MediBeacon®
Transdermal GFR

Transdermal GFR System (TGFR) Clinician Brochure

The TGFR is comprised of:

- Lumitrace® injection, fluorescent tracer agent
- MediBeacon® TGFR Sensor, light source and photo detector
- MediBeacon® TGFR Monitor, calculates and displays transdermal GFR

℞ only

Please see page 5 for Indication for Use and Important Safety Information about the TGFR and Lumitrace.

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MediBeacon®

Advancing Fluorescent Technology to Help Improve Patient Care

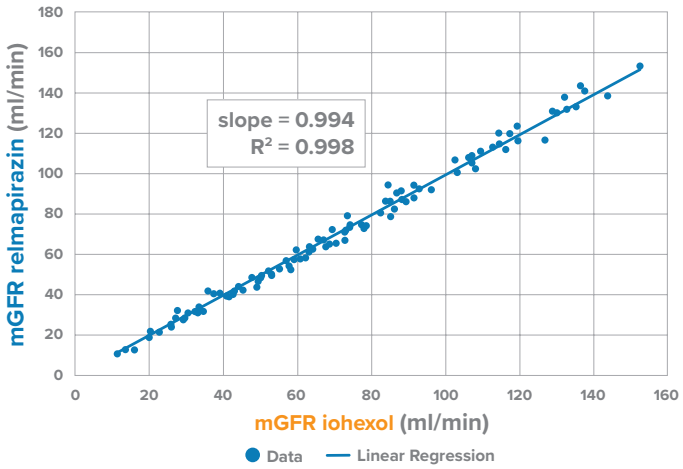
Point of Care Transdermal GFR

The MediBeacon® Transdermal GFR System (TGFR) is engineered for non-invasive detection of the change in levels of a fluorescent GFR tracer agent over time via a sensor placed on the patient's skin. The rate of change in the emitted fluorescence from Lumitrace is automatically calculated and displayed on the monitor yielding a transdermal GFR (tGFR).

The MediBeacon TGFR includes Lumitrace (relmapirazin), an exogenous GFR tracer agent administered as an IV bolus injection, the use of which, with serial blood draws, has been shown to be equivalent to iohexol plasma clearance for determination of measured GFR (mGFR) in clinical studies.[1]

GFR relmapirazin *(MB-102)* vs. GFR iohexol

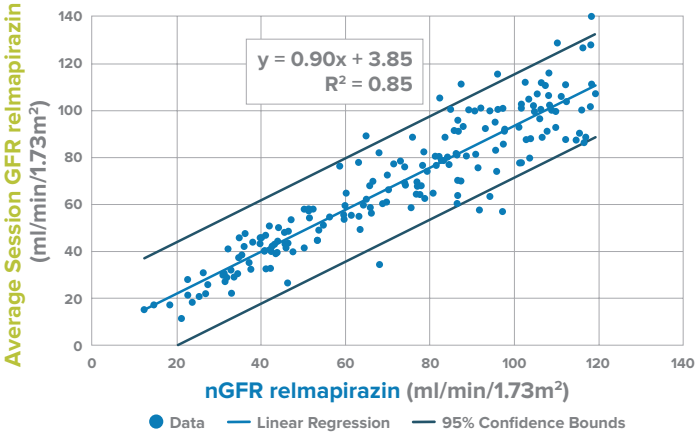
Established equivalence of relmapirazin plasma mGFR versus iohexol plasma mGFR



The rate of decrease of Lumitrace fluorescence measured on the skin has been shown in clinical studies to be highly correlated with nGFR (indexed mGFR) as determined via Lumitrace plasma clearance.

Average Session GFR vs. nGFR

Established correlation of tGFR reading to relmapirazin plasma nGFR



The TGFR Monitor displays information regarding the rate of decrease in Lumitrace fluorescence and how this changes over time.

The duration of a transdermal GFR monitoring session depends on a patient's kidney function.

[1] Dorshow RB, Debreczeny MP, Goldstein SL, Shieh JJ. Clinical validation of the novel fluorescent glomerular filtration rate tracer agent relmapirazin (MB-102). Kidney Int. 2024 Oct;106(4):679-687. doi: 10.1016/j.kint.2024.06.012.

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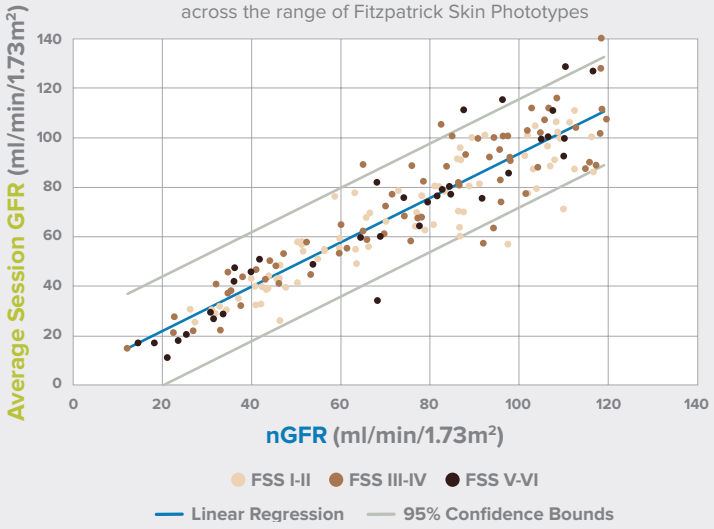
tGFR Across Skin Tones

The Transdermal GFR System (TGFR) has been designed to report a tGFR across the full range of human skin colors as quantified by the Fitzpatrick Skin Phototype (FSP).

After placement of the TGFR Sensor, the TGFR adjusts automatically for the patient skin tone before moving on to the monitoring session.

