

FILED DATE - JAN 02 2018

Department of Health

By: Angela Sanders
Deputy Agency ClerkSTATE OF FLORIDA
BOARD OF NURSINGIN RE: THE PETITION
FOR DECLARATORY
STATEMENT OF
DABRINA LEE BLOCKER

FINAL ORDER

THIS CAUSE came before the BOARD OF NURSING (hereinafter Board) pursuant to §120.565, Florida Statutes, and Rule 28-105, Florida Administrative Code, at a duly-noticed meeting in Deerfield Beach, Florida on December 8, 2017, for the purpose of considering the Petition for Declaratory Statement (attached as Exhibit A) filed by DABRINA LEE BLOCKER (hereinafter Petitioner). Having considered the petition, the arguments submitted by counsel for Petitioner, and being otherwise fully advised in the premises, the Board makes the following findings and conclusions.

FINDINGS OF FACT

1. This petition was noticed by the Board in Vol. 43, No. 127, dated June 30, 2017 of the Florida Administrative Register .
2. Petitioner is registered nurse licensed to practice nursing in the State of Florida, having license number RN 9388756.
3. Petitioner is employed by a gastroenterology practice.
4. Petitioner inquires whether it is within her scope of practice to administer the Bravo pH monitoring system without a physician physically present in the building where the system is administered.
5. The Bravo pH monitoring system records, stores, views, and analyzes gastroesophageal pH data to diagnose reflux disorders.

6. A small pH capsule is temporarily attached to the wall of the esophagus to capture and transmit pH data.
7. The capsule is attached to the esophagus by suction.
8. The location of the attachment is determined by reviewing pH levels.
9. The petition does not address what complications might occur and how they would be handled.
10. Use of suction can lead to bleeding, which would require assessment by a physician.

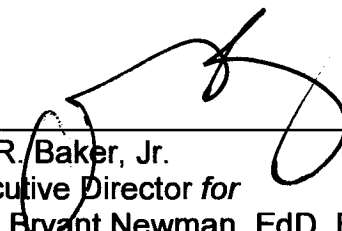
CONCLUSIONS OF LAW

1. The Board has jurisdiction over this matter pursuant to Section 120.565, Florida Statutes, and Rule 28-105, Florida Administrative Code.
2. The petition filed in this cause is in substantial compliance with the provisions of Section 120.565, Florida Statutes, and Rule 28-105, Florida Administrative Code.

WHEREFORE, the Board hereby finds that under the specific facts of the petition, as set forth above, it is not within the scope of Petitioner's nursing practice to administer Bravo pH monitoring capsule without a physician present.

DONE AND ORDERED this 2nd day of Jan, 2018.

BOARD OF NURSING



Joe R. Baker, Jr.
Executive Director for
Jody Bryant Newman, EdD, EdS, Chair

NOTICE OF APPEAL RIGHTS

Pursuant to Section 120.569, Florida Statutes, the parties are hereby notified that they may appeal this Final Order by filing one copy of a notice of appeal with the clerk of the department and by filing a filing fee and one copy of a notice of appeal with the District Court of Appeal within thirty days of the date this Final Order is filed.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing Final Order has been furnished by U.S. Mail to Petitioner DABRINA LEE BLOCKER, 1962 Well

Line Road, Cantonment FL 32533 and Kimberly S. Sullivan, Esquire, P.O. Box 13290, *js*
Pensacola FL 32591-3290, *and 921 N. Palafox St., Pensacola, FL 32501* and by email to Donna Oxford,

Donna.Oxford@myfloridalegal.com this 2nd day of January, 2018

Angel Sanders

Deputy Agency Clerk

06-28-'17 16:01 FROM MHW Law

850-435-7899

T-186 P0002/0022 F-414

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RECEIVED
DEPARTMENT OF HEALTH

17 JUN 29 AM 9:00

STATE OF FLORIDA
DEPARTMENT OF HEALTH
BOARD OF NURSING
TALAHASSEE, FLORIDA

OFFICE OF THE CLERK

DABRINA LEE BLOCKER,

Petitioner,

vs.

BOARD OF NURSING,

Respondent.

**PETITION FOR DECLARATORY STATEMENT
BEFORE THE FLORIDA BOARD OF NURSING**

Petitioner, Dabrina Lee Blocker, by and through her undersigned counsel and pursuant to Section 120.565, Florida Statutes, and Rule 28-105.001, Florida Administrative Code, petitions the Florida Board of Nursing (the "Board") for a final order setting forth declaratory statements on the particular set of facts and law presented herein, stating as follows:

Petitioner and Petitioner's Counsel's Contact Information

Petitioner Dabrina Lee Blocker ("Petitioner"), is a registered nurse licensed by the Florida Board of Nursing pursuant to Florida Statutes Chapter 464, holding license number RN 9388756. A copy of Petitioner's license is attached to this Petition as "Exhibit A." Petitioner's address is 1962 Well Line Road Cantonment, FL 32533. Petitioner is currently employed with Gastroenterology Associates of Pensacola, P.A. (hereinafter, "Gastroenterology Associates") located in Pensacola, Florida as a registered nurse.

