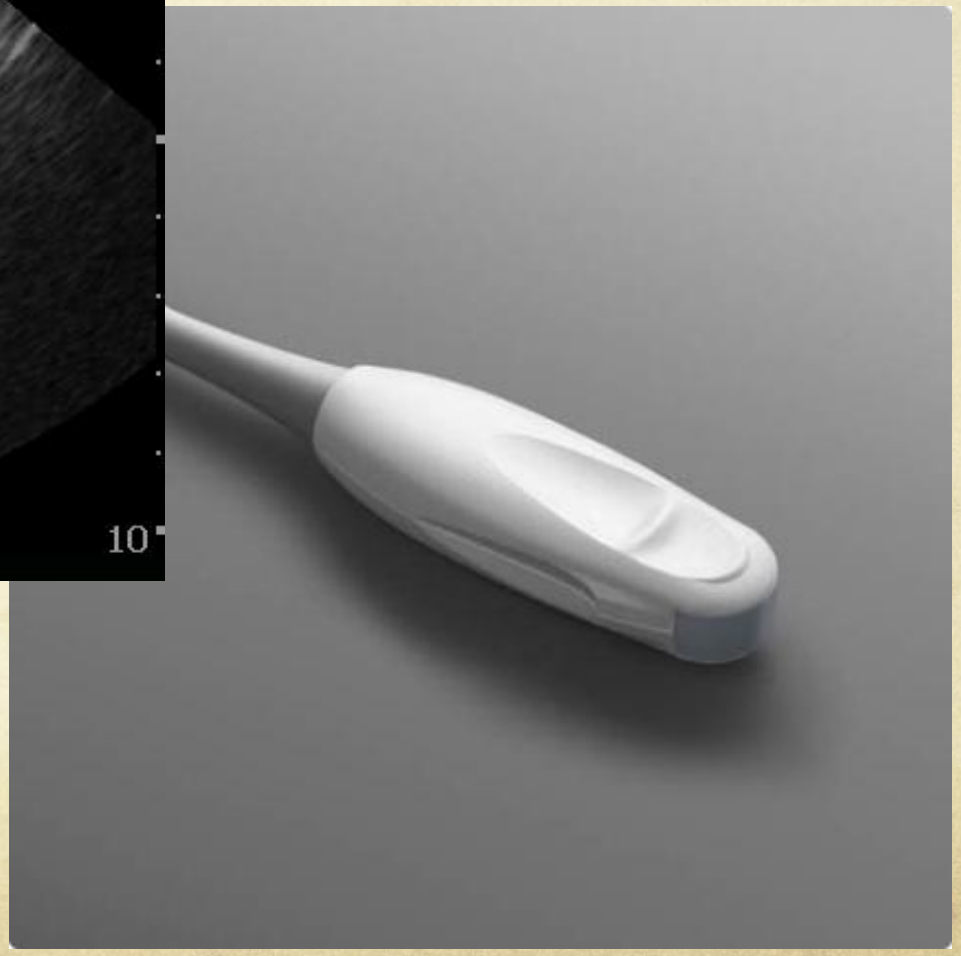


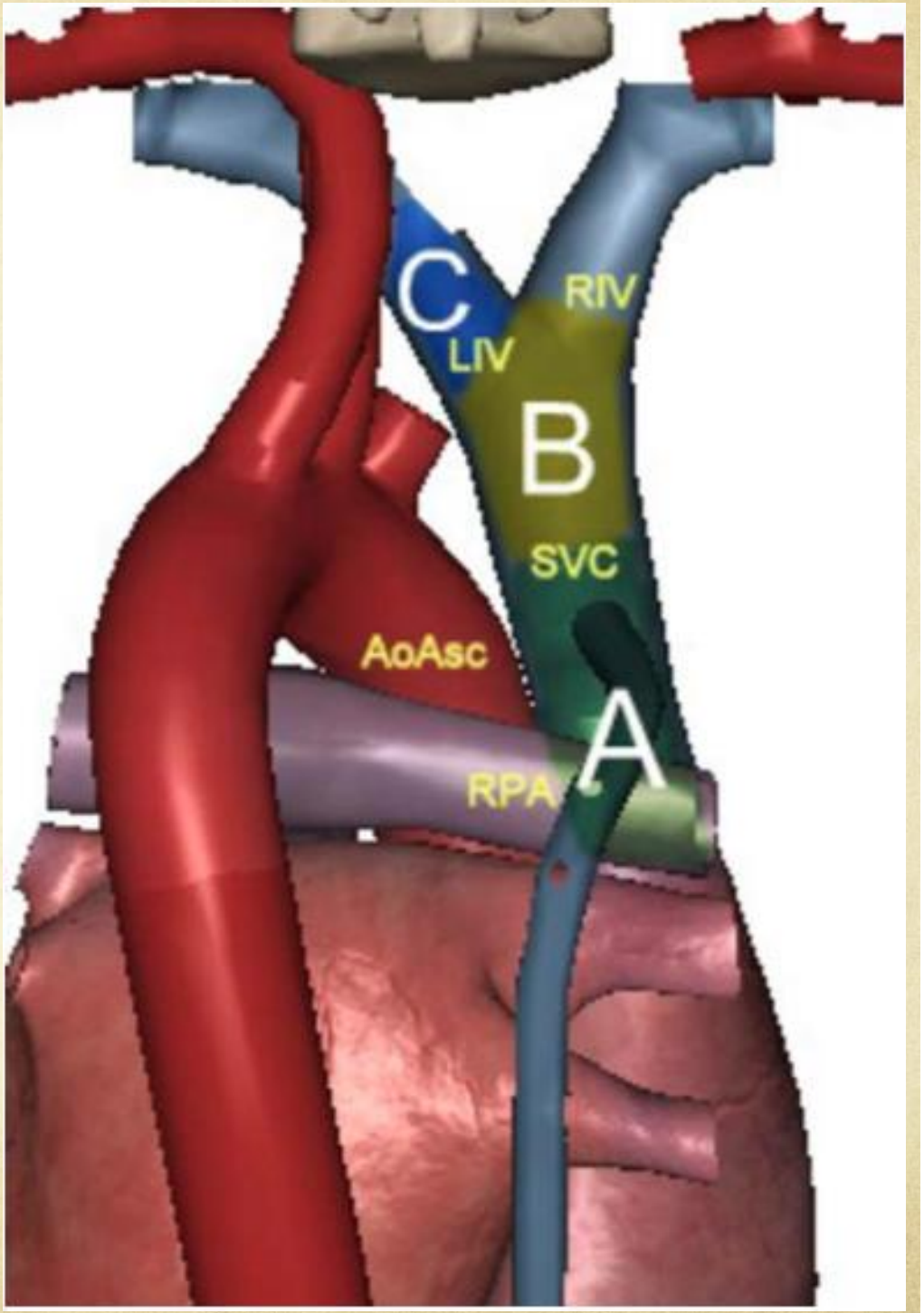
Catheter


A

Microconvex Probe



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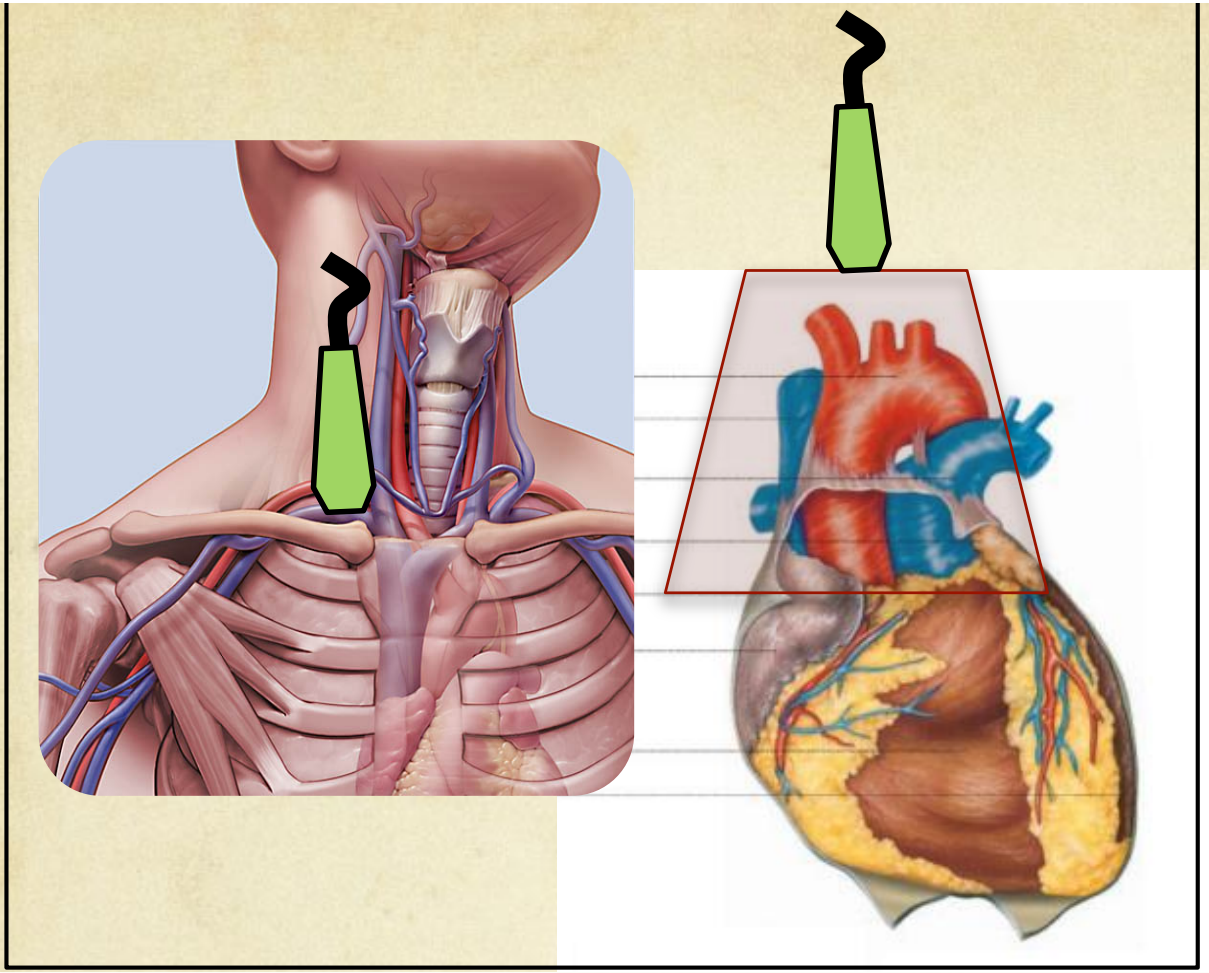

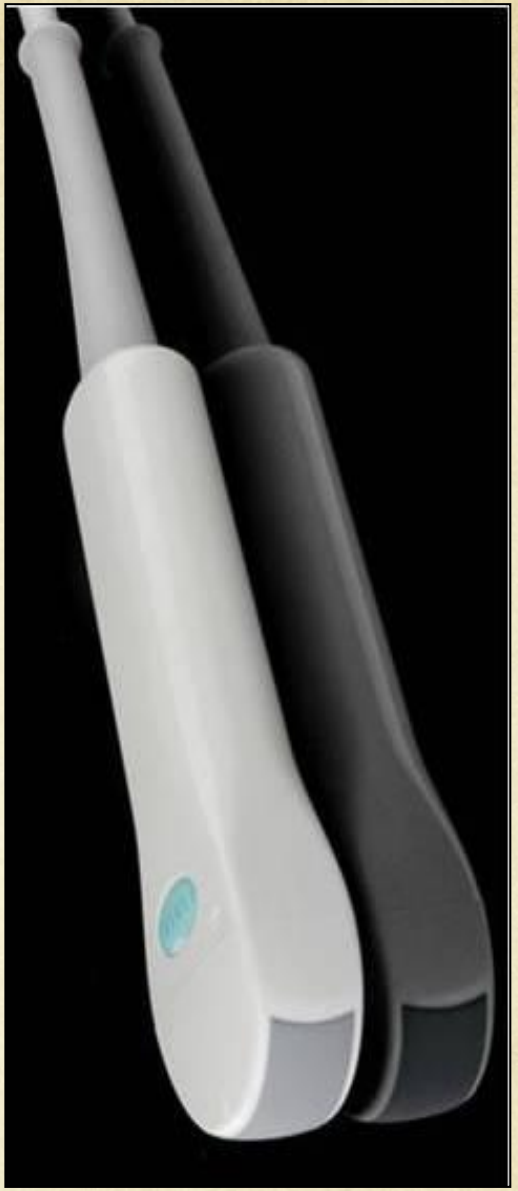

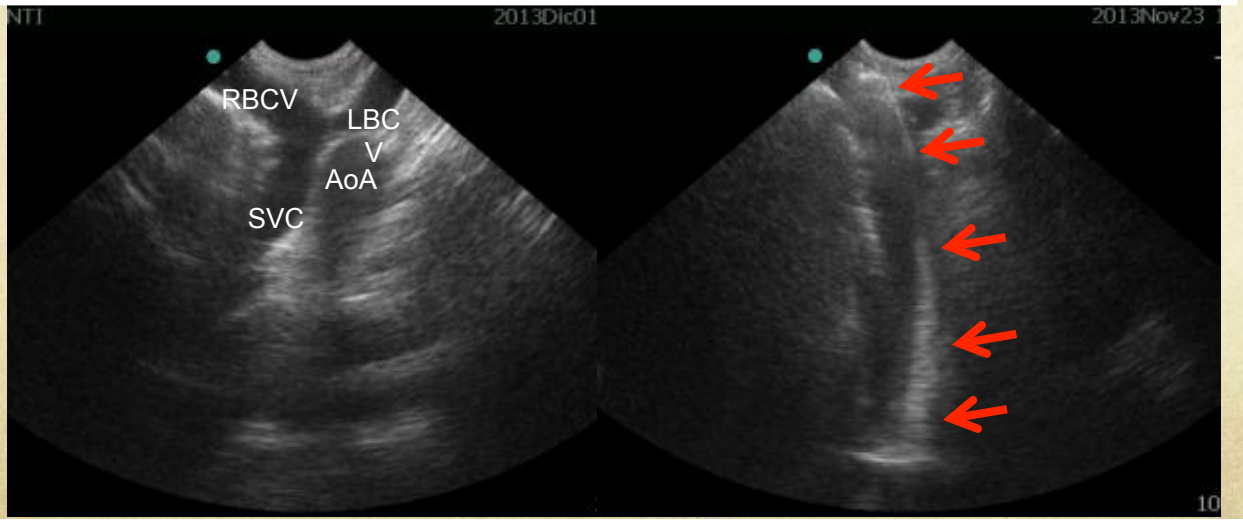
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Salva
Stampa
Annota
Opzioni
Esame
Paziente

ULTRASOUND

Many published studies

Different US methods have been validated for both tip location and tip navigation

Cost-effective – but requires training

Advantages of ultrasound

- No additional cost
- Completely safe
- Very accurate, particularly in pediatric patients and in skinny patients
- It can be used for ‘redirecting’ the catheter or the guidewire in the right direction

The best system for ‘redirecting’

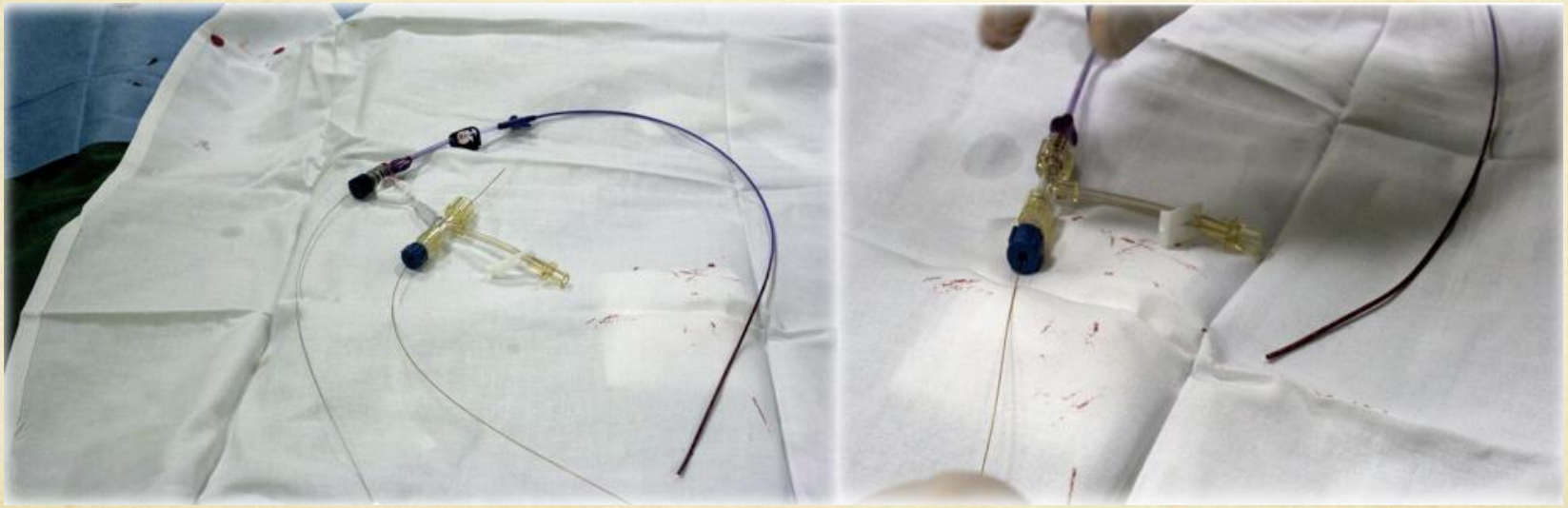
The best system for ‘redirecting’

‘Navigator’ for tip navigation

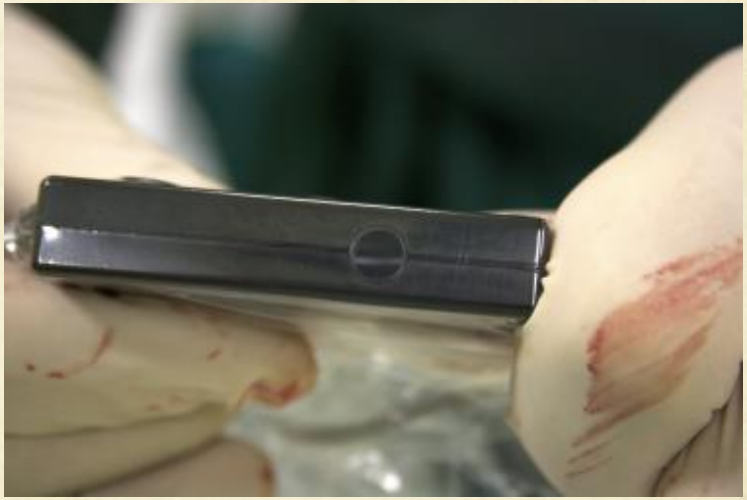
- In 30 PICC insertions, we adopted Navigator (Corpak) for tip navigation and IC-ECG for tip location (performed using Nautilus, Romedex). The Navigator device consists of a sterile stylet (diameter 1.1 Fr, length 106 cm) placed inside the catheter so that the tip of the stylet is at 1 mm from the tip. During insertion, the tip of the catheter can be followed and detected by an electromagnetic device. Also, the system tells whether the tip is pointing in the right direction or not.

The Navigator is wrapped in a sterile cover for US probes

The stylet of the PICC is removed and replaced by the stylet of the Navigator



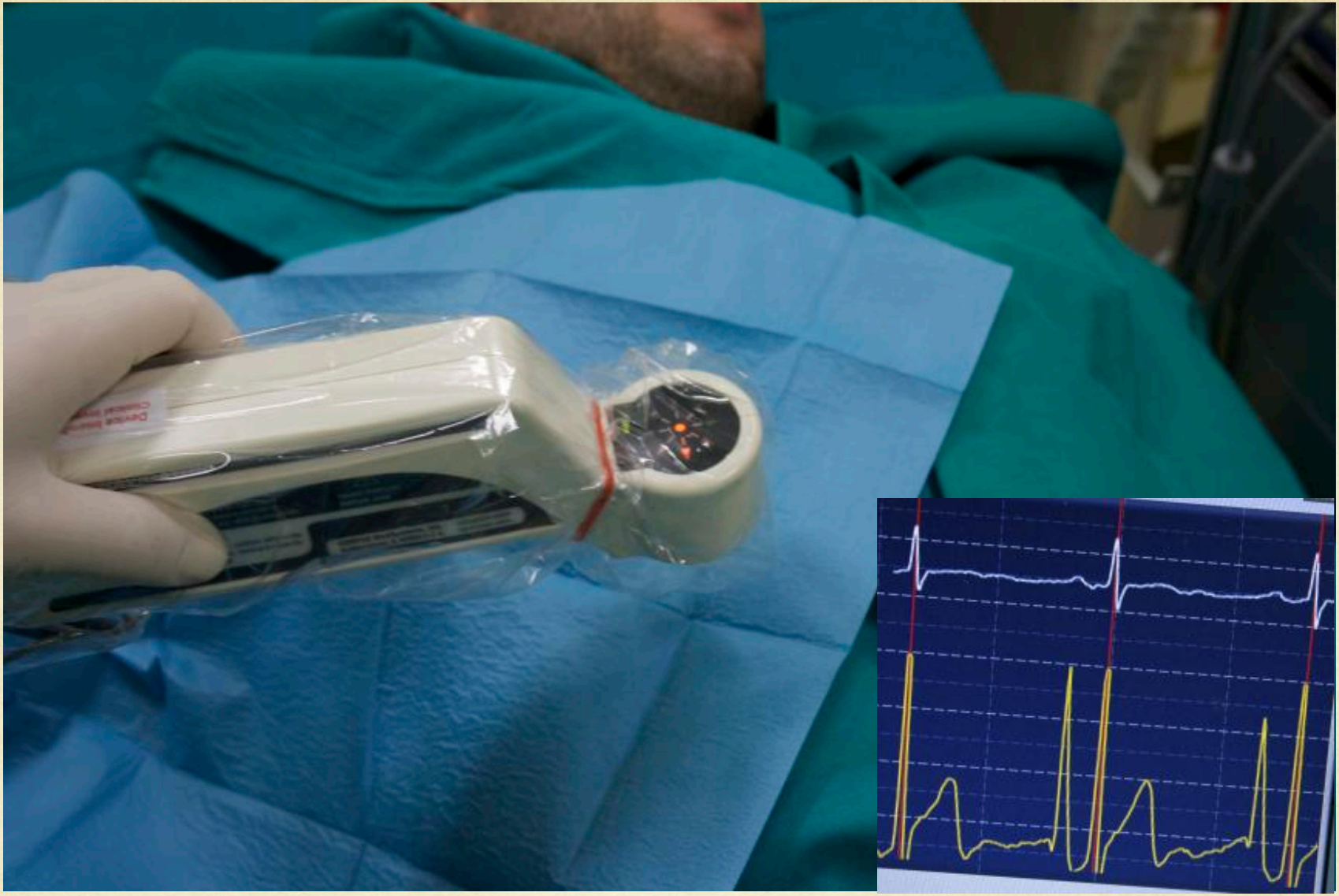
The cable of the Navigator stylet is inserted into a connecting device wrapped in the sterile cover



In all patients, the tip location verified by IC-ECG corresponded to the electromagnetic detection of the tip below the third intercostal space, with the tip pointing downward. In 3 cases, the Navigator detected that the tip had accidentally entered the ispilateral internal jugular vein and allowed us to correct its direction. In 2 cases, IC-ECG was not confirming the correct tip location, though the PICC had been threaded for the estimated length: the Navigator detected the tip of the catheter in the contralateral brachio-cephalic vein, pointing to the contralateral clavicle: this allowed to correct its direction.

Tip in ipsilateral IJV

Tip in controlateral BCV



Tip at the cavo-atrial junction

Navigator

The tip navigation system we tested – associated with IC-ECG - was clinically effective and easy to use. The Navigator has several advantages if compared to other navigation systems: (a) it can be utilized with any type of central VAD; (b) it tells both the approximated location of the tip below the thoracic cage and its direction; (c) it is highly cost-effective, since it may be used only if required (i.e., when difficulties can be anticipated and/or when they occur during the procedure).

NAVIGATOR

Abstracts in international conferences

No published studies

Cost- effective and accurate

Advantages of Navigator

- Easy to use
- It can be used with any central line
- Expensive, but cost-effective since it can be used only when some difficulty is anticipated or experienced
- It can be seen as a ‘surrogate’ tip location method in AF
- It gives ‘location’ and ‘direction’ of the tip

Though…

No **tip navigation** method has any sense today if it is not coupled with a **tip location** method

Tip navigation + tip location

1) IC-ECG with a standard or dedicated ECG monitor + tip navigation by ultrasound

2) IC-ECG with a standard or dedicated ECG monitor + tip navigation by Navigator

3) Integrated methods (in the same device)

Integrated methods

Visual indirect methods (Sherlock) and **non-visual** methods (doppler, pressure or ECG-based) for *tip navigation* are currently coupled/integrated with *tip location* methods.