Average Session GFR vs. nGFR

The TGFR has been demonstrated to assess tGFR across the range of Fitzpatrick Skin Phototypes



Data Legend

Fitzpatrick Skin Phototype[2]

FSP Types I-II
These lighter FSP tones range from pale white skin which is extremely sensitive, always burns and never tans. Examples range from individuals with red hair and freckles to fair skinned, fair haired Caucasians and northern Asians.

FSP Types III-IV
These medium FSP tones range from light to moderate brown skin which is mildly sensitive, sometimes burns and slowly tans or burns minimally and slowly tans. Examples range from Mediterranean and Middle Eastern Caucasians and southern Asians.

FSP Types V-VI
These darker FSP tones range from dark brown to black skin that is very resistant and rarely or never burns. Examples range from some Hispanics, Africans and Indigenous Australians.

[2] Australian Government – ARPANSA

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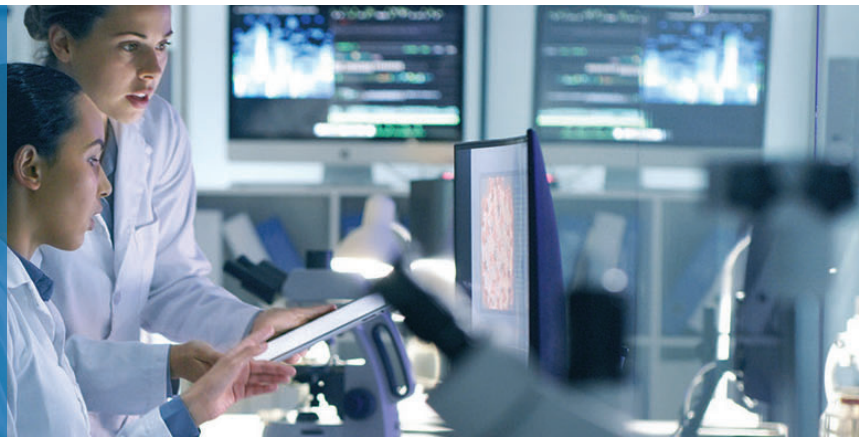
Understanding Renal Function is a Significant Clinical Challenge



Worldwide Epidemiology of Chronic Kidney Disease[3]

Extremely common

843.6 million in 2017

Approximately 1 in 10

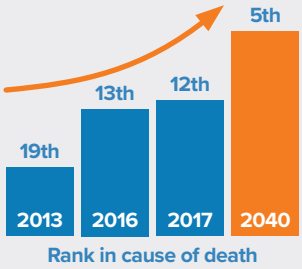
More prevalent in:

- Individuals with diabetes mellitus
- Racial minorities
- Women
- Elderly
- Individuals with hypertension

Increasing death rate

+41.5%

1990 to 2017



[3] Csab P. Kovesdy, Epidemiology of chronic kidney disease: an update 2022, Kidney International Supplements, Volume 12, Issue 1, P7-11, April 2022, 12,doi:10.1016/j.kisu.2021.11.003.

Accuracy of the TGFR Pivotal Clinical Trial

The pivotal study objective was a comparison of Average Session GFR with plasma nGFR using P30. The acceptance criteria was 95% lower confidence interval greater than 85%.

The pivotal clinical study yielded a P30 value of 94.0% with an upper 95% confidence interval of 96.9% and a lower 95% confidence interval of 89.4%.

Pivotal Study Results

P30	Upper 95% CI	Lower 95% CI
94.0%	96.9%	89.4%

This means that 94% of the Average Session GFR values were within 30% of the measured GFR values (with a 95% confidence interval of 89.4-96.9%).

	Average Session GFR	eGFR*
P30	94%	92.9%
95% Confidence Interval	89.4%-96.9%	88.1%-96.1%

*The eGFR results above were obtained via a post hoc analysis, which was not the predetermined outcome measure from the study.

Other Relevant Subpopulation P30 Results

Patient Population	P30 Value	Upper 95% CI	Lower 95% CI
Stratum 1 (eGFR≥70mL/min/1.73m²) N=90	95.6%	98.8%	89.0%
Stratum 2 (eGFR<70mL/min/1.73m²) N=92	92.4%	96.9%	84.9%

Patient Population	P30 Value	Upper 95% CI	Lower 95% CI
FSP Type I-II N=77	96.1%	99.2%	89.0%
FSP Type III-IV N=69	92.8%	97.6%	83.9%
FSP Type V-VI N=36	91.7%	98.3%	77.5%

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Focused on Providing Insights to Clinicians

Possible Clinical Uses for Transdermal GFR

Chronic Kidney Disease (CKD)

CKD is a growing epidemic and has devastating consequences.

Therapy Dosing

An assessment of GFR is used to determine if patients are eligible for receiving some therapies, such as guideline-directed medical therapy for heart failure and anticancer drugs. Accurate assessment of kidney function can help reduce the risk of patients experiencing hyperkalemia from mineralocorticoid antagonists and toxicity from renally cleared chemotherapy.

Transplantation Donor Evaluation[4]

Evaluation of GFR is required as part of donor evaluation and is receiving increasing emphasis. Recent data from the general population demonstrate increased risks associated with reduced GFR. Data from kidney donors demonstrate increased risks of kidney disease after donation, including a small increase in the risk of kidney failure.

Kidney Function Assessment in the Hospital

Clinicians base patient categorization and sophisticated treatment decisions, sometimes extremely invasive and expensive therapies, on GFR levels. Bedside renal function assessments have the potential to yield information to aid in patient management. Identification of high-risk patients preoperatively could affect clinical decision making around surgical technique.

[4] J Am Soc Nephrol. 2017 Apr; 28(4): 1062–1071.