Petitioner is represented by Kimberly Sullivan, Esq., of the law firm of Moore, Hill & Westmoreland, P.A., 350 West Cedar Street, Suite 100, Pensacola, FL 32502, Tel. No. (850) 434-3541, Facsimile No. (850) 435-7899, email address ksullivan@mhw-law.com. For purposes of this proceeding, all correspondence and communication should be directed to the undersigned counsel for Petitioner.

Statutory Provisions on Which the Declaratory Statement is Sought

Section 120.565, Florida Statutes, provides that a "substantially affected person may seek a declaratory statement regarding an agency's opinion as to the applicability of a statutory provision, or of any rule or order of the agency, as it applies to the petitioner's particular set of circumstances." Further, the declaratory statement "is a means for resolving a controversy or answering questions or doubts concerning the applicability of statutory provisions, rules, or orders over which the agency has authority." Rule 28-105.001, F.A.C.

Petitioner seeks a determination from the Board as to whether it is within her scope of practice as a registered nurse to administer the Bravo pH monitoring system without a physician physically present in the building in which the Bravo pH monitoring system is administered.

Factual Background

The Bravo pH monitoring system records, stores, views, and analyzes gastroesophageal pH data to diagnose reflux disorders. Specifically, a small pH capsule is temporarily attached to the wall of the esophagus to capture and transmit pH data for up to four days. This system allows for the evaluation of heartburn symptoms and enables the confirmation of gastroesophageal reflux disease (GERD) by recording the frequency and duration of acid reflux. The process is administered as follows:

- Step 1: Position Bravo pH capsule in the esophagus
- Step 2: Apply suction to draw a small amount of tissue into the capsule's suction chamber
- Step 3: Depress plunger on handle to attach capsule
- Step 4: Remove delivery system from the esophagus

Once administered to the esophagus, the Bravo pH capsule immediately begins transmitting pH data. The patient wears a recorder for up to 96 hours, which captures the information from the capsule. This information is then uploaded into a computer for analysis. The capsule is disposable. A few days after its temporary adhesion, the capsule detaches from the esophagus and passes through the digestive tract. The Bravo pH monitoring system is approved by the FDA for individuals age four and older. A more exhaustive explanation of the Bravo pH monitoring system is attached to this Petition as "Exhibit B."

Questions to be addressed by the Board

- I. ~~a) Whether the Petitioner, as a registered nurse, may administer the Bravo pH monitoring system when a physician is not physically present?~~

Under Florida law, a registered nurse is any person licensed in this state to practice professional nursing. § 464.003(22) Fla. Stat. The "practice of professional nursing" means the following:

the performance of those acts requiring substantial specialized knowledge, judgment, and nursing skill based upon applied principles of psychological, biological, physical, and social sciences which shall include, but not be limited to:

(a) The observation, assessment, nursing diagnosis, planning, intervention, and evaluation of care; health teaching and counseling of the ill, injured, or infirm; and the promotion of wellness, maintenance of health, and prevention of illness of others.

(b) The administration of medications and treatments as prescribed or authorized by a duly licensed practitioner authorized by the laws of this state to prescribe such medications and treatments.

(c) The supervision and teaching of other personnel in the theory and performance of any of the acts described in this subsection.

A professional nurse is responsible and accountable for making decisions that are based upon the individual's educational preparation and experience in nursing.

§ 464.003(20) Fla. Stat.

Petitioner would administer the Bravo pH monitoring system as ordered or authorized by a duly licensed practitioner authorized to make such an order. Petitioner would comply with all applicable laws and standards of care as well as the policies and procedures established by Gastroenterology Associates in the administration of the Bravo pH monitoring system.

Petitioner asks the Board to consider whether Petitioner may administer the Bravo pH monitoring system when a physician is not present in the building. The gastroenterology practice for which Petitioner works maintains numerous buildings in which various services are provided. The administration of the Bravo pH capsule is provided in a separate building that

does not have an ongoing physician presence. Currently, certain physicians take turns providing coverage when the Bravo pH capsule is administered. However, this has proven inefficient and prevents the practice from meeting the high patient demand for this service. If Petitioner were able to administer the Bravo pH monitoring system without a physician in the building, she would be able to administer more Bravo pH monitoring systems, which would help meet the community's growing need for esophageal monitoring.

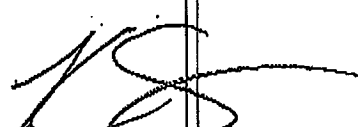
Other states allow nurses to administer items similar to the Bravo pH monitoring system without the physical presence of a physician. For instance, the Kentucky Board of Nursing previously authorized licensed nurses to insert and remove nasogastric tubes – a process that is arguably more invasive than the Bravo pH monitoring system – without the physical presence of a physician.¹ In its Advisory Opinion Statement, the Kentucky Board of Nursing held a licensed practical nurse may perform nasogastric intubation, which was defined as the placement of a tube into the stomach, under the “direction” of a registered nurse, physician, or dentist. The word “direction” was defined as a “communication of a plan of care, which is based upon an assessment and analysis of the patient by the registered nurse, physician or dentist, which establishes the parameters for the provision of care or for the performance of an act” and in which the “registered nurse, physician, or dentist is available to assess and evaluate patient response(s) and to assess, direct and evaluate nurse performance.” A copy of this Advisory Opinion Statement is attached to this Petition as “Exhibit C.”

