STABILITY SYSTEM II

Only from ScienTek Software, Inc.

Validation

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Introduction

What is STABIILITY SYSTEM II?

STABILITY SYSTEM II is a Windows-based program to compute the Mean Kinetic Temperature from temperature data collected from a storage area, such as storage chamber, warehouse, or even regional climate data.

STABILITY SYSTEM II is developed by Dr. Mike Yang, one of the principles of ScienTek Software, Inc. The program is complimentary of ScienTek Software, Inc. as a community service to the pharmaceutical industry and other applicable industries.

Terms of Use

Please observe the following terms of use of STABILITY SYSTEM II:

1. ScienTek Software, Inc. retains the copyright of this program. All rights are reserved.
2. Please do not distribute this program yourself even though it is complimentary. The copy that you have downloaded is for your personal use only. Direct all those who are interested in STABILITY SYSTEM II to ScienTek's website (www.StabilitySystem.com) to request the installation file.
3. All screenshots and diagrams from STABILITY SYSTEM II must be shown in its entirety when merged into other documents, whether hardcopy or electronic form.

Programming Language

STABILITY SYSTEM II is developed using Microsoft Visual Basic 6 (SP5) and is a 32-bit Windows program. Must install in a 32-bit Windows.

Request Install File

To request for install file, please visit either www.StabilitySystem.com or www.StabilitySystemII.com.

Hardware Requirements

A monitor with a minimum of XGA (1024 x 768 pixels) resolution is required.

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Online Help

Pressing the F1 key will display the context help information. The online help information is also searchable by selecting the **Search** button (or **Index** button in some Windows versions) on the Windows Help window.

> **Note:** If you are using Windows Vista, you cannot access the help file unless you follow these instructions. The instructions describe how to install **winhlp32.exe** on Windows Vista, so previous help files prior to Windows Vista can be viewed on Vista systems
>
> Microsoft has decided not to include winhlp32.exe by default, so each system needs to install the file manually.
>
> **Downloading and installing winhlp32.exe**
>
> 1. Go to the Microsoft Download Center: www.microsoft.com/downloads/
> 2. Search **winhlp32.exe vista** and press the **Go** button.
> 3. Click on the result titled **WinHlp32.exe for Windows Vista**.
> 4. Click the **Continue** button and follow the instructions on the resulting page.
> 5. There are 2 files for download. If you are not sure which file to download, then download both.
> 6. Execute <**Windows6.0-KB917607-x86.msu>** by double-clicking the file. It will check your system and let you know if it is the appropriate one for your system. If the file is not appropriate, try the other file < **Windows6.0-KB917607-x64.msu**>.

Suggestions and Comments

Please forward all suggestions and comments to Dr. Mike Yang at mikeyang@StabilitySystem.com.

About ScienTek Software, Inc.

In 1983, ScienTek Software, Inc. pioneered the application of the PC in the management of a typical stability testing program in the pharmaceutical industry. STABILITY SYSTEM, ScienTek's flagship product, is a comprehensive software tool to manage the pharmaceutical stability testing program. For detailed product information on STABILITY SYSTEM, please visit our web site at www.StabilitySystem.com.

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1. MKT file

A. Activation Energy in kJ/mole

I. Data set 1 – One temperature reading for each time period

Temperature File – **validation1.MKT**, included in the installation file. (If your Windows Regional Setting is set to one of locals that uses comma as the decimal separator, please use **validation1comma.MKT**.)

Temperature Readings in Celsius:

25.2
24.8
25.6
23.8
24.8

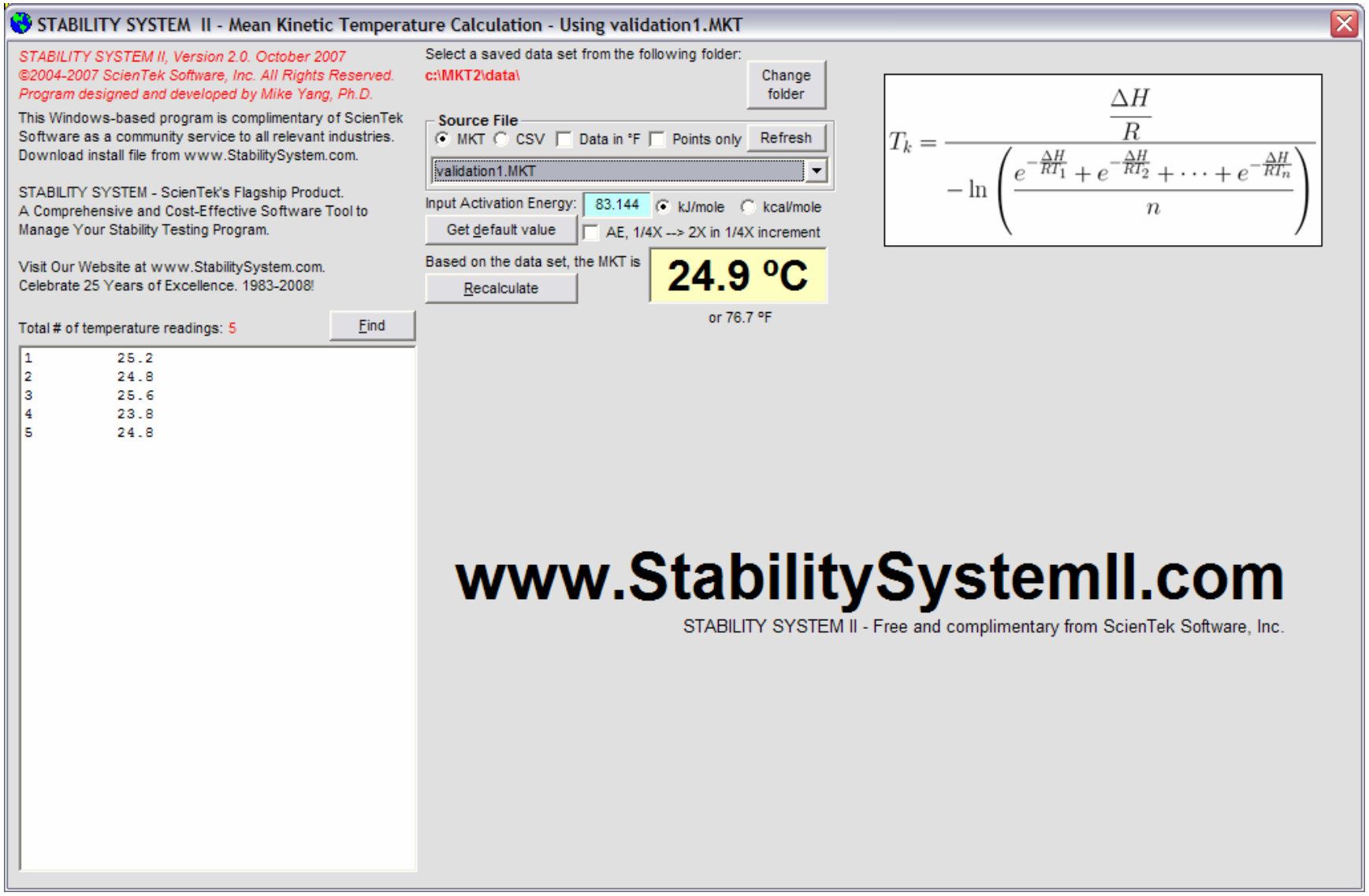
Manual Calculation

$\Delta H = 83.144$ kJ mole^{-1}
R = 8.3144 x 10-3 kJ mole^{-1} degree^{-1}
$\Delta H/R = 83.144/8.3144 = 10000$

T (C)	25.2	24.8	25.6	23.8	24.8
T (K)	298.3	297.9	298.7	296.9	297.9
$e^{-\Delta H/RT}$	2.790682×10^{-15}	2.639171×10^{-15}	2.887439×10^{-15}	2.35703×10^{-15}	2.639171×10^{-15}
$\Sigma\ e^{-\Delta H/RT}$	$13.283493 \times 10^{-15}$				