Indication for Use:

The MediBeacon® Transdermal GFR System (TGFR) is intended to assess the Glomerular Filtration Rate (GFR) in adult patients with impaired or normal renal function by noninvasively monitoring fluorescent light emission from an exogenous tracer agent over time. This device has been validated in patients with stable renal function.

The MediBeacon® TGFR is not approved for use in patients with GFR <15 ml/min/1.73 m^2, GFR >120 ml/min/1.73m^2, patients on dialysis, or anuric patients. The use of this device in patients with dynamic and rapidly changing renal function has not been validated. This device is not intended to diagnose acute kidney injury (AKI).

The MediBeacon® TGFR Sensor and exogenous tracer agent, Lumitrace® injection, are single use and are only used with the MediBeacon® TGFR.

The MediBeacon® TGFR Sensor is a single use device intended to attach to the patient's skin and excite fluorescence in Lumitrace® injection, the tracer agent, and measure the returning light intensity. The data is sent to the MediBeacon® TGFR Monitor.

Lumitrace® is an injectable exogenous fluorescent tracer indicated for use with the MediBeacon® Transdermal GFR System (TGFR) for Glomerular Filtration Rate assessment.

Contraindications: There are no known contraindications.

Warnings and Precautions:

- See ifu.medibeacon.com for full instructions, warnings, and cautions.
- In clinical studies no serious or severe adverse events have been observed.
- Lumitrace® injection has light absorbance at 266nm and 435nm, and broad fluorescent emission at ~560nm when excited at ~440nm. Any drug activated at these wavelengths should not be used in conjunction with Lumitrace.
- Lumitrace injection may interfere with clinical laboratory tests. DO NOT ADMINISTER if the patient is expected to need clinical laboratory testing while Lumitrace is present in their system (up to 72 hours for renally impaired patients). The presence of Lumitrace decreased B-Type Natriuretic Peptide (BNP) results by around 20% in limited testing.
- Bolus infusions may impact the GFR assessment temporarily while the vasculature-tissue equilibrium is re-established.
- During a TGFR session, the patient should be as still as possible, especially during the "Establishing Baseline" stage. The system is designed to compensate for light activity such as reading or eating after the Baseline stage.

MediBeacon
Life, illuminated.

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FACT SHEET FOR HEALTHCARE PROVIDERS

MediBeacon®
Transdermal GFR System

January 14, 2025

Point of Care GFR Assessment

This Fact Sheet informs you of the probable risks and benefits of the use of the MediBeacon® Transdermal GFR System (TGFR).

Indications for Use

The MediBeacon® Transdermal GFR System (TGFR) is intended to assess the Glomerular Filtration Rate (GFR) in adult patients with impaired or normal renal function by noninvasively monitoring fluorescent light emission from an exogenous tracer agent over time. This device has been validated in patients with stable renal function.

The MediBeacon® TGFR is not approved for use in patients with GFR <15 ml/min/1.73 m^2, GFR >120 ml/min/1.73m^2, patients on dialysis, or anuric patients. The use of this device in patients with dynamic and rapidly changing renal function has not been validated. This device is not intended to diagnose acute kidney injury (AKI).

The MediBeacon® TGFR Sensor and exogenous tracer agent, Lumitrace® injection, are single use and are only used with the MediBeacon® TGFR.

The MediBeacon® TGFR Sensor is a single use device intended to attach to the patient's skin and excite fluorescence in Lumitrace® injection, the tracer agent, and measure the returning light intensity. The data is sent to the MediBeacon® TGFR Monitor.

Lumitrace® is an injectable exogenous fluorescent tracer indicated for use with the MediBeacon® Transdermal GFR System (TGFR) for Glomerular Filtration Rate assessment.

Contraindications: There are no known contraindications.

All patients will receive the Fact Sheet for Patients: MediBeacon® Transdermal GFR System (TGFR).

What is the MediBeacon® Transdermal GFR System (TGFR)?

The MediBeacon® Transdermal GFR System (TGFR) provides an assessment of glomerular filtration rate (GFR) at the point of care. This system employs an intravenously administered fluorescent tracer agent which has been engineered to be excreted exclusively by the kidneys. Noninvasive transdermal fluorescence detection of the excretion rate of the agent is converted into a GFR reading by this system.

The Instructions for Use can be found at IFU.MediBeacon.com.

What fluorescent tracer agent is used as part of the TGFR?

The MediBeacon TGFR includes Lumitrace (relmapirazin), an exogenous GFR tracer agent administered as an IV bolus injection.

Full prescribing information can be found at IFU.MediBeacon.com.

℞ only

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- **Not for use in patients with dynamic or rapidly changing kidney function.**
- **Lumitrace® injection has light absorbance at 266 nm and 435 nm, and broad fluorescent emission at ~560 nm when excited at ~440 nm. Any drug activated at these wavelengths should not be used in conjunction with Lumitrace.**
- **Lumitrace injection may interfere with some in vitro clinical laboratory tests. The presence of Lumitrace decreased B-Type Natriuretic Peptide (BNP) results by around 20% in limited in vitro laboratory testing.**
- **DO NOT ADMINISTER if the patient is expected to need clinical laboratory testing while Lumitrace is present in their system (up to 72 hours for renally impaired patients).**

Report Adverse events, including problems with device performance or results, to MedWatch by submitting the online FDA Form 3500 (https://www.accessdata.fda.gov/scripts/medwatch/) or by calling **1-800-FDA-1088**

FACT SHEET FOR HEALTHCARE PROVIDERS

MediBeacon®
Transdermal GFR System

January 14, 2025

Point of Care GFR Assessment

TGFR Key Components:

- Lumitrace® (relmapirazin) injection is the novel and proprietary fluorescent tracer agent, intravenously administered to a patient and then subsequently excreted from the body by the kidneys.