There are two important points that should be noted with respect to the Kentucky Board of Nursing's Advisory Opinion Statement. First, a licensed nurse can insert a tube into a patient's stomach under the direction of a *registered nurse* as well as a physician or a dentist. Second, the definition of “direction” does not include the requirement that a registered nurse or physician or dentist be physically present at the time of the nasogastric intubation. In other words, a licensed nurse can place a nasogastric tube into a patient's stomach even when a registered nurse, physician, or dentist is not physically present in the building.

¹ The Kentucky Board of Nursing also held, in a 2003 Advisory Opinion, the placement of a Bravo pH capsule is within the scope of registered nursing practice. A copy of this Advisory Opinion is attached to this Petition as “Exhibit C.”

Conclusion

Petitioner seeks guidance as to whether it is within Petitioner's scope of practice, as a registered nurse, to administer the Bravo pH monitoring system when a physician is not present in the building. Petitioner seeks a declaratory statement as to whether this falls within Section 464.003(20) of the Florida Statutes and is therefore within the scope of practice of professional nursing.



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ksullivan@mhw-law.com
kgraham@mhw-law.com
Attorney for Petitioner

CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing is being delivered via U.S. Mail and facsimile transmission to the Florida Department of Health, Agency Clerk, 4052 Bald Cypress Way, Bin #A02, Tallahassee, Florida 32399-1703 (fax: 850-413-8743) on this 28th day of June, 2017.




Kimberly S. Sullivan

STATE OF FLORIDA
 DEPARTMENT OF HEALTH
 DIVISION OF MEDICAL QUALITY ASSURANCE

DATE EXPIRES	LICENSE NO.	CONTINUING EDUCATION NO.
02/24/2016	RN-9389756	2115400

APRIL 30, 2015



Richard Scott
 LICENSOR

John H. Armstrong, MD, FACS
 STATE SURGEON GENERAL

VOID

6962838

STATE OF FLORIDA
 DEPARTMENT OF HEALTH
 DIVISION OF MEDICAL QUALITY ASSURANCE

DATE OF BIRTH: 12/15/1958
 LICENSE NO.: RN-9389756
 CONTINUING EDUCATION NO.: 2115400

LOGIC

DATE: APRIL 30, 2015

Please use it in all correspondence with your client/employer and be responsible for notifying the Department in writing of any change in your mailing address and practice location address. If you have not received your renewal notice 30 days prior to the expiration date shown on this license, please call 850-435-7899.

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- If you do not know your user ID and password, click on "Get Login Help" or call our Customer Contact Center at (850) 435-6395 for assistance.

STATE OF FLORIDA
 DEPARTMENT OF HEALTH
 DIVISION OF MEDICAL QUALITY ASSURANCE
 LICENSEE SUPPORT SERVICES UNIT
 P.O. BOX 9920
 TALLAHASSEE, FLORIDA 32314-8920

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NAME CHANGE (ATTACH LEGAL DOCUMENTATION)

FIRST: _____ MIDDLE: _____ LAST: _____

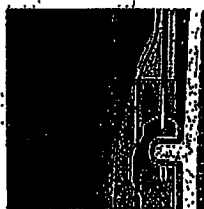
Copies made directly from original on 3/7/16
 Sharon Brooker

BRAVO™ REFLUX TESTING SYSTEM PROCEDURE OVERVIEW



Step One

Position pH capsule
in the esophagus



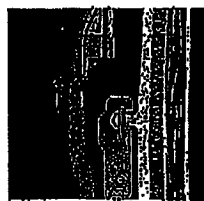
Step Two

Apply suction to draw
a small amount of
tissue into the capsule's
suction chamber



Step Three

Depress plunger on
handle to attach capsule



Step Four

Remove delivery system
from the esophagus



Step Five

Capsule immediately
begins transmitting
pH data



Patient wears the recorder for up to 96 hours while engaging in normal activity.

Upon completion of the study, information is uploaded to a computer for analysis. The disposable capsule detaches and passes through the digestive tract a few days later.

New Recorder Features

- Captures up to 96 continuous hours of esophageal pH data in a single procedure*
- New meal and supine event buttons*
- Improved calibration execution and recorder setup
- Direct data upload via USB
- Internal, rechargeable battery
- Compatible with AccuView™ pH-Z software

*Features are only available with AccuView™ software.

Exhibit B.



**Gastroenterology Associates of Pensacola
Endoscopy Center of Pensacola**

Wayne D. Cartee, M.D.
Roger M. Orth, M.D.
D. Scott Finelli, M.D.
Carl G. Speer, M.D.
Mounzer Saeed, M.D.
Fares S. Hakim, M.D., F.A.C.G.
K. Wayne Adkisson, M.D.
Patrick F. Reilly, M.D.
Richard R. Dobhan, M.D.
Frederic B. Newman, M.D.