$(\Sigma\ e^{-\Delta H/RT}) / 5$	$2.6566986 \times 10^{-15}$				
$-\ln (\Sigma\ e^{-\Delta H/RT}) / 5$	33.56169217				
$T_k = (\Delta H/R) / (-\ln (\Sigma\ e^{-\Delta H/RT}) / 5)$	10000/33.56169217 = 297.9587546 °K				
T_k	297.9587546 – 273.1 = 24. 8587546 °C or **24.9 °C** when rounded to 1 decimal place				

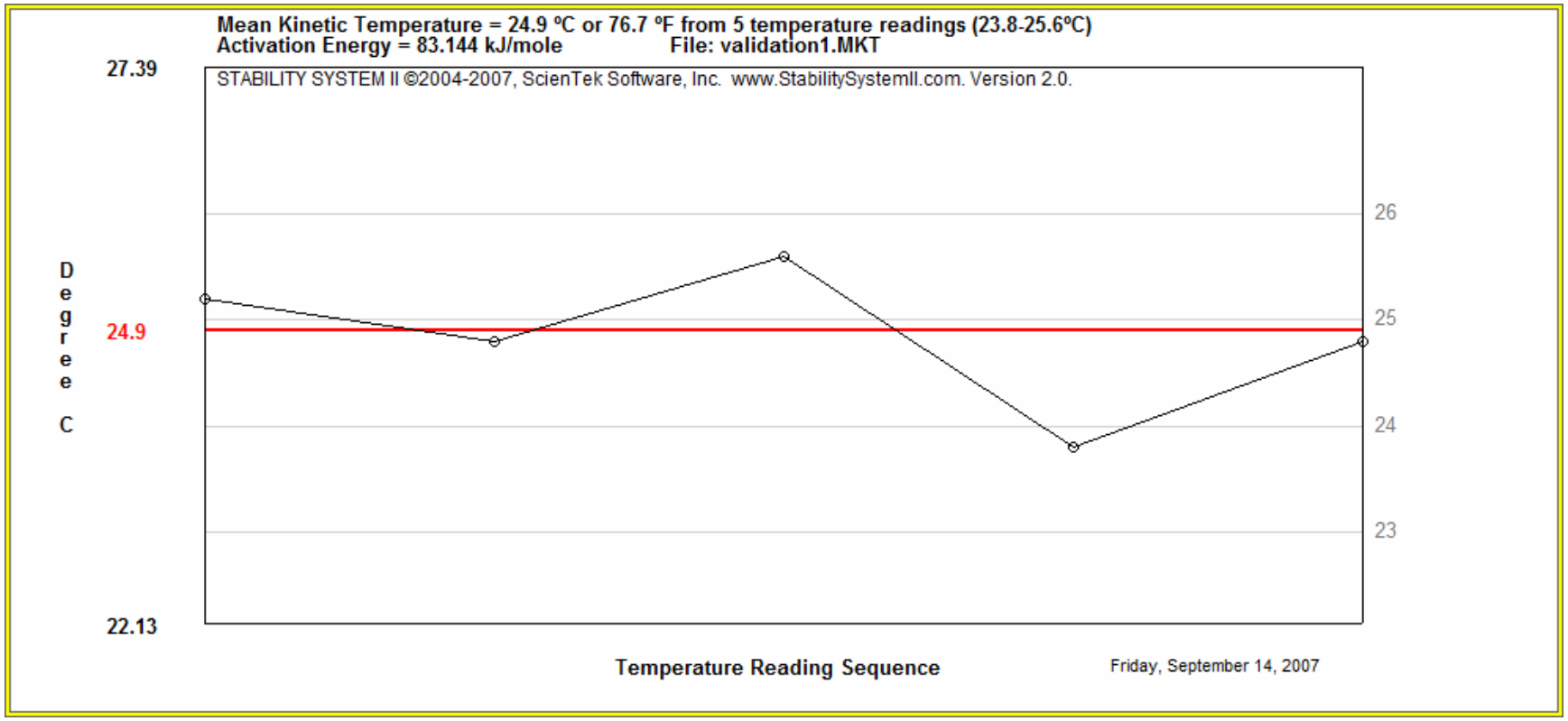
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STABILITY SYSTEM II *Calculation*



