S.L.P LTD. Scientific Laboratory Products

MEDICAL DESIGN EXCELLENCE AWARDS 2002 WINNER

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Summary of SleepStrip clinical studies.

SleepStrip has been studied in multiple studies in many countries. Studies procedure was similar in all studies – comparing the AHI as indicated by the SleepStrip, to that derived from a formal sleep study in the sleep lab.

Please note that all of these studies were conducted with the former SleepStrip version. Internal testing shows that the new version has at least the same accuracy as the previous version. More studies now underway in many locations are expected to provide more confirmation.

Accuracy of the SleepStrip against lab results is measured by three factors:

Correlation: giving a rough estimate of accuracy

Sensitivity: indication what percentage of positive patients was correctly diagnosed by the SleepStrip, and

Specificity: indication what percentage of negative patients was correctly diagnosed by the SleepStrip.

Sensitivity and Specificity change depending on the AHI defined as the threshold of positive indication. Most studies selected a threshold of 10, but testing the new version we have selected a value of 15 events per hour as the threshold for the positive indication, which is the currently accepted standard in the USA.

Sensitivity improves for higher threshold values (more severe patients), approaching 1 (100% chance of detection) for severe patients with AHI>50.

Clinical studies summary table

Location	# of patients	SleepStrip Version	Chief investigator	Compare to	Published in	Correlation	Threshold RDI	Sensitivity	Specificity
Paris France	20	4.1	Dr. P. Leger	Inlab PSG	Sleep 24/A294, 2001	0.91 (calculated from published data)	10	0.86	0.80
Marburg Germany	44	4.1	Dr. t. Penzel	Inlab PSG	ERJ 19:121-126, 2002	0.86	10	0.85	0.91
Brussels Belgium	39	4.1	Dr. M. Kerkhofs	Inlab PSG	ERJ 19:121-126, 2002	0.81	10	0.88	0.67
4 labs in Israel	205	4.1	Dr. P. Lavie	Inlab PSG	ERJ 19:121-126, 2002	0.7	10	0.87	0.52
Ulsan Korea	20	4.1	Dr. J. Kim	Inlab PSG	Poster, Korean Society of Otolaryngology meeting, 2001	No value given	10	0.75	0.91
Helsinki Finland	13	4.1	Dr. K. Hirvonen	Inlab PSG	Poster at the Sleep Apnea meeting, Helsinki 2003	No value given	10	0.87	0.60
4 labs in Israel	97	**4.2**	Dr. P. Lavie	Inlab PSG	SLP Internal study, unpublished. 2003	0.63	15	0.83	0.69

An additional study, published by Dr. C. Hanning from the UK, in J. Sleep Res. (2003) showed many failures of the SleepStrip, as well we very low accuracy. These results were traced to a defective production batch, and the study is now being repeated.

Conclusion by all (except UK) researchers was that the SleepStrip is a viable and effective tool fro low cost screening of large populations for suspected Sleep Apnea Syndrome.