Integrated Methods (navigation + location)

Sherlock 3CG (Bard)

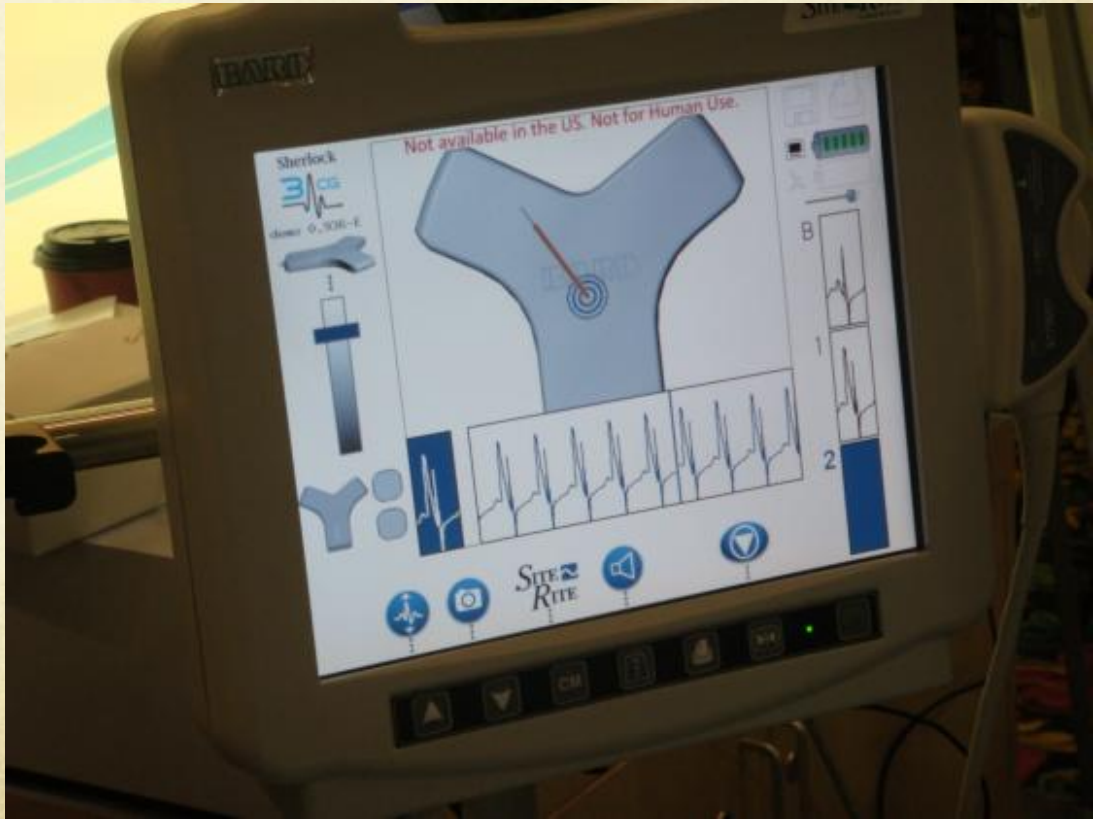
Vasonova VPS (Teleflex)

Catfinder (Elcam)

Delta (Romedex)

Sherlock 3CG (Bard)

Sherlock + Sapiens = Sherlock 3CG



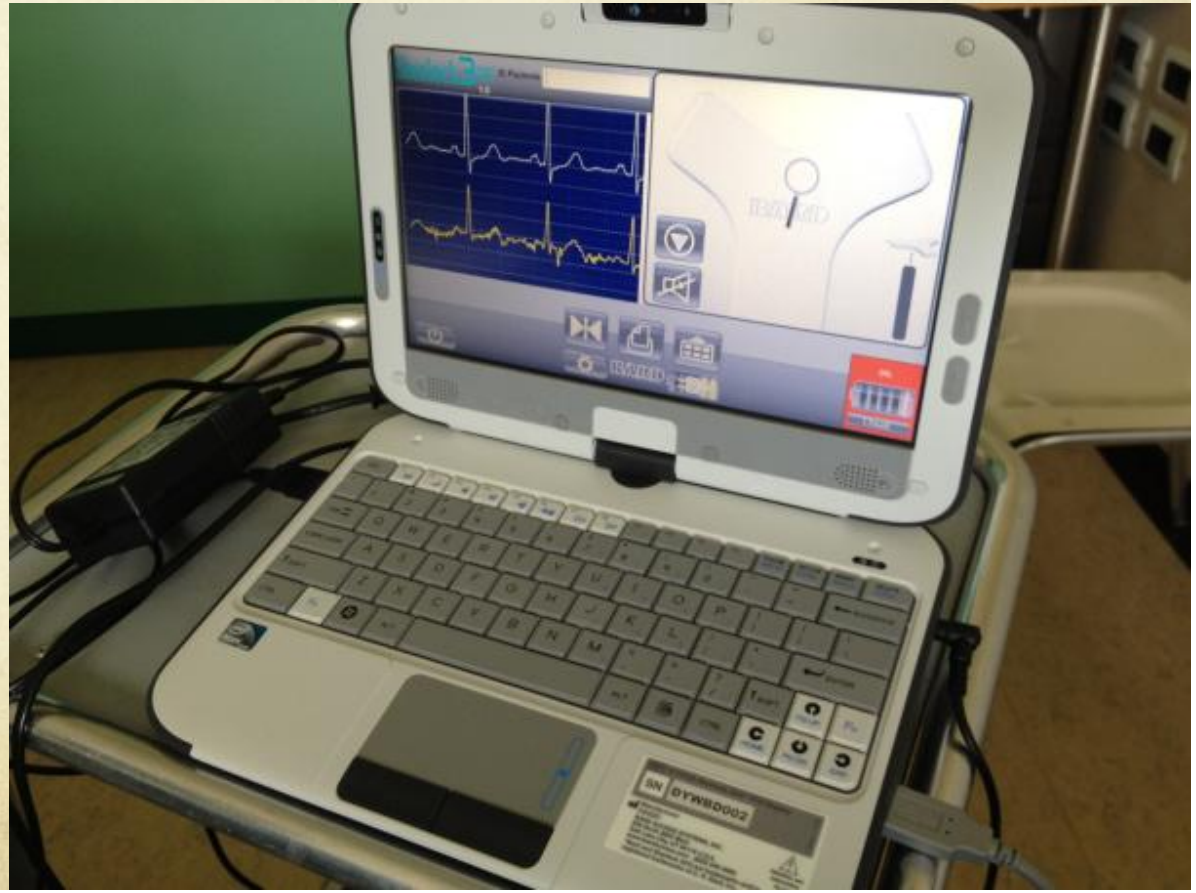

BAIRD
BAIRD


BAIRD
BAIRD


Patient ID
Exit Site Marking
BARD


BARD


Warning
Do Not cut tube



Sherlock 3CG

Many abstracts in international conferences

A few published paper on peer-reviewed journals (as from Pub Med)

Anaesthesia. 2014 Dec;69(12):1322-30. doi: 10.1111/anae.12785. Epub 2014 Jul 10.

Evaluation of the Sherlock 3CG Tip Confirmation System on peripherally inserted central catheter malposition rates.

Johnston AJ[1], Holder A, Bishop SM, See TC, Streater CT.

Anaesthesia. 2014 Jul 10. doi: 10.1111/anae.12785. [Epub ahead of print]

Evaluation of the Sherlock 3CG Tip Confirmation System on peripherally inserted central catheter malposition rates.

Johnston AJ, Holder A, Bishop SM, See TC, Streater CT.
John Farman Intensive Care Unit, Addenbrooke's Hospital, Cambridge University
Hospitals NHS Foundation Trust, Cambridge, UK.

20.5% malposition (?????)

Unacceptable study ?

2014

Anaesthesia. 2014 Dec;69(12):1322-30. doi: 10.1111/anae.12785. Epub 2014 Jul 10.

Evaluation of the Sherlock 3CG Tip Confirmation System on peripherally inserted central catheter malposition rates.

Johnston AJ[1], Holder A, Bishop SM, See TC, Streater CT.

⊕ Author information

Abstract

Peripherally inserted central catheters are often positioned blindly in the central circulation, and this may result in high malposition rates, especially in critically ill patients. Recently, a new technology has been introduced (Sherlock 3CG Tip Positioning System) that uses an electro-magnetic system to guide positioning in the superior vena cava, and then intra-cavity ECG to guide positioning at the cavo-atrial junction. In this observational study, we investigated how the Sherlock 3CG Tip Positioning System would affect peripherally inserted central catheter malposition rates, defined using a post-insertion chest radiograph, in critically ill patients. A total of 239 catheters positioned using the Sherlock 3CG Tip Positioning System were analysed. When an adequate position was defined as low superior vena cava or cavo-atrial junction, 134 catheters (56.1%; 95% CI 50-62%) were malpositioned. When an adequate position was defined as mid/low superior vena cava, cavo-atrial junction or high right atrium (≤ 2 cm from cavo-atrial junction), 49 (20.5%; 95% CI 16-26%) catheters were malpositioned. These malposition rates are significantly lower than our own historical data, which used a 'blind' anthropometric technique to guide peripherally inserted central catheter insertion.

NO EVIDENCE THAT IC-ECG BY SHERLOCK 3CG IS ANY BETTER THAN IC-ECG BY ANY OTHER MONITOR !!!

NO EVIDENCE THAT ECG-BASED TIP LOCATION + TIP NAVIGATION IS ANY BETTER THAN ECG BASED TIP LOCATION ALONE !!

More recently… 2015

Value Health. 2015 Nov;18(7):A369. doi: 10.1016/j.jval.2015.09.743. Epub 2015 Oct 20.

Modelled U.K. And U.S. Analyses Demonstrate Sherlock 3cg® Tip Confirmation System For Peripherally Inserted Central Catheter Placement Is Associated With Favourable Health Economic Outcomes.

Pswarayi C[1], Kara R[2], Hollmann S[3], Ferko N[3], Dawson D[1], Delatore P[4].

Appl Health Econ Health Policy. 2015 Aug 21. [Epub ahead of print]

Sherlock 3CG® Tip Confirmation System for Placement of Peripherally Inserted Central Catheters: A NICE Medical Technology Guidance.

Dale M[1], Higgins A, Carolan-Rees G.

NO EVIDENCE THAT IC-ECG BY SHERLOCK 3CG IS ANY BETTER THAN IC-ECG BY ANY OTHER MONITOR !!!

NO EVIDENCE THAT ECG-BASED TIP LOCATION + TIP NAVIGATION IS ANY BETTER THAN ECG BASED TIP LOCATION ALONE !!

2016

Br J Nurs. 2016 May 26;25(10):539-43. doi: 10.12968/bjon.2016.25.10.539.

Improving the patient experience with real-time PICC placement confirmation.

Bidgood C[1].

⊕ Author information

Abstract

Peripherally inserted central catheters (PICCs) are now widely used in health care. The use of ultrasound and the micro introducer set have led to an increase in successful insertion rates. However, malposition can still be a problem. This can lead to delays in treatment, increase in procedure time and repeated chest X-rays as well as placement failure. Evolving technologies mean that these challenges can now be overcome. This article describes how a tracking and tip confirmation system (Sherlock 3CG Tip Confirmation System, CR Bard) was used to improve the patient experience during PICC placements by preventing malposition and delays in the start of treatment. Of 88 PICCs placed with the system, all were in an acceptable position when confirmed by chest X-ray and therefore none required any further adjustments post insertion.

KEYWORDS: Audit; Central venous catheterisation; Misplacement; Service improvement; Vascular access devices

NO EVIDENCE THAT IC-ECG BY SHERLOCK 3CG IS ANY BETTER THAN IC-ECG BY ANY OTHER MONITOR !!!

NO EVIDENCE THAT ECG-BASED TIP LOCATION + TIP NAVIGATION IS ANY BETTER THAN ECG BASED TIP LOCATION ALONE !!

2016

Br J Nurs. 2016 Jan 27;25 Suppl 2:S17-21. doi: 10.12968/bjon.2016.25.Sup2.S17.

Confirming PICC tip position during insertion with real-time information.

Barton A[1].

⊕ Author information

Abstract

Peripherally inserted central catheters (PICCs) play a fundamental role in patient care in a variety of clinical and healthcare settings. Tip location is important for both safety and efficacy. New technologies may offer the possibility of safer, more efficient and more effective insertion. A prospective evaluation was carried out of a system providing real-time information on the tip's location, direction, and depth during insertion in a total of 488 patients at a single centre (65 patients in the initial study, plus follow-on case series reports in 423 patients). No tip malpositions were reported and, as a result, the institution has been able to waive the requirement for confirmatory chest X-ray after PICC insertion, thus minimising the delay before the PICC can be used and increasing staff and patient confidence in the procedure.

KEYWORDS: Central catheterisation; Electrocardiography; Nurse-led services; Vascular access

NO EVIDENCE THAT IC-ECG BY SHERLOCK 3CG IS ANY BETTER THAN IC-ECG BY ANY OTHER MONITOR !!!

NO EVIDENCE THAT ECG-BASED TIP LOCATION + TIP NAVIGATION IS ANY BETTER THAN ECG BASED TIP LOCATION ALONE !!

Appl Health Econ Health Policy. 2016 Feb;14(1):41-9. doi: 10.1007/s40258-015-0192-3.

Sherlock 3CG(®) Tip Confirmation System for Placement of Peripherally Inserted Central Catheters: A NICE Medical Technology Guidance.

Dale M[1], Higgins A[2], Carolan-Rees G[3].

Author information

Abstract

In current clinical practice, peripherally inserted central catheters (PICCs) are typically inserted using external anatomical measurements and a confirmatory chest X-ray, or using fluoroscopy. The Sherlock 3CG(®) Tip Confirmation System (TCS) allows magnetic tracking of the PICC tip during insertion and confirmation of the final location using ECG, meaning that most patients will not require a chest X-ray or fluoroscopy. The Sherlock 3CG(®) TCS was evaluated in 2014 by the UK National Institute for Health and Care Excellence (NICE) as part of the Medical Technologies Evaluation Programme. The company (C.R. Bard Ltd) identified four abstracts, one paper pending publication and questionnaire data from NHS users of the Sherlock 3CG(®) TCS. None of the evidence included a comparator arm. Placement accuracy of PICCs using the Sherlock 3CG(®) TCS where a chest X-ray was also used ranged from 79.5 to 100 %. The company reported that 9 out of 16 NHS centres that used the Sherlock 3CG(®) TCS were no longer using chest X-rays to routinely confirm PICC tip location. The evidence did not report the need for catheter repositioning, re-insertion, staff time savings, treatment delays, length of stay, quality of life outcomes or complications. The company's model found that the Sherlock 3CG(®) TCS was cost saving by GBP25.67 per patient compared to blind bedside PICC insertion. The External Assessment Centre (EAC) adapted the company's model to test alternative assumptions for nurse time, theatre cost, malposition rate and reinsertion method, and found that the Sherlock 3CG(®) TCS was cost incurring by GBP9.37 per patient compared to blind bedside PICC insertion. The use of the Sherlock 3CG(®) TCS in the UK NHS compared to blind PICC insertion using a confirmatory chest X-ray appears to hover around being cost neutral. Staff time and accuracy were key drivers in the model: evidence for these is sparse and the reality will vary in different situations. If evidence became available for outcomes after the initial insertion, such as replacement, complications and adverse events, the cost implications may change. The direction of this potential change is not known. NICE published guidance MTG24 in March 2015 recommending that the case for adoption of Sherlock 3CG(®) TCS was supported by the evidence.

NO EVIDENCE THAT IC-ECG BY SHERLOCK 3CG IS ANY BETTER THAN IC-ECG BY ANY OTHER MONITOR !!!

NO EVIDENCE THAT ECG-BASED TIP LOCATION + TIP NAVIGATION IS ANY BETTER THAN ECG BASED TIP LOCATION ALONE !!

Sherlock 3CG

Big challenge:

To try to prove that IC-ECG + Sherlock navigation has clear advantages over IC-ECG alone in term of cost-effectiveness.

(clinical study at Catholic University – just completed)

AVA 2015

Clinical use of Sherlock-3CG for positioning power injectable PICCs

Mauro Pittiruti, Giancarlo Scoppettuolo, Laura Dolcetti

Goals

- Tip location with Sherlock-3CG
  - Safety
  - Feasibility
  - Accuracy
- Tip navigation with Sherlock-3CG
  - Safety
  - Feasibility
  - Accuracy

Methods

- All consecutive patients candidate to PICC insertion in our Day Hospital of Infectious Disease or Oncology
  - Adults
  - Outpatients – PICC needed for DH/home
  - Informed consent
  - Availability of post-procedural chest x-ray

- In all patients: US-guided PICC placement using intra-procedural Sherlock-3CG + intra-procedural Nautilus + post-procedural chest x-ray

Patients and PICCs

130 adult patients

- 123 neoplastic + 7 infect.dis.
- 128 sinusal rhythm + 1 AF + 1 PM
- 76 females + 54 males
- Age range 24 - 84 y.o.
- BMI range 17 – 42

130 Bard Power PICCs, non-valved

- 94 picc 4F SL + 36 picc 5F DL
- 92 insertion in the basilic vein, 38 in a brachial vein
- 104 on the right arm, 26 on the left arm

Insertion

130 insertions

- 129 successes + 1 failure (but: success after shifting side)
- in 9 cases, tunnelling was required (vein too small in the ‘green’ zone: puncture of vein in the ‘yellow’zone’)
- no puncture-related complications
    - no nerve injury
    - no arterial puncture
- in 15 cases, an additional microintroducer kit (from Galt Medical) was needed
    - problems with Bard guidewire
    - problems with Bard introducer/dilator

Tip location

- Tip location by IC-ECG was performed in all patients who had visible P wave on basal ECG (128/130)

- Successful tip location with Sherlock-3CG was recorded in most cases 120/128
  - There was always a perfect match between IC-ECG with Sherlock-3CG and IC-ECG with Nautilus

- Problems in setting the Sherlock 3CG were recorded in 4 cases

- Difficult/impossible interpretation of IC-ECG on Sherlock 3CG occurred in 8/128
  - In these 8 patients, IC-ECG was performed with Nautilus only
  - All 8 problems were reported in the first 40 patients

Problems in setting the Sherlock 3CG

- Only in 4 cases
  - 2 cases in the first 40 patients
  - 2 cases in the second 90 patients
- Problem: loose/defective connection between shield and cable
- In all 4 cases, the tip location was nonetheless performed, though with some difficulties (inconstant ECG reading)

Difficult/impossible interpretation of IC-ECG on Sherlock 3CG

- Occurred in 8/128
  - All 8 problems were reported in the first 40 patients
    - Abnormal/disturbed ECG trace
    - Artifacts
    - Low wave voltage
    - No P increase
  - In these 8 patients, tip location by IC-ECG was performed with Nautilus only

Post-procedural chest x-ray

- AP view + lateral view in 101 cases
- Only standard AP view in 29 cases
- Tip visualized in 129/130 cases
- In all 128 cases performed with IC-ECG, the location of the tip was correct according to x-ray criteria
  - No malpositions
  - 'Sweet spot' criteria: all tips were ok
  - 'Carina' criteria: all tips were in 'acceptable' position
    - 108 caths were perfect (1-5 cm below the carina)
    - 14 caths were short (0-1 cm below the carina)
    - 5 caths were long (5-7 cm below the carina)

Tip navigation

- Tip navigation was successfully performed with Sherlock-3CG in 105/130
- In 25/130, there were problems
  - No visualization
  - Wrong visualization (tip ok according to IC-ECG, but wrongly directed according Sherlock)
  - Poor visualization (transient or unstable)
  - Failure of tip navigation occurred 17 times in the first 40 patients + 8 times in the following 90 patients (suggesting an effect of training)

Tip navigation

- In 20/105 cases, during the procedure, the tip was detected in the wrong direction, in the ipsilateral IJV (in all 20 cases, confirmed by US scan of IJV) and then it was successfully redirected
- Re-direction was sometimes difficult because of the limited movements of the neck of the patients (due to the shield and the drapes) and because of the difficulty in compressing the IJV with the US probe
- There was no case of wrong direction to the contralateral BCV

General comments on Sherlock-3CG

- Calibration was the main problem
  - Requires training (as proven by the higher incidence of navigation failures in the first 40 patients vs the following 90 patients)
  - Even after training, the calibration was ‘felt’ by the nurses as stressful and time-consuming
  - Key factor was the position of the cable vs the position of the shield
  - Another important disturbing factor was the presence of metallic objects on the patients (typically: in clothes of female patients)

General comments on Sherlock-3CG

- Another major problem was the high sensitivity of the system to possible sources of electrical/magnetic interference
  - Cell phones
  - Other electrical devices, if plugged (ultrasound, Nautilus, pumps, etc.)
  - This apparently affected both the performance of the IC-ECG and of the navigation

General comments on Sherlock-3CG

- Other technical aspects:
  - difficult connection between the shield and the cable (serious issue in 4 cases)
  - The shield was well tolerated by the patients, but the overall draping system was quite rigid and implied limited movements of the neck of the patient
    - Higher risk of wrong direction of the cath to the IJV
    - Some difficulties in redirecting the tip
    - Landmark measurement may be difficult
  - Printer failure (!?)
  - Poor quality of the micro-introducer kit – if compared to our standard PICCs
  - Lack of a safety block of the stylet – if compared to our standard PICCs

Comments on tip location

- The IC-ECG tip location with Sherlock 3CG was feasible in 120/128 cases (94%)
  - Faesibility might increase to 100% after proper training, as suggested by the clustering of the failures in the first 40 cases
- There was a perfect match with Nautilus in terms of IC-ECG
  - The Nautilus was easier to use and – in most cases - offered an ECG trace which was more stable, less prone to artifacts and of easier interpretation
- The accuracy of Sherlock-3CG in tip location was 100%, both if compared to Nautilus and if compared to post-procedural chest x-ray
  - Similar results were obtained either considering the carina criteria or the sweet spot criteria

Comments on tip navigation

- Tip navigation with Sherlock-3CG was feasible in 105/130 cases (81%)
- This was not affected by training, since it occurred both in the first 40 patients and in the following 90 patients
- Major problems were the high sensitivity of the system to many different disturbing factors and the need for calibration (often not easy to achieve)
- The forced position of the neck of the patient may somehow be a problem under different aspects:
  - Increased risk of the cath going into the IJV
  - Difficulty in redirecting the cath under US guidance

Conclusions

- Tip location and tip navigation with Sherlock-3CG were not associated with any complication – safety = 100%.
- As regards tip location, Sherlock-3CG showed a 94% feasibility and 100% accuracy
  - Feasibility might reach 100% after proper training.
- As regards tip navigation, Sherlock-3CG showed a 81% feasibility and 100% accuracy
  - Feasibility might increase, to some extent, after proper training, though it may always be limited by the features of the system (which is not user-friendly and it is highly sensitive to many disturbing factors)

Conclusions (2)

- The overall cost-effectiveness of Sherlock 3CG for tip location with IC-ECG - if compared to Nautilus or to other dedicated or non-dedicated ECG monitors - might be questioned, considering the higher cost and the higher complexity in setting and operating the system, while the results are similar or slightly worse.

- The overall cost-effectiveness of Sherlock 3CG for tip navigation – if compared to current methods for detecting a wrong direction (US scan, ECG navigation, Corpak Navigator, etc.) – is very poor, considering the higher cost, the higher complexity and the poor performance.

In summary:

The use of SCG was not associated with any complication (100% safety). As regards tip location, SCG showed 94% feasibility and 100% accuracy (though, feasibility might reach 100% after extended training). As regards tip navigation, SCG showed 81% feasibility and 100% accuracy (feasibility might increase, to some extent, after extended training).

Problems with Sherlock 3CG

- Expensive
- Not cost effective
- Not easy to use
- Can be used only with a very specific brand of PICCs
- Tip location is ok, but tip navigation is not always feasible

Vasonova VPS (Teleflex)

Vasonova: EKG + Doppler

Vasonova VPS

Many abstracts in international conferences

No published paper on peer-reviewed journals (as from Pub Med)

Girgenti et al

Successfully Eliminating Chest Radiography by Replacing It with Dual Vector Technology and an Algorithm for PICC Placement

(JAVA, June 2014).

- 30 patients (5 with AF)

Vasonova VPS

Big challenge:

To try to prove that IC-ECG + Doppler navigation has clear advantages over IC-ECG alone in term of cost-effectiveness.

Maybe in AF ???

