Baxter

COSMED
The Metabolic Company

Q-NRG+
METABOLIC MONITOR

SIMPLIFYING PERSONALIZED NUTRITION

FAST. ACCURATE. INTUITIVE.

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 >15 kg (33 lb) when using a canopy .
- Spontaneously breathing subjects age >6 yrs and >10 kg (22 lb) when using a face mask.
- Ventilated subjects age >10 yrs and >10 kg (22 lb).

The Q-NRG+ Portable Metabolic Monitors are intended to be used in professional healthcare facilities only.

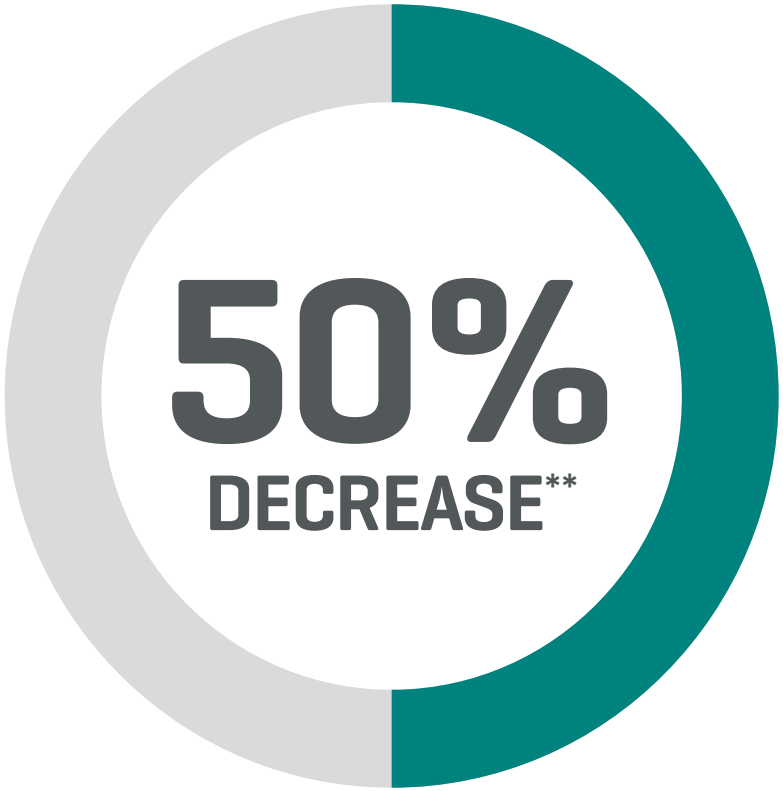
Precautions/Contraindications: Carefully re-check ventilator functionality after connection of the parts. Make sure that the patients cuff pressure is high enough to avoid air leakage.Manipulation of the ventilator circuit may cause leaks that may lower alveolar ventilation. For more information please refer to User's Manual

Optimal protein and energy nutrition* was associated with a **DECREASE IN 28-DAY MORTALITY** in mechanical ventilated, critically ill patients.[1]

Meeting both protein and energy targets was associated with a 50% decrease in 28-day mortality[1]

- Prospective, observational cohort study, 886 mechanically ventilated ICU patients
- Energy targets guided by indirect calorimetry (IC)

***Optimal nutrition for patients in the ICU is defined as the provision of energy guided by IC and the provision of protein of at least 1.2 g/kg.[1]**



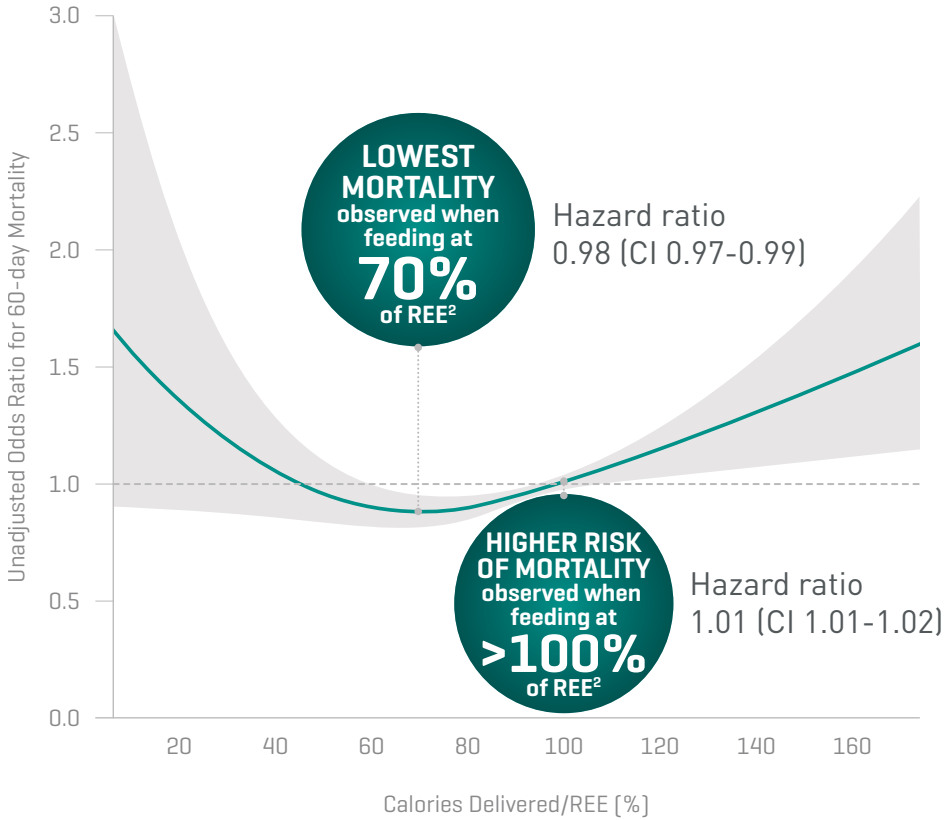
**Hazard ratio for protein + energy target patients was 0.51 (0.33-0.78, p=0.002) for 28-day mortality.

