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BAXTER AND COSMED ANNOUNCE U.S. FDA 510(K) CLEARANCE OF Q-NRG+ INDIRECT CALORIMETRY DEVICE

- *Compact, portable monitor that accurately measures patient's resting energy expenditure to help optimize nutrition therapy*
- *Technology replaces potentially inaccurate predictive equations*
- *Expected to launch in the United States at ASPEN Conference in March 2020*

DEERFIELD, Ill., FEBRUARY 12, 2020 – Baxter International Inc. (NYSE: BAX), a global leader in clinical nutrition, today announced the U.S. Food and Drug Administration (FDA) clearance of **Q-NRG+**, a metabolic monitoring device utilizing indirect calorimetry (IC) technology. IC is considered the “gold standard”¹ to accurately measure a patient's calorie needs, or resting energy expenditure (REE). These readings can help inform prescription and administration of nutrition therapy, which may include parenteral nutrition (PN), the intravenous administration of nutrients. **Q-NRG+** is expected to be available in the United States beginning at the ASPEN 2020 Nutrition Science & Practice Conference taking place March 28 – 31, 2020 in Tampa, Florida.

As part of its partnership with COSMED, Baxter has rights to bring **Q-NRG+** to at least 18 markets around the globe, with the potential for further expansion. The 510(k) clearance is the latest regulatory approval for **Q-NRG+**, which is currently available in 12 countries in Europe as well as Canada, Australia and New Zealand.

Hospital malnutrition is a serious public health issue in the United States. Approximately two million hospital stays in the U.S. involve malnutrition,² and almost a quarter of U.S. patients with malnutrition were readmitted to the hospital within 30 days of discharge.³ Hospitalized patients with malnutrition may require PN therapy if they cannot be fed orally or enterally (tube feeding).

Traditional methods of estimating caloric requirements use predictive equations that are based on factors like weight, height, gender and age. However, research has shown that these

equations often result in inaccurate measurements and could result in overfeeding or underfeeding.^{4,5}

“It can be challenging to prescribe clinical nutrition without knowing the exact caloric needs of a patient,” said Heather Knight, general manager, U.S. Hospital Products, Baxter. “With **Q-NRG+**, clinicians will have access to the latest technology to accurately measure energy requirements and won’t have to rely on predictive equations or dated technology – which can be cumbersome and time consuming.”

Q-NRG+ is designed around flexibility and hospital efficiency, and features a compact, portable design that can be easily moved between patient rooms. The device requires minimal time to warm-up and calibrates automatically between uses. **Q-NRG+** can be used to test both adult and pediatric patients, as well as spontaneously breathing or mechanically ventilated patients.

Indications for Use

The **Q-NRG+** portable metabolic monitors are indicated for the measurement of resting energy expenditure (REE) for spontaneously breathing and ventilated patients, within the following populations:

- Spontaneously breathing subjects weighing more than 15 kilograms (33 pounds) when using a canopy.
- Spontaneously breathing subjects more than 6 years old and weighing more than 10 kilograms (22 pounds) when using a face mask.
- Ventilated subjects more than 10 years old and weighing more than 10 kilograms (22 pounds).

Rx Only. The **Q-NRG+** portable metabolic monitors are intended to be used in professional healthcare facilities only. For safe and proper use of the devices mentioned herein, refer to the complete instructions in the Operator's Manual.

About Baxter

Every day, millions of patients and caregivers rely on Baxter’s leading portfolio of critical care, nutrition, renal, hospital and surgical products. For more than 85 years, we’ve been operating at the critical intersection where innovations that save and sustain lives meet the healthcare providers that make it happen. With products, technologies and therapies available in more than 100 countries, Baxter’s employees worldwide are now building upon the company’s rich heritage of medical



breakthroughs to advance the next generation of transformative healthcare innovations. To learn more, visit www.baxter.com and follow us on [Twitter](#), [LinkedIn](#) and [Facebook](#).

About COSMED

COSMED, established in 1980, is a privately-owned company that designs and manufactures cardio pulmonary and metabolic diagnostic equipment. COSMED solutions address needs of the healthcare, academic and industry markets to assess human metabolism, exercise physiology, pulmonary function and body composition for clinical and research purposes. COSMED products include a full range of spirometers, indirect calorimetry, cardio pulmonary exercise testing and body composition systems including software. COSMED headquarters are located in Rome, Italy with direct operations in Australia, France, Germany, Hong Kong, Netherlands, Switzerland, UK and United States, and a network of business partners covering more than 80 countries. Visit www.cosmed.com to know more about COSMED.

*This release includes forward-looking statements concerning Baxter and **Q-NRG+**, including **Q-NRG+** effectiveness and risks and expectations with regard to its availability in the United States. The statements are based on assumptions about many important factors, including the following, which could cause actual results to differ materially from those in the forward-looking statements: satisfaction of regulatory and other requirements; actions of regulatory bodies and other governmental authorities; product quality, manufacturing or supply issues; patient safety issues; changes in law and regulations; and other risks identified in Baxter's most recent filing on Form 10-K and other SEC filings, all of which are available on Baxter's website. Baxter does not undertake to update its forward-looking statements.*

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Baxter is a trademark of Baxter International Inc. **Q-NRG** is a trademark of COSMED.

¹ Frankenfield D, Ashcraft C. Estimating Energy Needs in Nutrition Support Patients. *Journal of Parenteral and Enteral Nutrition*. 35(5). 2011. 563-570.

² Weiss AJ, et al. Characteristics of Hospital Stays Involving Malnutrition, 2013. HCUP Statistical Brief #210.

³ Fingar K, et al. All-Cause Readmissions Following Hospital Stays for Patients with Malnutrition, 2013. HCUP Statistical Brief #218.

⁴ Neelemaat F, de van der Schuren M, Thijs A, et al. Resting energy expenditure in malnourished older patients at hospital admission and three months after discharge: Predictive equations versus measurements. *Clinical Nutrition*. 31 (2012) 958-966.

⁵ Zusman O, Kagan I, Bendavid I, et al. Predictive equations versus measured energy expenditure by indirect calorimetry: A retrospective validation. *Clinical Nutrition*. 38 (2019) 1206-1210.