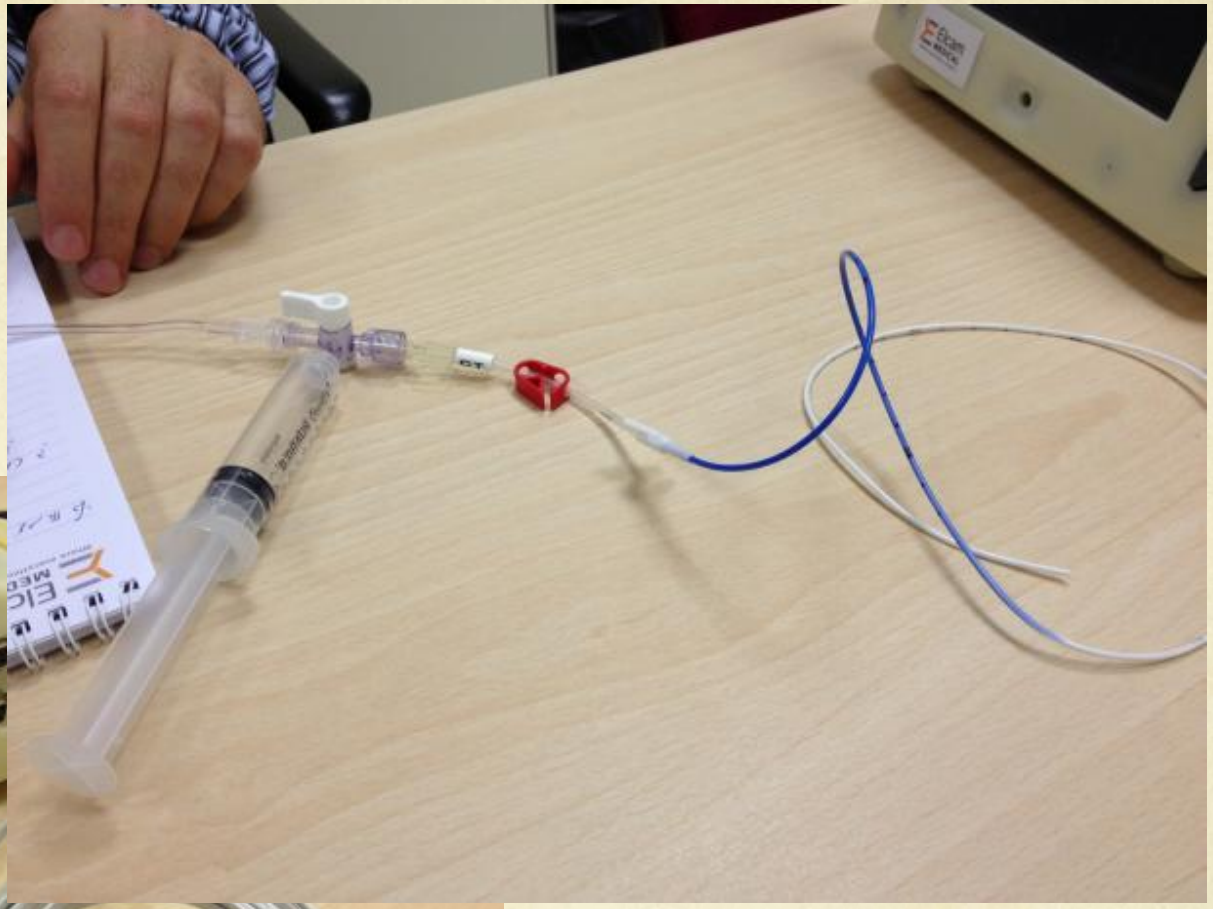
Problems with Vasonova

- Very expensive
- Not cost effective
- Not easy to use
- The real role of doppler for tip location is unclear and unproven

Catfinder (Elcam)

Catfinder

Elcam




Distance
Target
Message
Copying files...
Bat
100%
ECG
Elcam
MEDICAL

Catfinder (Elcam)

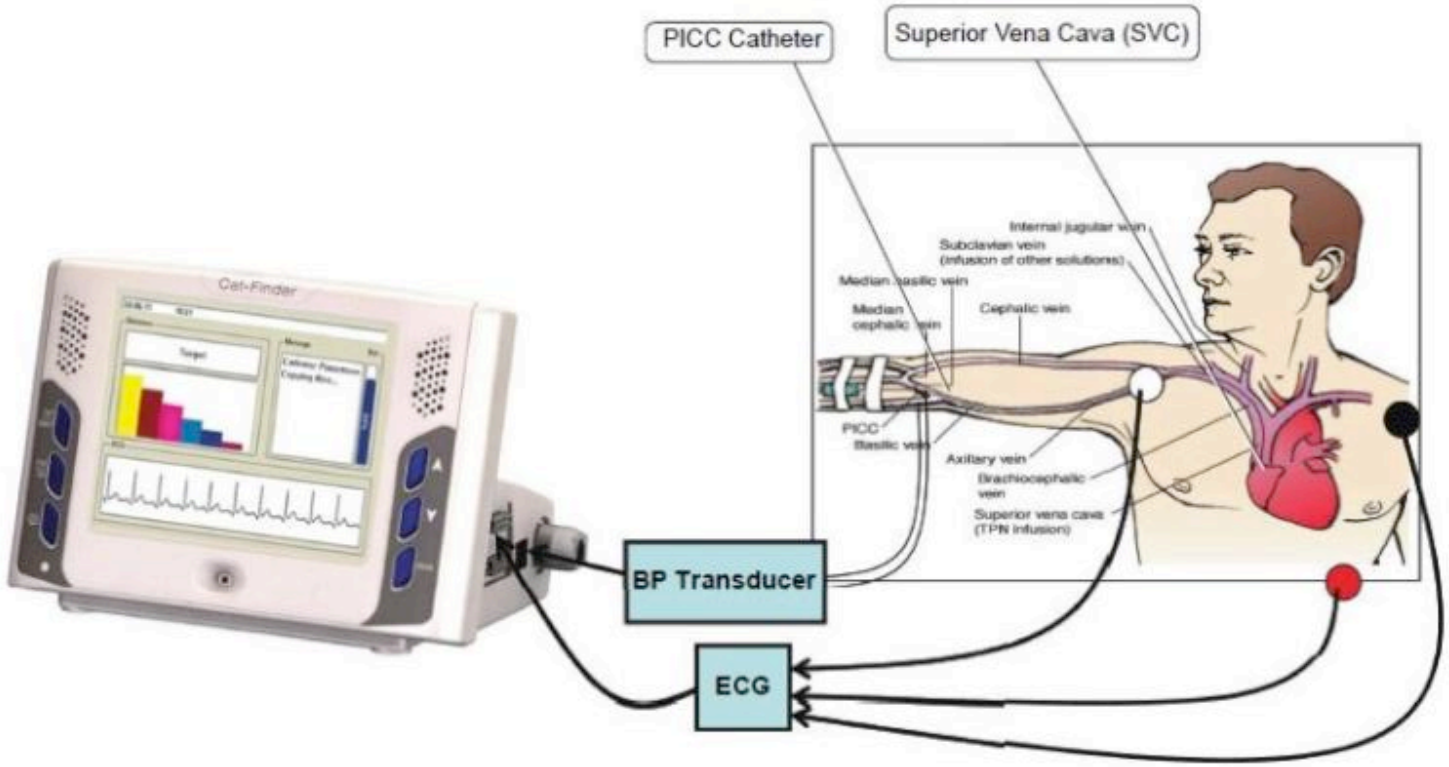
A few abstracts available

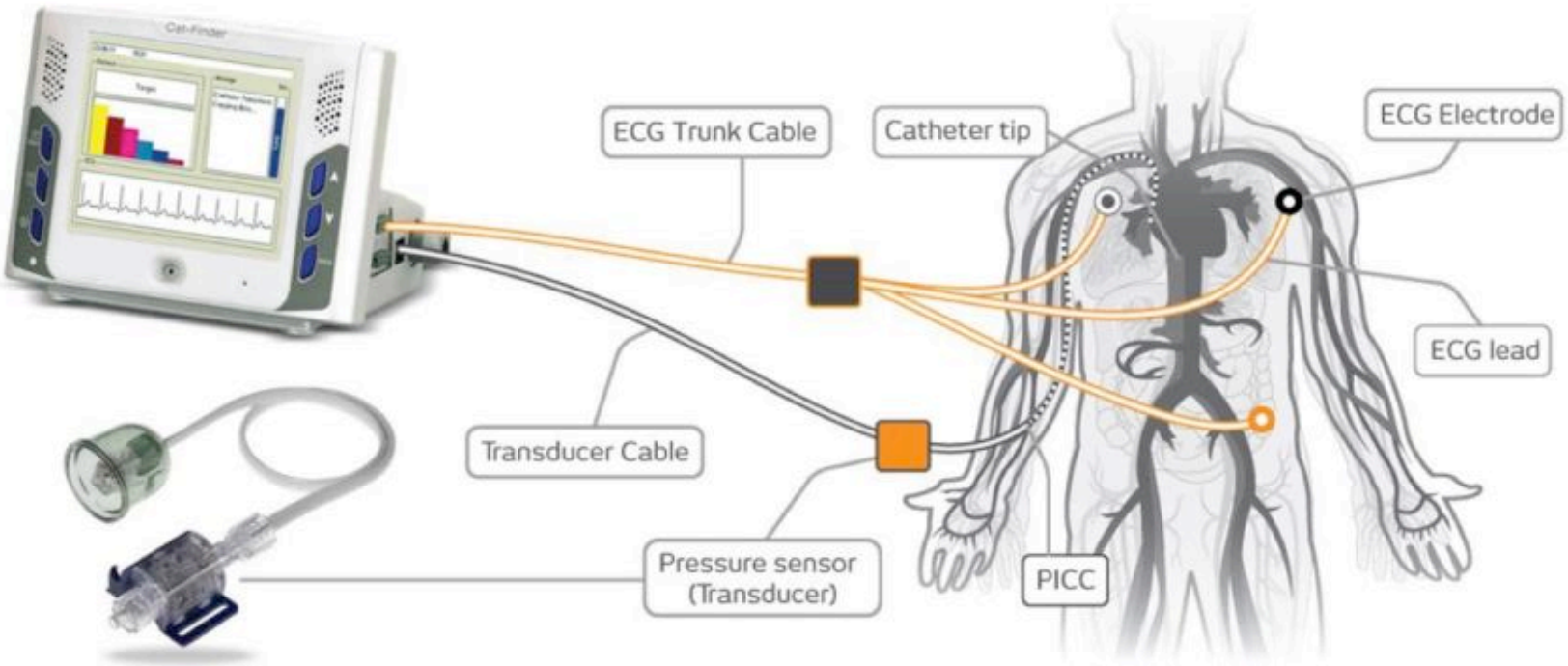
No published paper on peer-reviewed journals (as from Pub Med)

A study just completed in our University Hospital

- The primary endpoint of our study was to evaluate the accuracy of the CatFinder Navigational Device (CFND) as a tip location method for peripherally inserted central venous access devices in adult patients, as compared to the Intracavitary ECG method (IECG).
- The secondary endpoint was to evaluate CFND as a tip navigation method, able to detect the wrong direction of the catheter during insertion.


Cat-Finder
21.01.2010 17:10
Distance
Advance the catheter 4 cm
and press the Pedal(FB)
(Catheter > 10 cm far from the junction)
Message
Bat
GUI Start UP
System Test
Go to clinical
26%
ECG
Mode


PICC Catheter
Superior Vena Cava (SVC)
Cat-Finder
Internal jugular vein
Subclavian vein
(infusion of other solutions)
Median basilic vein
Median cephalic vein
Cephalic vein
PICC
Basilic vein
Axillary vein
Brachiocephalic vein
Superior vena cava (TPN infusion)
BP Transducer
ECG


ECG Trunk Cable
Catheter tip
ECG Electrode
ECG lead
Transducer Cable
Pressure sensor
(Transducer)
PICC

Method

- We studied adult patients candidate to placement of PICCs or PICC-ports.
- Patients with known ECG abnormalities or cardiac disease of any type were excluded.
- The target was to place the tip at the cavo-atrial junction. In all cases, tip location was verified by IECG. Any case of suspected wrong direction of the catheter was checked by ultrasound scan.

Results (1)

- Out of 136 enrolled patients, CFND was applicable in 131 cases (5 cases were excluded because of abnormal ECG) and feasible in 111 cases (in 20 cases, technical problems occurred during the procedure: air bubbles in the system, catheter cut too short, abnormal pressure reading, human errors in the method, etc.).

Results (2)

- There were no complications directly or indirectly related to CFND.
- Comparing with IECG, 87 tips were placed within 2cm from the target, while 17 were placed > 2cm from target (13 at ± 3cm; 4 at ± 4cm).
- In 7 cases CFND detected a wrong direction (to the ispilateral jugular vein), confirmed by ultrasound.

Conclusions (1)

- Applicability of CFND was 96%
- feasibility was 85%
- safety was 100%

(feasibility is expected to improve by solving the technical issues above described)

Conclusions (2)

- If compared to IECG, accuracy was 84% (considering a range of ± 2cm) and 96% (± 3cm).
- Unacceptable tip positions were 3% (in all of these cases, the catheter was too short).
- The accuracy in the diagnosis of a malposition in the IJV was 100%.
- Our study confirms the potential role of CFND for real time tip location and tip navigation.

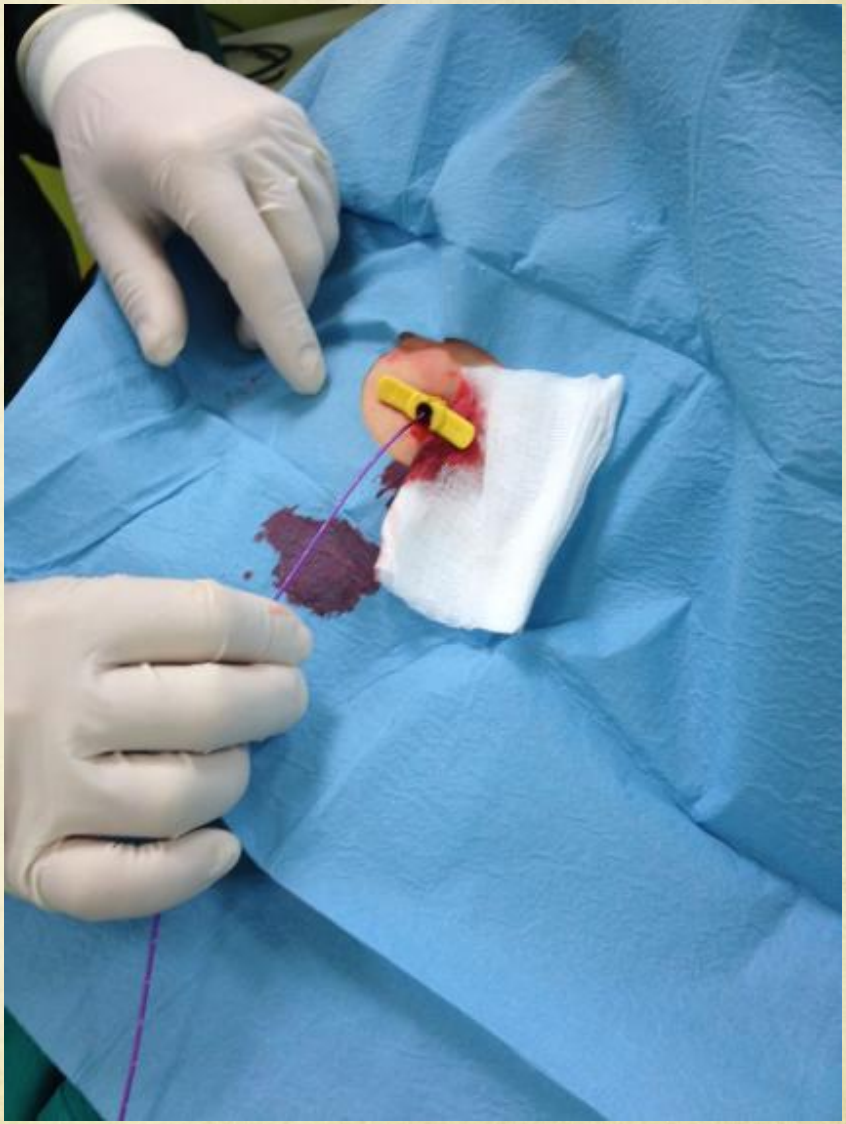
Problems with Catfinder

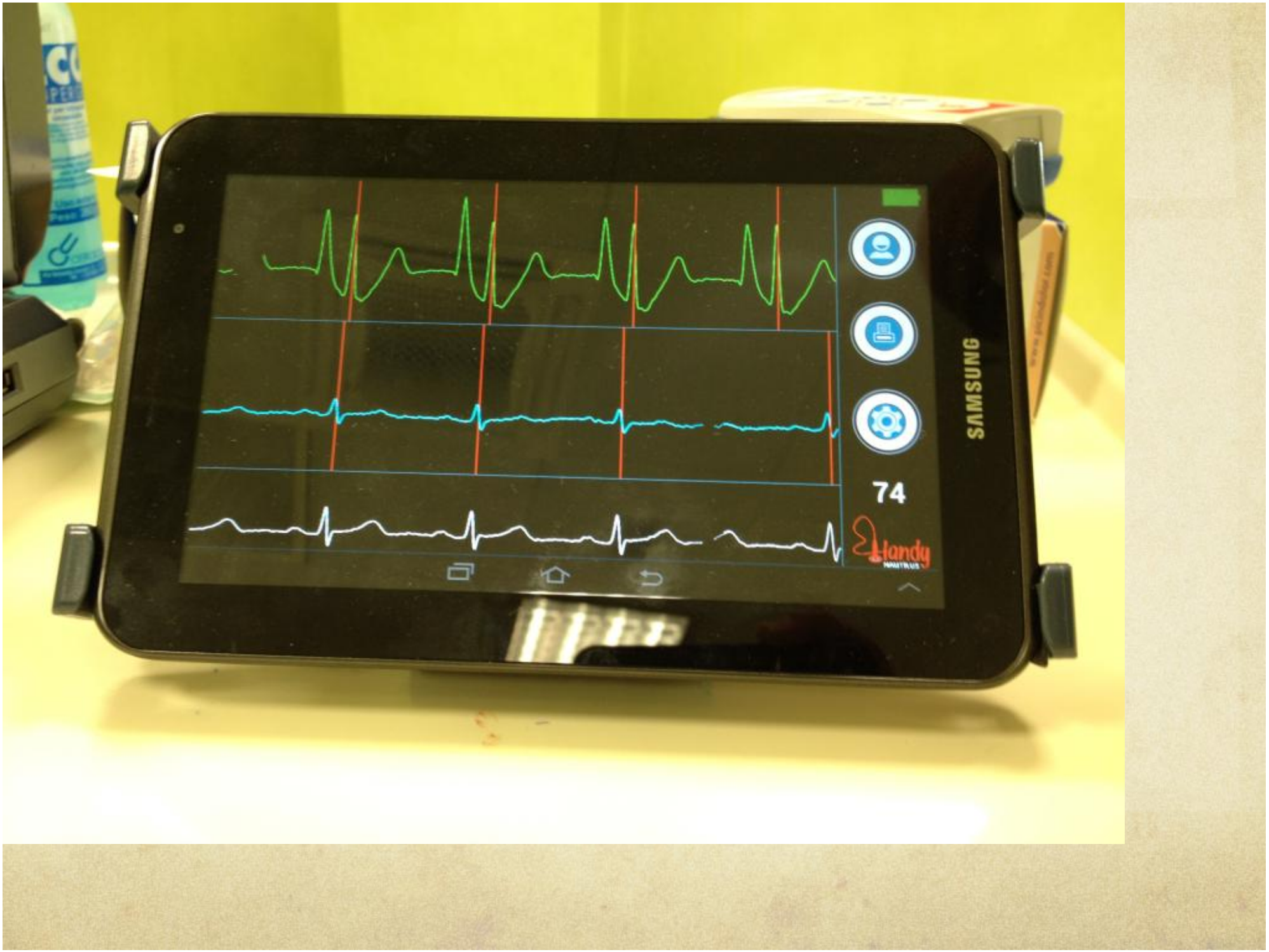
- Not cost effective
- Not easy to use
- Limited applicability
- It takes time
- Accuracy: high for tip navigation, somehow less for tip location

Delta (Romedex)


SAMSUNG
83
Handy

ECG navigation (Romedex)

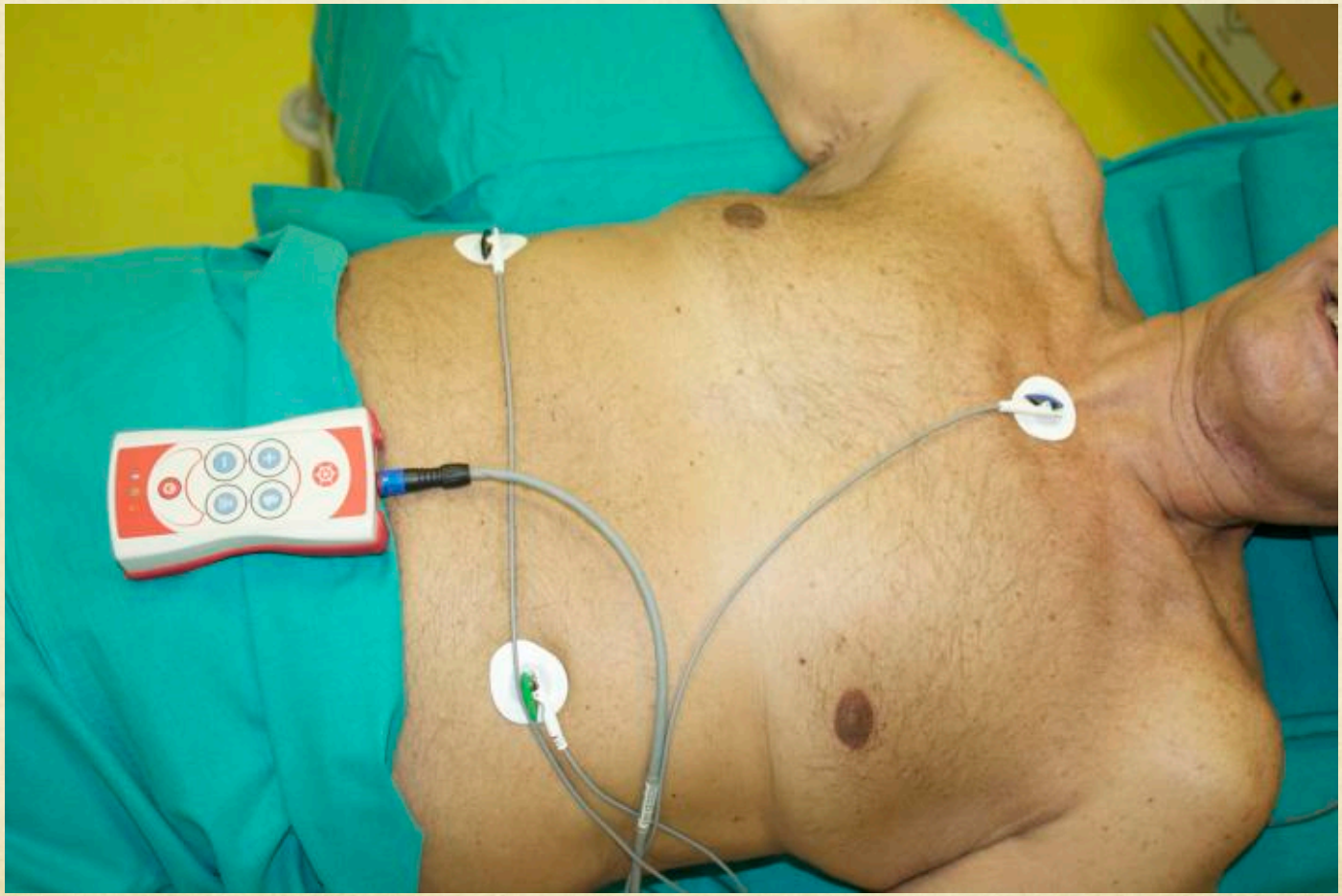


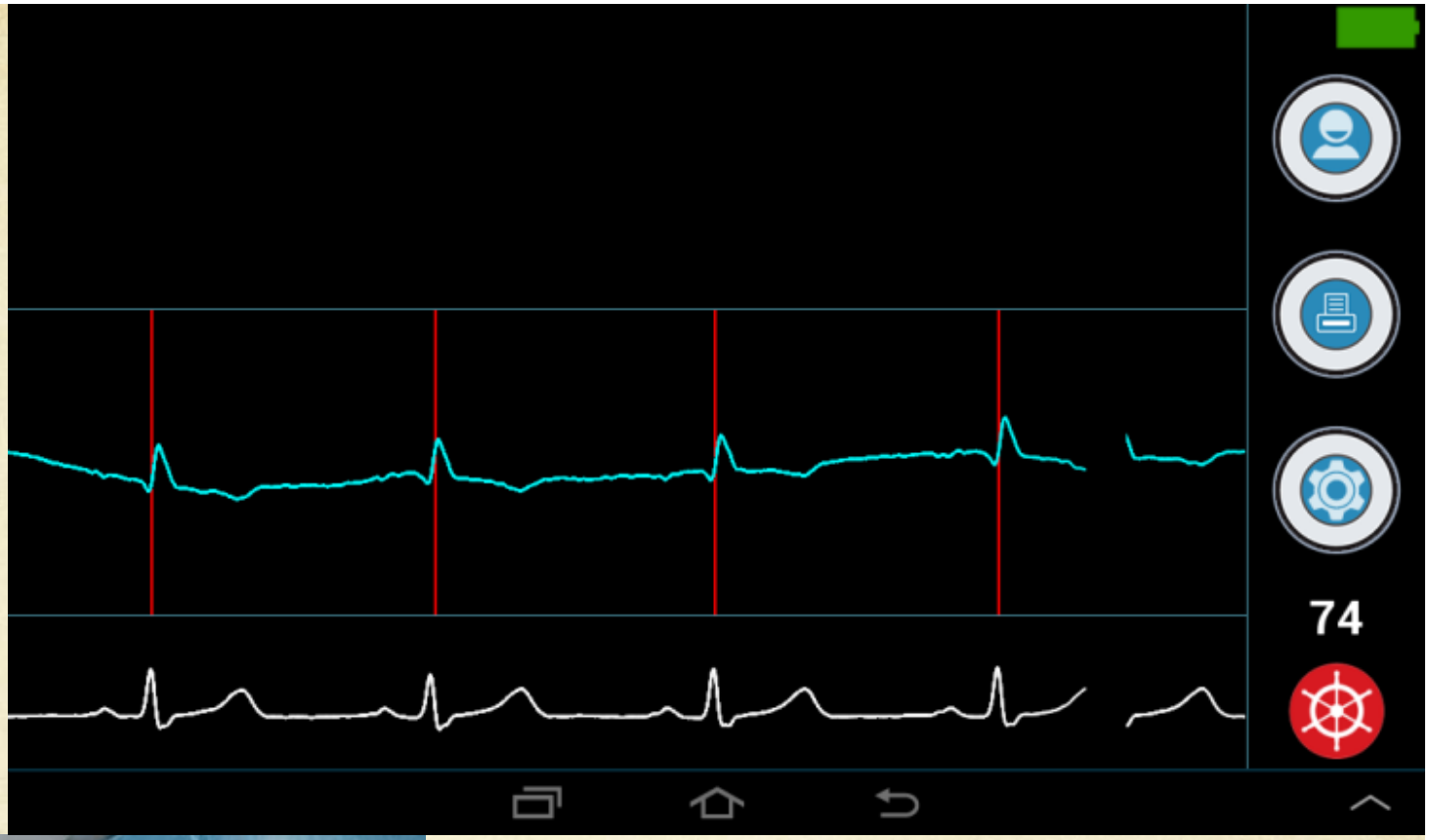

SAMSUNG
74
Handy


SAMSUNG
250
Handy
NAUTILUS


SAMSUNG
250
Handy

PICC insertion using Delta

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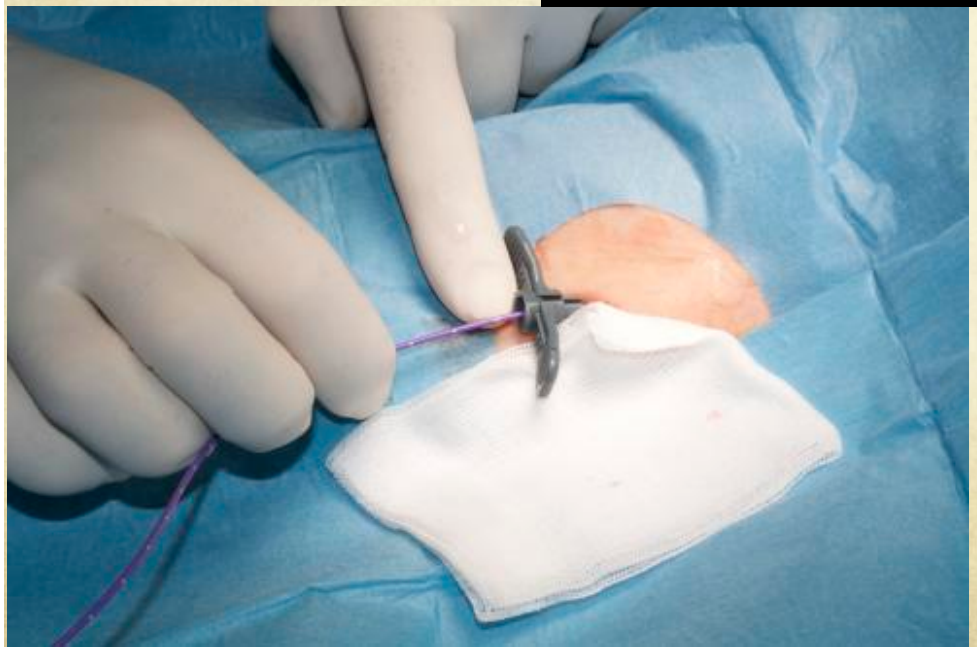