**POLICY/PROCEDURE
Wireless Capsule Bravo pH Monitoring**

I Policy Guidelines

1. The following are the indications for the procedure:

- The Bravo pH monitoring system with accessories is intended to be used for gastroesophageal pH measurement and monitoring of reflux
- Using the delivery system, the Bravo capsule is positioned and attached in the patient's esophagus, following either endoscopy or manometry
- The pH software analysis program is intended to record, store, view, and analyze gastroesophageal pH data to diagnose reflux disorders
- The Bravo pH monitoring system has FDA clearance for ages 4 and up

2. The following are contraindication for the procedure:

- Bravo pH monitoring is contraindicated in patients with bleeding diathesis, strictures, severe esophagitis, varices, or obstructions
- It is also contraindicated in patients with pacemakers or implantable cardiac defibrillators

3. Procedure Risks

Potential complications when using the Bravo pH monitoring system include, but are not limited to, the following events: perforation; premature detachment of the pH capsule; failure of the pH capsule to detach from the esophagus within several days after placement; failure to attach to the esophagus; discomfort associated with the pH capsule; tears in the mucosa; capsule aspiration; capsule retention; and bleeding.

Medical, endoscopic, or surgical intervention may be necessary to address any of these complications, should they occur. Potential complications associated with endoscopic placement include perforation, hemorrhage, aspiration, fever, infection, hypertension, respiratory arrest, and cardiac arrhythmia or arrest. Potential complications associated with nasal intubation include sore throat, discomfort, and nasopharyngeal damage resulting in bleeding and soft tissue damage.

Endoscopy Division
4331 N Davis Hwy
Pensacola, Florida 32501
(850) 436-4563
Fax (850) 436-4570

Endoscopy Group, L.L.C.
4810 North Davis Hwy
Pensacola, Florida 32503
(850) 474-8988
Fax (850) 476-5312

Sacred Heart Division
3147 N 9th Avenue, Ste 311
Pensacola, Florida 32504
(850) 477-2597
Fax (850) 478-7941

The capsule contains a small magnet, and patients should not have an MRI study within 30 days of undergoing the Bravo pH test.

This information should not be used as a substitute for medical advice concerning specific diagnosis and treatment.

II Procedure Guidelines

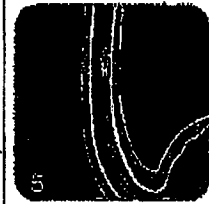
1. The patient's complete clinical/medical history and physical examination are carefully reviewed, making certain to check their history of anticoagulant use, latex allergy, and metal allergy. Also patient's history is reviewed for any implantable devices they may have.
2. The nurse performing the procedure then reviews the patient's last EGD report and records the measurement of the GE Junction and calculates 6 cm above that for capsule placement.
3. The nurse then brings the patient to the procedure room has them sit upright in the chair and explains the procedure to them has them sign consent and answers any questions they may have.
4. The nurse performs hand hygiene and dons gloves.
5. The patient's throat is sprayed with Hurricane spray to induce a numbing effect.
6. The probe is then marked appropriately with the measurement for placement.
7. The patient is assessed making sure throat is numb in order for the probe to be placed.
8. Once the patient is comfortable the nurse advances the delivery system through the mouth down the throat with the flexible tip and capsule facing the patients tongue pointing downward to the appropriate measurement.
9. Once the probe is in the correct place based on the marking on the delivery system (6cm above GE Junction based on EGD measurement) hold the delivery system as straight and horizontal as possible, suction is then hooked to the catheter, and turned on. Once the suction reaches 550mm Hg a timer is set for 30 seconds to allow tissue to fill the suction chamber. If either the patient or the delivery system moves during that time the 30 second count is restarted.
10. Maintaining a horizontal position, remove the safety tab and swiftly press the plunger on top of the handle all the way down until it stops at its locking position. Remove your thumb and wait approximately 5 seconds. Using your thumb, rotate the plunger from the side one-eighth (1/8) of a turn clockwise.
11. Once the plungers has sprung back make sure the white line is visible on the 6th rib of the plunger.
12. Ensure that the vacuum source is turned off and remove the delivery system.

13. The patient is reassessed once the probe has been placed for any signs of complications or distress.
14. The nurse unglives and performs hand hygiene.
15. The patient is given an information sheet about wireless capsule esophageal pH monitoring and told to call our office with any questions or concerns that may arise during their 48 hours of monitoring.
16. Patient is instructed to return the monitoring device to our office 48 hours after their capsule is placed so that we may download their study.
17. Once study is downloaded it is sent to the physician of record to be interpreted.