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Conclusion

The manual calculation and the **STABILITY SYSTEM II** program produce the same mean kinetic temperature for the same data set.

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II. Data set 2 – Low and high temperature reading for each time period

Temperature File – **validation2.MKT**, included in the installation file. (If your Windows Regional Setting is set to one of locals that uses comma as the decimal separator, please use **validation2comma.MKT**.)

Temperature Readings in Celsius:

24.2/26.2
23.5/26.1
24.8/26.4
22.6/25.0
23.7/25.9

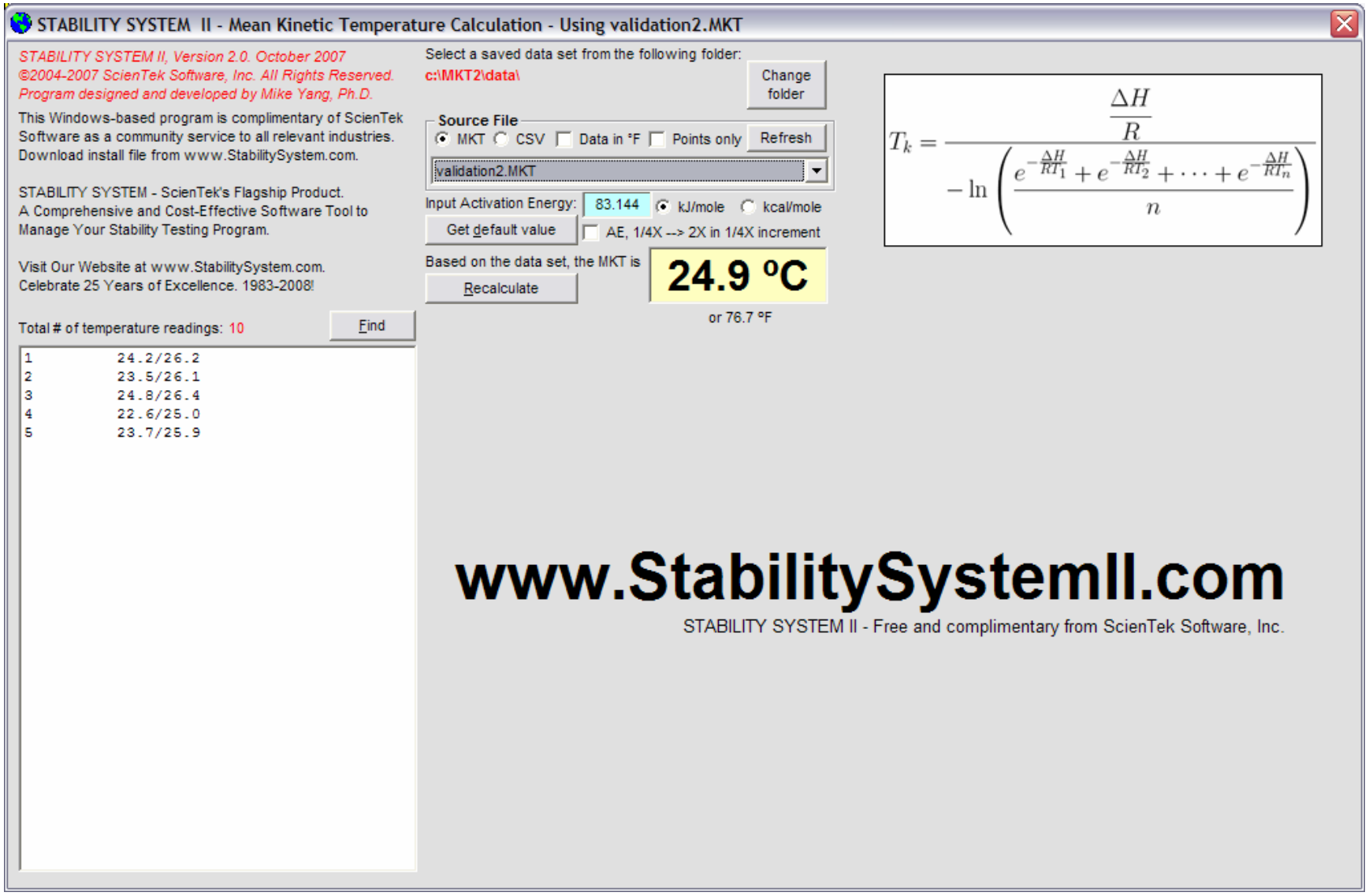
Manual Calculation

Temperature probe	Low Temperature °C	High Temperature °C	Arithmetic mean °C
Period 1	24.2	26.2	**25.2**
Period 2	23.5	26.1	**24.8**
Period 3	24.8	26.4	**25.6**
Period 4	22.6	25.0	**23.8**
Period 5	23.7	25.9	**24.8**

The arithmetic means for each time period are used in the manual calculation. The arithmetic mean for Data Set 2 is exactly the same as that in Data Set 1. Therefore the manual calculation produces the same mean kinetic Temperature of 24.9 °C.

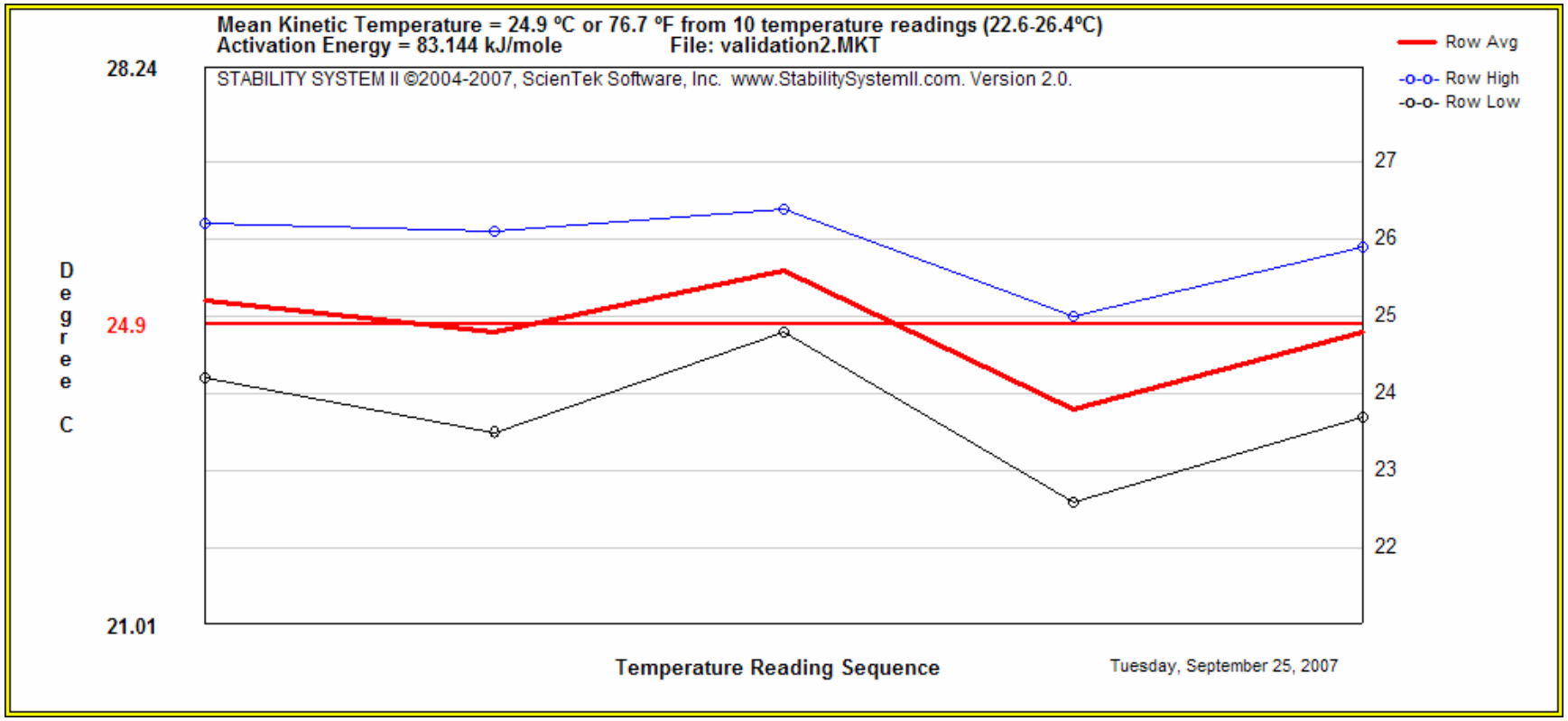
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Conclusion

The manual calculation and the **STABILITY SYSTEM II** program produce the same mean kinetic temperature for the same data set.