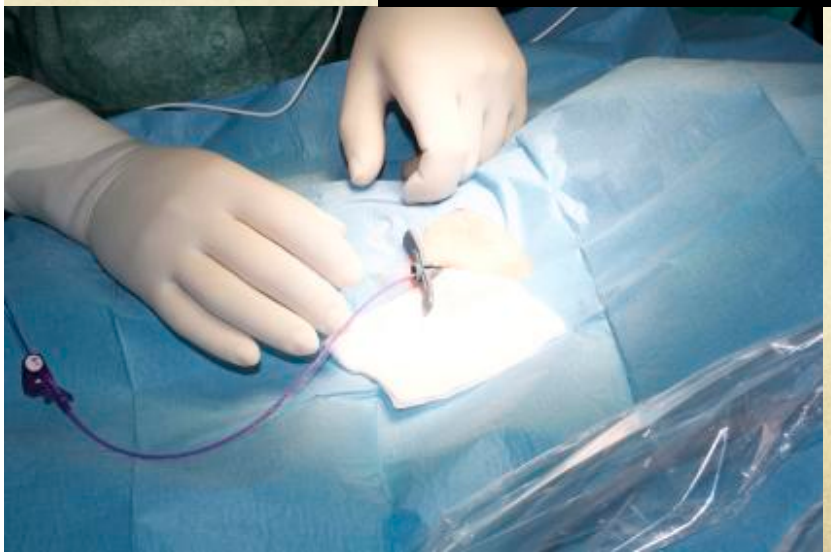

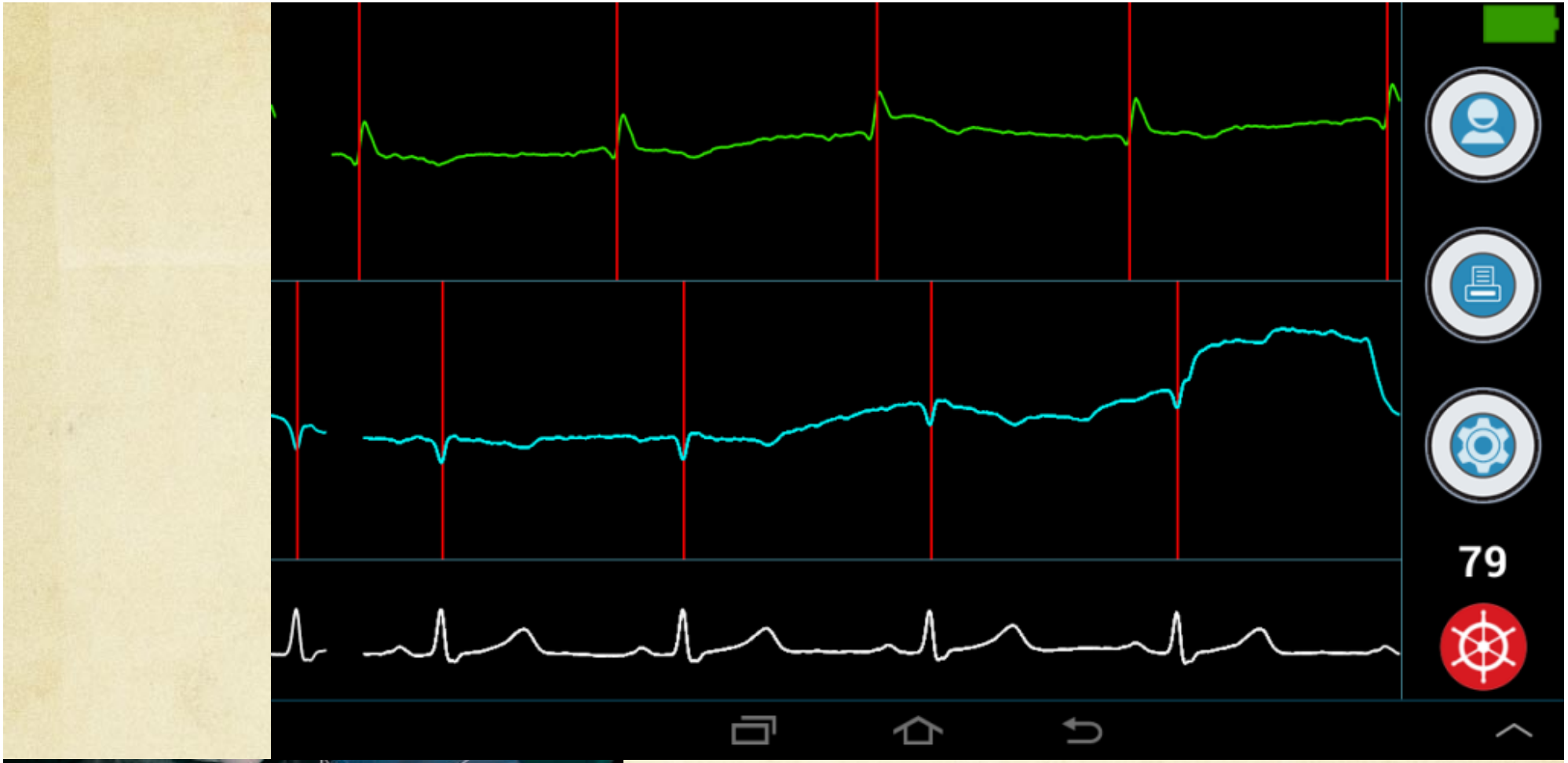
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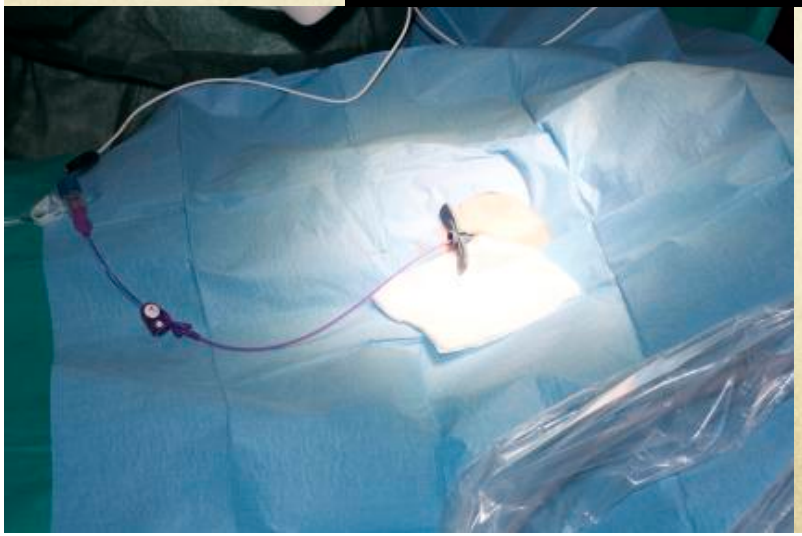

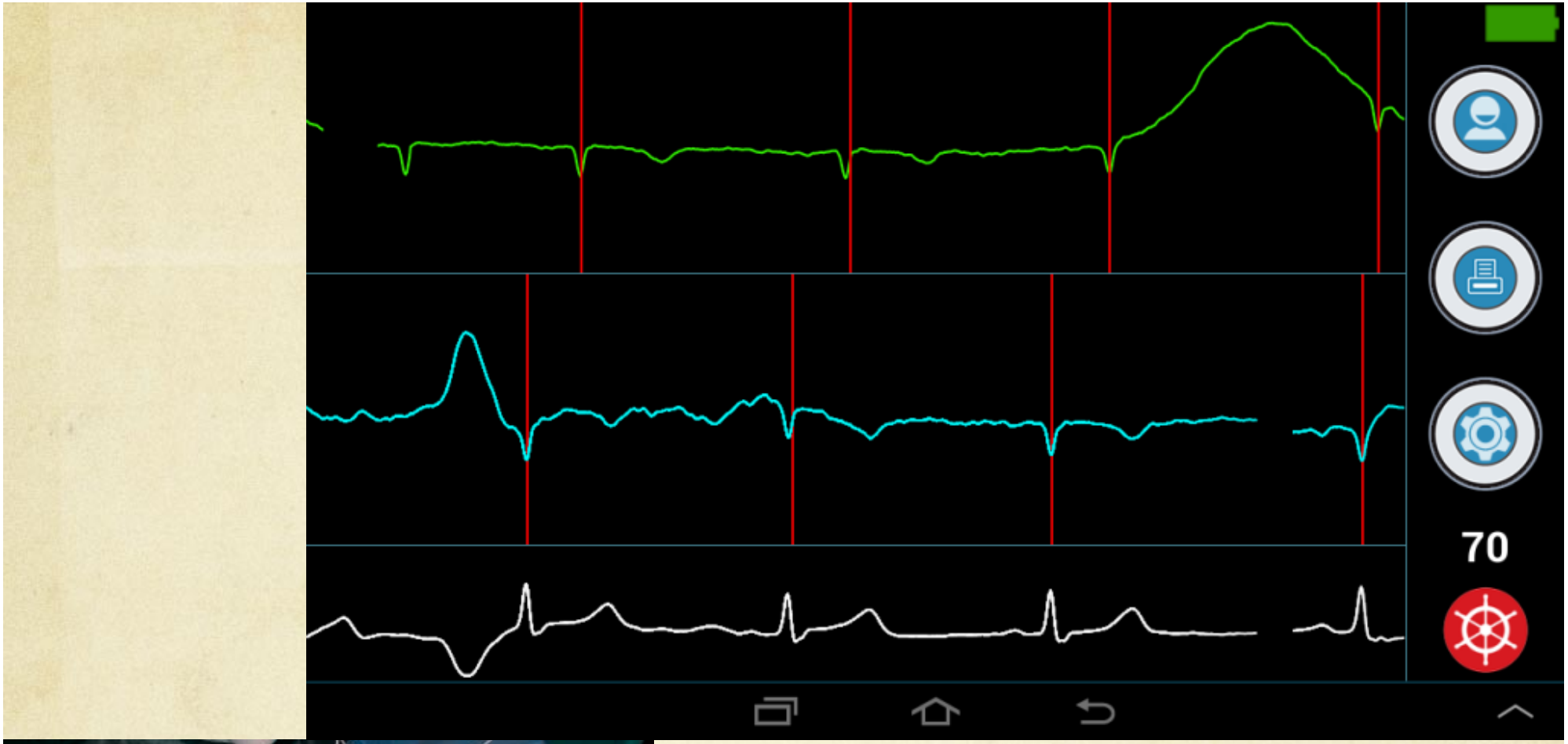
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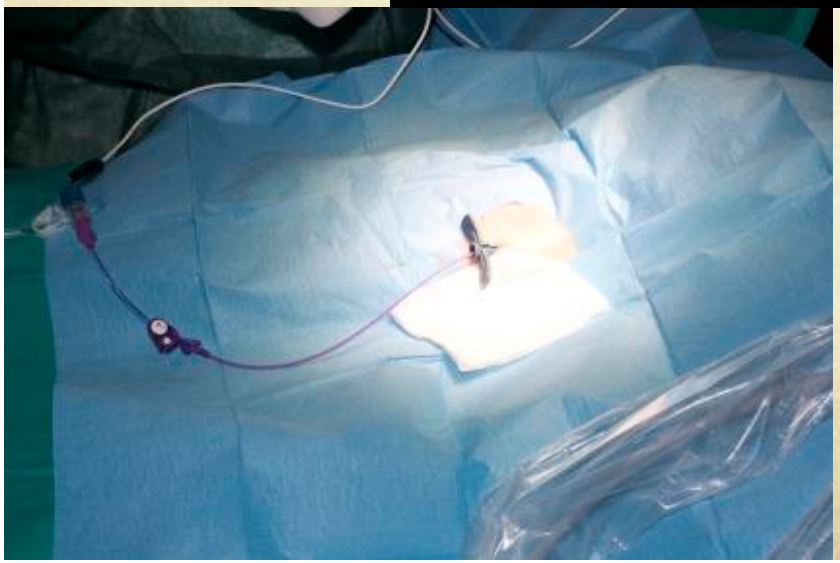

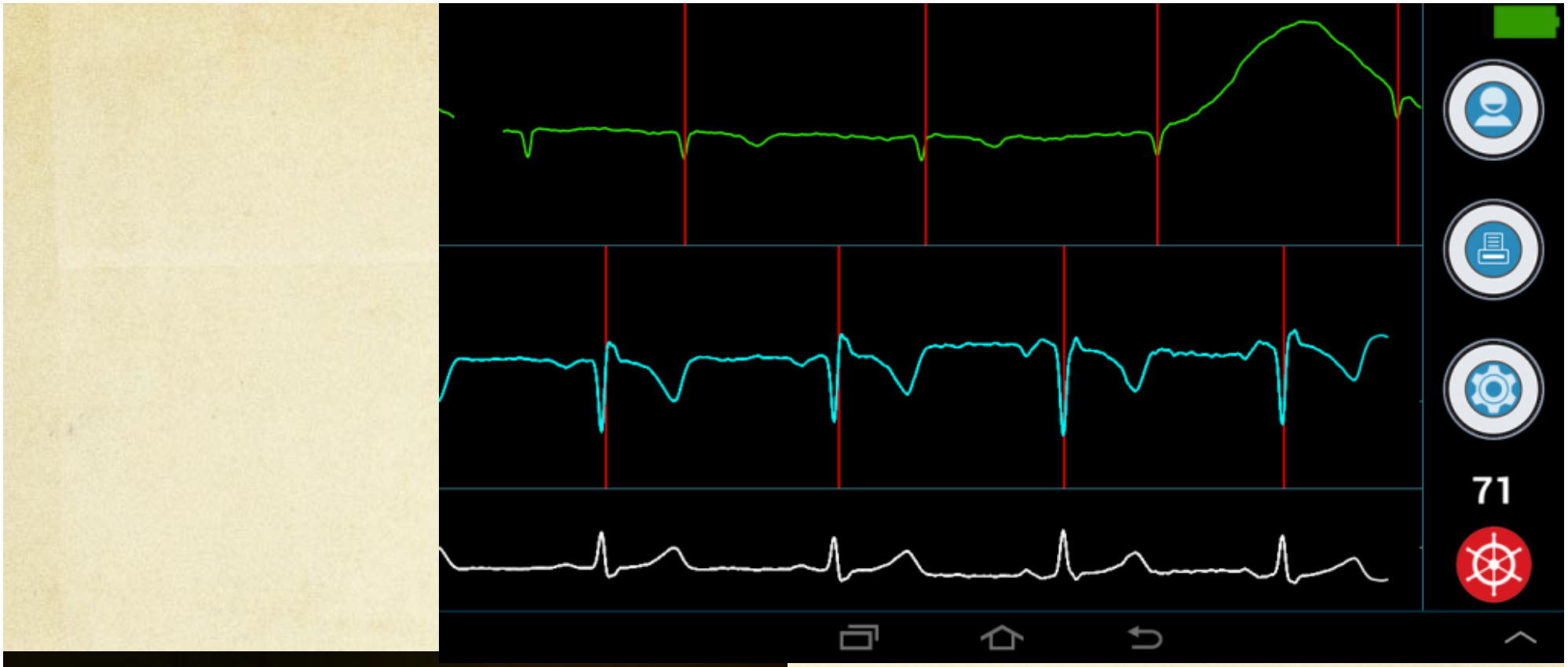
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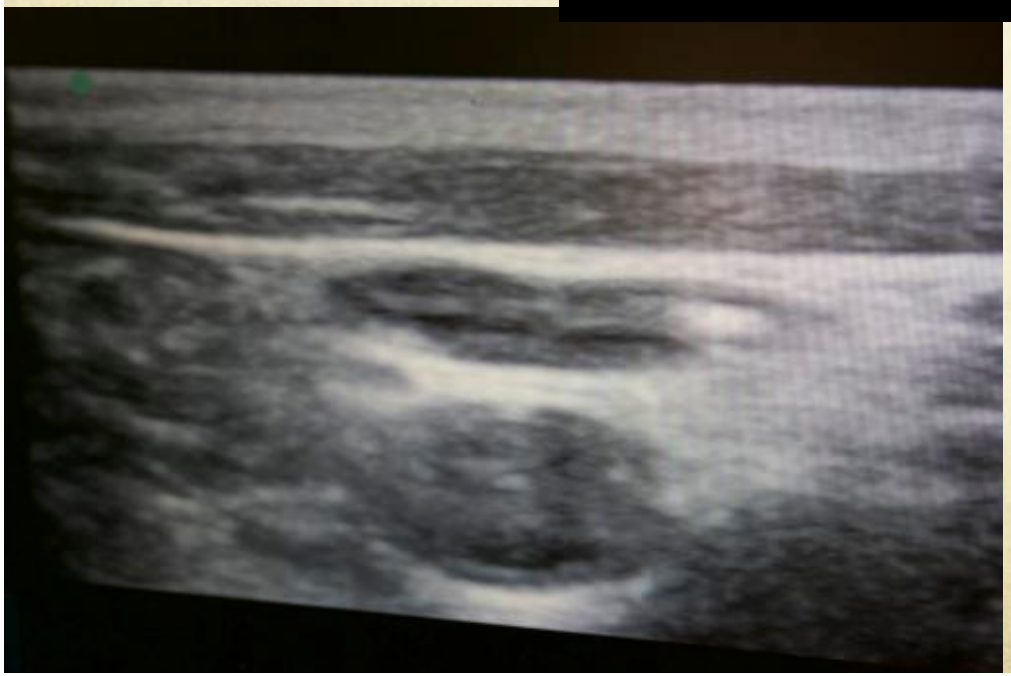

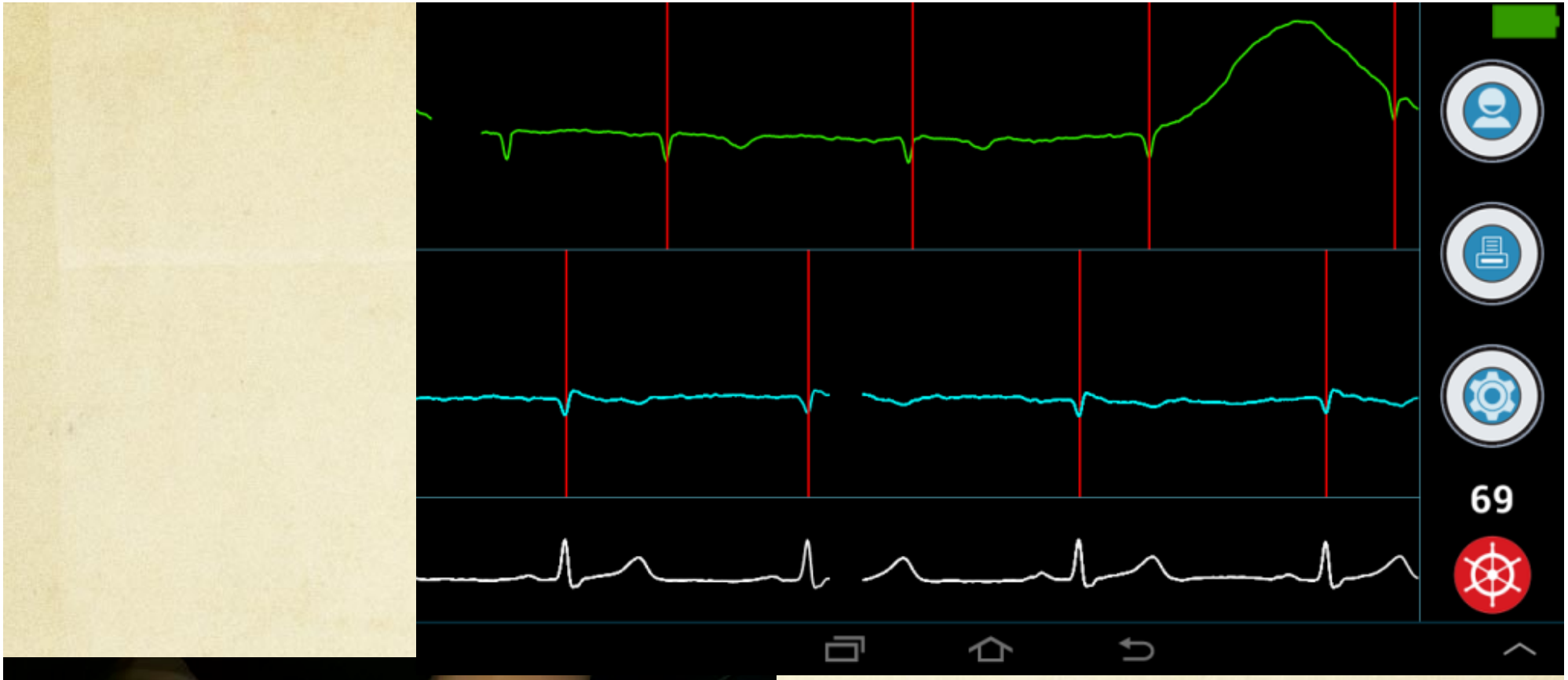
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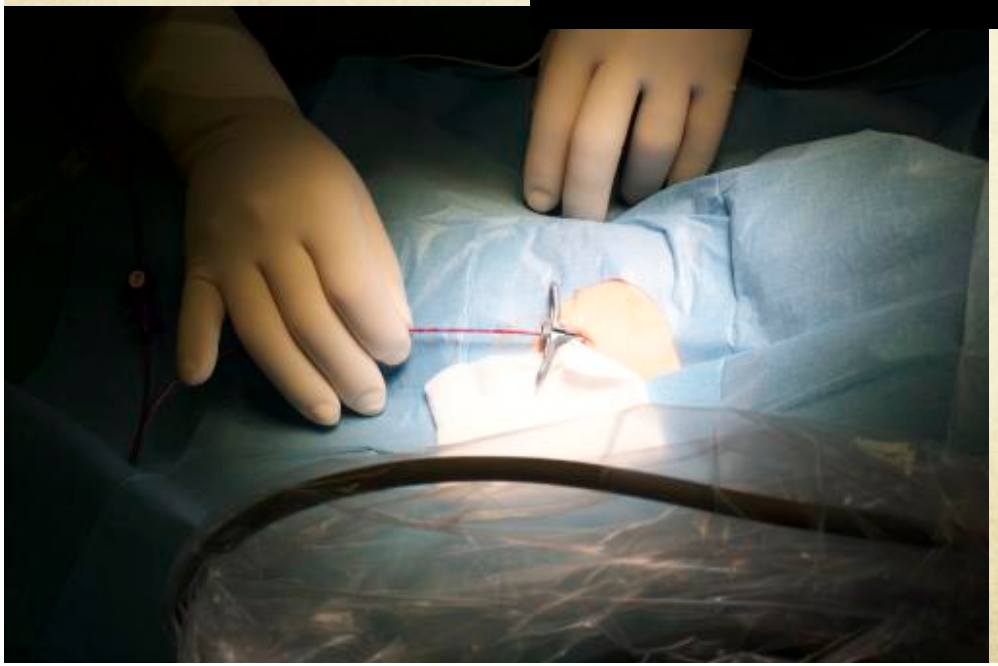

