

**Interpretive Guideline**

Title: Registered Nurse Utilization of the Sapiens TCS or Other Comparable Device to Confirm Peripherally Inserted Central Catheter (PICC) Tip Placement in Adults.

Guidelines for registered nurse (RN) utilization of the Sapiens TCS (device), or other comparable electrocardiogram (EKG) PICC tip confirmation device, to confirm the location of a PICC tip in adults in accordance with a valid, authorized provider order:

Utilization of the device during the PICC insertion to confirm the PICC tip location for purposes of initiating intravenous therapy may be within the scope of registered nursing practice if the following guidelines are observed:

- A. The RN has a valid order from an authorized provider to place and confirm PICC tip location using the device. For purposes of this Interpretive Guideline, an authorized provider is an individual who is authorized to practice in the state of Ohio and is providing the order in the course of the individual's professional practice that includes IV therapy and PICC tip confirmation utilizing the device.
- B. The RN has acquired and documented knowledge, skills and competency in PICC placement and PICC tip location utilizing the device for purposes of initiating intravenous therapy consistent with the order.
- C. With a valid order that specifies the EKG p-wave changes to be observed during PICC insertion, the RN may, consistent with the order:
 1. Provide documentation of the patient's EKG p-wave changes observed and recorded at the time the RN places the PICC to the authorized provider to confirm that the PICC tip is in the appropriate location and to then authorize the initiation of IV therapy;

-OR-

 2. Identify and document the specific EKG p-wave parameters included in the authorized provider orders to be observed for purposes of confirming PICC tip location and initiating IV therapy.

D. In executing a nursing regimen to utilize the device, the registered nurse should perform the following activities:

1. Determine and document the patient's baseline cardiac rhythm;
2. Identify and document through a cardiac rhythm strip recording that the patient has an identifiable "p-wave," and that the patient's cardiac rhythm does not preclude the use of the device for PICC tip location confirmation;
3. Notify the authorized provider of the presence of any patient parameter in which the use of the device is contraindicated. Contraindications include the presence of atrial fibrillation, or any cardiac rhythm in which a p-wave is absent or not identifiable, or other contraindications listed in the device manufacturer's published information; and
4. Place the PICC using the device only in clinical settings and environments where the patient's safety and well-being will be supported by use of required sterile techniques, availability of cardiac monitoring with real time EKG recordings, and the availability of additional health care personnel to respond to complications.

In utilizing the device to confirm PICC tip placement, the registered nurse should not:

1. Engage in activities that constitute the practice of medicine and surgery in Ohio;
2. Confirm PICC tip placement using the device without a valid order to place and confirm the PICC tip location and the p-wave parameters to be observed and documented for purposes of the confirmation;
3. Utilize the device on pediatric patients; or
4. Utilize the device in circumstances where the use of the device is contraindicated.

Considerations in Use of the Device (Rule 4723-4-03, Ohio Administrative Code (OAC))

1. The RN who utilizes the device or other comparable EKG PICC tip confirmation device, to place and confirm PICC tip location in adults should maintain documentation of his/her acquisition of education, demonstrated competency, and other documentation that ensures practice is guided by the employing facility/institutional policies and procedures, and the manufacturer's published information for the use of the device.

2. The RN's education/training and demonstrated competence should include the following:
 - a. Cardiovascular anatomy and physiology as it pertains to PICC placement and verification of PICC tip location;
 - b. Indications and contraindications for the use of the device, e.g., atrial fibrillation, inconsistent or unidentifiable p-wave on EKG recording;
 - c. Techniques and procedures for PICC insertion and removal;
 - d. Identification of EKG p-wave morphology as it pertains to proper PICC tip placement;
 - e. Signs and symptoms of infusion therapy complications and actions to be taken in the event of complications;
 - f. Interpretation of cardiac rhythms and identification of rhythms that contraindicates the use of the device;
 - g. Proper use of the device consistent with provider orders and the manufacturer's published information;
 - h. Infection control standards pertaining to PICC insertion and placement, and the care of patients who have PICC lines; and
 - i. Nursing care of patients receiving IV therapy through PICC placement and maintenance including: observation and monitoring of EKG changes; applicable patient teaching; providing a safe environment and other nursing considerations that may also be established through institutional policy and consistent with Chapter 4723-4, OAC.

Accountability and Responsibility of Nurses

Section 4723.01(B) of the Ohio Revised Code (ORC) defines the scope of practice for the registered nurse. Rule 4723-4-03, OAC, holds registered nurses responsible for maintaining and demonstrating current knowledge, skills, abilities, and competence in rendering nursing care within their scope of practice.

The registered nurse must apply the Nurse Practice Act (Chapter 4723, ORC) and rules regulating the practice of nursing (Chapters 4723-1 to 4723-27, OAC) to the specific practice setting. Further, the registered nurse must utilize good professional judgment in determining whether or not to engage in a given patient-care related activity, consistent with the law and rules, and guided by the Board *RN and LPN Decision Making Model*. It is critical to note that the law and rules require that the licensee provide nursing care only in circumstances that are consistent with their education, experience, knowledge, and demonstrated competency.