- MediBeacon® TGFR Sensor is a single use, sensor containing the light source and photo detector for the noninvasive detection of the transdermal fluorescence from Lumitrace injection and is attached to one of several positions on the body using a biocompatible adhesive. This transdermal sensor has a built-in cable that connects to a display monitor.

- MediBeacon® TGFR Monitor is the display monitor and provides power to the TGFR sensor, provides the user interface, digitizes the data acquired from the TGFR Sensor, contains the algorithms to run the TGFR Sensor and convert the output to GFR, and displays the GFR to the clinician and/or caregiver.

Key Characteristics

- Point of Care
- May take 8-24 hours to yield GFR results depending on the patient's renal function
- No blood draws
- IV line insertion required
- No urine collection
- Nonradioactive, non-iodinated fluorescent tracer agent
- Limited patient movement allowed for 8-24 hours while the GFR is being assessed.

Accuracy

A. Average Session GFR results comparison with measured GFR results (nGFR in the pivotal trial):

94% of the Average Session GFR values obtained using this device were within 30% of the measured GFR values (with a confidence interval of 89.4%-96.9%). This was the outcome of the pivotal trial.

P30 Value	Upper 95% CI	Lower 95% CI
94.0%	96.9%	89.4%

B. Average Session GFR results comparison with estimated GFR (eGFR) results (using the creatinine-based 2009 CKD-EPI equation)

	Average Session GFR	eGFR*
P30	94.0%	92.9%
95% Confidence Interval	89.4-96.9%	88.2-96.1%

*The eGFR results above were obtained via post hoc analysis (which was not the predetermined outcome measure from the study).

In the pivotal trial, 94.0% of the Average Session GFR values obtained using this device were within 30% of the measured GFR values and 92.9% of the eGFR values (creatinine based 2009 CKD- EPI equation) were within 30% of the measured GFR values. The confidence intervals overlap (see table above).

Report Adverse events, including problems with device performance or results, to MedWatch by submitting the online FDA Form 3500 (https://www.accessdata.fda.gov/scripts/medwatch/) or by calling **1-800-FDA-1088**

Clinical Study Performance Results

The main clinical study was a global, multicenter, open-label, pivotal trial studying the safety and pharmacokinetics of Lumitrace and the use of the TGFR in subjects with normal and impaired renal function, and with different skin color types, comparing the Average Session GFR value computed from transdermal GFR (tGFR) values to plasma derived indexed GFR (nGFR), measured GFR.

The primary endpoint of the pivotal clinical study was the performance measure of P30 for the Average Session GFR with respect to nGFR, with a lower limit of the 95% confidence interval greater than 85%. This means that 94% of Average Session GFR values were within 30% of the measured GFR (which was the reference standard), with a confidence interval of 89.4-96.9%.

This P30 value is the number of measurements of Average Session GFR values that differ by no more than 30% from the measurement of nGFR.

The clinical study yielded a P30 value of 94.0%, with a lower 95% confidence interval of 89.4% (and an upper 95% confidence interval of 96.9%). Thus, the primary endpoint was achieved. This means that 94% of the Average Session GFR values (with a confidence interval of 89.4 -96.9%) were within 30% of the measured GFR values (nGFR).

Patients were grouped into Stratum 1 (eGFR ≥70 mL/min/1.73m^2) and Stratum 2 (eGFR < 70 mL/min/1.73m^2). For Stratum 1 the study yielded a P30 value of 95.6%, with a lower 95% confidence interval of 89.0% (and an upper 95% confidence interval of 98.8%). For Stratum 2 the study yielded a P30 value of 92.4%, with a lower 95% confidence interval of 84.9% (and an upper 95% confidence interval of 96.9%).

Clinical Study Performance Results (continued)

Fitzpatrick Skin Phototypes (FSP) groups, FSP Type I-II (N=77), FSP III-IV (N=69) and FSP Type V-VI (N=36). For FSP Type I-II, the study yielded a P30 value of 96.1%, with a lower 95% confidence interval of 89.0% (and an upper 95% confidence interval of 99.2%). For FSP Type III-IV the study yielded a P30 value of 92.8%, with a lower 95% confidence interval of 83.9% (and an upper 95% confidence interval of 97.6%). For FSP Type V-IV the study yielded a P30 value of 91.7%, with a lower 95% confidence interval of 77.5% (and an upper 95% confidence interval of 98.3%).

In post hoc analysis, which was not the predetermined outcome measure from the study, the screening eGFR was compared to the plasma GFR of Lumitrace resulting in a P30 of 92.9% (CI 88.1%-96.1%). The eGFR was calculated using the creatinine-based 2009 CKD-EPI equation.

The following may affect the effectiveness/accuracy of this device:

- Subjects were enrolled across a range of skin tones, but individual skin tones were not powered to provide statistical significance (see data above).
- IV fluid bolus administration
- Patient movement during the 8-24 hours that the device takes to produce GFR results.

Product Safety Information

In clinical trials, there were no serious adverse effects or deaths. For patients receiving a 7 ml dose of Lumitrace, the most common adverse effects included:

- Injection site extravasation (9/412, 2%)
- Headache (5/412, 1%)
- Ecchymosis (3/412, 1%)

There are no available data on LUMITRACE use during pregnancy to evaluate for a drug associated risk of major birth defects, miscarriage or adverse maternal or fetal outcomes.

There are no data on the presence of relmapirazin in human milk, the effects on the breastfed infant or the effects on milk production.

