



Health Technology Review	
Technology Ref.:	HTA22028
Technology Name:	seca mBCA 554
Approvals by International Bodies:	HIPAA and GDPR and ISO 27017 and 27018
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<b>Short Description of the Technology:</b>	<p>The technology has one hardware component and one software component that work together.</p> <p><b>Hardware component:</b> The seca mBCA 554 is device that uses Bioelectrical impedance (BIA) in a standing position which is mainly used in hospitals, medical practices, outpatient and inpatient health care facilities, and in medically oriented fitness facilities in accordance with national regulations. The seca BIA standing aid is used in combination with a compatible seca scale for bioimpedance measurement in persons as of a height of 130 cm.</p> <p><b>Software component:</b> The seca analytics 125 software is a cloud-based software required to analyse bioimpedance measurements, when used in conjunction with seca medical Body Composition Analysers seca 554, the seca analytics 125 software receives body weight and body height data for calculation of Body Mass Index (BMI) to monitor weight changes and growth process. This includes the following parameters: Weight, Height and Body Mass Index (BMI) as well as bioelectrical impedance (reactance Xc and resistance R) data for estimation of body composition and provide and estimation of body composition.</p>
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<b>Health Technology Assessment Team Recommendation:</b>	<b>Approve</b>
<b>Summary of Review:</b>	
<p>The mBCA 554 is a new body composition analyzer measuring bioimpedance in standing position developed by seca. The use of bioelectrical impedance analysis (BIA) is widespread both in healthy subjects and patients. BIA allows the determination of the fat-free mass (FFM), skeletal muscle mass (SMM), fat mass (FM), extracellular water (ECW) and total body water (TBW) when using appropriate population, age or pathology-specific BIA equations and established procedures.</p>	
<b>Advantages</b>	<b>Disadvantages</b>
The BIA is non-invasive, relatively inexpensive, it does not expose to ionizing radiation, is subject friendly and can be performed easily and very fast. Measurement time: 17 seconds	The Patient shall follow the guidance and instructions prior conducting the test in seca mBCA 554 device to ensure accurate results and measurements.
Its improved graphical analysis provides an	The device with BIA technology could not be

accurate and comprehensive picture of the body composition in seconds and makes bioimpedance analysis an even more valuable support for therapy and diagnosis	used on all patients; such as Patients with Electronic implants, Active prostheses, Electronic life-support systems & Portable electronic medical device
Rapid assessment of vital body composition, such as fat mass, visceral fat, skeletal muscle mass, body water and phase angle with medical precision	BIA is altered by silicone breast implants that appear as fat
Visual summary in an easy-to read format.	Risk of Patient Data security leak
Safe to use – No risk on Patients and Professionals	

We recommend an **approval of using this technology** with the following conditions:

1. To utilize the device as per the manufacturer instructions in a clinical setting.
2. To comply with DOH Standard on Patient Healthcare Data Privacy Standard.
3. Establishing a proper quality monitoring process and reporting of any adverse events or unwarranted consequences including safety issues of employees.
4. Provision of regular updates and reports about the product to DOH upon request.
5. Any other documents or information requested regarding the product and cost to finalize the approval process.

**Moreover**, DOH has the right to stop the product at any stage if deemed necessary, initial conditions and any subsequent conditions must be satisfied before obtaining final approval. Failure to do so will reflect in provoking the approval.

### Technology Image





## Population, setting and intended user for Technology “seca mBCA 554”

- **Population/ Intended User;**
  - Any patients of any age groups except babies
- **To be performed by:**
  - By Healthcare professional
- **Clinical Setting:**
  - Clinical settings
- **Condition of use:**
  - As per Manufacturer instructions
- **Exclusion criteria:**
  - Bioimpedance Analysis may not be performed on persons with:
    - Clinical use of BIA: should not be used for the below mentioned subjects as there no existing accurate, validated and proven BIA algorithms/equations for interpretation/estimation of the Body masses.
      - Extremes of BMI ranges – (<16 or >34 kg/m<sup>2</sup>)
      - In severely malnourished and anorexia nervosa patients (BMI <16 kg/m<sup>2</sup>), results of BIA can dangerously impact the management of Refeeding syndrome of such subjects.
      - Medical conditions which change serum electrolytes, hematocrit and blood flow,
      - All Subjects with abnormal hydration and fluid statuses.
      - Subjects who are undergoing Chemotherapy & Radiation therapy.
      - Neuromuscular diseases (e.g. Duchenne muscular dystrophy, post-traumatic paraplegia/hemiplegia)
      - Patients having HIV-infection, and liver cirrhosis
      - Patients on hemodialysis, peritoneal dialysis, and chronic renal failure.
      - Patients with acromegaly.
      - Pregnant women.
      - Elderly
      - Patients having Implanted devices and metallic devices