In this statement the Board does not announce a new policy but instead gives licensees specific instructions regarding their obligations under existing law and rules.

Licensees should review the following:

Section 4723.01(B), ORC

Section 4723.151, ORC

Rule 4723-4-03, OAC

Rule 4723-4-06, OAC

Rule 4723-4-07, OAC

July 17, 2012 Letter from the State Medical Board of Ohio (attached)
Utilizing Interpretive Guidelines

A complete copy of the Nurse Practice Act and the rules adopted thereunder are available for review and download from the Board of Nursing website at www.nursing.ohio.gov on the Law and Rules page. All Interpretive Guidelines and the Utilizing Interpretive Guidelines document are available on the Practice RN and LPN page.

Approved: September 20, 2012

Reapproved: March 20, 2014

Revised: March 16, 2016

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State Medical Board of Ohio

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July 17, 2012

Betsy Houchen, J.D., M.S., R.N.
Executive Director
Ohio Board of Nursing
17 South High Street, Suite 400
Columbus, OH 43215-7410

Dear Ms. Houchen:

This letter is in response to your inquiry concerning the use of new technology by registered nurses to confirm peripherally inserted central catheter [PICC] placement via ECG, also referred to as EKG. Specifically you inquire:

- Is it within the minimal standards of care for a physician to utilize and rely on electrocardiogram “p” wave changes for purposes of verifying PICC tip location?
- If so, is it within the minimal standards of care for a physician to personally observe the electrocardiogram that was recorded by the RN at the time the RN placed the PICC, to determine appropriate PICC tip location and to then authorize initiation of infusion therapy?
- Is it within the minimal standards of care for a physician to include in the PICC insertion order the electrocardiogram “p” wave parameters to be observed by the RN that verifies PICC tip location and authorizes the initiation of infusion therapies?

To assist the State Medical Board of Ohio (Medical Board) in researching this question, your agency forwarded information on the Sapiens Tip Confirmation System [Sapiens TCS]. The Sapiens TCS is new technology that purports that observation and documentation of electrocardiogram “p” wave changes during PICC insertion and at terminal placement may be used as a reliable indicator of PICC tip location in adults, and may be used in lieu of the chest x-ray method of verification. You have indicated that registered nurses are authorized to insert PICC lines when they obtain a patient specific order from an authorized health care provider. You have also indicated that RNs may interpret EKGs for the purpose of providing nursing care.

The Medical Board’s Group 2 Committees have carefully considered the question before it. At its July 12, 2012 meeting, the Medical Board approved the following response by the Scope of Practice Committee:

Section 4731.34, Ohio Revised Code, defines the practice of medicine and surgery, osteopathic medicine and surgery, and podiatric medicine and surgery in pertinent part as follows:

(A) A person shall be regarded as practicing medicine and surgery, osteopathic medicine and surgery, or podiatric medicine and surgery, within the meaning of this chapter, who does any of the following:

(3) ***

(a) Examines or diagnoses for compensation of any kind, direct or indirect; ***

A PICC is a catheter inserted via peripheral vein with the tip located in the vena cava as a delivery mechanism for infusion therapy. Once the PICC tip is inserted, confirmation that the tip is located in the vena cava is essential to ensure that the medicine is properly received by the body. Common means of confirming the location of the PICC tip is by x-ray or fluoroscopy. However, as a result of technological advancements, the Sapiens TCS uses changes in P-wave morphology to identify the tip placement.

According to information provided in a brochure entitled, "Confirm & Clear: PICC Tip Confirmation without Chest X-ray," Bard Access Systems,

http://www.bardaccess.com/assets/pdfs/brochures/MC_0774_01_Sapiens_phase2_%20brochure%20update_web.pdf, the Sapiens TCS is indicated for PICC tip placement confirmation in adults. It is designed to assist registered nurses in placing the PICC tip while allowing the visual confirmation of the placement for documentation in the patient chart.

In reviewing this matter, the Medical Board also solicited input from an Ohio licensed pulmonologist who practices critical care medicine. The pulmonologist described the Sapiens TCS as a device that functions to locate the PICC tip based upon its relationship to the sino-atrial node, as determined by electrical conductivity through a column of saline in the lumen of the PICC. The P-wave inverts as the PICC passes the sino-atrial node on insertion. When the PICC is withdrawn, a specified amount of the change in the P-wave verifies the placement of the tip of the PICC line. The method requires that the health care provider using the device to determine the PICC tip placement be able to recognize the P-wave and its inversion.

The Sapiens TCS literature warns that under certain circumstances the PICC tip placement must be confirmed via x-ray. The warnings include the following:

Any alterations of cardiac rhythms that change the normal presentation of the P-wave limit the use of this technology. In these instances, confirm PICC tip location using an alternate method. <http://bardaccess.com/imaging-sapiens.php>.

