MediBeacon

Transdermal, Continuous, Measurement of Renal Function

Transdermal measurement of Glomerular Filtration Rate (mGFR) is used extensively in preclinical nephrology research. MediBeacon's system allows calculation and tracking of an animal's kidney function over time without requiring the animal to be restrained during monitoring.

Determination and monitoring of mGFR is essential for various preclinical studies, e.g. characterization of renal function, assessment of new and existing kidney therapeutics, evaluation of nephrotoxicity, screening of novel chemical or medical agents, and fundamental understanding of kidney function.

Historically, the research standard for measuring renal function has required several blood draws as a function of time and subsequent sophisticated laboratory analysis to measure tracer agent concentrations in each blood sample. This methodology using blood and/or urine sampling is labor-intensive, and multiple blood draws put a strain on the animal.

Utilization of the MediBeacon® device and a fluorescent tracer agent is independent of blood sampling, urine collection, and laboratory assays and thus enables streamlined preclinical trial design and execution.

To obtain a quote for the Transdermal Mini GFR Monitor contact **sales@medibeacon.com.**

Successful Use in Nephrology Research

MediBeacon technology is used by leading medical schools, academic centers, research institutes, contract research organizations and pharmaceutical companies worldwide to enhance preclinical assessment of kidney therapeutics, evaluate nephrotoxicity, and gain fundamental understanding of kidney function in animals.

Research using the MediBeacon preclinical product has been featured at scientific meetings worldwide. There are over **250 peer-reviewed publications and conference abstracts** in which this transdermal mGFR technique has been used.

For the latest research references see **www.medibeacon.com/publications/**.

PRECLINICAL Leading researchers worldwide rely on MediBeacon

technology.

Key Advantages*

- Longitudinal GFR measurements in the same animal are possible.
- System can be used in conscious, freely-moving mice, rats, and larger animals.
- Changes of GFR can be observed earlier compared to endogenous markers.
- Streamlined specimen-free trial design and execution are the result.

*Similar to the system currently in human clinical studies.

System

- Device and patch are affixed to animal.
- Fluorescent tracer agent is administered.^{(a)(b)}
- Software analyzes data from the device.

(a) NOT FOR HUMAN USE (b) The Fluorescent tracer agent is administered IV into the animal.



Optimized Design^(c)

- Over 50% Smaller Device
- Adjustable Sampling Rate
- Robust Battery Interface
- Reduced Motion Artifacts
- Enhanced Data Precision
- Supports Mac or PC



(c) Comparison is to previous version of the Transdermal GFR Monitor.

Preclinical Device – Technical Specifications

The instrument contains light emitting diodes which excite the fluorescent tracer agent and a photodiode that collects the light emission.

After amplification and digitization, the data sets are subsequently stored in the internal memory of the device. The data is transferred to a PC or Mac via USB connection. A basic software package is provided with the device. For each transfer, an additional MediBeacon Measurement Code must be used. Measurements Codes are acquired together with each order of consumables. An advanced evaluation software product (Studio 2) is sold separately.

Measurement kits which include the necessary consumables and Measurement Codes required for use of the Transdermal Mini GFR Monitor are sold separately.^{(d)(e)}

(d) NOT FOR HUMAN USE

(e) For information regarding compatible fluorescent tracer agents contact us at sales@medibeacon.com.



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About MediBeacon®

MediBeacon is a medical technology company focused on advancing fluorescent tracer agents and transdermal detection technology to provide vital and actionable measurement of organ function.

Measurements of organ function at the point of care have the potential to provide information that will help healthcare providers to fundamentally change the standard of care in numerous clinical situations. It is our mission to provide doctors with information that empowers them to make better decisions faster. Use of the technology in a clinical research setting offers the possibility to help researchers reduce time to market for life-saving pharmaceuticals by giving them data that can help determine whether and how fast therapies are working.

The U.S. Food and Drug Administration has granted Breakthrough Device designation to the Transdermal GFR Measurement System (TGFR). Clinical studies in subjects with normal and impaired kidney function are ongoing. The TGFR is engineered to allow non-invasive detection of the change in patient levels of fluorescent GFR tracer agent (Lumitrace) over time via a sensor placed on the patient's skin. The rate of decrease in the emitted fluorescence from Lumitrace[®] is automatically calculated and displayed on the monitor yielding a measured GFR or kidney function.



MediBeacon Clinical Study Transdermal GFR Measurement System

MediBeacon products are in various stages of clinical development and are not yet approved for human use.

MediBeacon Inc. 425 N. New Ballas Road Suite 100 St. Louis, MO 63141 United States

+1 (314) 269-5808 info@medibeacon.com

Huadong Medicine Co., Ltd

No. 866, Mogan Mountain Road Hangzhou, ZJ 310011 China

+86-(0)571-89908581 info@eastchinapharm.com

MediBeacon GmbH

Cubex41 Theodor-Kutzer-Ufer 1-3 68167 Mannheim Germany

+49 (0)621-150283-15 sales@medibeacon.com