Providing optimal nutrition with energy intake, guided by IC and high protein, significantly reduced 28-day mortality in ICU patients.[1]

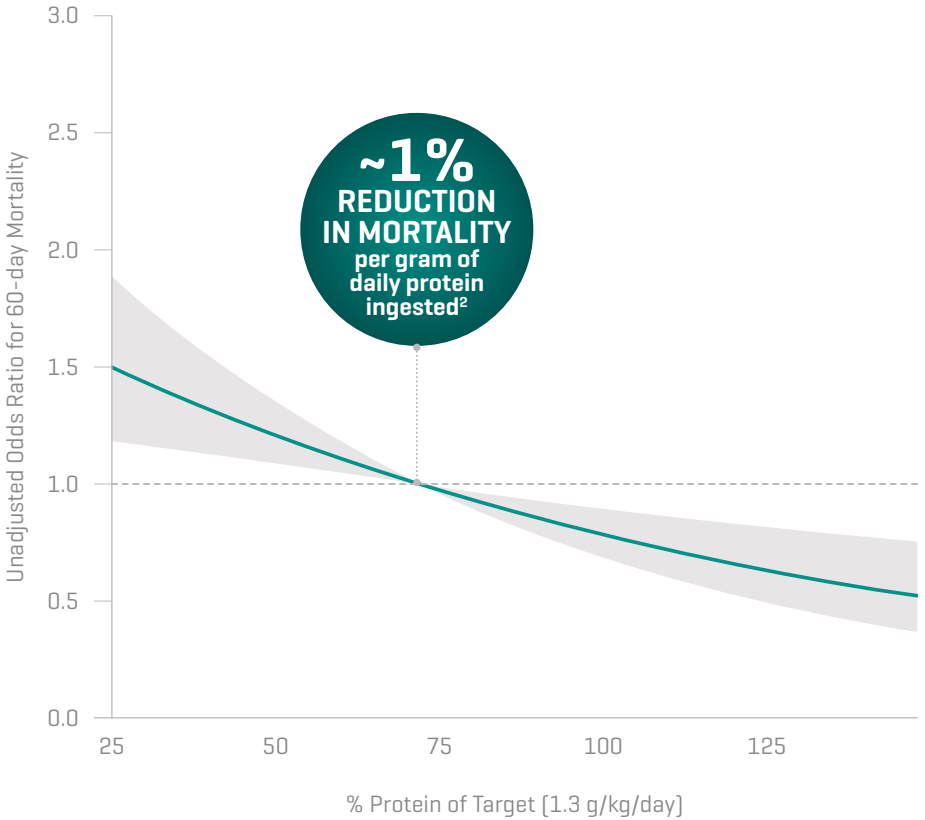
Reaching protein and energy targets was associated with a **DECREASE IN 60-DAY MORTALITY.**[2]

- Retrospective study, 1,171 mechanically ventilated ICU patients[2]
- Association found between the ratio of calories delivered/resting energy expenditure (REE) measured by IC and 60-day mortality.[2]
- These findings provide a basis for future randomized controlled trials comparing specific nutritional regimens based on IC measurements.