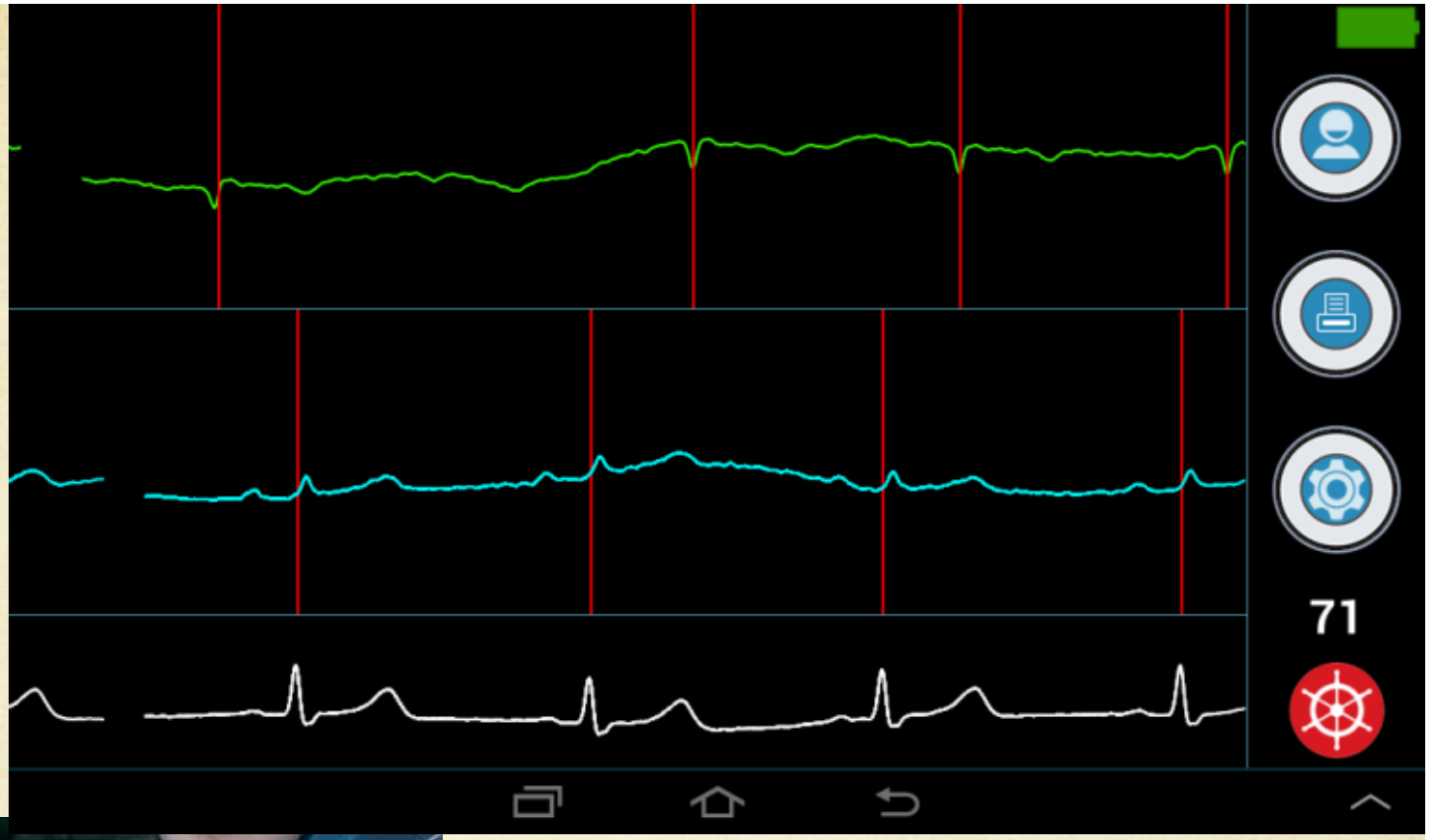
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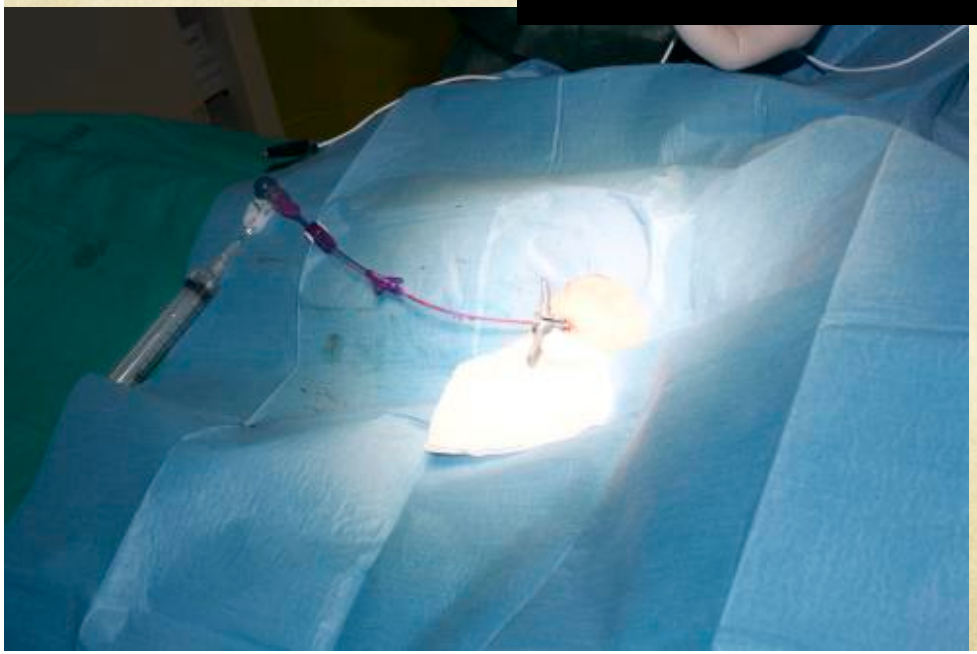

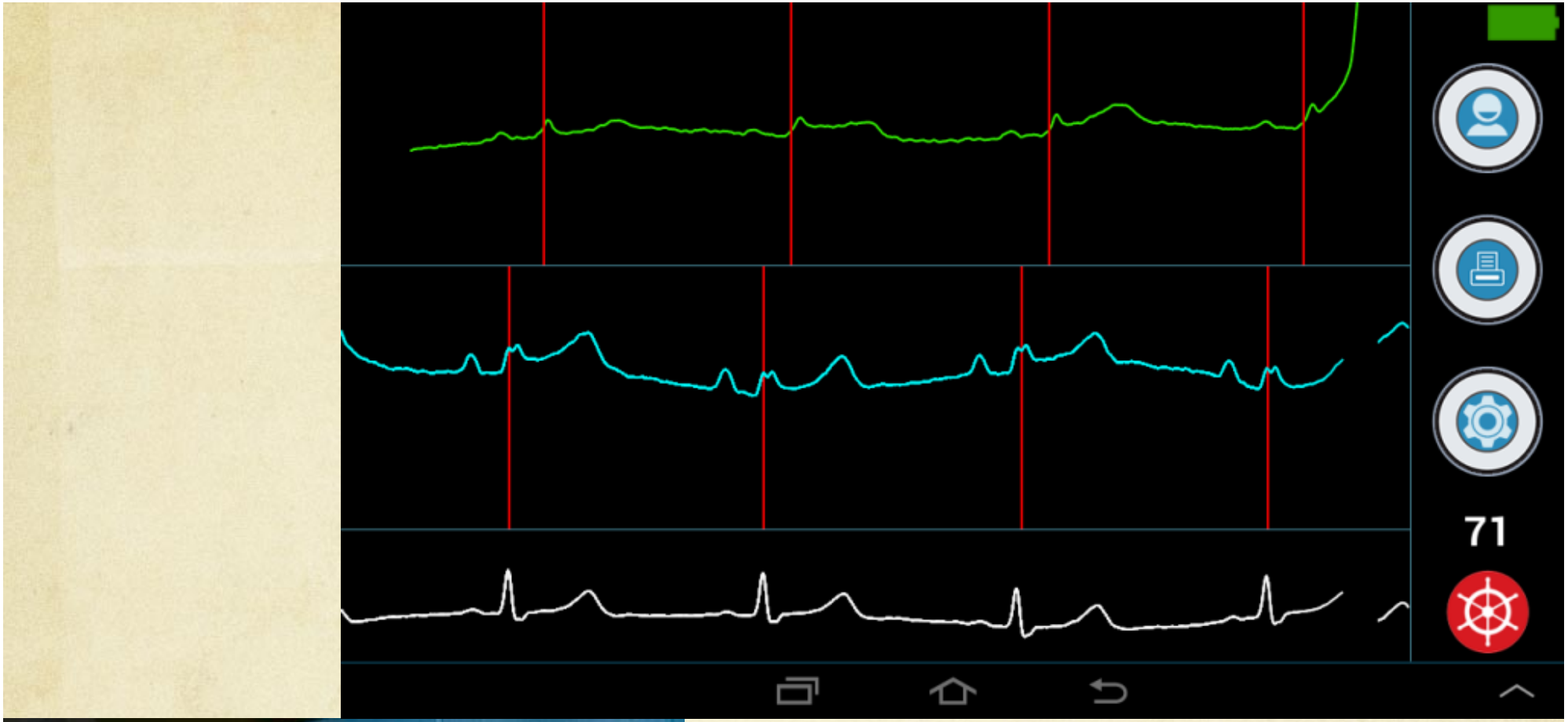
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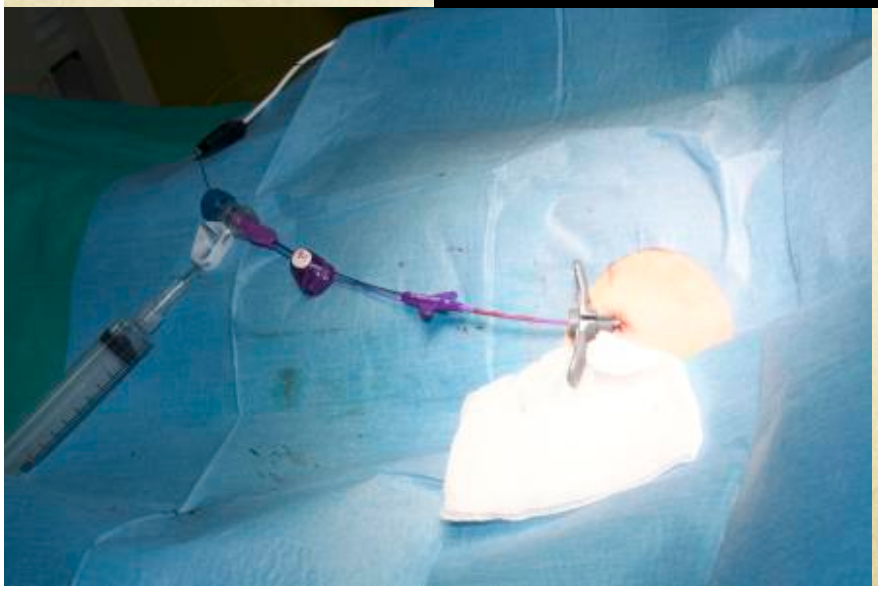

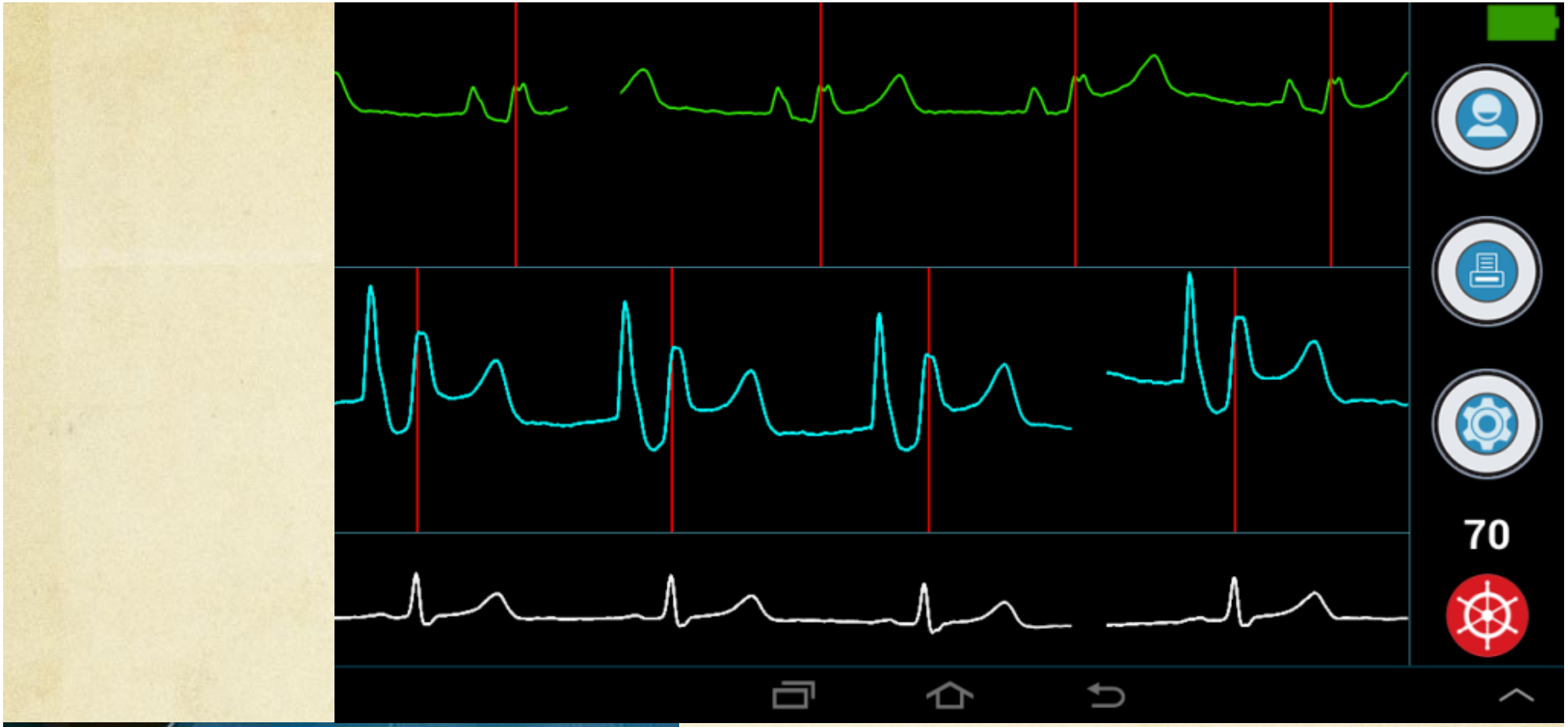
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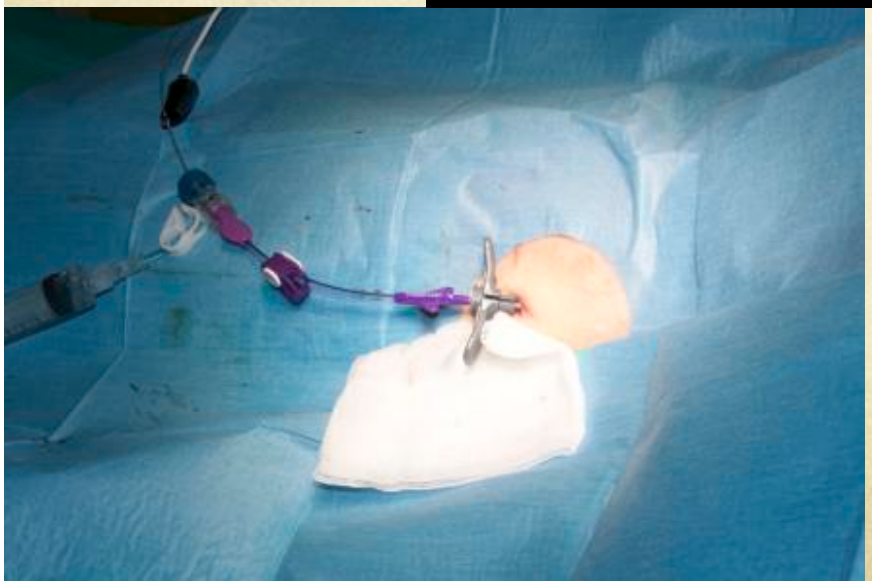

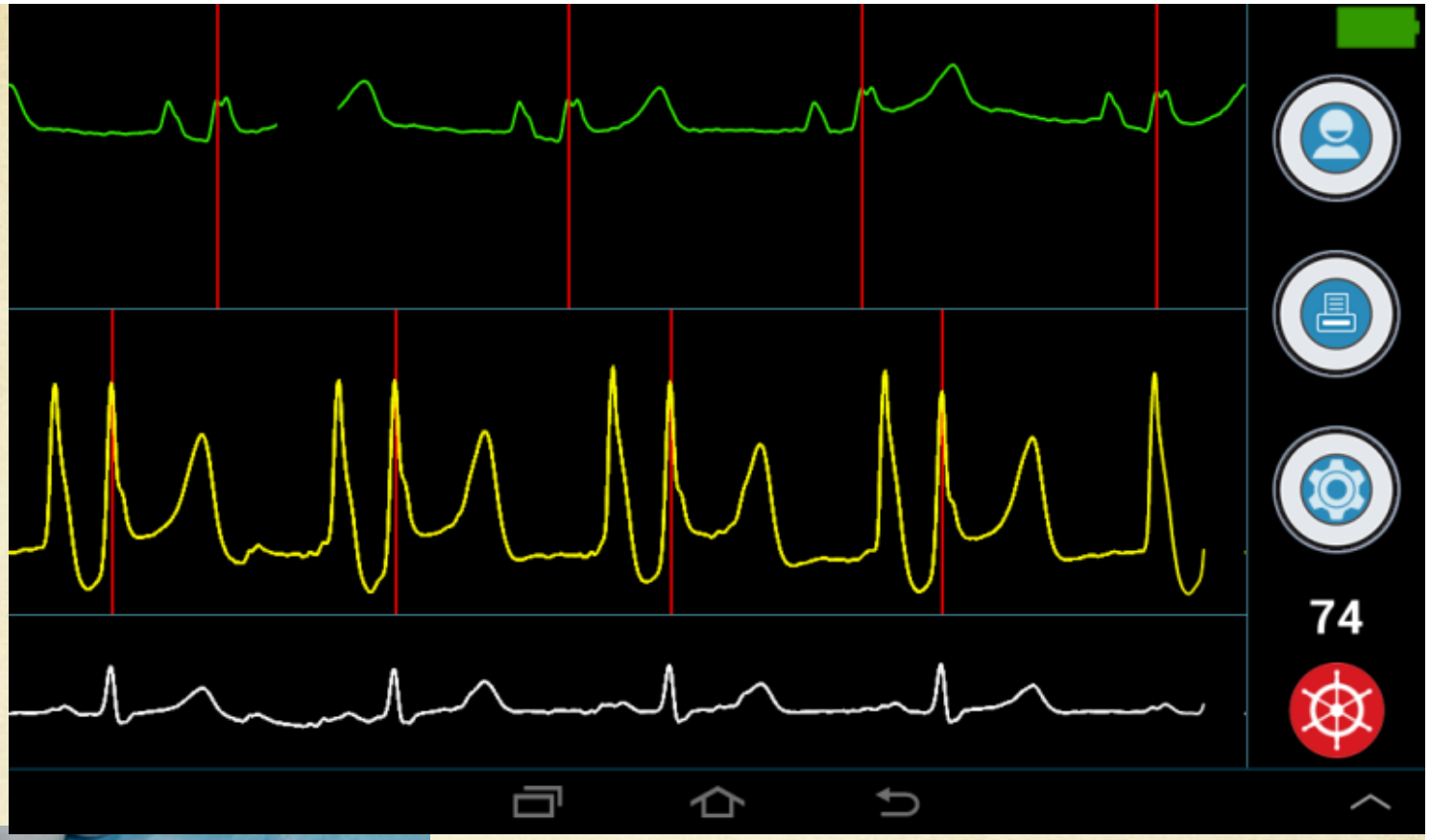
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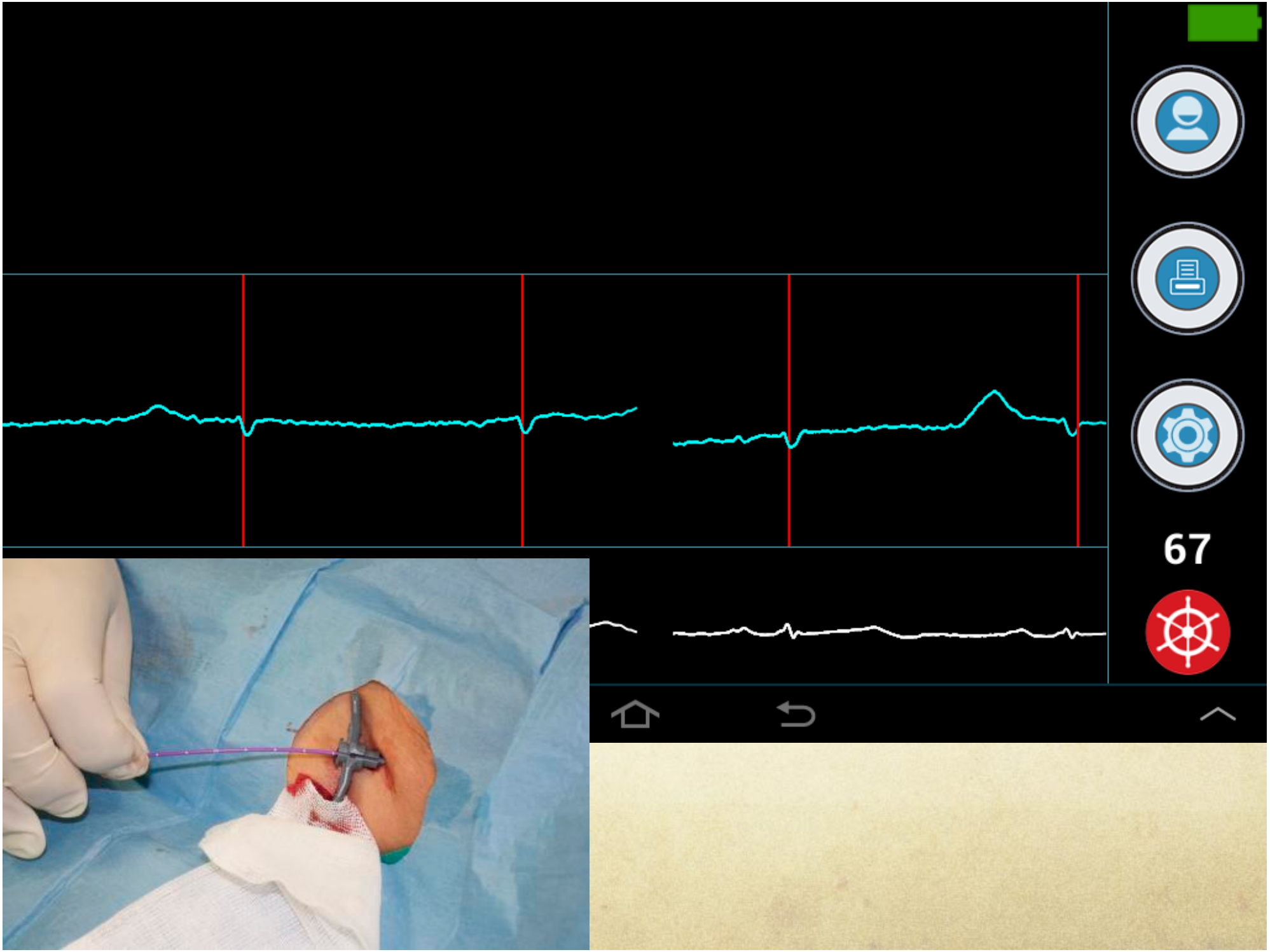
PICC insertion with Delta (2)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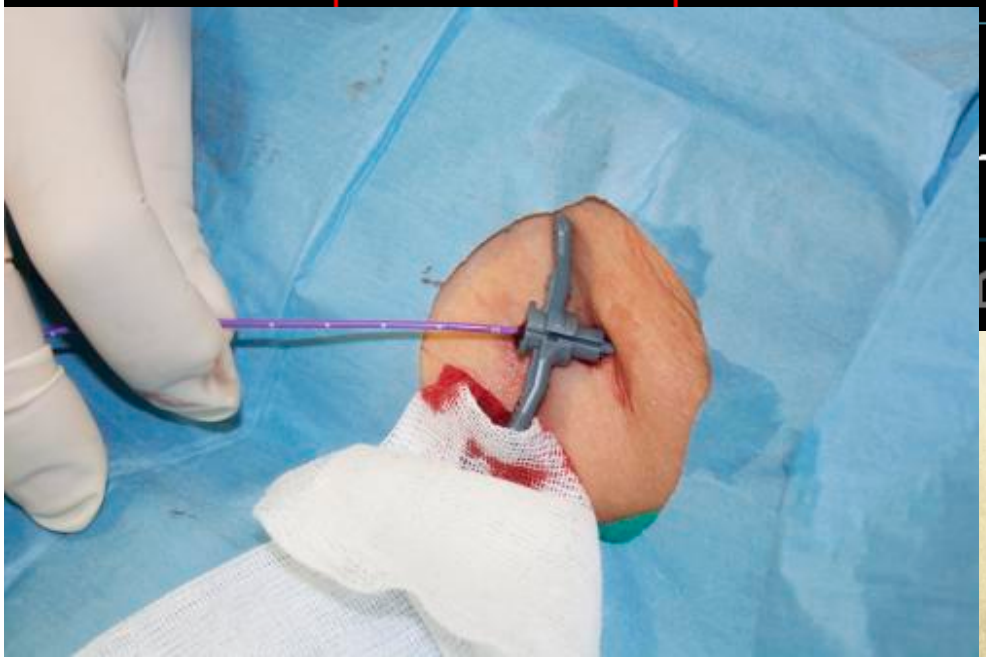