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B. Activation Energy in kcal/mole

The relationship between kJ/mole and kcal/mole is:

kJ/mole = kcal/mole * 8.3144 / 1.987

Therefore, 83.144 kJ/mole is the same as 19.87 kcal/mole since

83.144 kJ/mole = 19.87 kcal/mole * 8.3144 / 1.987

As such, using 83.144 kJ/mole and 19.87 kcal/mole on the same data set must produce the same MKT.

I. Data set 1 – One temperature reading for each time period

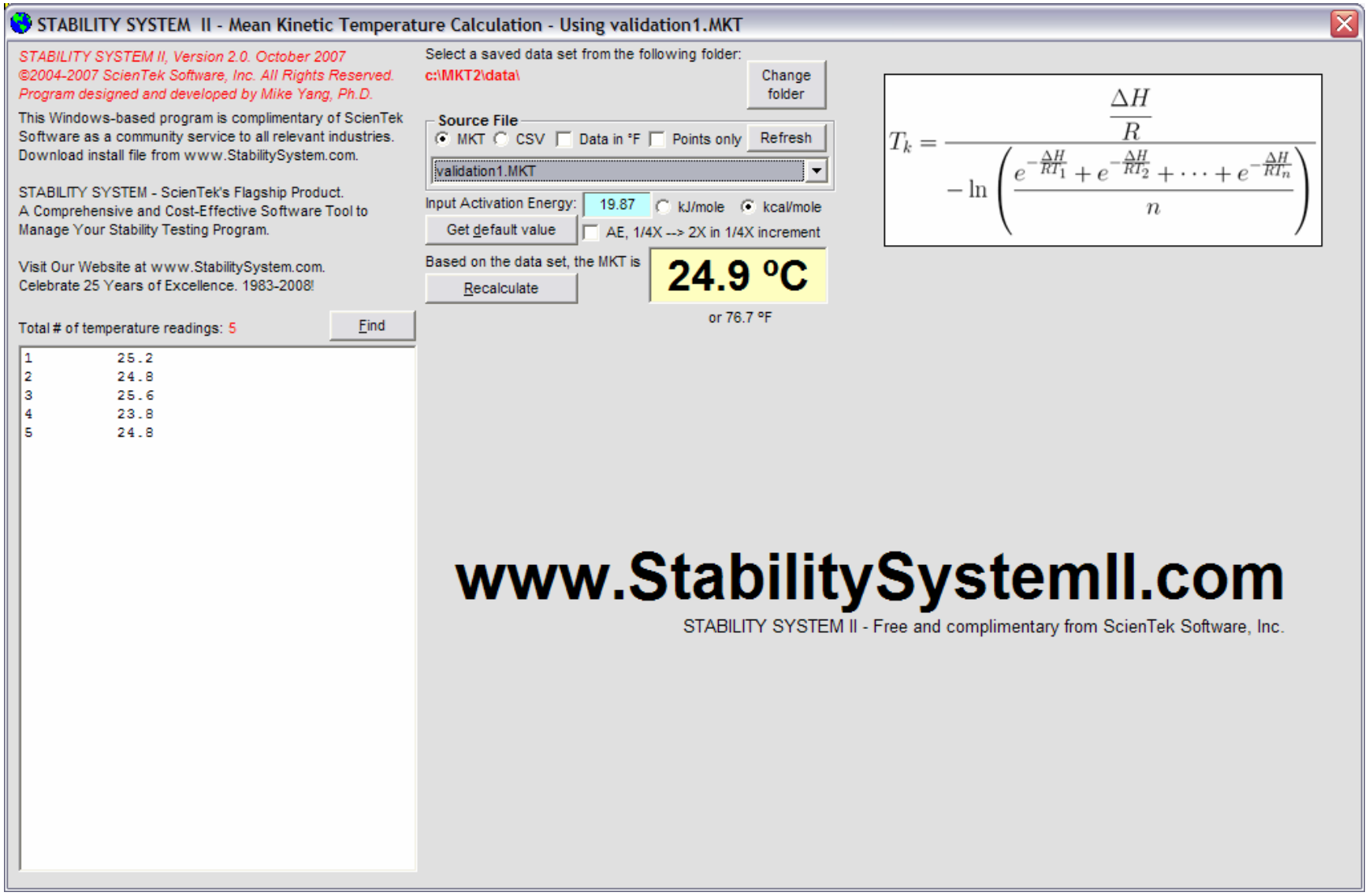
Temperature File – **validation1.MKT**, included in the installation file. (If your Windows Regional Setting is set to one of locals that uses comma as the decimal separator, please use **validation1comma.MKT**.)