CALORIES



PROTEIN

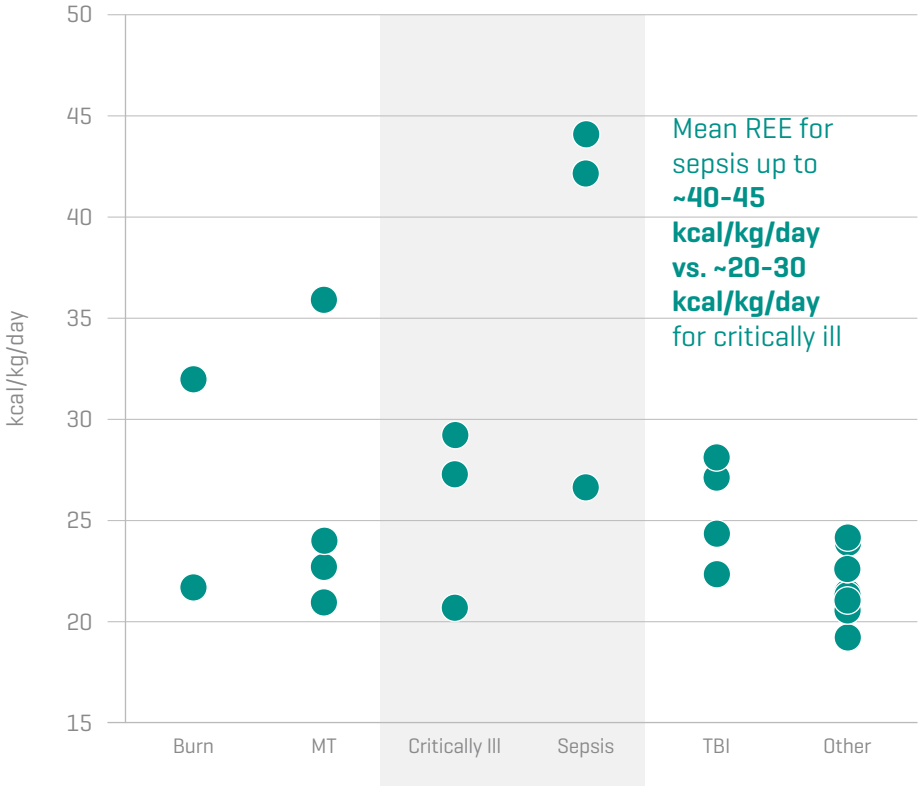


Maximising protein while meeting calorie targets, guided by IC, is important to the survival of critically ill patients.[2]

Energy needs in critically ill patients are **DYNAMIC.**[3]

ENERGY NEEDS VARY BY CONDITION OF THE PATIENT[3]

REE was measured in various conditions over the course of an illness and showed a dynamic pattern

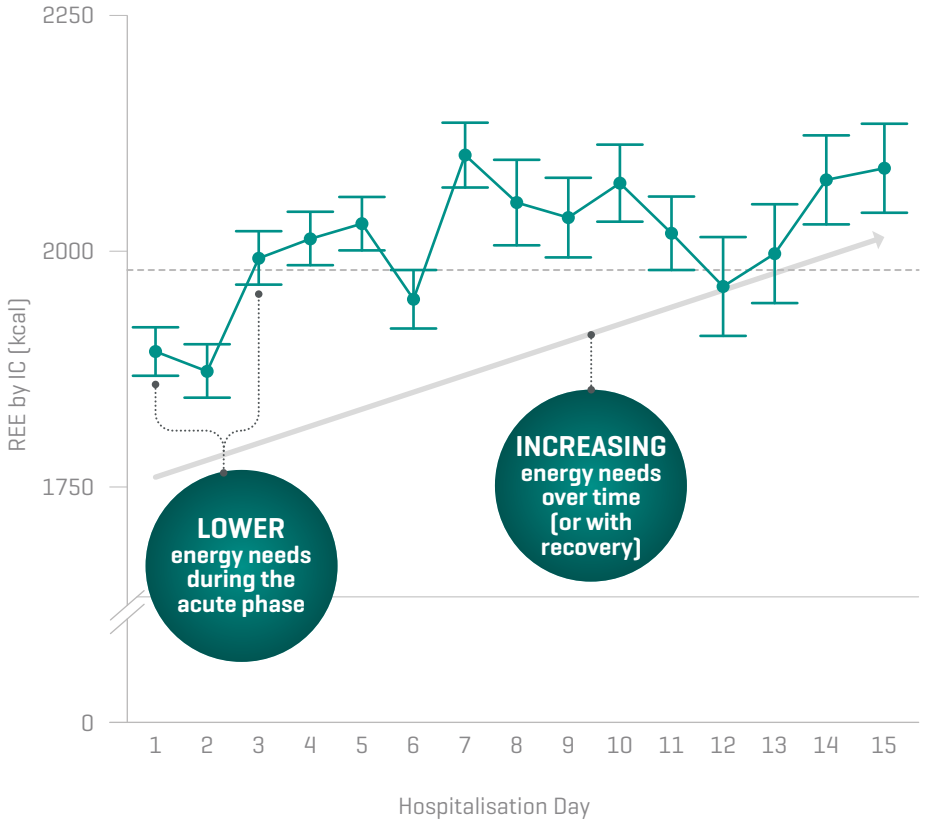


Each dot represents the mean of measured REE of each group in the studies.