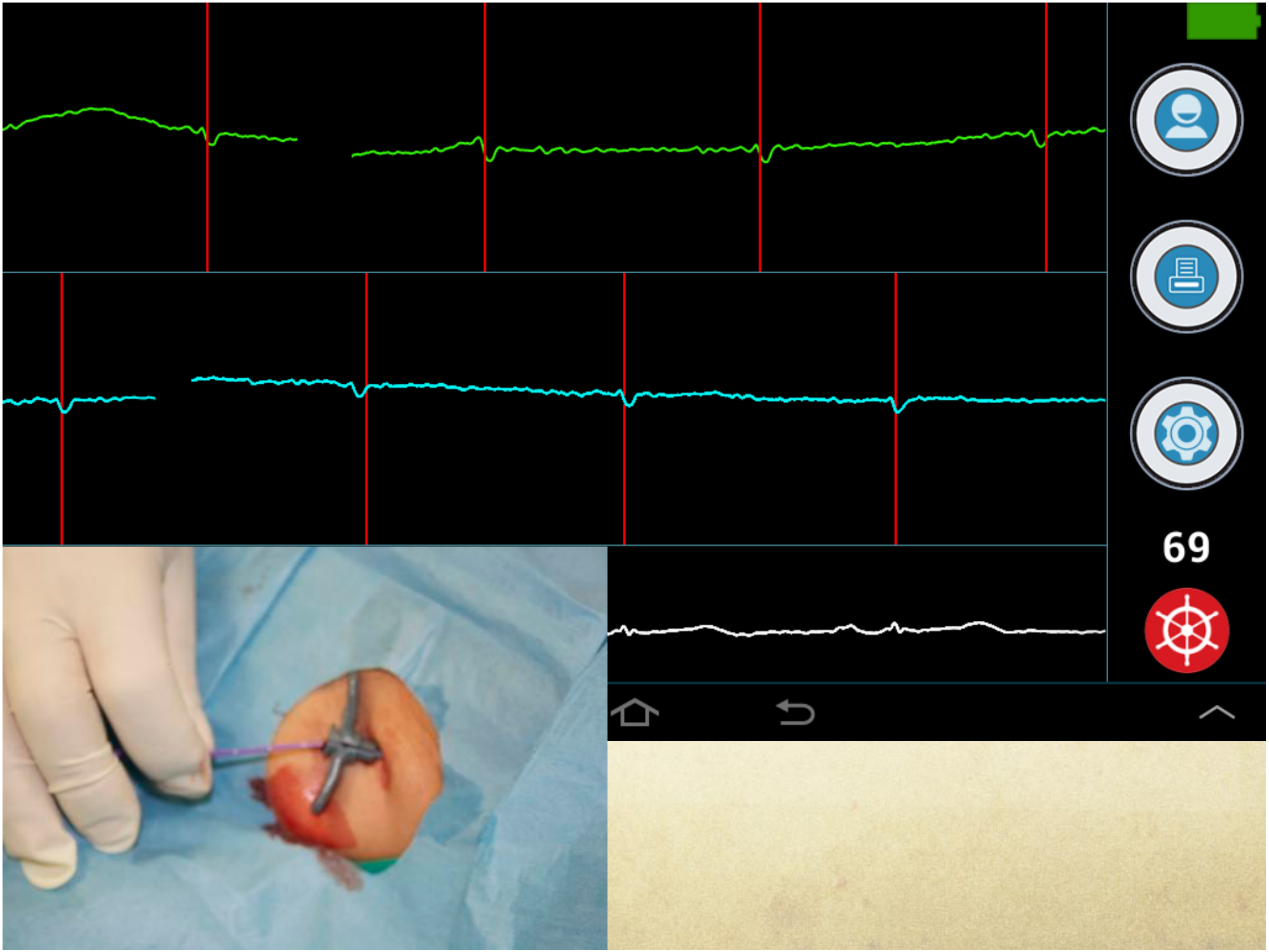
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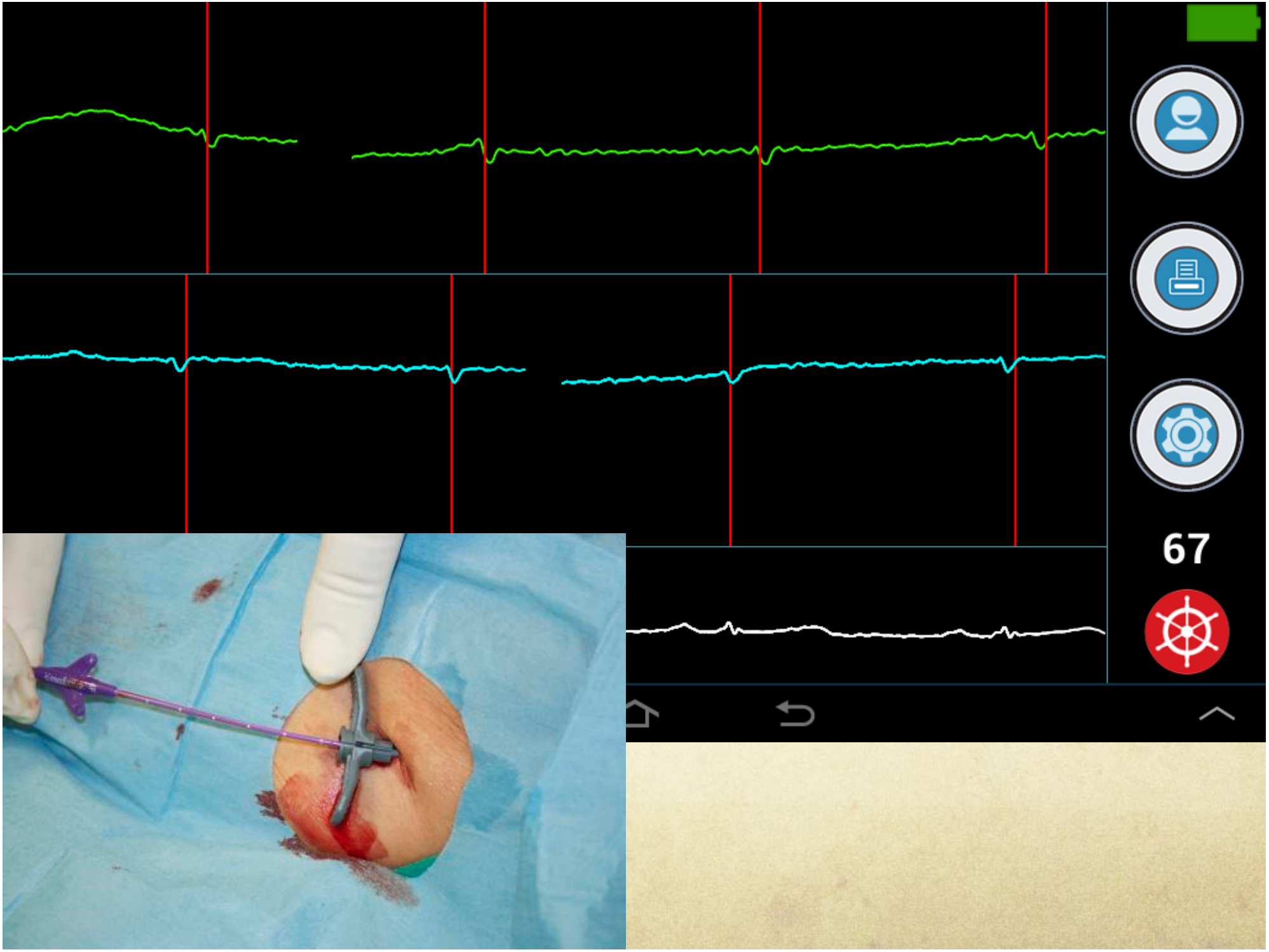
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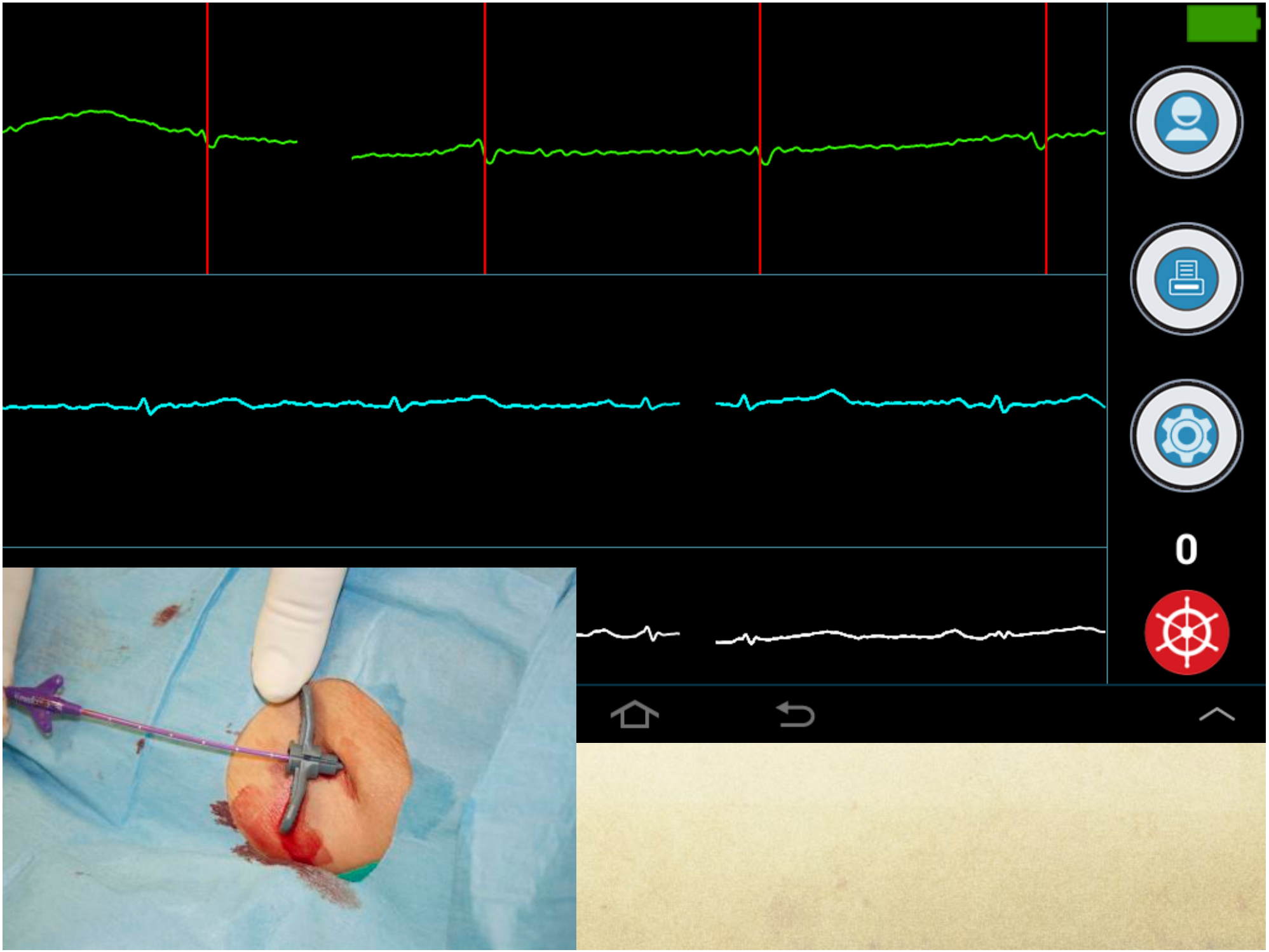
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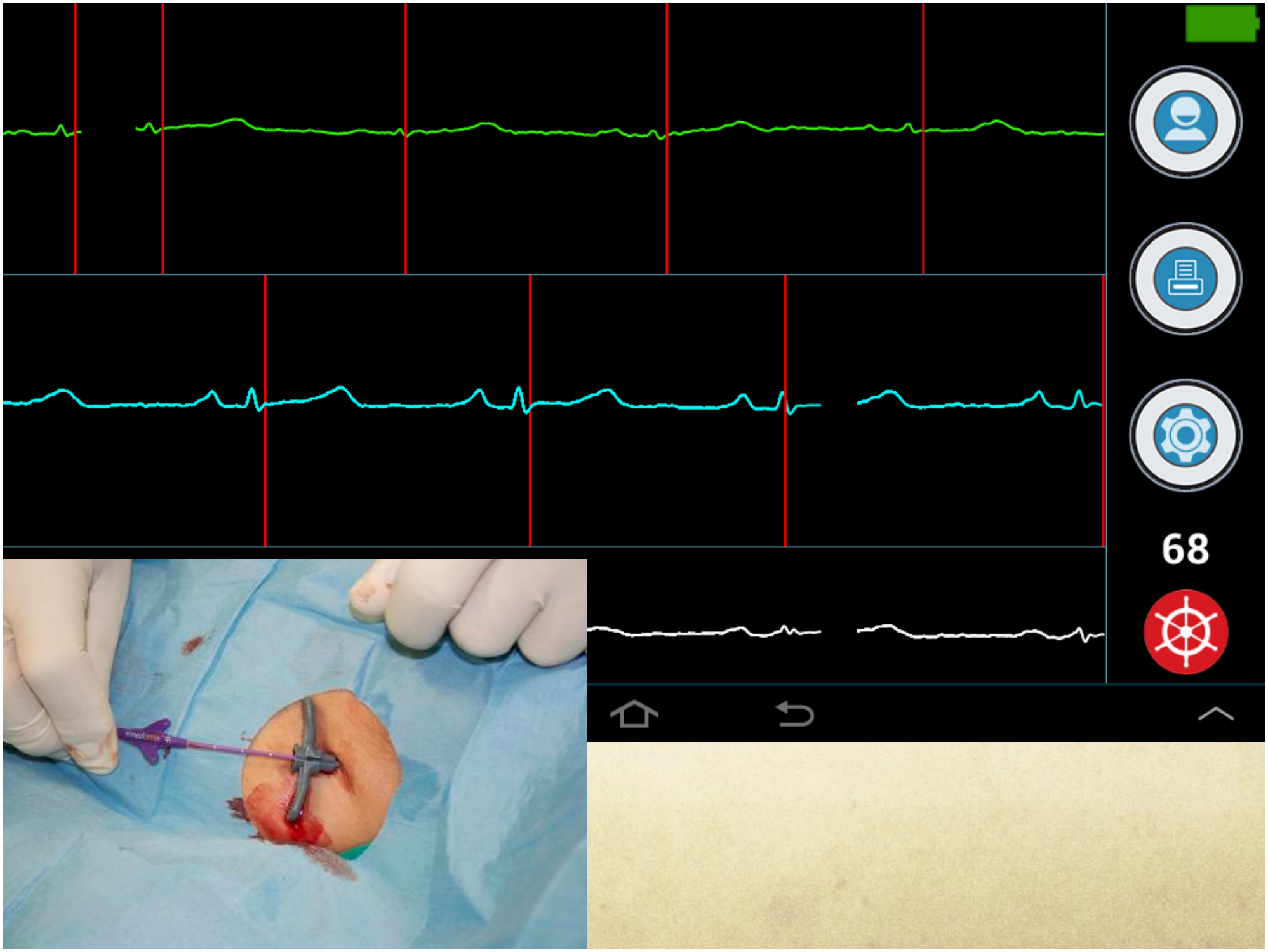
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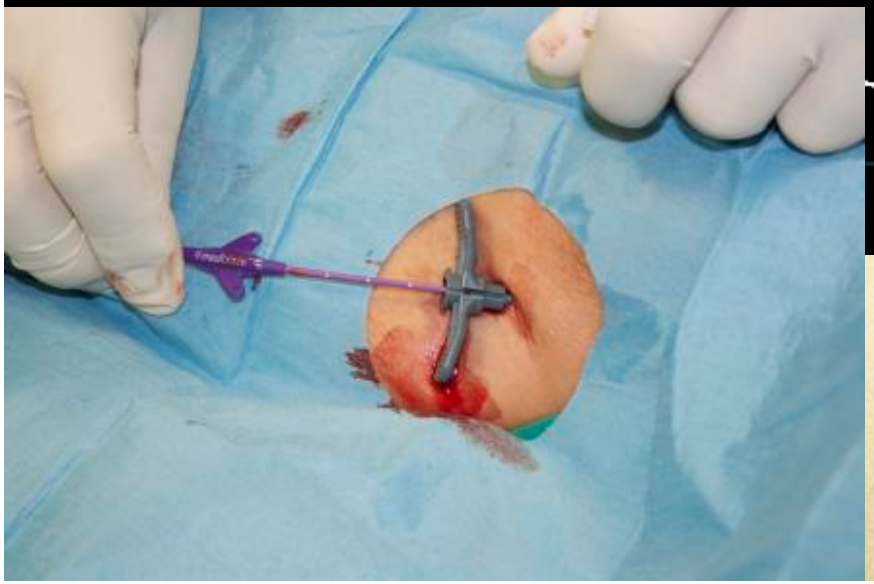

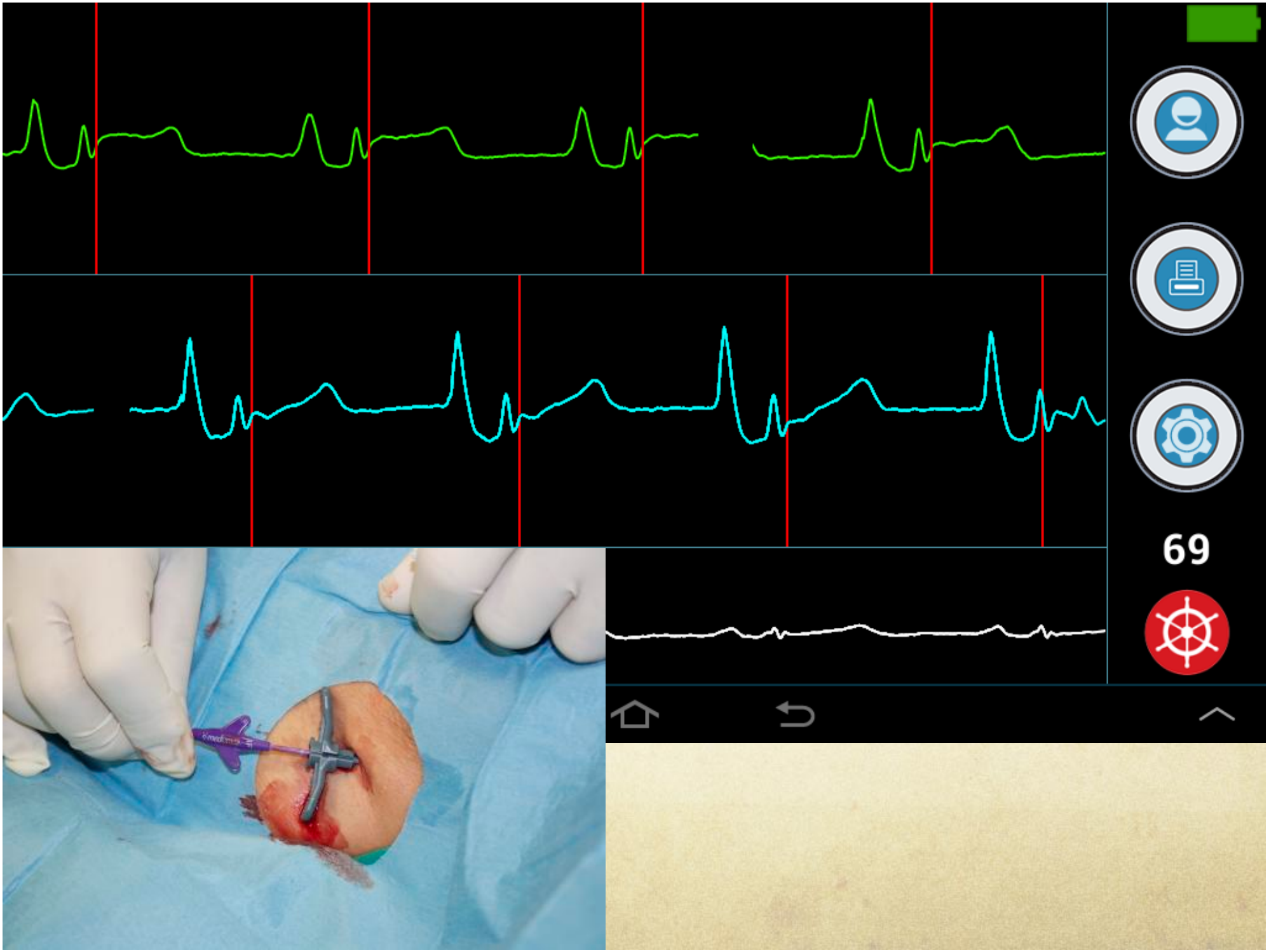
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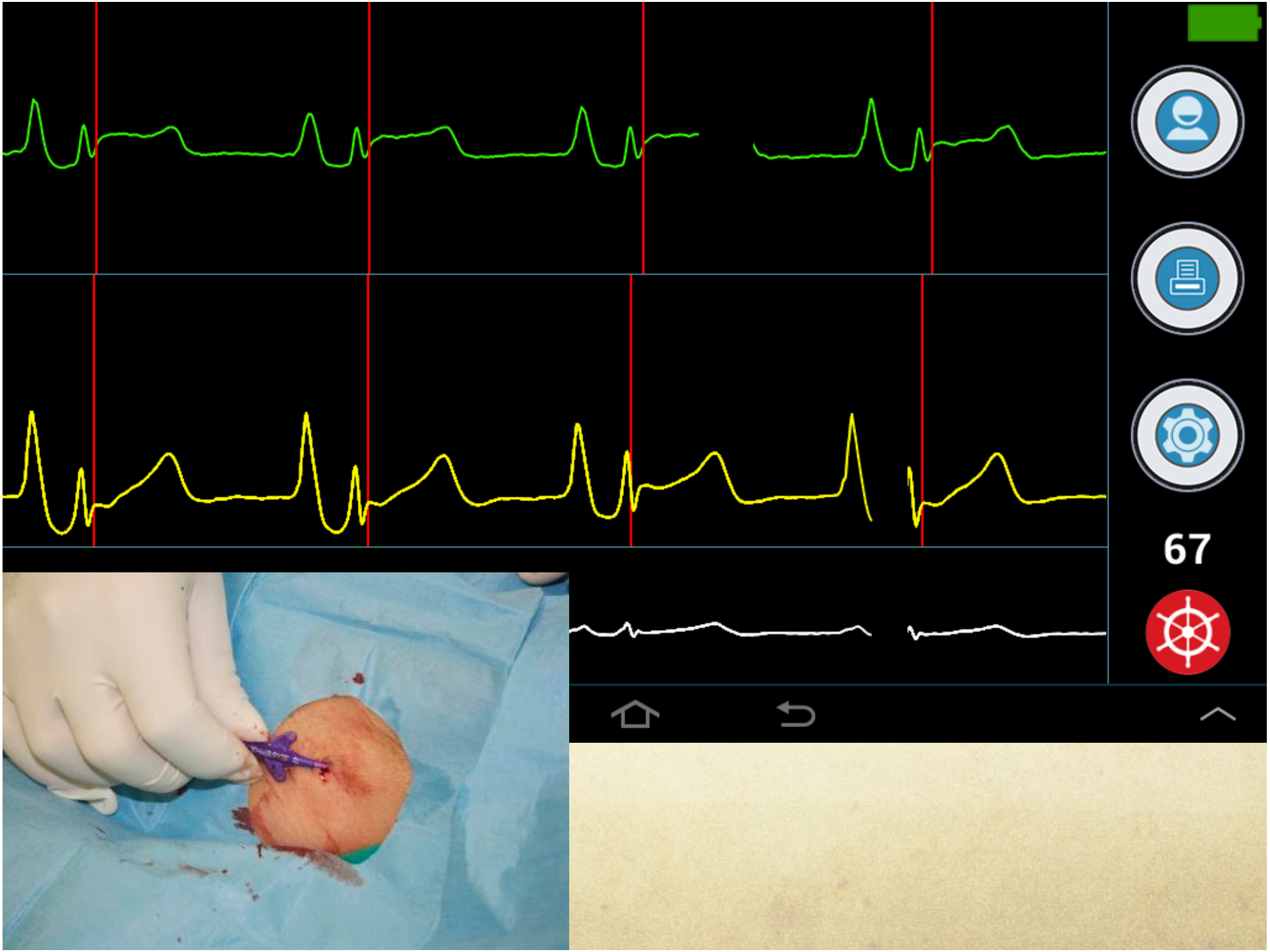

67


LONDON

Our studies with Delta

Pilot study on tip location (207 pts)

WoCoVA 2014

Tip location study in children (85 pts)

AVA 2015

Pilot study on tip location + navigation (26 pts)

AVA 2014

GAVeCeLT

Gli Accessi Venosi Centrali a Lungo Termine

A NEW WIRELESS DEVICE FOR THE INTRACAVITARY ECG TECHNIQUE

Introduction

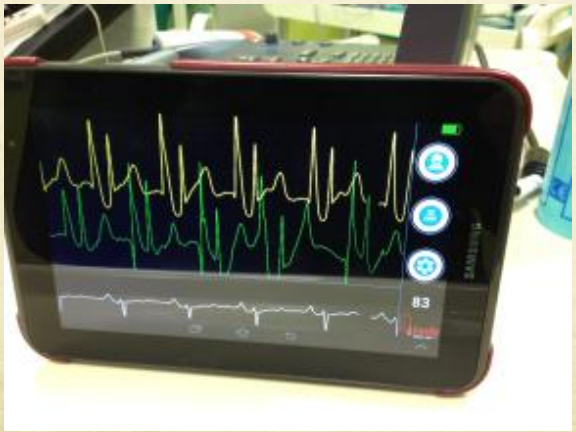
The intracavitary ECG method (IC-ECG) is adopted in clinical practice as an easy, cost-effective and accurate methodology for assessing the central location of the tip of venous access devices (VAD).

Introduction (2)

We report our preliminary experience with **a new wireless system specifically dedicated to the IC-ECG** (Nautilus Handy/Delta, Romedex), which consists of a small box connected to the ECG cables, sending data to a smartphone or a tablet by bluetooth technology.

The phone/tablet is provided with a software application which allows to display both the surface and intracavitary ECG.

The system can be operated by command buttons placed on the box or directly by touching the screen of the phone/tablet.



