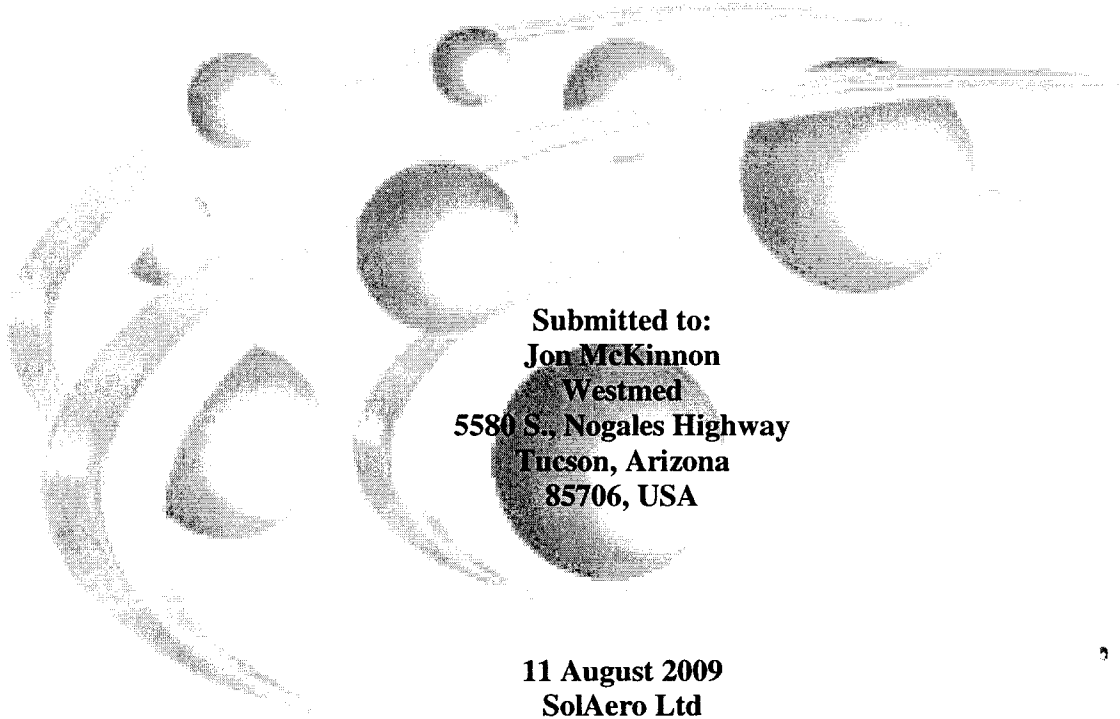


**Assessment of Aerosol Output
Trudell Aeroeclipse
Westmed Circulaire**

Final Revised Report



**Submitted to:
Jon McKinnon
Westmed
5580 S., Nogales Highway
Tucson, Arizona
85706, USA**

**11 August 2009
SolAero Ltd**

Confidentiality and Use of This Report

This report and the information herein are strictly confidential, and are protected by the laws relating to confidential information and proprietary rights, including copyright. This report is provided to Westmed (the "**Customer**") for the sole purpose of R&D evaluation and comparison evaluating nebulized aerosol, and it may not be used for any other purpose or by any other party without the prior written consent of SolAero Ltd.

Disclaimer

This report is limited in a number of ways, including:

- ❑ The observations, statements, beliefs, opinions, suggestions and conclusions set forth herein are those of SolAero Ltd. and not the officers, directors, employees, consultants, shareholders, associates or affiliates of SolAero Ltd.
- ❑ No part of this report should be construed as professional advice of any nature or kind. Without in any way limiting the generality of the foregoing, this report does not, in whole or in part, represent or constitute advice or services associated with any profession governed by statute and/or regulatory bodies, societies and/or associations, and the Customer is urged to consult its own professional advisors with respect to such matters.
- ❑ This report is limited by the scope of the investigations made, time constraints and available information and the scope of the engagement entered into between the Customer and SolAero Ltd.
- ❑ This report is based on information, statements and representations provided or made by the Customer and its officers, directors, employees, consultants or others. SolAero Ltd. has relied upon such information, statements and representations, and SolAero Ltd. has not independently verified same.
- ❑ During the course of providing the services to you and in compiling this report, SolAero Ltd. relied upon information, documents, writings, statements, representations and warranties made or provided by or through the Customer and/or the officers, directors, employees, consultants or others, which SolAero Ltd. did not independently verify (collectively referred to herein as "**Information**"). If SolAero Ltd. discovers or become aware that any of the Information is inaccurate in any regard or if SolAero Ltd. discovers or is provided with new or different Information, SolAero Ltd. reserves the right to alter any action, work product, report, observation, statement, comment, belief, opinion, suggestion or conclusion made, generated, developed, delivered or provided by SolAero Ltd. to give effect to any new or different Information SolAero Ltd. believes to be true or more accurate.