MT = multiple trauma, TBI = traumatic brain injury

Adapted from Rattanachaiwong S, et al. Clin Nutr 2018, doi.org/10.1016/j.clnu.2018.12.035.

ENERGY NEEDS VARY OVER COURSE OF HOSPITAL/ICU STAY[3]



Mean REE of critically ill patients by hospitalization day.
ICU = intensive care unit, REE = resting energy expenditure

Adapted from Rattanachaiwong S, et al. Clin Nutr 2018, doi.org/10.1016/j.clnu.2018.12.035.

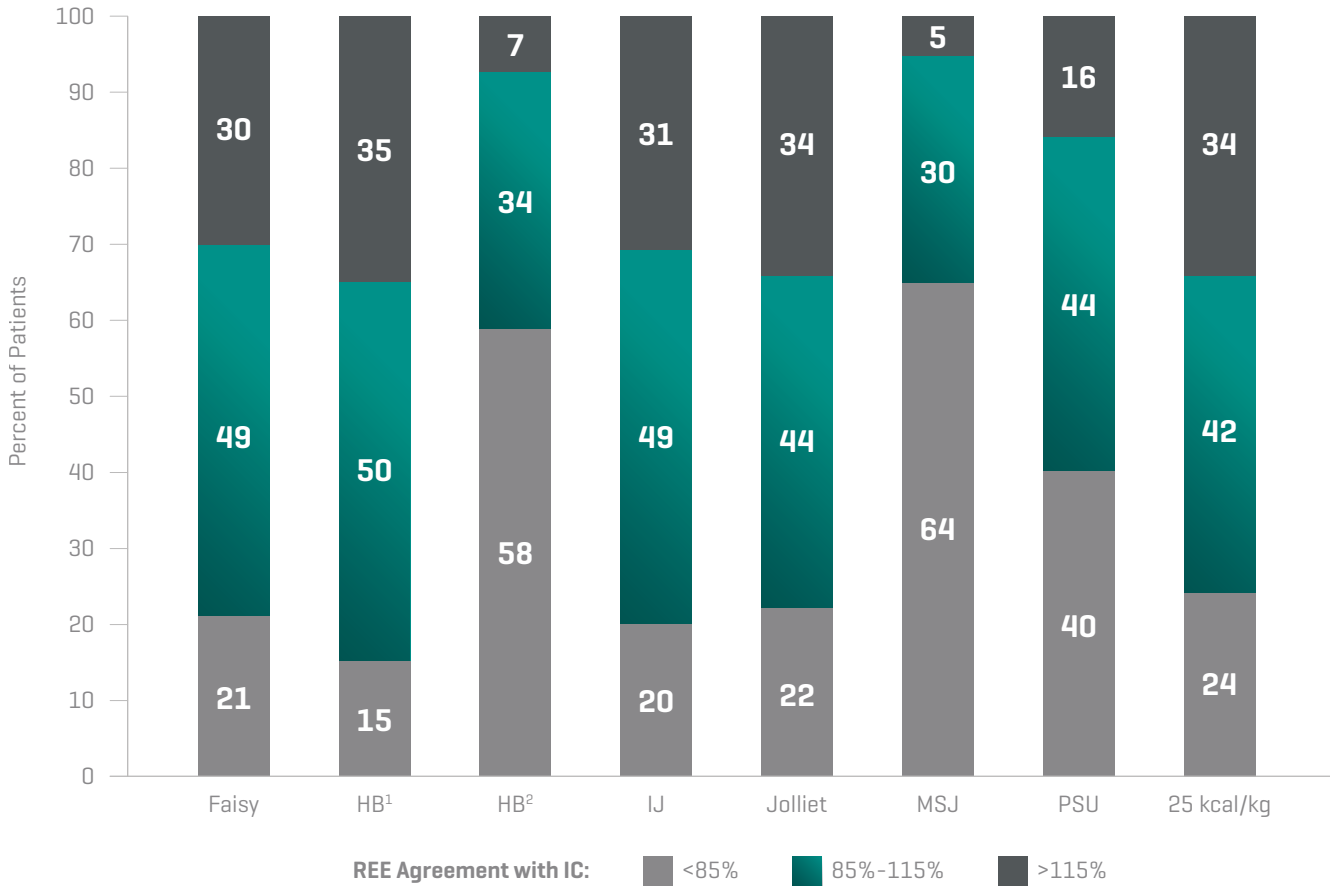
Using indirect calorimetry throughout the ICU stay can detect a variability in a patient's REE.[3]

Predictive equations are **INACCURATE.**[4]

- Single centered retrospective validation study, 1,440 patients with a total of 3,573 measurements[4]
- Data was drawn from a computerized system and included REE and other variables required by equations. Measurements were restricted to 5 REE per patient to avoid bias. A total of 8 equations were examined.

