

TANNERMEDICO A/S

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Post market clinical data evaluation

Collected in 2009

This post market surveillance and clinical data evaluation is performed according to Directive 93/42/EEC, Guideline on a Medical Device Vigilance System (MEDDEV 2.12-1 rev 5, April 2007) and TannerMedico A/S guideline for Post Market Surveillance (document 56 50).

These guidelines furthermore describe the European system for the notification and evaluation of INCIDENTs and FIELD SAFETY CORRECTIVE ACTIONS (FSCA) involving MEDICAL DEVICES, known as the Medical Device Vigilance System, including the Post Market Surveillance.

The principal purpose of the Medical Device Vigilance System is to improve the protection of health and safety of patients, USERS and others by reducing the likelihood of reoccurrence of the INCIDENT elsewhere. This is to be achieved by the evaluation of reported INCIDENTs and, where appropriate, dissemination of information, which could be used to prevent such repetitions, or to alleviate the consequences of such INCIDENTs.

These guidelines are intended to facilitate the uniform application and implementation of the Medical Device Vigilance System requirements contained within the Directive for Medical Devices (MDD), 93/42/EEC.

As part of the Post Market Surveillance activities, clinical data from Danish users of the Medical Devices (Asonor) is collected periodically to measure any change in the performance or adverse effect of the product. The data is also used to evaluate if any potential improvement of the Medical Device can be made.

The leaflet in the Danish consumer box is periodically extended with a customer questionnaire. All feedback collected and grouped in 3 main groups, called low snores, medium snores and heavy snores.

Clinical data for Asonor, August 2009

	total		Low snores		Medium snores		Heavy snores	
	no	%	no	%	no	%	no	%
No of questionnaire	158	100%	8	5%	43	27%	107	68%
Measured effect in %	135	85%	6	75%	37	86%	92	86%
No effect in %	23	15%	2	25%	6	14%	15	14%

The clinical data shows that 68% of the filed questionnaire coming from heavy snores, 27% from medium snores and 5% from low snores. The best effect/performance is measured at the medium and heavy snores with the effect of 86% and the lowest effect is measured at the low snores with the effect of 75%.

The average effect/performance measured is 85%.

The data is consistence with previously performed clinical studies and collected clinical data.



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Follow is enclosed the questionnaire used for the collection of the clinical data.

Customer questionnaire

<h2>SPØRGESKEMA</h2> <p>For at kunne produktudvikle bedst muligt, vil vi gerne have din hjælp. Vi beder dig derfor udfylde dette skema.</p>	
Hvor køber du Asonor?	Kommentaren:
<input type="checkbox"/> Apoteket <input type="checkbox"/> Matas <input type="checkbox"/> Helsekostforretning <input type="checkbox"/> Internettet <input type="checkbox"/> Andet.....
Hvordan fik du kendskab til Asonor?	Må vi benytte dine svar til pressemeddelelser og lign.?
<input type="checkbox"/> Annonce <input type="checkbox"/> Bladomtale <input type="checkbox"/> Råd fra familie/venner	<input type="checkbox"/> Ja <input type="checkbox"/> Nej
Er du:	Navn:..... Adresse:.....
<input type="checkbox"/> Småsnorker <input type="checkbox"/> Medium <input type="checkbox"/> Storsnorker	Alder:..... Tlf.:..... E-mail:.....
Har Asonor levet op til forventningerne?	Kan indsendes anonymt. Sendes til:
Egen bedømmelse	TannerMedico A/S Agern Allé DK- 2970 Hørsholm
<input type="checkbox"/> Ja <input type="checkbox"/> Delvis <input type="checkbox"/> Nej	<input type="checkbox"/> Ja <input type="checkbox"/> Delvis <input type="checkbox"/> Nej
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