In pregnant rats and rabbits, no evidence of harm to the fetus was observed following intravenous administration of LUMITRACE at doses up to 225 and 113 mg/kg/day (highest doses tested), respectively, which correspond to approximately 8 times the MRHD of 260.4 mg/day based on body surface area. Animal reproduction studies are not always predictive of human response.

What are the approved available alternatives?
The most common clinical practice for GFR estimation is to use a clinical laboratory test for creatinine and/or cystatin C levels and an estimation equation.

Precautions:

- Not MRI compatible
- Bolus fluid infusions may impact the GFR readings temporarily while the vasculature-tissue equilibrium is reestablished
- High energy electromagnetic and radio frequencies (e.g., cauterizing or electrosurgical equipment) may interfere with system performance

Where can I go for updates?

Clinical practice guidelines and CDC Kidney Disease Surveillance System can be accessed electronically at these websites:

- **KDIGO Guidelines: Guidelines – KDIGO**
- **CDC Kidney Disease Surveillance System: Kidney Disease Surveillance System (cdc.gov)**

Additional information on the MediBeacon Transdermal GFR System is available on the MediBeacon website

MediBeacon Inc.:
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St. Louis, MO 63141
Contact number: 1-314-269-5808
Label Website: IFU.MediBeacon.com
General Information: MediBeacon.com

MediBeacon® Transdermal GFR

Quick Guide 1

Refer to the Instructions for Use for complete information before use.

ifu.medibeacon.com

℞ only

Indication: The MediBeacon® Transdermal GFR System (TGFR) is intended to assess the Glomerular Filtration Rate (GFR) in adult patients with impaired or normal renal function by noninvasively monitoring fluorescent light emission from an exogenous tracer agent over time. This device has been validated in patients with stable renal function.

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Lumitrace® is an injectable exogenous fluorescent tracer indicated for use with the MediBeacon® Transdermal GFR System (TGFR) for Glomerular Filtration Rate assessment.

Contraindications: There are no known contraindications.

Warning and Precautions: Lumitrace® injection may interfere with clinical laboratory tests. DO NOT ADMINISTER if the patient is expected to need clinical laboratory testing while Lumitrace® is present in their system (up to 72 hours for renally impaired patients). The presence of Lumitrace® decreased B-Type Natriuretic Peptide (BNP) results by around 20% in limited testing.

These cards are for quick reference only. Please read the Instructions for Use before initial use and for complete instructions on this system.

more

ML-0001-600-310

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MediBeacon® Transdermal GFR

Quick Guide 2

Before you start, have the following at the patient location:

1. TGFR Monitor on pole, plugged into a suitable power outlet
2. TGFR Sensor, skin prep supplies, and cable securing tape
3. One vial of Lumitrace® (relmapirazin) injection, for intravenous use

TGFR Sensor Location

Select the sensor site carefully. Once the sensor adhesive has been attached to the skin, the placement cannot be changed without replacing the entire sensor. Removing the sensor may cause temporary mild skin redness. This area cannot be used for a session until the skin returns to its normal color.

Caution: Do not remove adhesive liner and place sensor until the site is properly selected and prepared.

1. The pectoralis major is the best location, on the flat area below the clavicle.
2. Pick a FLAT, clean area with no skin variations, scars, tattoos, etc. With the release liner still ON the sensor, you can assess a good contact area to ensure the sensor will rest securely against the skin.
3. Plan for cable securement: The cable must be looped and secured towards the center of the chest.

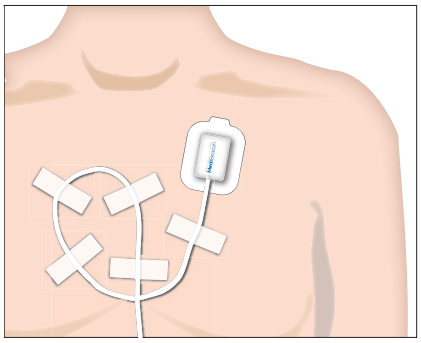
Refer to the Instructions for Use for complete information before use.
ifu.medibeacon.com

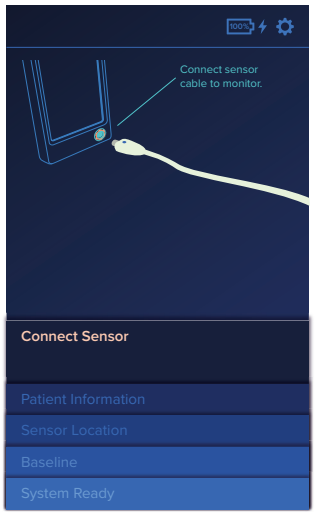
MediBeacon® Transdermal GFR

Quick Guide 3

Place the TGFR Sensor

1. Remove all hair from the site, at least as large as the full area of the sensor. Body hair clippers are recommended. Avoid shaving or depilating creams.
2. Gently but thoroughly clean the area where the sensor will be placed with an IPA alcohol wipe. Allow the skin to dry (>30 seconds). Allow any redness to dissipate before placing sensor.
3. Prepare the cable anchor site.
4. Pull the paper liner off of the sensor to expose the adhesive.
5. Place the sensor on the patient by pressing the sensor down at the center of the sensor, and then press down on all areas of the flexible outer portion until it is well-adhered over the full sensor area.
6. Secure the sensor cable as shown. Anchoring with tape in five places will inhibit cable movement and potential for errors during a session.





urn the monitor on with the power button on the back. After a brief power up sequence, the *Connect Sensor Screen* will appear.