Largest among numerous studies comparing measured REE with IC vs predictive equations[4,9,10]

PREDICTIVE EQUATIONS ARE ACCURATE FOR NO MORE THAN 50% OF ICU PATIENTS[4]



[1]With a correction factor of 1.3.
[2]No correction factor.
HB = Harris-Benedict, IC = indirect calorimetry, IJ = Ireton-Jones, PSU = Penn-State

Adapted from Zusman O, et al. Clin Nutr. 2019;38(3):1206-1210.

Determining energy needs using predictive equations can lead to over- or under-feeding.[4]

IC to **MEASURE** energy expenditure.[6,7]

Indirect Calorimetry and Nutrition Guidelines for ICU Patients[5,7]

ASPEN 2016	ESPEN 2019			
Indirect Calorimetry	**Indirect Calorimetry**		**Acute Phase**	**Late Phase**
We suggest that indirect calorimetry (IC) be used to determine energy requirements when available and in the absence of variables that affect the accuracy of measurement.[7] Quality of evidence: very low The target for these guidelines is intended to be the adult (>=18 years) critically ill patient expected to require a length of stay greater than 2 or 3 days in a medical ICU.	**In critically ill mechanically ventilated patients, energy expenditure should be determined by using indirect calorimetry.**[5] Grade of recommendation: B – strong consensus (95% agreement)	**If indirect calorimetr is used, isocaloric nutrition rather than hypocaloric nutritior can be progressively implemented** after the early phase of acute illness.[5] Grade of recommendation: 0 – strong consensus (95% agreement)	**Hypocaloric** nutrition (not exceeding 70% of EE) should be administered in the **early phase of acute illness.**[5] Grade of recommendation: B – strong consensus (100% agreement)	**After day 3, caloric delivery can be increased up to 80-100% of measured EE.**[5] Grade of recommendation: 0 – strong consensus (95% agreement)

ASPEN guidelines suggest the use of IC to accurately measure patients' energy needs.[7]

INTRODUCING Q-NRG+

Designed *by* clinicians *for* clinicians.

International Multicentric Study for Indirect Calorimetry (ICALIC)[6]

"Indirect calorimetry is a tool of paramount importance, necessary to optimize the nutrition therapy of patients with various pathologies and conditions." – ICALIC group

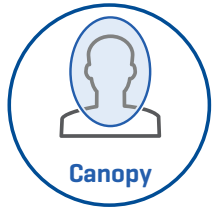
GOAL

Develop a new IC device that addresses barriers according to the needs of the clinician

CONCLUSION

Partnered with industry to design the next generation technology that is:

- Accurate
- Easy to use
- Affordable



- Spontaneously breathing subjects >15 kg (33 lb) when using a canopy
- Spontaneously breathing subjects age >6 yrs and >10 kg (22 lb) when using a face mask.
- Ventilated subjects age >10 yrs and >10 kg (22 lb).

COSMED has designed an indirect calorimeter device for measuring REE in both ventilated and spontaneously breathing patients.

NEXT GENERATION TECHNOLOGY.

FAST

- ~10-15 minutes to run test including warm up time
- Minimal calibration time

EASY TO USE

- Real-time, user-friendly dashboard
- Downloadable data in PDF or Spreadsheet file
- Portable and easily transported between rooms
- Flexibility to use on intubated and spontaneously breathing patients