Temperature Readings in Celsius:

25.2
24.8
25.6
23.8
24.8

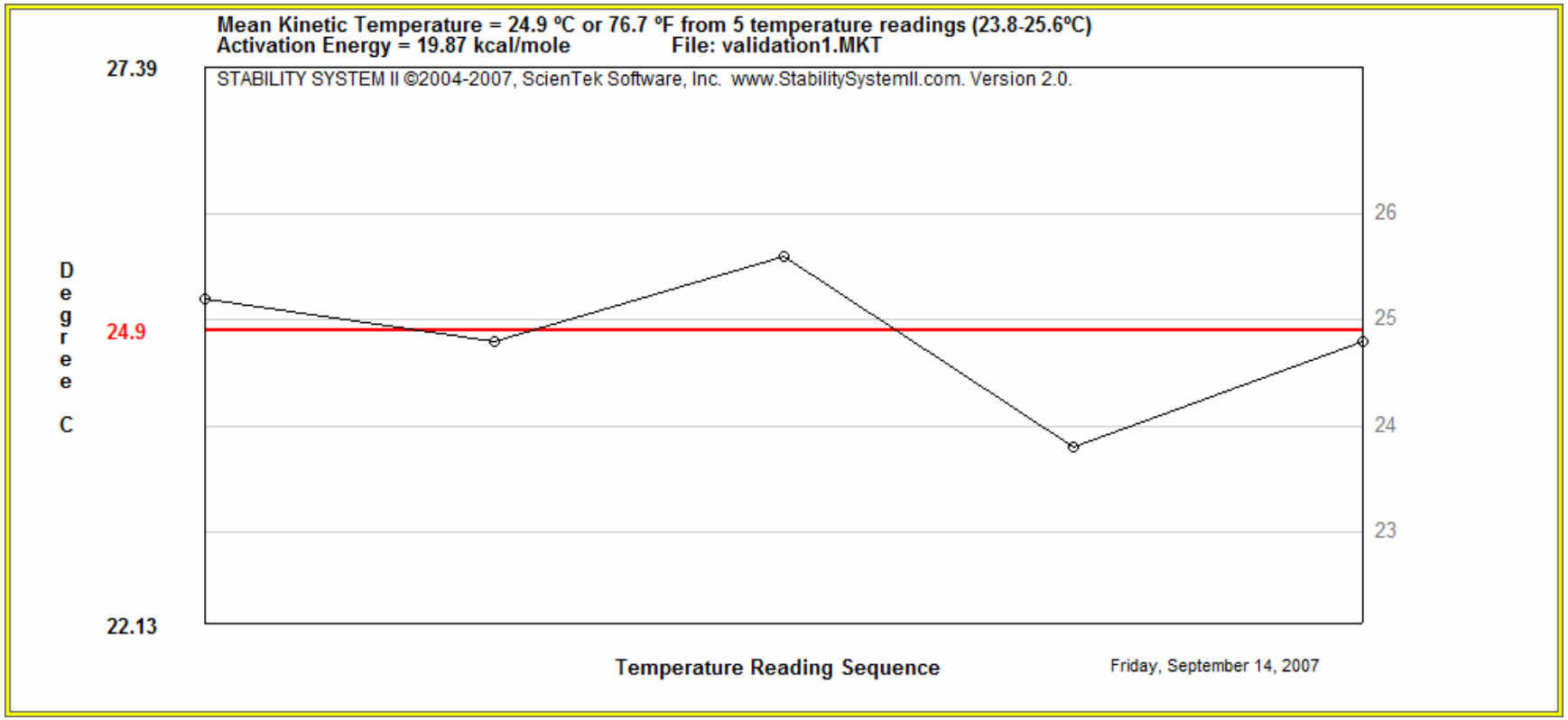
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Conclusion

Using an activation energy of 19.87 kcal/mole indeed produce the same mean kinetic temperature for the activation energy of 83.144 kJ/mole as shown in Section A.I.

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II. Data set 2 – Low and high temperature reading for each time period