Quick Reference Guide

Capsule Delivery

1. Position Bravo[®] pH capsule in the esophagus.
 - Remove the capsule with delivery device from the pH buffer and rinse it in sterile water.
 - Determine attachment location and mark it on the delivery device.
 - With the vacuum source off, carefully advance the delivery device through the mouth (with the capsule facing the patient's tongue) to the desired location in the esophagus.
 - Holding the delivery device as straight as possible in a relaxed, horizontal position, stabilize it by the patient's mouth to ensure it does not move.
2. Apply suction to draw a small amount of tissue into the capsule's suction chamber.
 - Attach the vacuum hose to the handle.
 - Verify that vacuum knob is set to maximum and turn the vacuum source on.
 - After the vacuum level reaches at least 550 mmHg and stabilizes, hold the delivery system in place for at least 30 seconds to allow the tissue to fill the suction chamber.
3. Attach capsule.
 - Remove the safety tab from the Bravo handle.
 - Press the plunger down with your thumb until it clicks into position; remove your thumb from the plunger.
 - Using your thumb, rotate the top of the plunger clockwise 1/8th of a turn to release the capsule from the delivery device.
 - Ensure that the white line is visible above the handle body. If not, use your thumb to raise the plunger until the white marking is visible.
4. After ensuring the vacuum source is off, remove delivery system from the esophagus.
5. Capsule immediately begins transmitting pH data.
 - Verify that the recorder is on and receiving data



GIVEN
IMAGING

Quick Reference Guide**Data Upload**

1. Connect the Bravo⁺ recorder to your PC using the supplied **USB cable**. (Fig. 1)
2. Open AccuView™ by double-clicking the AccuView icon on your desktop. (Fig. 2)
3. Click **Upload**. A progress bar appears. Once the upload is complete, the **Edit Information & Diary** screen appears. (Fig. 3)
4. If more than one protocol is available for the Bravo pH capsule, select the desired one from the **Protocol** list. (Fig. 4)
5. Click **OK**. (Fig. 4)
6. Unplug the **USB cable**. You may proceed with editing the study. Be sure to save the study in the AccuView analysis software.



Fig. 1



Fig. 2



Fig. 3

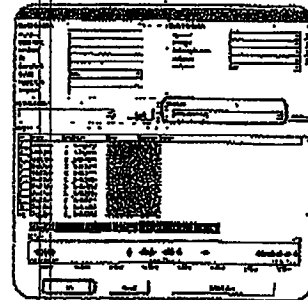


Fig. 4

CAPSULE-BASED pH MONITORING SYSTEM

The Bravo™ reflux testing system, a unique capsule-based ambulatory pH test, captures esophageal pH data for up to 96 continuous hours in a single procedure.

It utilizes a small pH capsule that is temporarily attached to the wall of the esophagus to transmit pH data for up to four days. This convenient procedure enhances patient satisfaction and compliance while providing improved diagnostic yield to support early detection.

Patient-friendly Procedure

- Better tolerated and preferred by patients over catheter-based pH monitoring¹
- Patients can maintain regular diet and activities throughout the procedure¹
- Well-tolerated by children age of 4 and older²
- Reduces barriers to care, like social embarrassment, as there are no outward signs that the procedure is taking place

Easy to Use

- Placement procedure is simple to perform
- User-friendly AccuView™ software v5.2 facilitates efficient analysis and reporting of study results
- Fits seamlessly into your workflow—simply place capsule during a routine endoscopy

Clinical Advantages of the Extended Bravo™ Reflux Testing System

- Up to 96-hour testing provides four times the data of catheter-based tests, supporting greater test sensitivity,^{1,3} increasing detection of symptoms⁴ and improving diagnostic yield⁵
- Enables diagnosis in cases of failed catheter-based pH studies when 24-hour results are inconclusive⁶
- Offers an alternative for catheter-intolerant patients⁶
- Allows for evaluation of patients off-PPI therapy, which is clinically beneficial in patients with refractory GERD^{5,7}
- Has a strong impact on outcomes and patient management²



AccuView™ software v5.2

SYSTEM COMPONENTS

The Bravo™ reflux testing system consists of the following components:

- pH capsule with delivery device
- pH recorder
- AccuView™ software v5.2
- Calibration stand, vacuum pump and accessories

Ordering Information

pH Capsule

pH capsule with delivery device, 5-pk

pH Recorder

pH recorder
Carry case
Carry strap
Charger EU
USB cable
Document mini CD

pH Accessory Kit

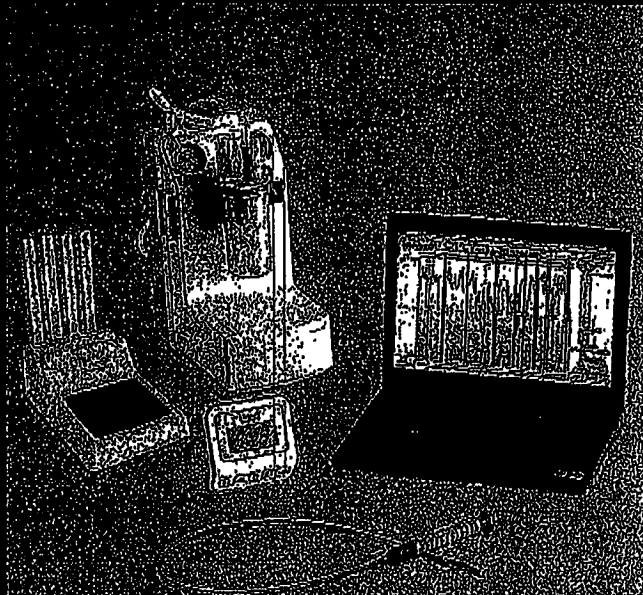
Calibration stand
Buffer solution, pH7.01 (bottle)
Buffer solution, pH1.07 (bottle)
Vacuum pump (220v)
Vacuum pump tubes, 10-pk
Vacuum pump filters, 10-pk