ACCURATE

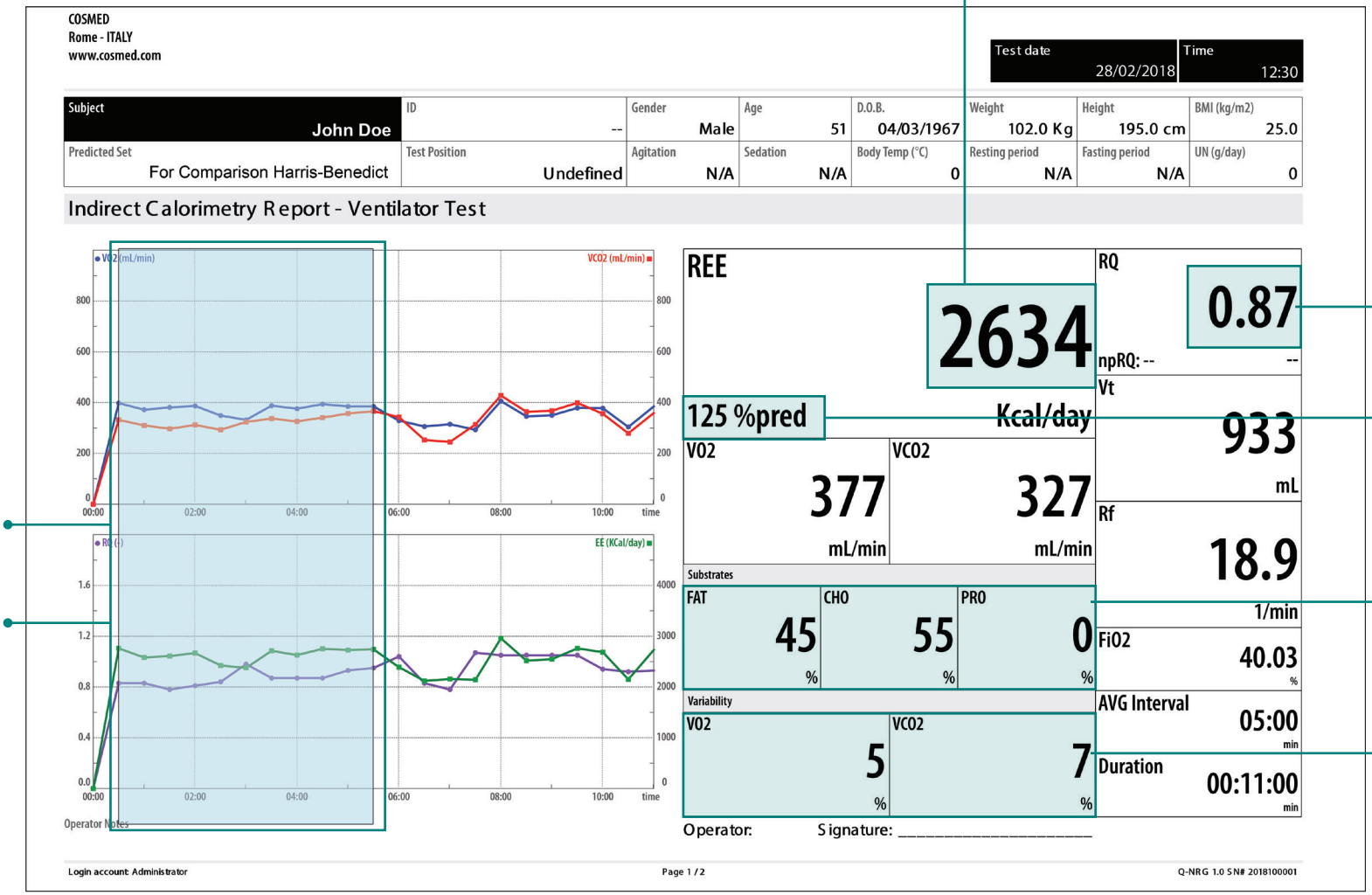
- REE within +/-3% or 36 kcal/day, whichever is greater
- Range (0-7200 kcal/day)

Indications for Use: The Q-NRG+ portable Metabolic Monitors are indicated for the measurement of REE for spontaneously breathing and ventilated patients, with some limitations in accordance with labeling, within the following population: spontaneously breathing subjects >15 Kg (33 lb), when tested with the Canopy dilution technique, ventilated subjects > age 10 and 10 Kg (22lb), and spontaneously breathing subjects > age 6 and 10 Kg (22 lb), when tested with Face Mask. The Q-NRG+ Portable Metabolic Monitors are intended to be used in professional healthcare facilities only. This device is not suitable for operating in presence of flammable anesthetic gases or gases other than O_2, CO_2, N_2 and water vapor. The device is to be used by physicians or by trained personnel under the responsibility of a physician. The device is not intended as a continuous monitoring device for surveillance of vital physiological processes. Warnings: This device measures clinical parameters used to aid diagnosis and it is intended only as an adjunct device in patient assessment. In case of disturbing conditions, the shutdown is allowed because the safety of the device towards patients and operators is not affected, since the final evaluation is performed on the outcome data measured during a complete test. No modification of this device is allowed. For more information on this medical device, please refer to User Manual.

Q-NRG+ is a standalone indirect calorimeter that overcomes IC barriers and allows for everyday use in the clinical setting.

Q-NRG+ Sample Report

Simple and Intuitive User Interface



Patient REE

Non Protein-RQ substrate utilization (.7 -1.0: .7 burning fats, .8-.85 burning mixed diet, 1.0 or greater burning carbs (VCO2/VO2=RQ)

Comparison of REE vs. PE (predictive equation)

Shows Macronutrient breakdown If 24-Hr Urine collection results are available

Coefficient of variation

Best 5 Minutes

Touchscreen allows custom selection

Sample printout of a hypothetical Q-NRG+ patient REE results in a comprehensive format to facilitate metabolic assessment.