Conditions listed as inappropriate for use of the Sapiens TCS include where the P-wave is not present, not identifiable, or is intermittent or where there is no observable change in the P-wave.

Although your inquiry asks whether certain actions comport with the minimal standards of care, it is not necessary to address that specific question. The determination of whether the provision of medical services is within the minimal standards of care must be determined upon a case-by-case

basis, and the questions posed may be answered without pronouncement of whether the minimal standards of care are met in hypothetical situations.

Your first question asks whether it is within the minimal standards of care for a physician to utilize and rely on electrocardiogram “p” wave changes for purposes of verifying the PICC tip location. It is clear that physicians may use FDA cleared medical devices for the approved use as appropriate to the medical situation presented. The Sapiens TCS was given 510(K) clearance by the FDA on October 20, 2011 for use in guidance and intended positioning of PICCs as an alternative method to chest x-ray and fluoroscopy for PICC tip placement in adult patients. Accordingly, a physician may use the Sapiens TCS for the guidance and intended positioning of PICCs as an alternative method to chest x-ray and fluoroscopy for PICC tip placement in adult patients where its use is medically indicated.

You then ask whether it is within the minimal standards of care for a physician to personally observe the electrocardiogram that was recorded by the RN at the time the RN placed the PICC, to determine appropriate PICC tip location and to then authorize initiation of infusion therapy. A physician may authorize further treatment after reviewing the results of a test conducted by another provider authorized to perform the test. The physician is expected to follow-up if there is any question, for example, as to the accuracy of the test results, the results are unclear, or the results show a possible condition that might contravene the next step of treatment. You have indicated that registered nurses are authorized to insert PICC lines when they obtain a patient specific order from an authorized health care provider. The Board of Nursing is authorized to determine whether a registered nurse may conduct an EKG as part of the placement of a PICC. Assuming that the Board of Nursing determines that the registered nurse may do so, a physician may personally observe an electrocardiogram that was recorded by the RN at the time the RN placed the PICC, to determine appropriate PICC tip location and to then authorize initiation of infusion therapy.

Finally, you ask whether it is within the minimal standards of care for a physician to include in the PICC insertion order the electrocardiogram “p” wave parameters to be observed by the RN that verifies PICC tip location and authorizes the initiation of infusion therapies. In the past, the Medical Board has opined that the limited interpretation of an x-ray for the purpose of verifying the placement of the PICC tip prior to the initiation of infusion therapy is the practice of medicine limited to physicians. However, the technology at issue allows the ability to determine the placement of the PICC tip based upon its relationship to the sino-atrial node, as determined by electrical conductivity shown in an EKG. You have indicated that a registered nurse may interpret EKGs for the purpose of providing nursing care. Nursing care includes the initiation of infusion therapy as ordered by a physician. Accordingly, a physician may include in the PICC insertion order for each specified patient the electrocardiogram “p” wave parameters to be observed for verification of the PICC tip location as authorization for the initiation of infusion therapy.¹

In summary, a physician may use devices such as the Sapiens TCS for the guidance and intended

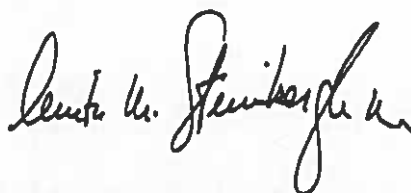
¹ The Nursing Board requires registered nurses who implement orders for PICC placement and PICC tip verification to have acquired the education, knowledge and skills necessary to safely insert a PICC and to verify the PICC tip placement using the Sapiens device, and requires the nurse to further consult with the physician when the nurse identifies patient EKG information, such as the presence of atrial fibrillation or other cardiac arrhythmia in which the p-wave is either absent or intermittent, where the use of the Sapiens device to confirm tip placement is contraindicated.

positioning of PICCs as an alternative method to chest x-ray and fluoroscopy for PICC tip placement in adult patients where its use is medically indicated. If the Board of Nursing determines that a registered nurse may conduct an electrocardiogram, a physician may personally observe an electrocardiogram that was recorded by the RN at the time the RN placed the PICC, to determine an appropriate PICC tip location and to then authorize initiation of infusion therapy. Finally, a physician may include in the PICC insertion order for each specified patient the electrocardiogram "p" wave parameters to be observed for verification of the PICC tip location as authorization for the initiation of infusion therapy.

Thank you for the cooperation of the Ohio Board of Nursing in the resolution of this matter. Please contact Sallie Debolt, General Counsel, at (614) 644-7021, should you have questions regarding this response.

This letter is only a guideline and should not be interpreted as being all inclusive or exclusive. The Board will review all possible violations of the Medical Practices Act and/or rules promulgated thereunder on a case by case basis.

Sincerely,

A handwritten signature in black ink, appearing to read "Anita M. Steinbergh". The signature is fluid and cursive, with a large initial 'A' and 'S'.

Anita M. Steinbergh, D.O.
Chair
Group 2 Committees