AccuView™ Software

AccuView™ pH-Z software v5.2
U-224 USB to serial cable

Miscellaneous

Vacuum pump suction tubes, 10-pk
Vacuum pump filters, 10-pk
Vacuum pump kit (canister and tubing)



TAKING CARE FURTHER TOGETHER

Medtronic's pH capsule works with your endoscopy and your software to help you understand your patient's reflux. For more information, please ask your doctor, representative and/or Medtronic distributor.

Caution: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner. Rx only.

Important Information: The risks of the Bravo™ reflux testing system include: premature detachment, discomfort, failure to detach, failure to attach, capsule aspiration, capsule retention, tears in the mucosa, bleeding and perforation. Endoscopic placement may present additional risks. Medical, endoscopic or surgical intervention may be necessary to address any of these complications, should they occur. Because the capsule contains a small magnet, patients should not have an MRI study within 30 days of undergoing Bravo™ reflux testing. Please refer to the product user manual or givenimaging.com for detailed information.

References: 1. Isang D et al. *J Gastroenterol Surgery* 2005;9:1044-1052. 2. Li, JCY et al. *Clin Gastroenterol* 2008;41:613-618. 3. Pandolfino J et al. *Gastroenterology* 2008;134:120-126. 4. Hoshino T et al. *Gastroenterology* 2008;134:120-126. 5. Hoshino T et al. *Gastroenterology* 2008;134:120-126. 6. Smith R et al. *Am J Gastroenterol* 2008;103:71-76. 7. Gerson et al. *Am J Gastroenterol* 2008;103:71-76. 8. US 7,907,168 © 2015 Medtronic. All rights reserved. Medtronic, Medtronic logo and Further Together are trademarks of Medtronic. 6130 or 6130A are trademarks of a Medtronic company.

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06-28-17 16:08 FROM- MHW Law

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KENTUCKY BOARD OF NURSING

312 Whittington Parkway, Suite 300
Louisville, Kentucky 40222-5172

ERNEST FLETCHER
~~GOVERNOR~~
GOVERNOR

December 15, 2003

Kim Preston, RN
Nurse Coordinator
Heartburn Treatment Center
Highlands Regional Medical Center
5000 KY Route 321
Prestonsburg, KY 41653

Dear Ms. Preston:

During the meeting held December 11 and 12, 2003, the Kentucky Board of Nursing considered your letter dated June 25, 2003, requesting an advisory opinion as to whether the insertion of a "Bravo" pH Capsule is within the scope of registered nursing practice.

KRS 314.011(6) defines "registered nursing practice" as: ~~State~~

...The performance of acts requiring substantial specialized knowledge, judgment, and nursing skill based upon the principles of psychological, biological, physical, and social sciences in the application of the nursing process in:

- a) The care, counsel, and health teaching of the ill, injured or infirm;
- b) The maintenance of health or prevention of illness of others;
- c) The administration of medication and treatment as prescribed by a physician, physician assistant, dentist, or advanced registered nurse practitioner and as further authorized or limited by the board, and which are consistent either with American Nurses' Association Standards of Practice or with Standards of Practice established by nationally accepted organizations of registered nurses. Components of medication administration include, but are not limited to:
 1. Preparing and giving medications in the prescribed dosage, route, and frequency, including dispensing medications only as defined in subsection (17)(b) of this section;
 2. Observing, recording, and reporting desired effects, untoward reactions, and side effects of drug therapy;
 3. Intervening when emergency care is required as a result of drug therapy;
 4. Recognizing accepted prescribing limits and reporting deviations to the prescribing individual;
 5. Recognizing drug incompatibilities and reporting interactions or potential interactions to the prescribing individual; and
 6. Instructing an individual regarding medications;

AN EQUAL OPPORTUNITY EMPLOYER M/F/D
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Exhibit C

Kim Preston

Page 2

December 15, 2003

- d) The supervision, teaching of, and delegation to other personnel in the performance of activities relating to nursing care; and
- e) The performance of other nursing acts which are authorized or limited by the board, and which are consistent either with American Nurses' Association Standards of Practice or with Standards of Practice established by nationally accepted organizations of registered nurses. *ASNA*

KRS 314.021(2) states:

All individuals licensed under provisions of this chapter shall be responsible and accountable for making decisions that are based upon the individuals' educational preparation and experience in nursing and shall practice nursing with reasonable skill and safety.

* Following review of the question and information provided in your letter, and the statutes governing nursing practice, it was the advisory opinion of the Board that the placement of a "Bravo" pH Capsule is within the scope of registered nursing practice, for the registered nurse who possesses the requisite educational preparation and current clinical competence to perform the procedure in a safe, competent manner.