8. Plug the sensor into the connection port on the front of the monitor.

Refer to the Instructions for Use for complete information before use.
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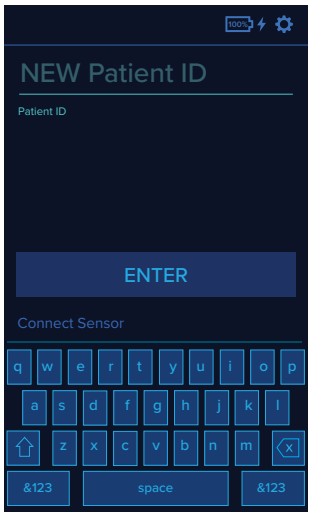
MediBeacon® Transdermal GFR

Quick Guide 4

Pre-Injection:

The *Patient ID Screen* appears after plugging in the sensor.



Enter Patient Information:

1. Enter Patient ID data and tap "ENTER". The screen will advance to *Sensor Location*.

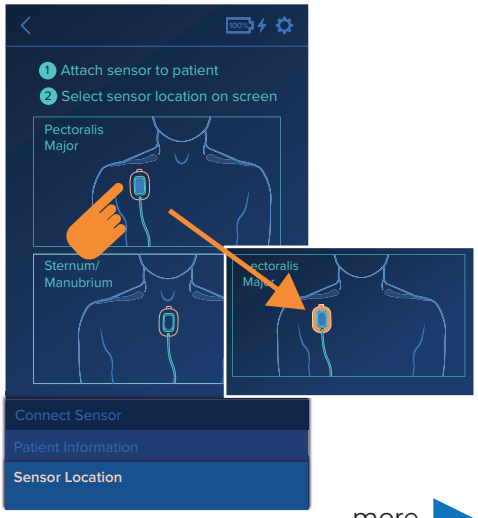
NOTE: If starting a new session with the same patient, clearance of any remaining Lumitrace injection before starting a new session may be required. **See Quick Guide 12.**

Confirm Sensor Location

1. Select the sensor location on the screen.
2. The sensor icon will highlight.
3. The screen will advance to *Skin Tone Adjustment Screen*.

Skin Tone (screen not shown)

1. A *Skin Tone Adjustment Screen* will appear. **Keep the patient very still during this step to optimize accuracy.**
2. After skin tone adjustment, the screen will automatically advance to the *Establishing Baseline Screen*.



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Refer to the Instructions for Use for complete information before use.
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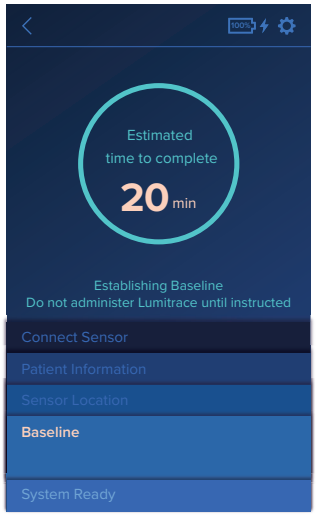
MediBeacon® Transdermal GFR

Quick Guide 5

Establishing Baseline:

1. The *Establishing Baseline Screen* will appear and automatically start a countdown.
2. Baseline can take up to 21 minutes to complete. The patient should remain still during baseline. After baseline completion, the screen will automatically advance to the *Administer Lumitrace Screen.*



NOTE: If Baseline cannot be established, the *Baseline Timeout Screen* will appear.

Press “RESTART” and keep the patient still in an attempt to establish baseline.

If baseline is still not achieved, refer to the Troubleshooting section in the Instructions for Use.

Refer to the Instructions for Use for complete information before use.
ifu.medibeacon.com

MediBeacon® Transdermal GFR

Quick Guide 6

Injection:

Administer Lumitrace® (relmapirazin) Injection, for intravenous use, only when the screen to the right appears.

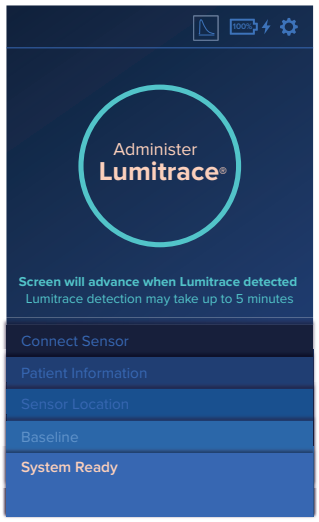
1. Follow the instructions per the package insert for preparation, withdrawal, and injection of Lumitrace into the patient's IV.

NOTE: Any previously injected Lumitrace must be cleared from the patient prior to administering a second injection. See the Instructions for Use for wait times.

2. Administer the Lumitrace Injection, for intravenous use.

3. As soon as the monitor detects the Lumitrace, the display will estimate an approximate time until a first GFR result will appear.
4. A "starburst" icon will appear within 2-5 minutes, indicating Lumitrace has been detected.

NOTE: If the Lumitrace injection is not detected, or equilibration is not reached, different prompt screens will appear. See the Instructions for Use.