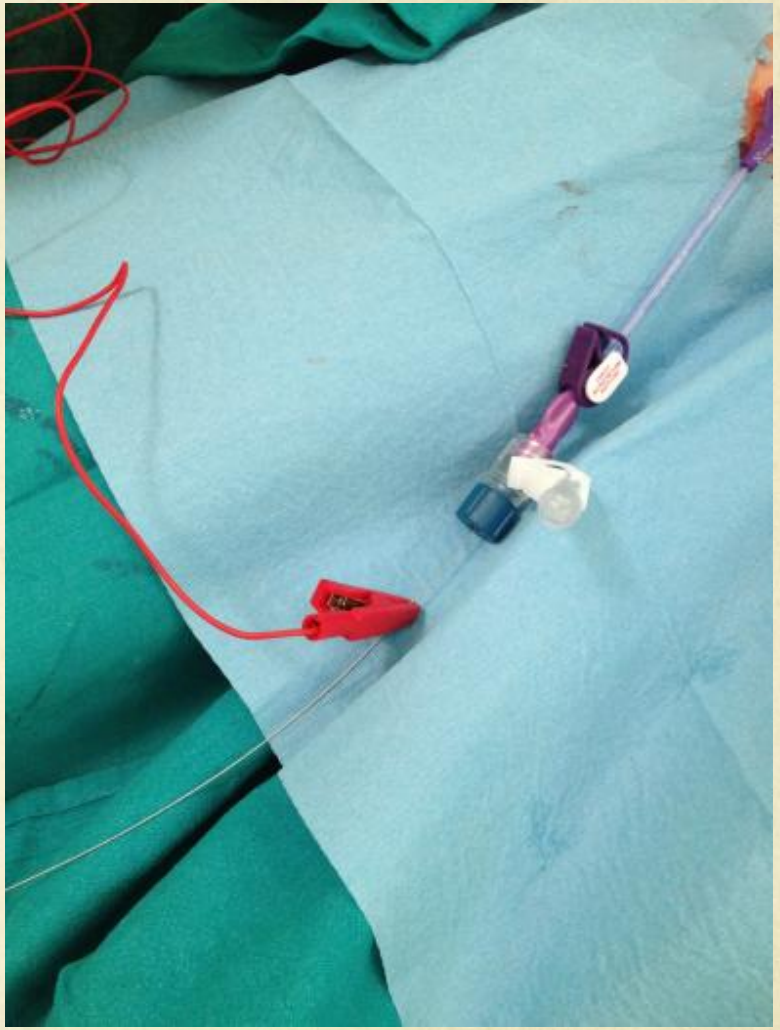

Handy
NAUTILUS

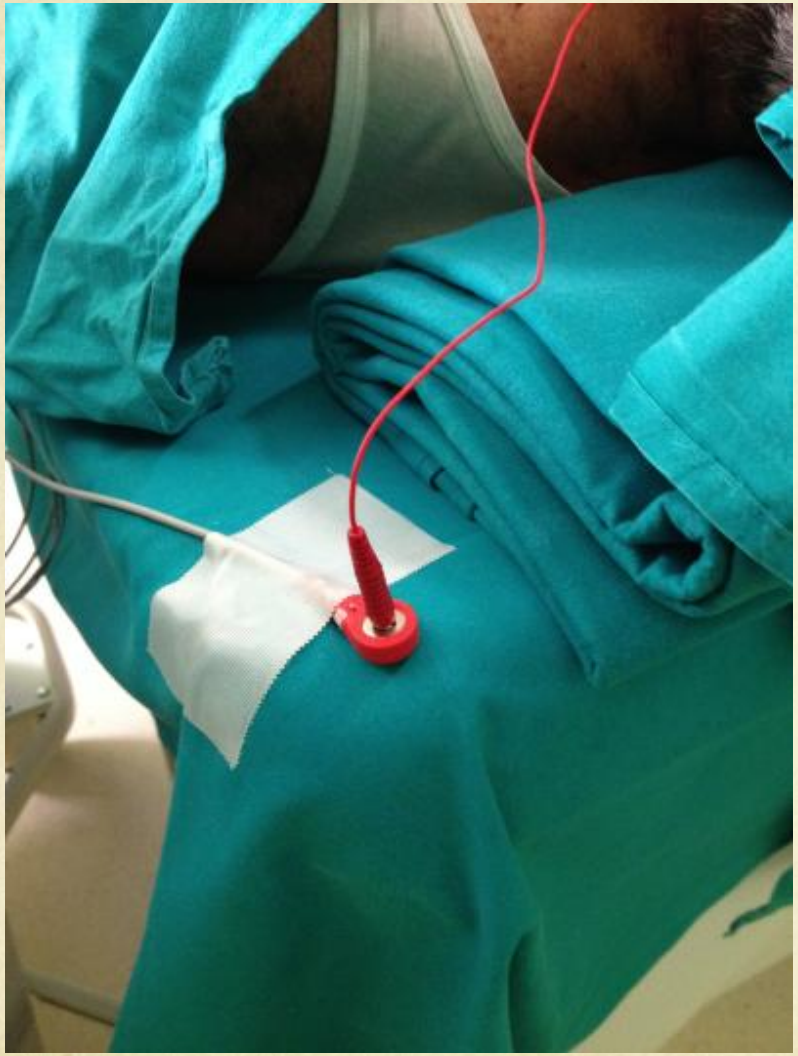
Methods

The IC-ECG method is performed according to the standard procedure.

The identification of the peak of the P wave (corresponding to the cavo-atrial junction) is made easy by the freeze function, which can be operated either from the box or from the phone/tablet.

At any time, the display can be saved and/or printed for documentation.



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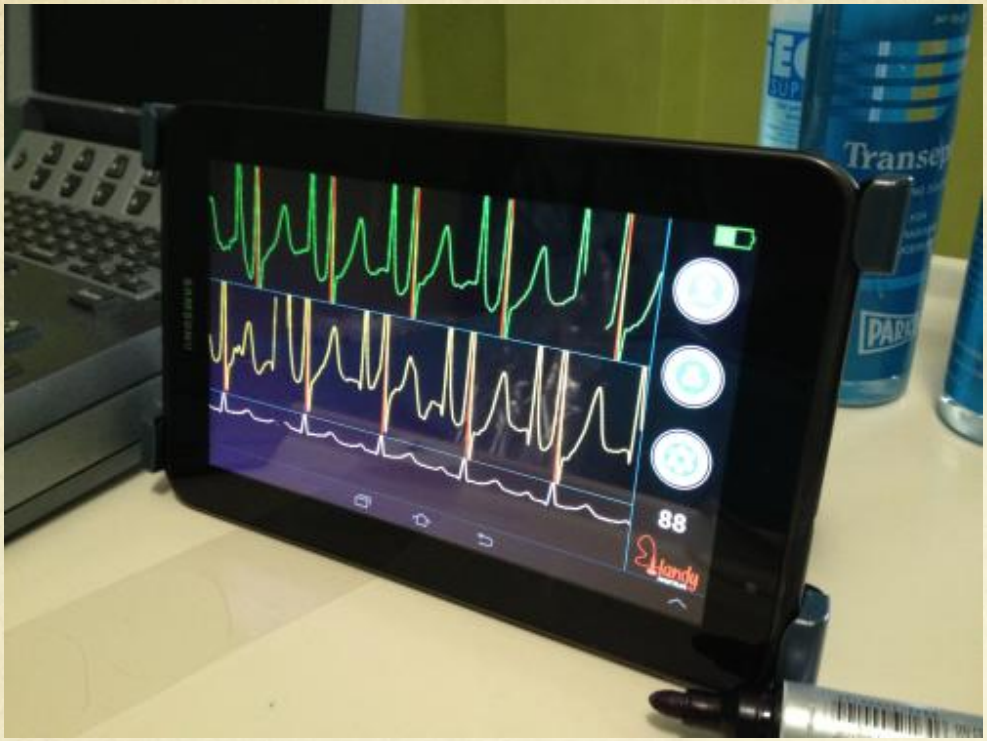
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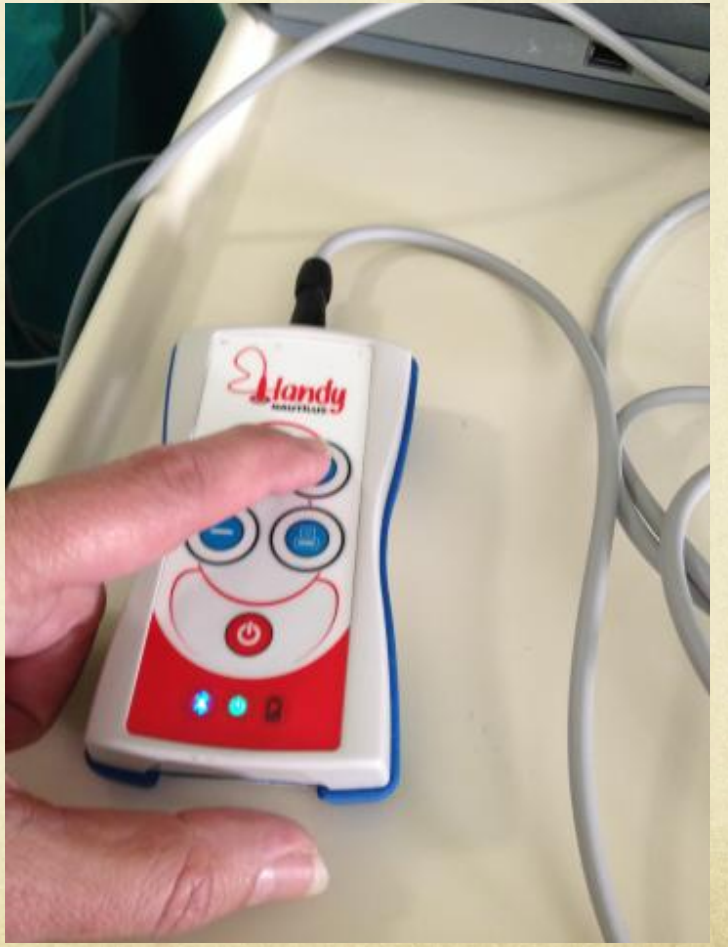
Handy


Handy

Results

The new device was adopted for tip location in **207** central VADs (154 PICCs, 49 ports, 2 short term CICCs and 2 cuffed-tunneled catheters) placed after cannulation of different veins (96 basilic, 41 brachial, 57 axillary-subclavian, 6 internal jugular, 7 brachio-cephalic) .

The P wave was evident on basal ECG in all patients.

A peak of the P wave was easily detected in all patients.

Results (2)

The P wave was evident on basal ECG in all patients.

A peak of the P wave was easily detected in all patients.

In **36** patients (28 PICCs and 8 ports), the procedure was simultaneously carried out both with a standard dedicated ECG device (Nautilus, Romedex) and with the new wireless device: no differences were noted in terms of performance.

Catheters	N°
PICCs	154
PORTs	49
Cuffed tunnelled catheters	2
CICCs	2

VEINS	N°
basilic	96
brachial	41
axillary-subclavian	57
internal jugular	6
brachio-cephalic	7

Conclusions

This new wireless system for IC-ECG had an optimal clinical performance in terms of applicability and feasibility.

Transmission of the data to the moveable device by bluetooth simplified the wire connections.

Conclusions (2)

Some potential advantages over other ECG monitors are:

- the system is light and easy to carry - which makes it ideal for bedside insertion;

- it can be operated by the same professional inserting the VAD;

- it implies no risk of electrical hazard;

- it can be used on a personal portable device, allowing easy storage of data and easy printing for documentation.

GAVeCeLT

Gli Accessi Venosi Centrali a Lungo Termine

Central venous access in neonates and children: tip location using a new wireless device for intracavitary ECG

Purpose

Tip location of central lines is particularly important in children and ideally it should be assessed during the procedure.

We have adopted the intracavitary ECG method (IC-ECG) since a decade.

We report our recent experience with a wireless device for IC-ECG.

Methods

We reviewed all centrally (CICC) and peripherally inserted central catheters (PICC) placed in our Pediatric Intensive Care Unit (PICU) using a wireless IC-ECG device (Delta, Romedex).

All insertions were performed according to our PICU protocol: sedation or general anesthesia, ultrasound scan of all veins, maximal barrier precautions, skin antisepsis with 2% chlorhexidine, ultrasound guided venipuncture using a micro-introducer kit, tip location by IC-ECG (maximal height of the P wave = cavo-atrial junction), securement of the catheter by cyanoacrylate glue, sutureless device and transparent dressing.

Results (1)

Wireless IC-ECG was used in 85 children (age range 2 hrs – 12 y.o.: 58 patients were < 2 y.o.). Lowest weight was 1100 g.

We inserted 81 non-cuffed catheters (power injectable, polyurethane, non-valved, open ended; 3Fr single lumen or 4Fr double lumen): 55 CICCs (in 95%, cannulation of the brachio-cephalic vein + tunneling to the infraclavicular area) and 26 PICCs (cannulation of deep veins of the arm; in 75%, cannulation of the axillary vein at the axilla + tunneling to the arm or to the lateral thoracic area).

In 4 cases, we inserted tunneled, cuffed CICCs (5Fr single lumen) for long term I.V. therapy: all 4 were children > 6 years.

Results (2)

We had no insertion-related complications.

IC-ECG was easily performed in all cases.

Post-procedural confirmation of tip location was performed by echocardiography or (in a few cases) by chest x-ray: no malposition was detected.

Conclusion

Tip location with the new wireless IC-ECG device was applicable, feasible, safe and accurate in 100% of our pediatric patients, even in small neonates.

GAVeCeLT

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Tip navigation + tip location

Purpose

Intracavitary ECG (IC-ECG) is currently used for assessing catheter tip location of central venous access devices (CVAD) at or around the cavo-atrial junction (CAJ).

Navigation support for CVAD is currently provided by other methods, such as electromagnetic or doppler-based.

In this pilot study, we tested a brand new application of IC-ECG for catheter tip navigation.

Method

IC-ECG-based tip navigation was performed using a wireless device (Delta, Romedex) - which is already available on the European market for IC-ECG tip location - modified so to support a new original software.

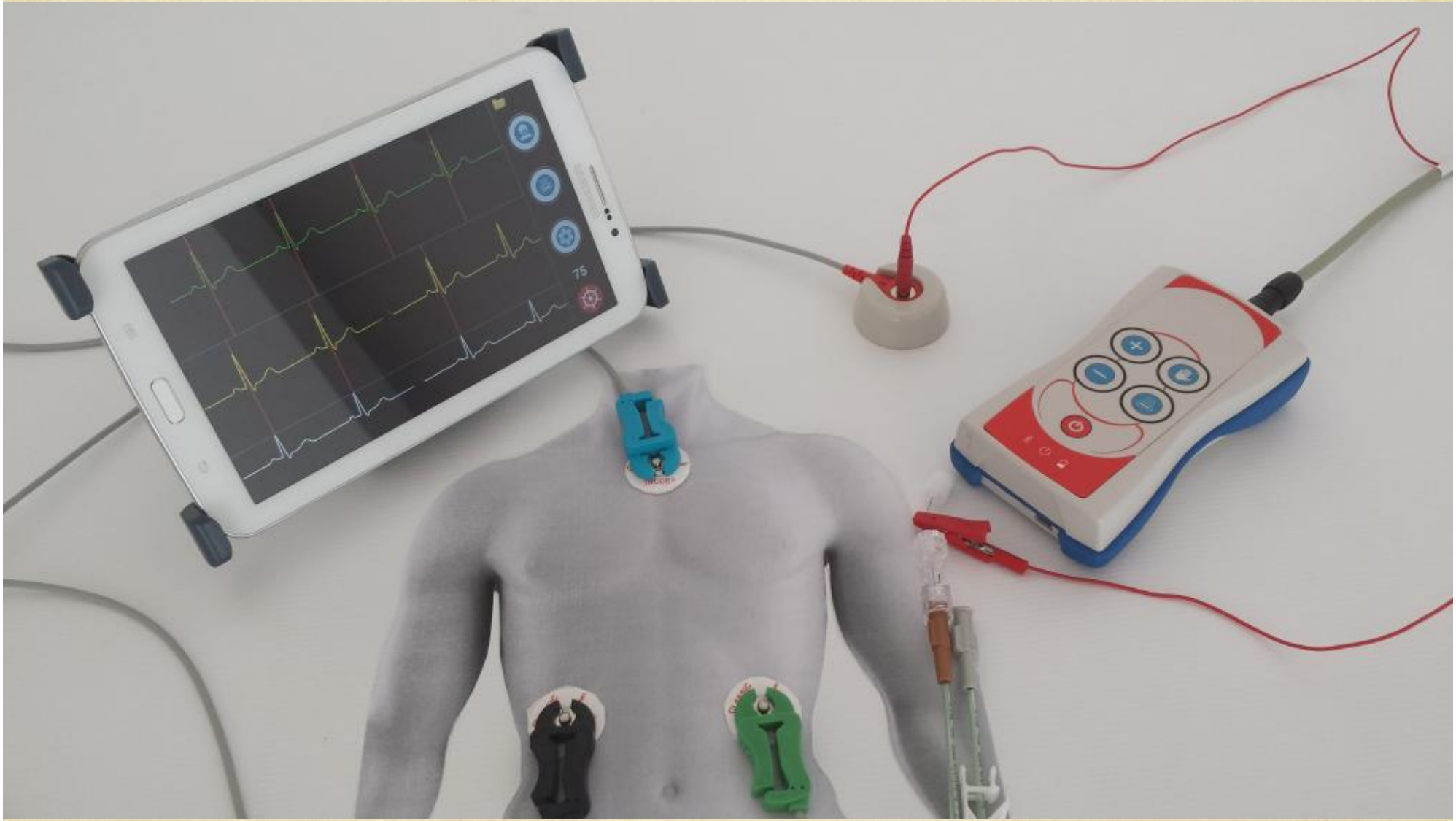
Method

One **control electrode** is placed on the patient's chest over the manubrium of the sternum just below the presternal notch.

The catheter is connected to a **second electrode** using a saline adapter.

A **third electrode** is placed for reference on the patient's left lower abdomen.

A novel ECG-based navigation signal is computed in real time combining the ECG signals from the tip of the catheter and from the control electrode, and is transmitted from the wireless device to a smartphone, by bluetooth.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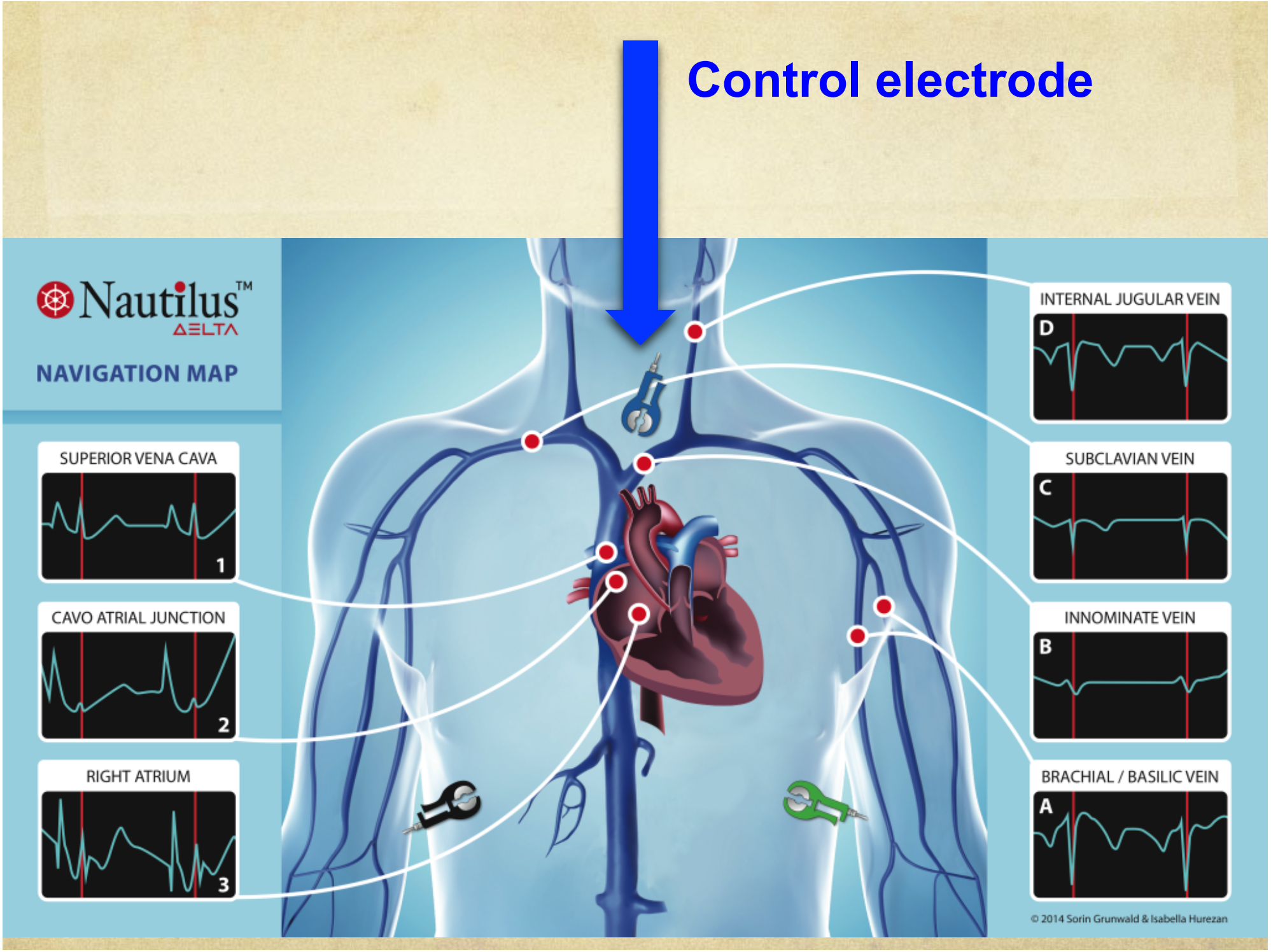

Control electrode
Nautilus™
ΔΞLTA
NAVIGATION MAP
SUPERIOR VENA CAVA
1
CAVO ATRIAL JUNCTION
2
RIGHT ATRIUM
3
INTERNAL JUGULAR VEIN
D
SUBCLAVIAN VEIN
C
INNOMINATE VEIN
B
BRACHIAL / BASILIC VEIN
A
© 2014 Sorin Grunwald & Isabella Hurezan

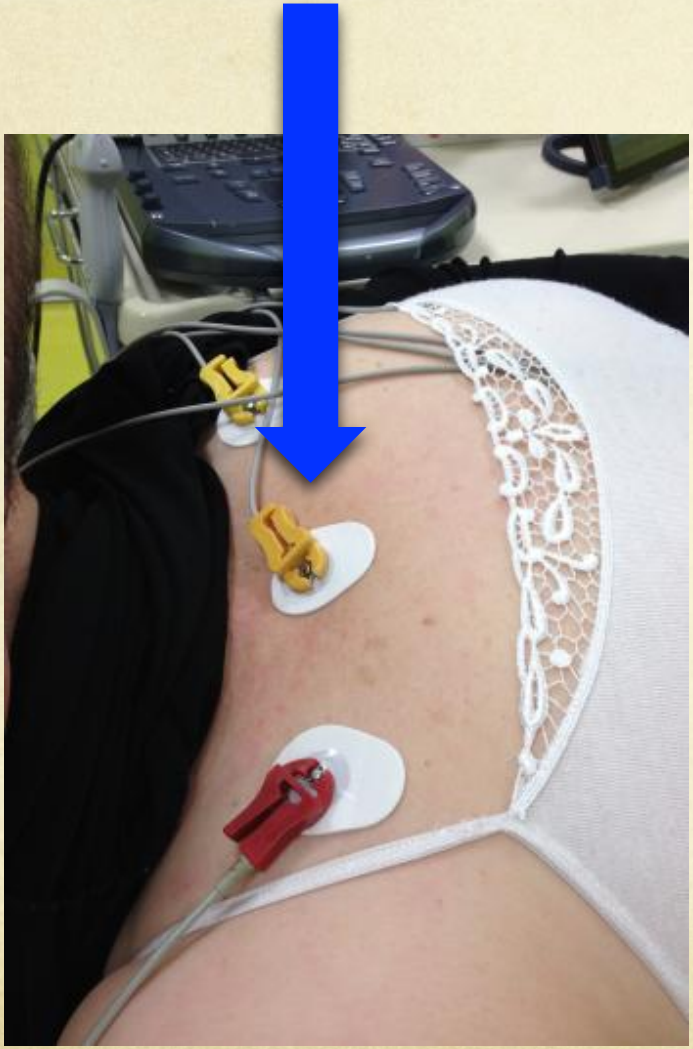
Results

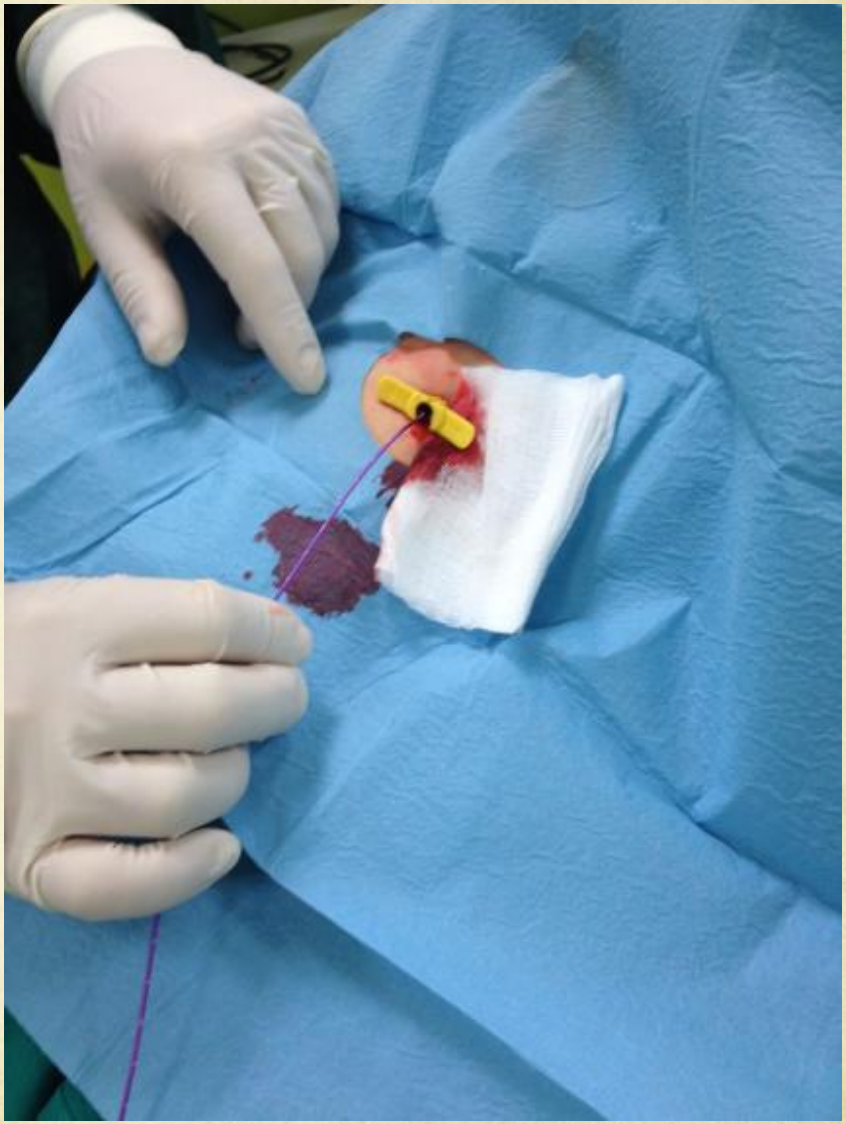
The new technique was used in **26** PICC placements.