Abbreviations: REE – Resting Energy Expenditure; Predicted Set – Compared to a selected predictive equation; VO2 – Oxygen Consumed; VCO2 – Carbon Dioxide Produced; RQ – Respiratory Quotient (VCO2/VO2); Vt – Tidal Volume; Rf – Respiratory Frequency; FiO2 – Fraction of Inspired Oxygen; CHO – Carbohydrates; PRO – Protein; AVG - Average; EE - Energy Expenditure, npRQ - non-protein respiratory quotient; mL/min - Milliliter/minute; min - minute

For more information on this medical device, please refer to User Manual.

4 Steps to Help Achieve **Optimal Nutrition**.

RE-ASSESS ENERGY NEEDS THROUGHOUT STAY

IF NECESSARY, ADJUST Rx

1

ASSESS

Use **Q-NRG+** on eligible patients to determine their REE (kcal)

2

PRESCRIBE

Interpret Indirect Calorimetry (IC) results to determine energy targets; determine protein needs and appropriate volume

3

DELIVER

Administer appropriate nutrition intervention (EN, SPN, or PN)*

4

MONITOR

Ensure patient receives optimal nutrition

*EN = Enteral Nutriton, SPN = Supplemental Parenteral Nutrition, PN = Parenteral Nutrition

Q-NRG+ Technical Specifications

Product		
Part Number	C09092-12-99 (North America)	
Indications for Use	Resting Energy Expenditure (REE) measurement on mechanically ventilated and spontaneously breathing subjects*	
Standard Packaging	Q-NRG+, USB cable, power cable, User Manual	
Test Kit (Single-use)	Flow-REE, FiO_2 and FeO_2/CO_2 sampling lines, FiO_2 Vent Adapter, HME or standard filter	
Measurement Modes		
Ventilator	Standard	
Canopy Hood	Optional	
Face Mask	Optional	
Main Parameters	**Range**	**Accuracy**
VO_2	10-1000 mL/min	±3% or 5mL/min
VCO_2	10-1000 mL/min	±3% or 5mL/min
RQ	0-2.00	±5% or 0.04
REE	0-7200 kcal/day	±5% or 36 kcal/day
Flowmeter	**Ventilator**	**Canopy/Mask**
Type	Disposable Pneumotach (Flow-REE)	Bidirectional digital turbine
Flow Range	0.01 – 1.6 L/s	0.05 - 2 L/s
Accuracy	<2% or 100mL/min @1-25 L/min	< 2% or 100mL/min @1-25 L/min
Resistance	2.3 cmH_2O s/L @ 1 L/s	<0.25 cmH_2O s/L @ 1 L/s
Calibration	Automatic via Internal Blower	With 3L calibration syringe (monthly)
Gas Sensors	**O_2**	**CO_2**
Gas Exchange Sampling	Micro Dynamic Mixing Chamber (patented)	
Type	Galvanic Fuel Cell (GFC)	Digital NDIR
Range	0-75%	0-10%
Accuracy	<0.05% Vol	<0.05% Vol
Resolution	0.01% Vol	0.01% Vol
Calilbration	Automatic via gas cylinder (monthly)	

Report	
Export Modes	USB, Bluetooth®
Export Formats	PDF, CSV, XML
Hardware	
Display	10.1" Transmissive TFT LCD, 1024x600, 65k colors, capacitive touch screen
Power	Battery: Li-Ion "smart" (3 hours autonomy) Main: 100V-240V ±10%; 50/60Hz, 1.5A @100VAC, 1.0A @240VAC
Wireless Connectivity	Bluetooth (2.1 + EDR Class II - Range 10 m line-of-sight)
Wired Connectivity	1 USB-device (5kV galvanic-insulated), 2 x USB Host, RS-232, LAN
Weight & Dimensions	4.65 kg (10.3lb), 31x21x27cm (12.2x8.3x10.6in)
Environmental Ranges	Temp. +10°C to +35°C. Humidity: 5-93% (non condensing). Atmospheric pressure: up to 3011m
PC Sofware (optional)	
Languages	Italian, English, Spanish, French, German, Portuguese, Greek, Dutch, Turkish, Russian, Chinese (Traditional & Simplified), Korean, Romanian, Polish, Czech, Norwegian, Hebrew
OS Requirements	Windows 7, 8, 10
Security & Quality Standards	
MDD (93/42/EEC Class IIa), Safety (Class I IEC 60601-1), EMC (IEC 60601-1-2), Telemetry (ETSI EN 301 489-17)	