Introduction

On behalf of Jon McKinnon (Westmed), aerosol output were determined for Trudell Aeroeclipse and Westmed Circulaire nebulizer systems using methods based on EN13544-1 unless otherwise described.

2 Trudell Aeroeclipse nebulizers and 3 Westmed Circulaire nebulizer systems were received from Westmed. The experimental design was specified by Jon McKinnon (letter June 8, 2009). The modifications to the European standard included: 1) increasing the tidal volume from 500mL to 600mL; and 2) to include a 1:3 inhalation:exhalation ratio in addition to the standard 1:1 inhalation:exhalation ratio. The 1:3 inhalation:exhalation ratio was changed from the initial request of a 1:4 inhalation:exhalation ratio as the Pari Compass breathing machine did not function properly at a 1:4 ratio.

Pressure/Flow rates were determined for the jet nebulizers and are part of the appended data. A representative nebulizer was chosen for determination of aerosol output testing.

Aerosol Output

For each aerosol output test, the Aeroeclipse nebulizer was weighed at the following intervals: empty, full, after 1 minute of nebulization, after 4 minutes of nebulization and a final weight at cessation of nebulization. All weights were recorded and are available in the appended data set. The components of the Westmed Circulaire system were weighed separately as: nebulizer, mouthpiece and filter assembly and Circulaire reservoir bag. These weights were also recorded at the same intervals as AeroEclipse

The Circulaire nebulizer system's expiratory resistor valve was set to the minimum (10 degrees). The Aeroeclipse system was set in the breath actuated mode.

Both nebulizers were set up to run at a flow rate of 7 L/min and had an initial fill solution volume of 3mL. Nebulization was allowed to proceed until 1 minute after sputtering occurs.

Volume fill of 3.0mL of 1%NaF was added to the test nebulizer which was subsequently operated at 7L/min flow rate. A Pari Compass breath simulation machine was programmed to have a 600mL tidal volume, 1:1 or 1:3 duty cycle, 15 breaths per minute (BPM). A fresh inhalation filter was placed between the nebulizer and the breathing machine at the start, 1 minute, 4 minute and final nebulization intervals. After testing was complete the filter material was stored in a clean vial and 18mLs of 25 % TISAB (total ionic strength adjustment buffer) was added to each of the collected inhalation filters. The quantity of NaF was measured from each filter using a fluoride specific ion electrode, and quantified against a standard curve prepared to bracket the expected NaF concentrations.

Results

All numerical results of nebulizer aerosol outputs (both NaF as well as weights) using the breath simulator are provided in the appendix¹. Table 1 summarizes the aerosol outputs for the 1st minute of nebulization, the 1st - 4th minute of nebulization, the 4th minute – final filter and then a Total column which is the sum of the 1st three. The total nebulization time is presented in the final column.

Table 1	NaF 1 min µl	NaF 1min-4min µl	NaF 4min-end µl	NaF TOTAL µl	nebulization time mins'sec
Trudell Aeroeclipse 1:1 duty cycle, 3mL volume fill and 600mL inhalation volume					
AE#1	140	375	605	1120	9'46
AE#2	161	420	530	1111	9'02
Trudell Aeroeclipse 1:3 duty cycle, 3mL volume fill and 600mL inhalation volume					
AE#3	104	240	409	753	9'59
AE#4	110	269	393	772	9'22
Westmed Circulaire 1:1 duty cycle, 3mL volume fill and 600mL inhalation volume					
WMC#5	227	676	45	948	5'11
WMC#6	161	612	162	935	5'31
Westmed Circulaire 1:3 duty cycle, 3mL volume fill and 600mL inhalation volume					
WMC#7	162	392	98	652	5'20
WMC#8	183	535	154	872	5'18