The Kentucky Board of Nursing issues advisory opinions as to what constitutes safe nursing practice. As such, an opinion is not a regulation of the Board and does not have the force and effect of law. It is issued as a guidepost to licensees who wish to engage in safe nursing practice.

Should you have any other questions or if we may be of further assistance to you, please contact Bernadette M. Sutherland, MSN, RN, Nursing Practice Consultant, at the Board office 502-329-7007.

Sincerely,

M. Susan Jones, MSN, RN
PRESIDENT

Sharon M. Weisenbeck

By: Sharon M. Weisenbeck, MS, RN
Executive Director

BMS:bjm

cc: William E. Dunlop, MD

AOS #11
Gastric
Intubation
(Reviewed 5/2013)



KENTUCKY BOARD OF NURSING
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ADVISORY OPINION STATEMENT

**ROLES OF NURSES IN THE INSERTION AND REMOVAL OF A NASOGASTRIC TUBE AND
IN THE REINSERTION OF A GASTROSTOMY TUBE**

The Kentucky Board of Nursing is authorized by Kentucky Revised Statutes (KRS) Chapter 314 to regulate nurses, nursing education and practice, promulgate regulations and to issue advisory opinions on nursing practice, in order to assure that safe and effective nursing care is provided by nurses to the citizens of the Commonwealth.

The Kentucky Board of Nursing issues advisory opinions as to what constitutes safe nursing practice. As such, an opinion is not a regulation of the Board and does not have the force and effect of law. It is issued as a guideline to licensees who wish to engage in safe nursing practice, and to facilitate the delivery of safe, effective nursing care to the public.

Opinion: Roles of Nurses in the Insertion and Removal of a Nasogastric Tube and in the Reinsertion of a Gastrostomy Tube
Approved Date: 6/85
Revised: 2/86; 12/87; 1/93; 4/96; 2/05; 4/08
Editorial Revision: 1/2011; 5/2012
Reviewed: 5/2013

Accountability and Responsibility of Nurses

In accordance with KRS 314.021(2), nurses are responsible and accountable for making decisions that are based upon the individuals' educational preparation and current clinical competence in nursing, and requires licensees to practice nursing with reasonable skill and safety. Nursing practice should be consistent with the *Kentucky Nursing Laws*, established standards of practice, and be evidence based.

Rationale for Advisory Opinion

The Kentucky Board of Nursing has received numerous inquiries regarding the role of nurses, primarily licensed practical nurses, in the insertion and removal of nasogastric tubes. Following study, the Board issued this advisory opinion statement.

Advisory Opinion**1. Nasogastric Intubation -- LPN**

"Nasogastric intubation" means the placement of a tube into the stomach. The specific type of tube to be inserted should be determined after evaluation of multiple factors, including but not limited to the following: a) order of a qualified provider, b) individual patient need, c) manufacturer product information, d) precautions and potential complications associated with the specific tube, e) available research data, and f) availability of x-ray equipment to evaluate the placement of the tube. Written approved facility policy, and nursing policy and procedure should be established delineating the specific type of nasogastric tubes that may be utilized in the health care setting.

It is within the scope of licensed practical nursing practice, for the nurse who is educationally prepared and clinically competent in the performance of the procedure, to insert a nasogastric tube into the stomach of a patient who has normal anatomy and physiology of the respiratory and gastrointestinal tracts, when the nasogastric tube is placed into the stomach for such purposes as gavage, lavage for toxic substances, collection of nasogastric samples or administration of medications. If there is any question as to the safe performance of the procedure, the licensed practical nurse should consult with the registered nurse, physician, dentist, or the patient's provider.

- A. ~~The licensed practical nurse should perform this procedure under the direction of a registered nurse, physician, or dentist.~~
- B. The licensed practical nurse who performs this procedure is responsible for having documented evidence of adequate educational preparation and experience to perform this act as required by KRS 314.021(2). Such educational preparation should be acquired in an approved precensure education program for practical nurses or through successful completion of a Board approved continuing education course for the performance of the procedure.
- C. The licensed practical nurse should perform this procedure according to a written nursing policy and procedure that is consistent with the definition of "licensed practical nursing practice."

2. Nasogastric Intubation -- RN

It is within the scope of registered nursing practice, to insert a nasogastric tube into a patient who has a condition that alters the normal anatomy and physiology of the respiratory or gastrointestinal tract. If there is any question as to the safe performance of the procedure, the registered nurse should consult the patient's medical provider.

3. Removal of a Nasogastric Tube

¹ "Direction" means communication of a plan of care, which is based upon an assessment and analysis of the patient by the registered nurse, physician or dentist, which establishes the parameters for the provision of care or for the performance of an act. The registered nurse, physician, or dentist is available to assess and evaluate patient response(s) and to assess, direct and evaluate nurse performance.

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It is within the scope of nursing practice, for the nurse who is educationally prepared and clinically competent in the performance of the procedure, to remove a nasogastric tube.