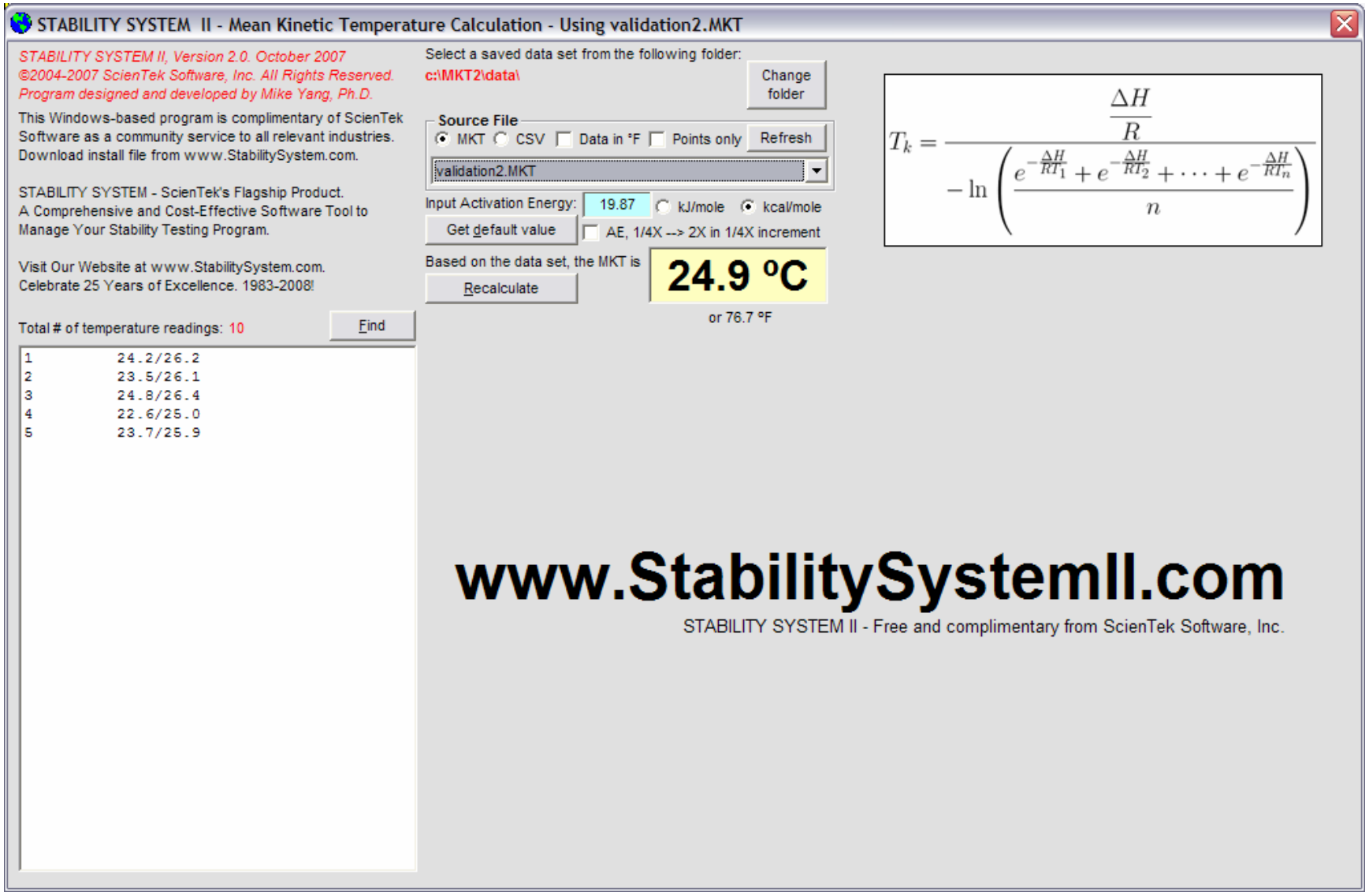
Temperature File – **validation2.MKT**, included in the installation file. (If your Windows Regional Setting is set to one of locals that uses comma as the decimal separator, please use **validation2comma.MKT**.)

Temperature Readings in Celsius:

24.2/26.2
23.5/26.1
24.8/26.4
22.6/25.0
23.7/25.9

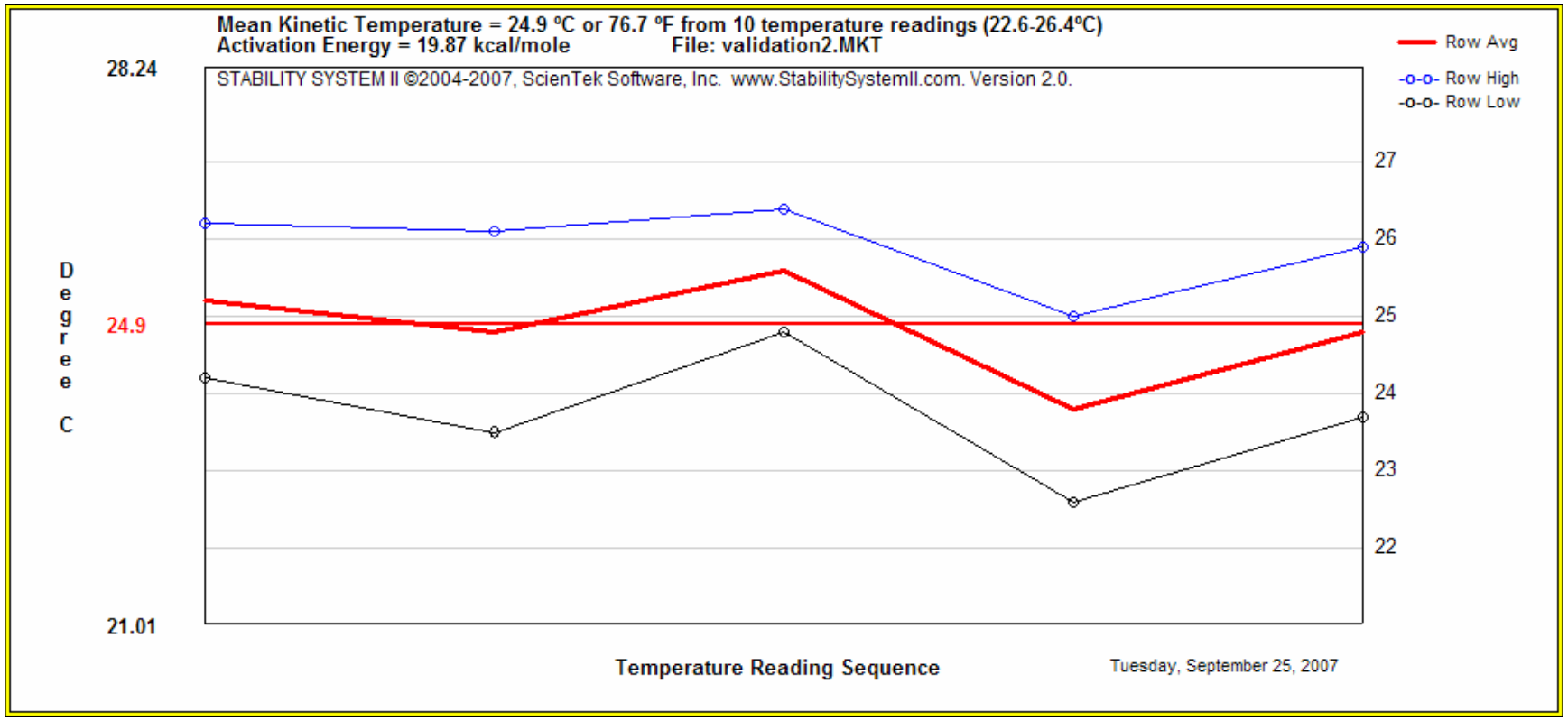
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Conclusion

