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Interim Clinical Presentation of Comparative Home use Study: A Prospective Single Centre Evaluation of the Accuracy and safety of the sugarBEAT® Non invasive Continuous Glucose Monitor (CGM) System: An interim Evaluation

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Author

Dr T Rahman, MBBS, PhD

Clinical research Manager,

Nemaura Medical Inc.,

Study Objective

A EU based study to determine the safety and accuracy of the sugarBEAT® CGM to support FDA submission

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Study Design

Prospective single arm, single centre study

Accuracy and safety assessed over on 75 patients over 525 wear days

Venous blood samples used as reference for in-clinic portion of study

Abbott Freestyle Optimum Neo BGM used as reference for Home Study Portion

Study Methods

>25 subjects enrolled for screening

25 subjects selected after screening in stage 1, of which 12 were Type 1 and 13 Type 2 diabetic

No subjects lost due to drop out in stage 1

All 25 subjects completed 2 days home study and 3 days in-clinic study, in stage 1

12 subjects wore devices bilaterally during in-clinic phase

13 subjects had single device during in-clinic phase

25 subjects wore single device during home stage

All subjects blinded to real time glucose display. All devices used single BGM calibrations per day.

Baseline Characteristics

Variable	
Age (Range and Mean)	20 years to 70 years, Mean age 45.2
Gender	12 Male, 13 Female
Type 1/Type 2	12 Type 1/13 Type 2

Accuracy vs Glucose Range
In-clinic portion of study 1-point calibration

Range of Glucose Levels (mMol/L)	Number of paired (BGM-CGM) points	Paired points within ±15% /15	Paired points within ±20% /20	Paired points within ±25% /25	Paired points within ±30% /30	Paired points within ±40% /40
Overall	**121**	52.89	59.50	80.17	92.56	99.17
<6	4	25.00	25.00	25.00	50.00	75.00
6-10	25	52.00	52.00	72.00	88.00	100.00
10-14	27	51.85	55.56	74.07	96.30	100.00
14-18	41	58.54	68.29	92.68	97.56	100.00
18-25	18	50.00	61.11	88.89	88.89	100.00
25-35	6	50.00	66.67	66.67	100.00	100.00

The performance evaluation included the proportion of the CGM system values that are within 15 to 40% of relative difference of reference value at glucose levels >80 mg/ dL and 20 mg/ dL of absolute difference at glucose level ≤80 mg /dl, ref: http journals.sagepub.com doi pdf /10.1177/1932296814559746

Interim Comparative MARD for home study phase as Primary Accuracy Metric

Device	Number of Subjects	Paired Data Points with BGM	Nominal MARD	Reference BGM	Daily Finger Stick Calibrations
Senseonics Eversense*	**23**	829	14.80%	Nova Biomedical StatStrip Xpress	2
Dexcom G5*	23	829	16.30%	Nova Biomedical StatStrip Xpress	2
Abbott Libre Pro*	23	829	18.00%	Nova Biomedical StatStrip Xpress	Factory calibrated
sugarBEAT®	25	126	16.30%	Abbott Freestyle Optimum Neo	1

**http:// www.diabetesincontrol.com /accuracy comparison of the dexcom g5 abbott freestyle libre pro and senseonics eversense/*

Safety Evaluation

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Past Studies

>100 Patient days wear time No major adverse events or skin irritation reported.

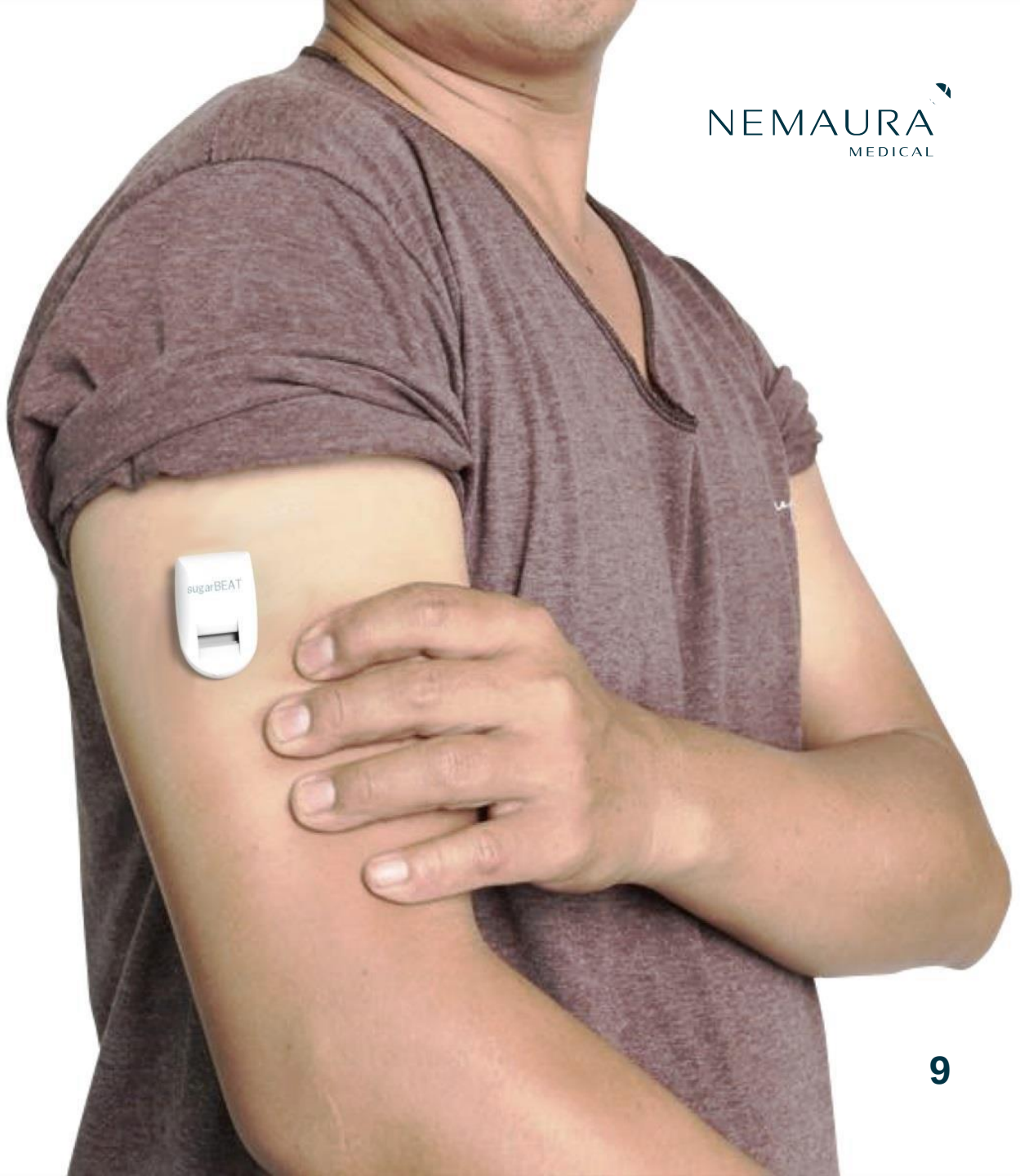
525 Patient days wear time No major adverse events or skin irritation reported

Current Studies

125 Patient days to date with no major adverse events or skin irritation reported.

Conclusion

The interim analysis indicates the home portion of the study shows accuracy levels, measured using overall nominal MARD, as being comparable to independently published data on the three market leading CGM’s.



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