

# RightSpot™ Gastric pH Indicator for Placement of NG/OG Tubes Intended for the Stomach

True Bedside CLIA Waived Testing

As the POC Coordinator accuracy, simplicity, safety, and compliance mean everything. Critical Devices Corporation, Inc. announces the availability of RightSpot™ Gastric pH Indicators. These are the only FDA Cleared, CLIA Waived products that use pH for confirming gastric acidity for tubes intended to end in the stomach.

## **The RightSpot Gastric pH Indicator: A Truly Closed System for Safer Bedside Testing**

Each RightSpot™ Gastric pH Indicator provides a closed system of specimen collection and testing, using approx. 50 µL of aspirate, and incorporates an on-device color reference key specific to the pH of Gastric or Plural Fluids. Fluids are contained, analyzed, and reported without contamination to the environment or exposure to the patient or clinician. And, by selecting colors which can be interpreted by even those with achromatopsia (colorblindness), any clinician can use it and no colorblindness testing is required.



### **RightSpotpH Small Bore**

### **RightSpotpH Standard**

## **Recommendation to Use pH prior to an X-ray**

The primary identifier of a properly placed NG or OG tube tip is a pH reading of 5.5 or less. The use of gastric pH readings, prior to an x-ray, is endorsed by organizations including ASPEN, AACN, CHA, NHS-UK, and the PSMF. Studies show radiation exposure from x-rays increases the risk of future radiation induced cell damage, including cancers. Alarmingly this risk is increased in neonates due to their immature and highly sensitive cells. Therefore justification of the need for x-rays need to be considered and alternative testing done if possible. Test can be completed in seconds while x-rays may take substantially longer. A confirming result supersedes the need for an x-ray thus saving patients from unnecessary radiation exposure and the hospital from additional costs and delays in treatment.

## **Auscultation or Visualization of Aspirate are NOT Endorsed to Confirm Tip Position**

Conversely tube auscultation, commonly referred to as a “Whoosh Test”, and visualization of gastric aspirate independent of pH are considered inconclusive and have resulted in tubes misplaced in the esophagus or lungs leading to respiratory complications and death. These methods have shown to lack clinical evidence and, per recommendations from numerous safety and nursing organizations, should immediately be discontinued.

## **Proper Tube Insertion Depth Increases Success of Aspirate Retrieval for pH Testing**

Without proper insertion depth the ability to obtain adequate aspirate is compromised. By working with the clinicians and recommending best practice success will be attained. Therefore direct distance nose-ear-mid-umbilicus (NEMU) or age-related, height-based (ARHB) equations should be used to determine nasogastric/orogastric (NG/OG) tube placement. While direct distance nose-ear-xiphoid (NEX) returned no specific evidence in the literature to support its use. The investigators in one study found that only 59% of tubes placed using NEX were inserted correctly compared with 97.1% for NEMU.

## **QC Program and Single Unit Product Packaging Meets Waived Status Requirements**

QC Program requires testing of 2 random devices with known buffer solutions (3 pH and 7 pH) per lot number per shipment. Buffer solutions are available through many sources including: Carolina Biological Supply Company ([www.carolina.com](http://www.carolina.com)).

Each Indicator is individually packaged (see image below) in high density co-polymer foil with proprietary surface treatment to prevent air, light, and humidity penetration. Heat resistant packaging allows storage at temperatures -40°C to 52°C. And excellent ultraviolet absorption of the package reduces fading of the pH paper. These added measures ensure excellent unit-to-unit performance thus eliminating variability and guaranteeing accuracy and reproducibility.

Each package is individually identified with Product Code, Lot Number, and Expiration Date which simplifies inventory control, tracking, storage, and billing. Reimbursement is available by using the CPT Code 83986QW.

## **Correlation Performance versus a pH Meter Yields Exceptional Results**

Actual patient testing was performed in a NICU on 31 patients resulting in 240 samples against a pH meter. The reported Correlation was 0.9714 with a Variance of 0.108. And because we open them individually at time of use reproducibility remains exceptional.

## **Unique Sample Acquisition Method Negates Interference from Specimen Color**

Opacity of specimen does not hinder determining the resulting pH. Specifically the specimen is aspirated to the back of the paper and not over it. So even dried coagulated blood that resembles coffee grounds does not interfere with obtaining a correct result.

## **Support during Validation, Correlation, Procedure and Training Preparation, and Staff Education is Provided**

Sample Protocols, Competencies, Proficiencies, Written Tests, Lanyards, and even Training Videos are available for inservice education. You will be supported by a highly trained and competent training force during hands-on product inservice and implementation. Troubleshooting guides as how to best assure obtaining aspirate, and steps to take if you don't, are formulated as flowcharts to assist the clinician as well.



**Proprietary Packaging**

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RightSpot™ Gastric pH Indicator is a registered trademark of RightBio Metrics

ENFit® is a registered trademark of GEDSA

ASPEN: American Society for Parenteral and Enteral Nutrition

AACN: American Association of Critical Care Nurses

CHA: Children's Hospital Association

NHS-UK: National Health Service for the United Kingdom

PSMF: Patient Safety Movement Foundation

Studies available upon request.

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<sup>1</sup><https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/results.cfm>

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<sup>2</sup>Wallingford K, Rubarth LB. Development and Evaluation of a Radiation Safety Program in the NICU. *Neonatal Netw.* 2017;36(5):306–312. doi:10.1891/0730-0832.36.5.306

<sup>3</sup><https://www.childrenshospitals.org/quality-and-performance/patient-safety/alerts/2012/blind-pediatric-ng-tube-placements>

<sup>4</sup><https://ir.library.louisville.edu/cgi/viewcontent.cgi?article=1027&context=dnp>

<sup>5</sup><https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3726362/>