Refer to the Instructions for Use for complete information before use.
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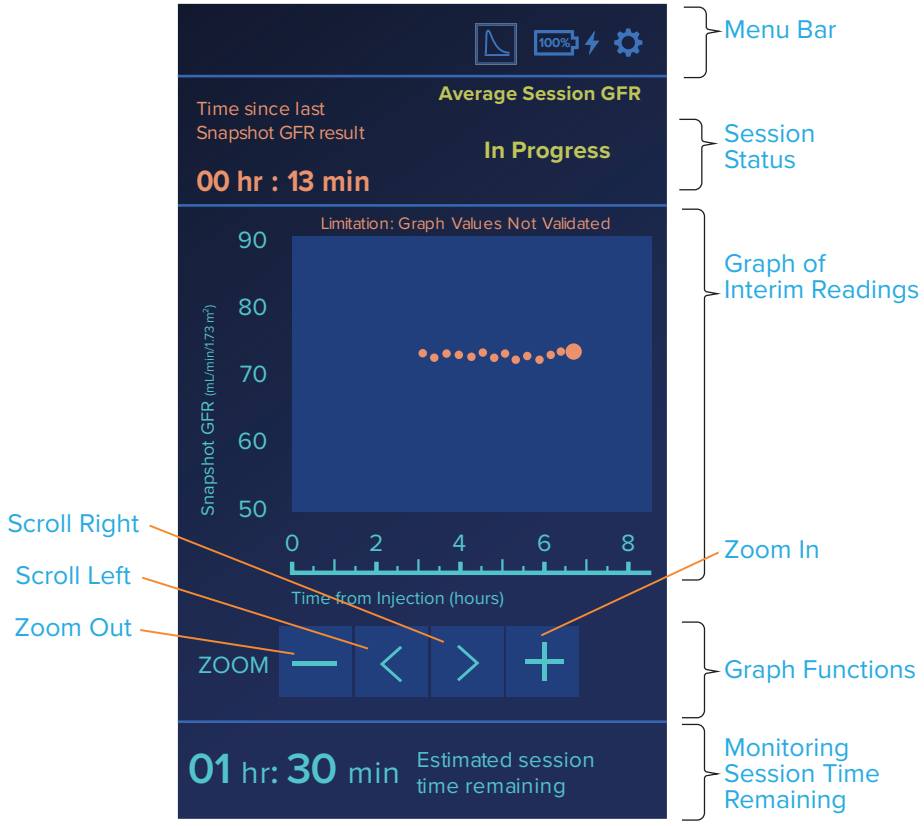
Quick Guide 7

Session Monitoring:

Once the session starts displaying results, the *Monitoring Screen* below appears, and will update with a new datapoint on the graph about every 15 minutes. Use the Graph Function buttons to scroll or zoom on the graph.



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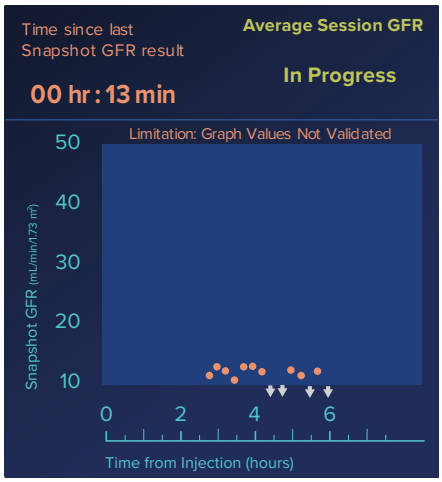
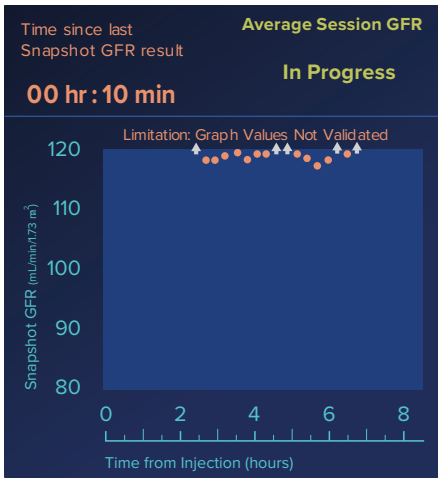
Quick Guide 8

Monitoring:

High or Low Readings

Readings above 120 or below 10 will be displayed with an arrow, as shown below. These values are out of the effective measurement range of the TGFR.





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Quick Guide 9

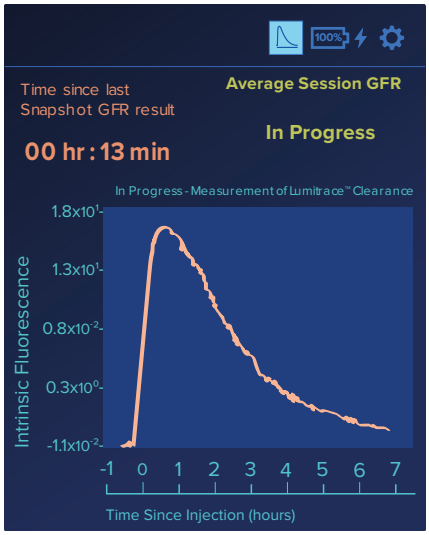
Monitoring:

Clearance Graphs

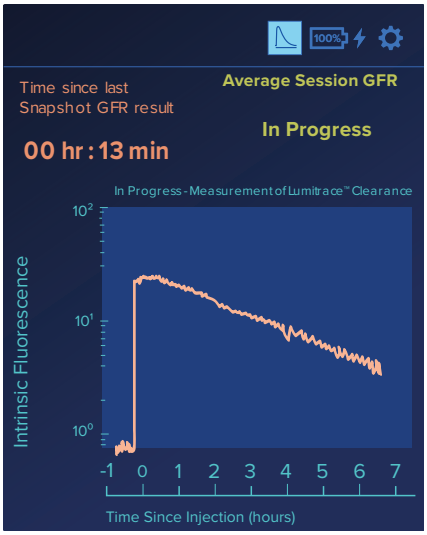
Tap the “Graph” icon in the top bar button to see clearance graphs.

- **Press once** for clearance linear (left) and
- **Press twice** for a semi-log scale (right).
- **Tap the “Graph”** icon again to return to the monitoring screen.