Indications for Use: This device is indicated for the measurement of REE for spontaneously breathing and ventilated patients, with some limitations in accordance with labeling, within the following population: spontaneously breathing subjects 15 Kg (33 lb), when tested with the Canopy dilution technique, ventilated subjects > age 10 and 10 Kg (22lb), and >5 Kg (33 lb), when tested with the Canopy dilution technique, ventilated subjects > age 10 and 10 Kg (22lb), and spontaneously breathing subjects > age 6 and 10 Kg (22 lb), when tested with Face Mask. This device is not suitable for operating in presence of flammable anesthetic gases or gases other than O2, CO2, N2 and water vapor. The device is to be used by physicians or by trained personnel under the responsibility of a physician. The device is not intended as a continuous monitoring device for surveillance of vital physiological processes. Warnings: This device measures clinical parameters used to aid diagnosis and it is intended only as an adjunct device in patient assessment. In case of disturbing conditions, the shutdown is allowed because the safety of the device towards patients and operators is not affected, since the final evaluation is performed on the outcome data measured during a complete test. No modification of this device is allowed. Precautions/Contraindications: Carefully re-check ventilator functionality after connection of the parts. Make sure that the patients cuff pressure is high enough to avoid air leakage. Manipulation of the ventilator circuit may cause leaks that may lower alveolar ventilation. For more information on this medical device, please refer to User Manual.

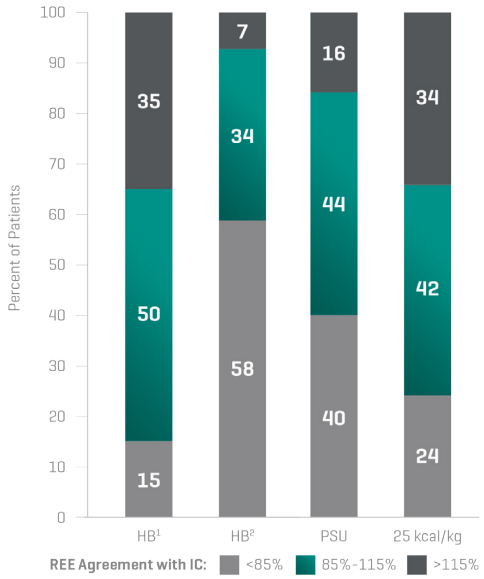
References and Technical Specs

1. Weijs PJ, et al. JPEN 2012;36:60-68.
2. Zusman O, et al. Critical Care 2016;20:367.
3. Rattanachaiwong S, et al. Clin Nutr 2018, doi.org/10.1016/j.clnu.2018.12.035.
4. Zusman O, et al. Clin Nutr. 2019;38(3):1206-1210.
5. Singer P, et al. Clin Nutr 2019;38:48-79.
6. Oshima T, et al. Clin Nutr 2017;36:651-662.
7. McClave SA, et al. JPEN J Parenter Enteral Nutr 2016;40:159-211.
8. Heidegger P, et al. Lancet 2013;381:385-393.
9. COSMED Q-NRG Metabolic Monitor User Manual 2019.
10. Graf S, et al. Clin Nutr 2017;36:224-228.
11. DeWaele E, et al. Minerva Anestesiologica 2015;81:272-282.
12. Frankenfield DC, et al. JPEN 2011;35:563-570.

INTRODUCING Q-NRG+

Helping to optimize nutrition therapy for your patients.

Predictive equations are accurate for no more than 50% of ICU patients[4]



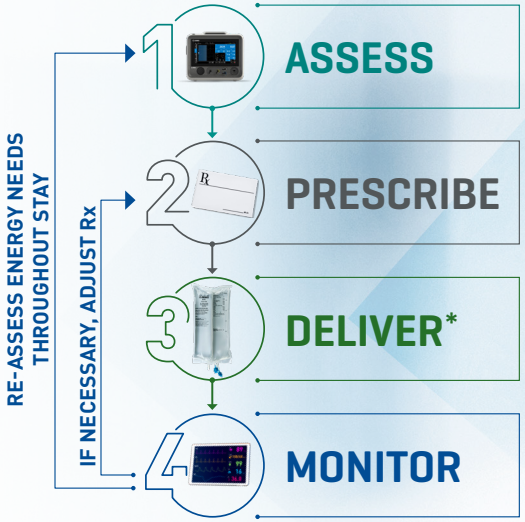
[1] With a correction factor of 1.3.
[2] No correction factor.
HB = Harris-Benedict, IC = indirect calorimetry, IJ = Ireton-Jones, PSU = Penn-State

Adapted from Zusman O, et al. Clin Nutr. 2019;38(3):1206-1210.

Q-NRG+, the next generation of IC technology, enables **individualized metabolic measurements**[8]

"Indirect calorimetry is a tool of paramount importance, necessary to optimize the nutrition therapy of patients with various pathologies and conditions."[6]

4 Steps to Achieve **Optimal Nutrition**



***Baxter has a comprehensive PN portfolio, covering a broad spectrum of energy, protein, and other nutrients.**

Rx only. For more information on this medical device, please refer to User Manual.

USMP/QNRG/19-0001(1) 2/2020

Baxter Healthcare Corporation
One Baxter Parkway
Deerfield, IL 60015
www.baxter.com