4. Reinsertion of a Gastrostomy Tube

- A. It is within the scope of nursing practice, for the nurse who is educationally prepared and clinically competent in the performance of the procedure, to change a previously inserted gastrostomy tube into a mature stoma site upon an order of a qualified provider. If there is question as to the safe performance of the procedure, the nurse should consult with the patient's medical provider prior to the reinsertion of the gastrostomy tube.
- B. ~~The licensed practical nurse should perform this procedure under the direction of a registered nurse, physician, or dentist.~~
- C. The nurse who performs this procedure is responsible for having documented evidence of adequate educational preparation and experience to perform this act as required by KRS 314.021(2). Such educational preparation should be acquired in an approved prelicensure education program or through successful completion of a Board approved continuing education course. The performance of the procedure should be in accordance with written nursing policy and procedure.

Magnet Nasal Tube Retaining Device

The placement and removal of a nasal tube retaining device/system used to prevent nasal tube pullouts are within the scope of registered nursing practice. The registered nurse would place the device after a physician/APRN has completed an individual assessment of the patient and issued medical authorization for its placement. Following placement, the patient should be reassessed by a physician/APRN to assure its correct placement and that no complications have occurred. The registered nurse who places and /or removes a nasal tube retaining device must possess the requisite educational preparation and current clinical competence to perform the procedure in a safe, competent manner

Determining Scope of Practice

KRS 314.021(2) holds all nurses individually responsible and accountable for the individual's acts based upon the nurse's education and experience. Each nurse must exercise professional and prudent judgment in determining whether the performance of a given act is within the scope of practice for which the nurse is both licensed and clinically competent to perform. In addition to this advisory opinion statement, the Kentucky Board of Nursing has published "Scope of Practice Determination Guidelines" which contains a decision tree chart providing guidance to nurses in determining whether a selected act is within an individual nurse's scope of practice now or in the future. A copy of the RN and LPN guidelines may be downloaded from the Board's website <http://kbn.ky.gov/NR/rdonlvres/74A5FF75-543D-4E12-8839-720B7623DA87/0/ScopeDeterminGuidelines.pdf> and a copy of the APRN guidelines may be downloaded from the Board's website <http://kbn.ky.gov/practice/Documents/APRN%20Scope%20of%20Practice%20%20Decision%20Making%20Model.pdf>

Approved: 6/86

Revised: 2/86; 12/87; 1/93; 4/96; 2/05; 4/08

Editorial Revision: 1/2011; 5/2012

Reviewed: 5/2013

Applicable Statutes From the Kentucky Nursing Laws¹

KRS 314.011(6) defines "registered nursing practice" as:

... The performance of acts requiring substantial specialized knowledge, judgment, and nursing skill based upon the principles of psychological, biological, physical, and social sciences in the application of the nursing process in:

- a) The care, counsel, and health teaching of the ill, injured or infirm.
- b) The maintenance of health or prevention of illness of others.
- c) The administration of medication and treatment as prescribed by a physician, physician assistant, dentist, or advanced practice registered nurse and as further authorized or limited by the board, and which are consistent either with American Nurses' Association Standards of Practice or with Standards of Practice established by nationally accepted organizations of registered nurses. Components of medication administration include, but are not limited to:
 1. Preparing and giving medication in the prescribed dosage, route, and frequency, including dispensing medications only as defined in subsection (17)(b) of this section;
 2. Observing, recording, and reporting desired effects, untoward reactions, and side effects of drug therapy;
 3. Intervening when emergency care is required as a result of drug therapy;
 4. Recognizing accepted prescribing limits and reporting deviations to the prescribing individual;
 5. Recognizing drug incompatibilities and reporting interactions or potential interactions to the prescribing individual; and
 6. Instructing an individual regarding medications.
- d) The supervision, teaching of, and delegation to other personnel in the performance of activities relating to nursing care.
- e) The performance of other nursing acts which are authorized or limited by the board, and which are consistent either with American Nurses' Association Standards of Practice or with Standards of Practice established by nationally accepted organizations of registered nurses.

KRS 314.011(10) defines "licensed practical nursing practice" as:

... The performance of acts requiring knowledge and skill such as are taught or acquired in approved schools for practical nursing in:

- a) The observing and caring for the ill, injured, or infirm under the direction of a registered nurse, a licensed physician, or dentist;
- b) The giving of counsel and applying procedures to safeguard life and health, as defined and authorized by the board;
- c) The administration of medication or treatment as authorized by a physician, physician assistant, dentist, or advanced practice registered nurse and as further authorized or limited by the board which is consistent with the National Federation of Licensed Practical Nurses or with Standards of Practice established by nationally accepted organizations of licensed practical nurses;
- d) Teaching, supervising, and delegating except as limited by the board;

¹ A copy of the Kentucky Nursing Laws may be downloaded from the Kentucky Board of Nursing website at <http://kbn.ky.gov>.

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- e) The performance of other nursing acts, which are authorized or limited by the board and which are consistent with the National Federation of Licensed Practical Nurses' Standards of Practice or with Standards of Practice established by nationally accepted organizations of licensed practical nurses.

06-28-17 16:01 FROM- MHW Law

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REMARKS:

- Urgent
 For your review
 Reply ASAP
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