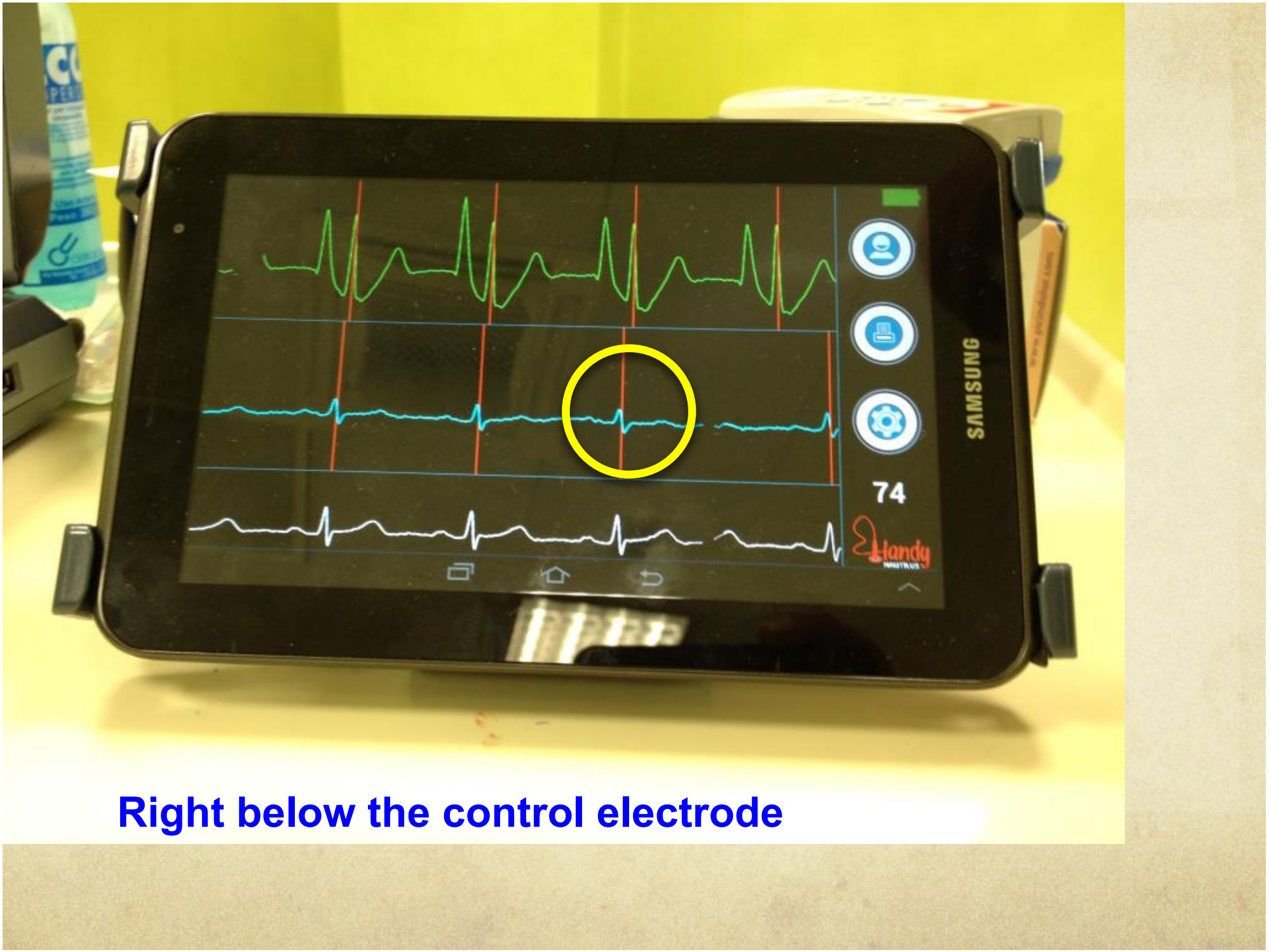
In all procedures, IC-ECG-based navigation signal successfully indicated whether the tip was moving towards or away from the CAJ; the catheter tip location at CAJ was confirmed by using the maximum P-wave criterion, as in traditional IC-ECG methods.

There were no procedure-related complications.

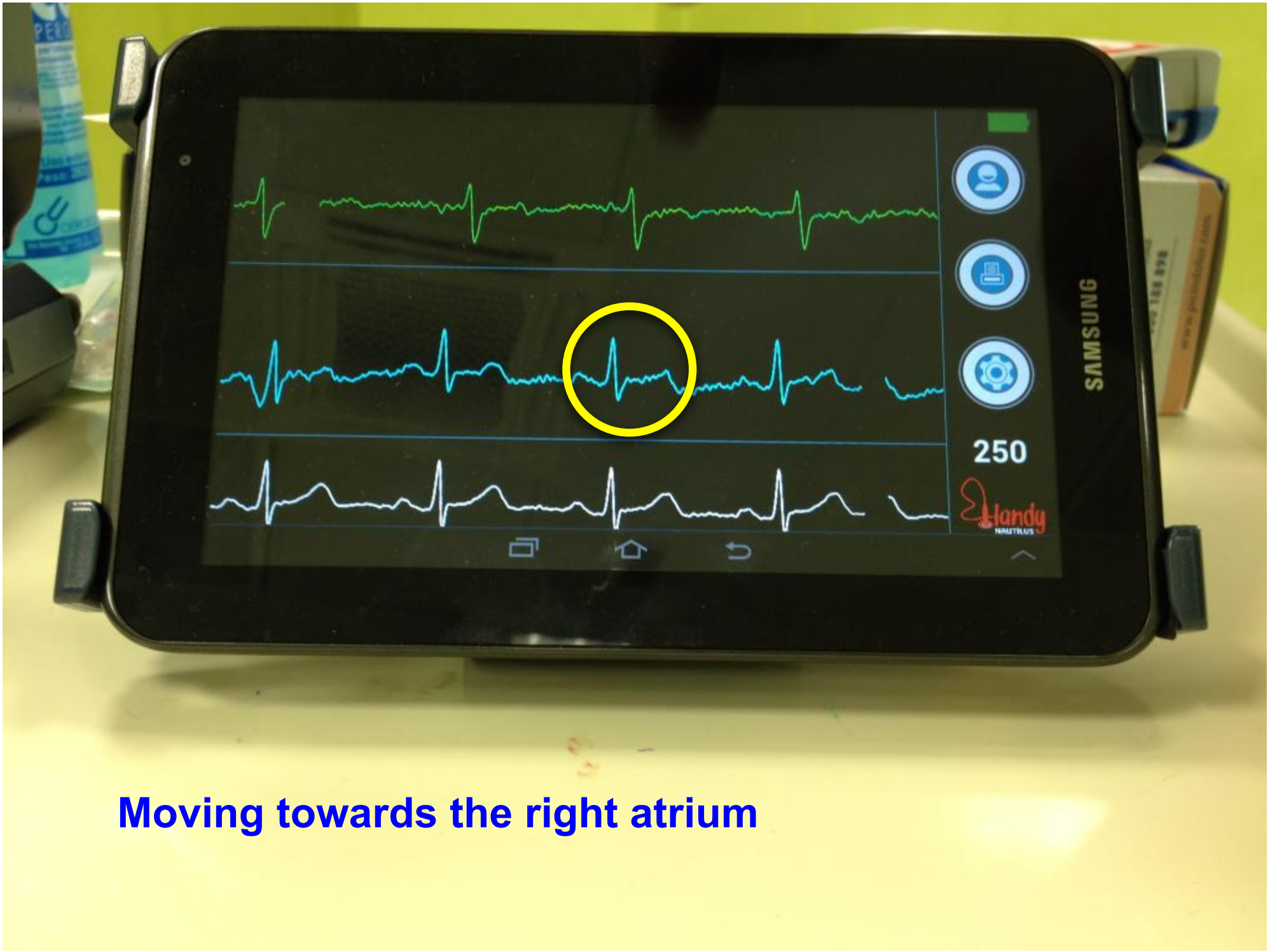
Control electrode



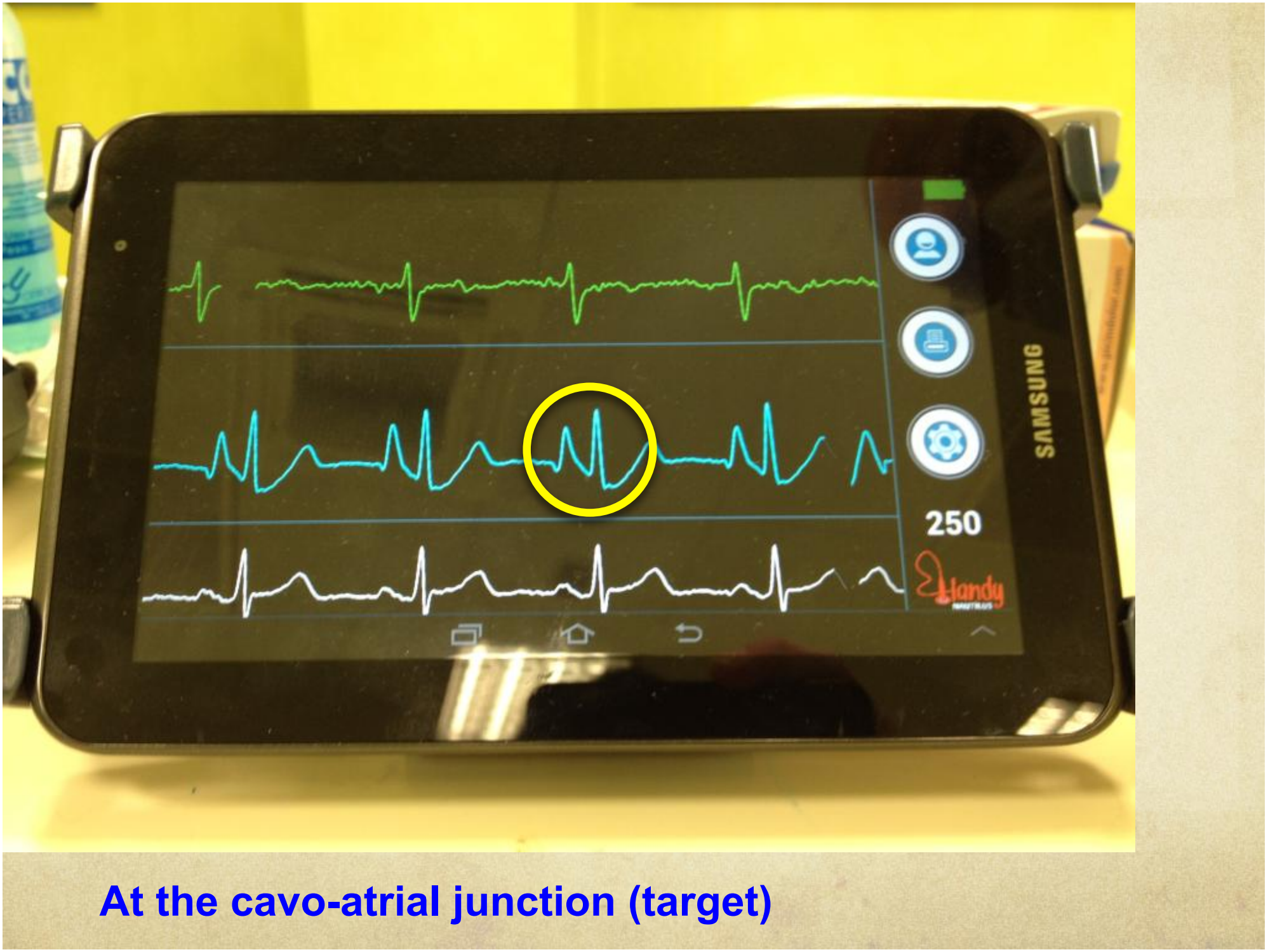




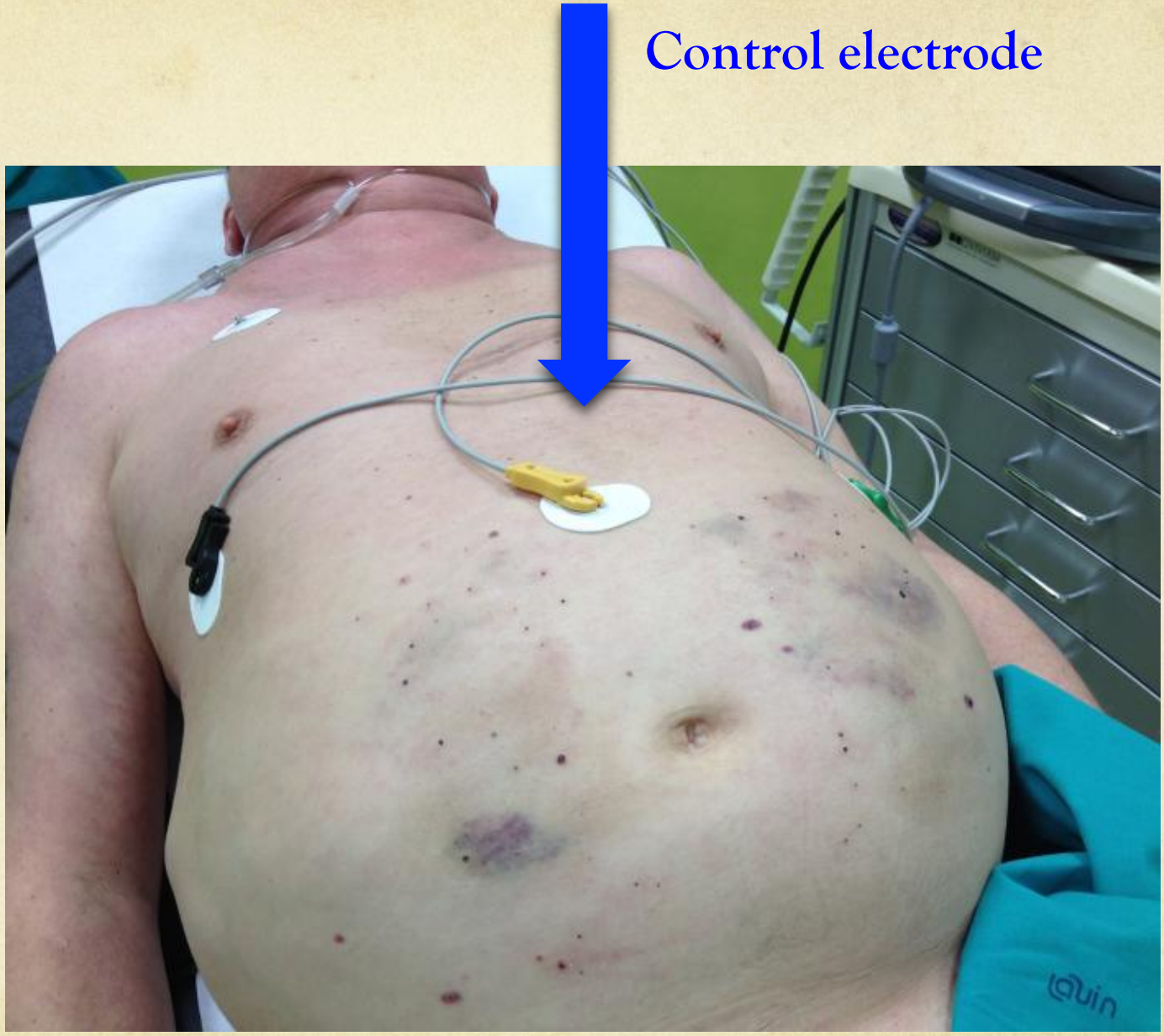
Right below the control electrode



Moving towards the right atrium

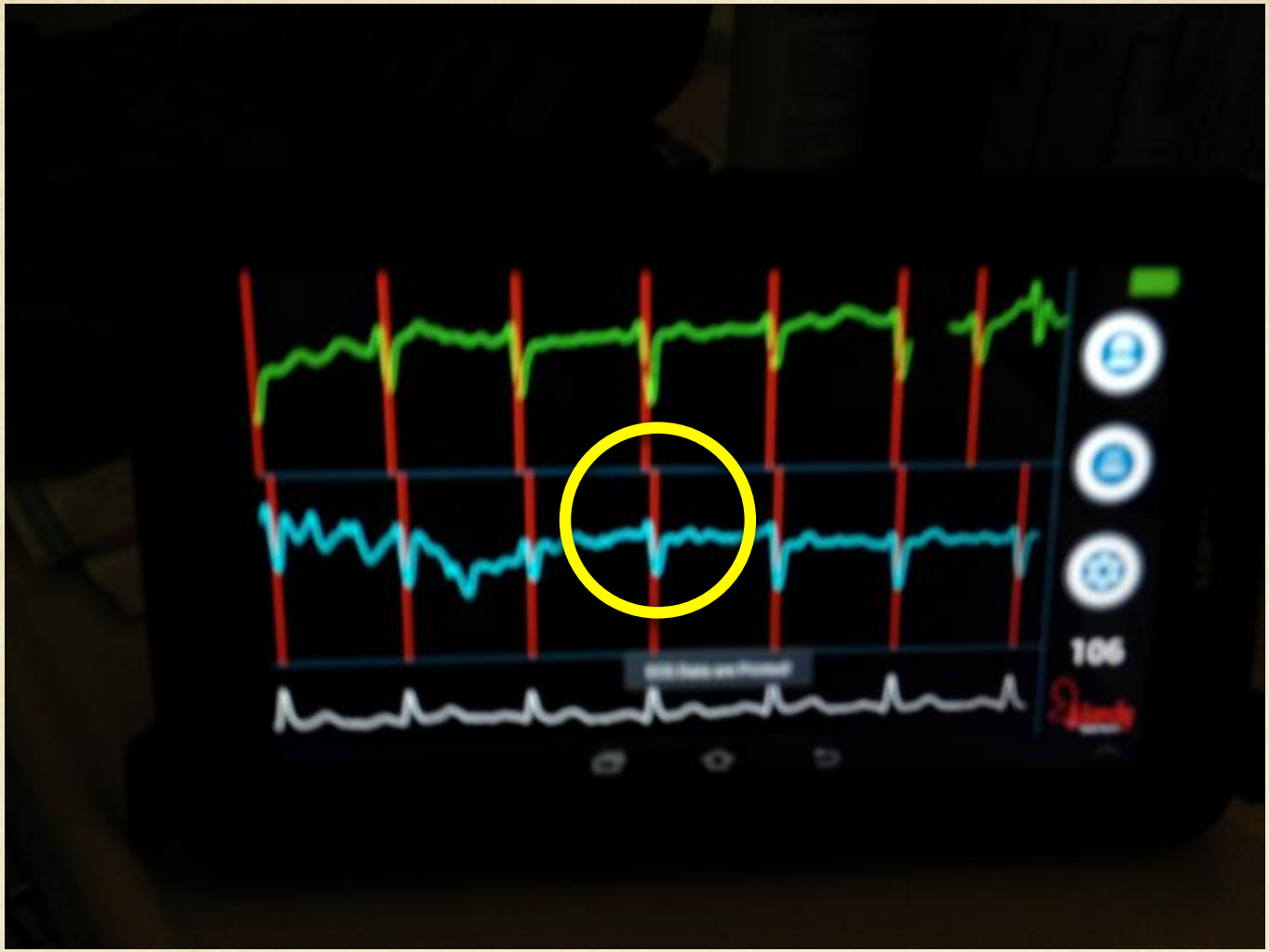


At the cavo-atrial junction (target)

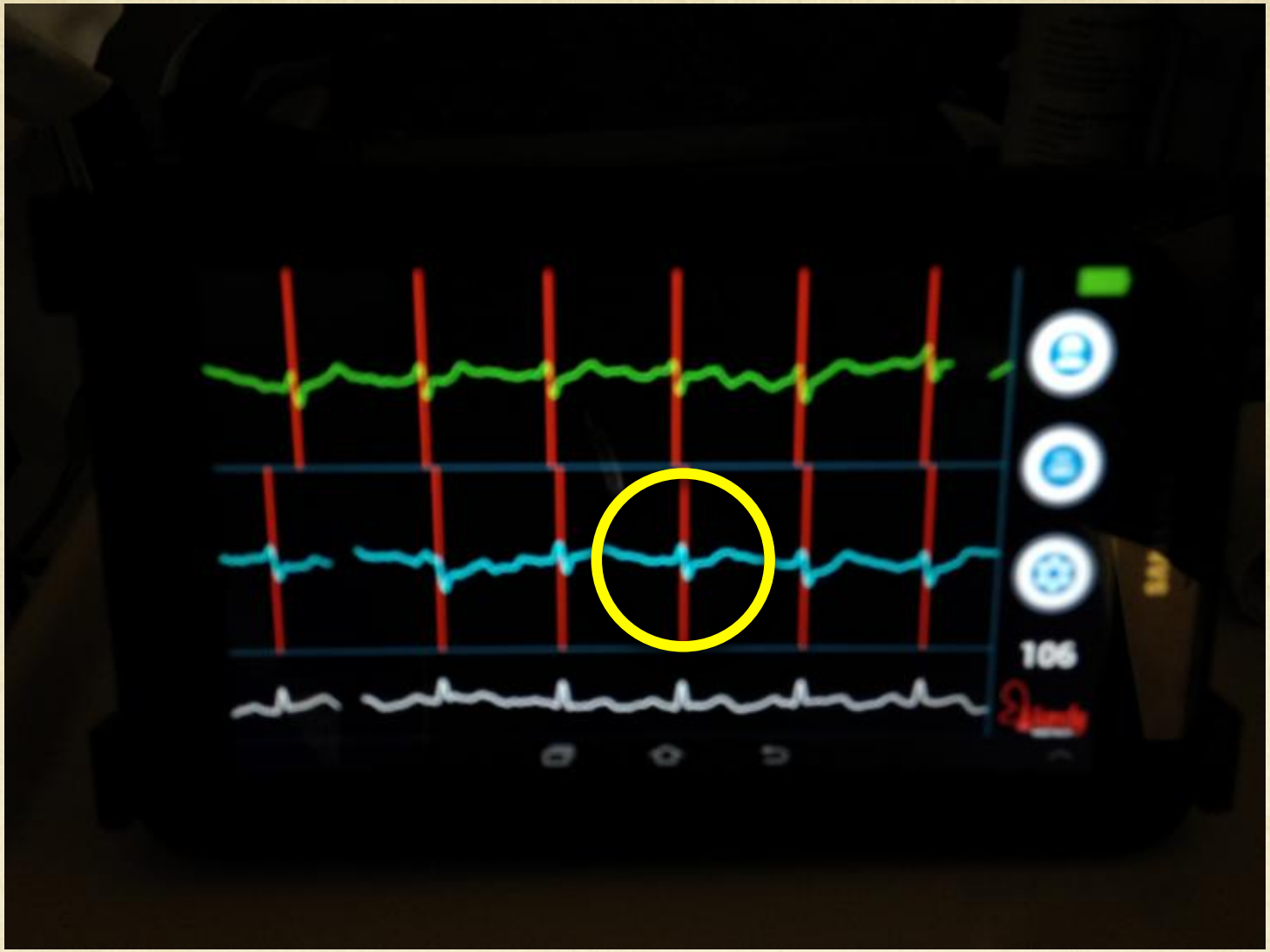


ECG navigation in inferior vena cava

Landmark measurement



Moving towards the right atrium



Right below the control electrode (target)

Conclusions

In our pilot study, this new methodology was successful and particularly easy to apply.

The relevant clinical implication is that clinicians may use a single IC-ECG device for both **tip navigation** and **tip location**.

Further data about the applicability, feasibility and accuracy of this technique will be provided as soon as available.

DELTA

Abstracts in international conferences

No published study yet

Very promising: easy, accurate, inexpensive, cost-effective

Advantages of tip location by Delta

- Easy to use
- Accurate
- No additional cost
- It can be used with any kind of central line
- It can be done with the same 3 electrodes used for ECG-based tip location
- Wide applicability (also in cases where ECG based tip location is not applicable)

Conclusions

First conclusion

There is no hard evidence that tip navigation is necessary during PICC insertion, though it may be useful (or ‘reassuring’ for the operator).

On the contrary, a proper method for tip location is always necessary.

Second conclusion

In most central line insertion, ultrasound may be the easiest, simplest, most easily available and most cost-effective method for tip navigation.

It accurately detects the ‘wrong’ direction to the ipsilateral IJV and the ‘right’ direction into the BCV in adults; it detects the direction inside both BCV and SVC in neonates and infants.

It helps to re-direct the catheter or the guidewire to the right direction

UNIVERSITÀ CATTOLICA del Sacro Cuore

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Grazie dell'attenzione

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