One Tap



Two Taps



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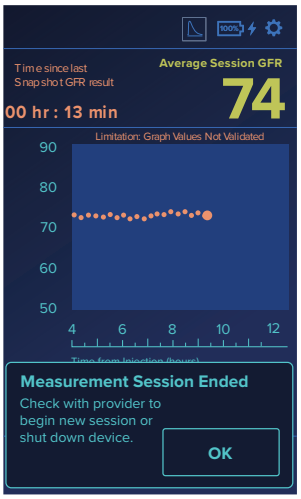
Quick Guide 10

End of Session:

TGFR assessment stops when the level of the Lumitrace is cleared below an accurate detection level. A *Measurement Session Ended* prompt will appear.

1. The *Average Session GFR* will display. The Average Session GFR is a weighted average of readings obtained during the session. Be sure to manually transcribe the *Average Session GFR* displayed on the screen before proceeding.
2. Tap “OK”.
3. **Collect Data**
   Tap “SHOW LIST” to access individual “Snapshot” results if desired. Tap “HIDE LIST” to return to the main screen.

   NOTE: Be sure to transcribe Average Session GFR prior to selecting “End Session”. **After ending a session, data will not be accessible.**
4. Tap “End Session” after the data is transcribed.



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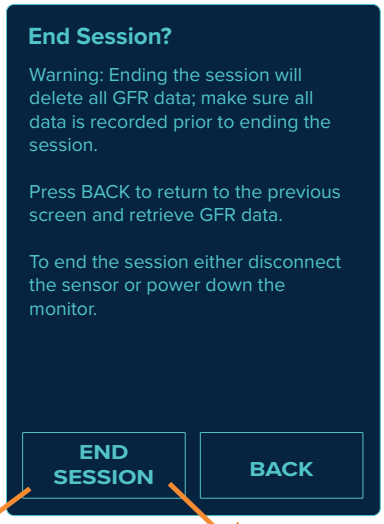
Quick Guide 11

Confirm End of Session

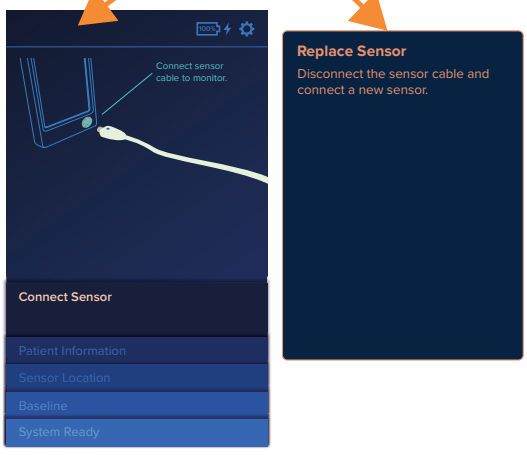
5. Tap “END SESSION” to complete the session. Tap “BACK” to return and collect data if required.
6. If sensor was already unplugged, the *Connect Sensor Screen* will appear, ready to start with a new sensor. If the sensor is still plugged in, a *Replace Sensor Screen* will appear to replace the sensor. Unplug the used sensor. The display will return to the *Connect Sensor Screen*.

   Follow the instructions below to remove the used sensor, and **use a NEW sensor for the next session.**



Removing a Used TGFR Sensor

7. **Slowly peel the sensor’s adhesive** from the patient, being careful to ensure separation from the skin without harm. Start by loosening the adhesive from the skin at the pull tab located at the top of the sensor. Stabilize the skin near the sensor holding the skin down while slowly peeling the sensor away.
8. Discard the used sensor following the institution policy for disposable skin-contacting leads and device components.



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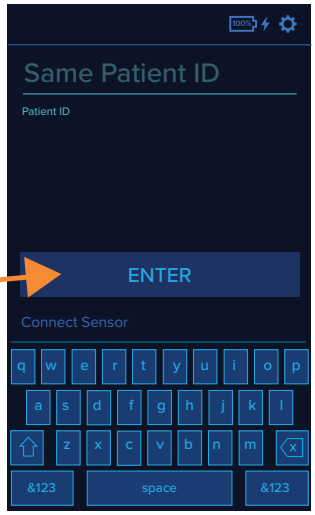
Quick Guide 12

New Session with the Same Patient:

The *Patient ID Screen* appears after plugging in a new sensor. **You must use a new sensor for each session.**

Enter Patient Information:

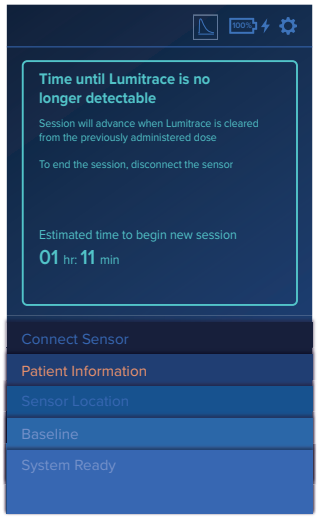
1. Enter the same Patient ID data as the previous session and tap “ENTER”.



NOTE: The Patient ID entry must match exactly, or the monitor will interpret the entry as a “new” patient.

2. A display will provide a countdown until the previous injection will be adequately cleared to start a new session.
3. The display will advance to the *Sensor Location Screen* at the end of the countdown.

Follow the steps on **Quick Guide 3** to select sensor location and proceed with the new session.



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Quick Guide 13

Cleaning and Disinfection Instructions

The sensor should be discarded after each use according to institution policy. The disposable sensor is single-use and should generally not need cleaning. If cleaning is necessary for the sensor, use the same instructions for cleaning and disinfection of the monitor below.

Cleaning:

Using a mild soap detergent and lint free cloth, wipe down the monitor and power cord.

Remove Detergent:

Using a damp cloth, wipe down the monitor and power cord.

Disinfection:

For the TGFR Monitor and its power cord, wipe down all surfaces with Bleach wipes ensuring surfaces remain wet for at least one minute.

Refer to the Instructions for Use for complete information before use.
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Transdermal GFR

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