Using an activation energy of 19.87 kcal/mole indeed produce the same mean kinetic temperature for the activation energy of 83.144 kJ/mole as shown in Section A.II.

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2. CSV file

A. Activation Energy in kJ/mole

I. Data set 3 – One temperature reading for each time period from 2 temperature probes

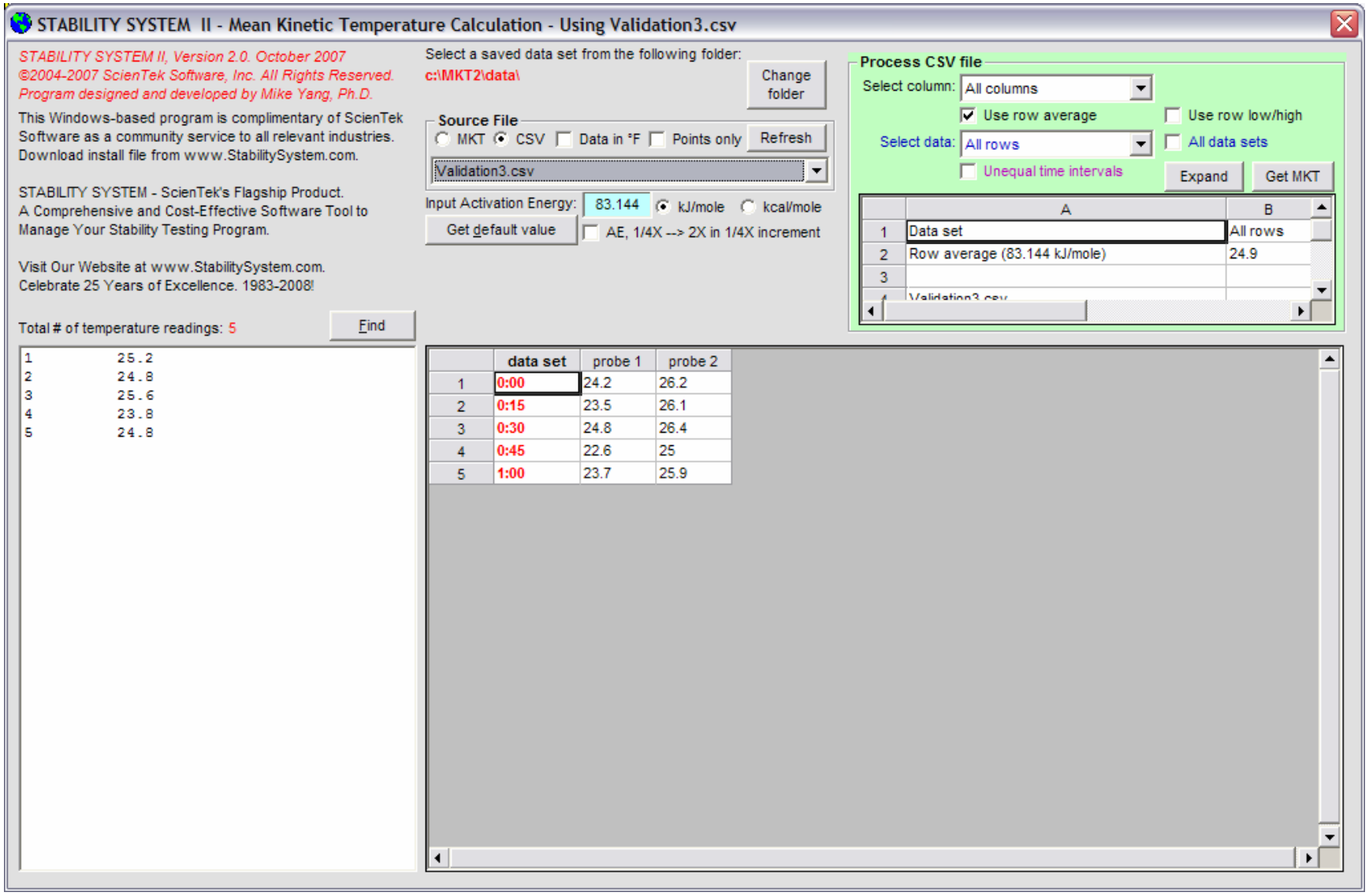
Temperature File – **validation3.CSV**, included in the installation file. (If your Windows Regional Setting is set to one of locals that uses comma as the decimal separator, please use **validation3comma.CSV**.)

Temperature Readings in Celsius:

data set	probe 1	probe 2
0:00	24.2	26.2
0:15	23.5	26.1
0:30	24.8	26.4
0:45	22.6	25
1:00	23.7	25.9

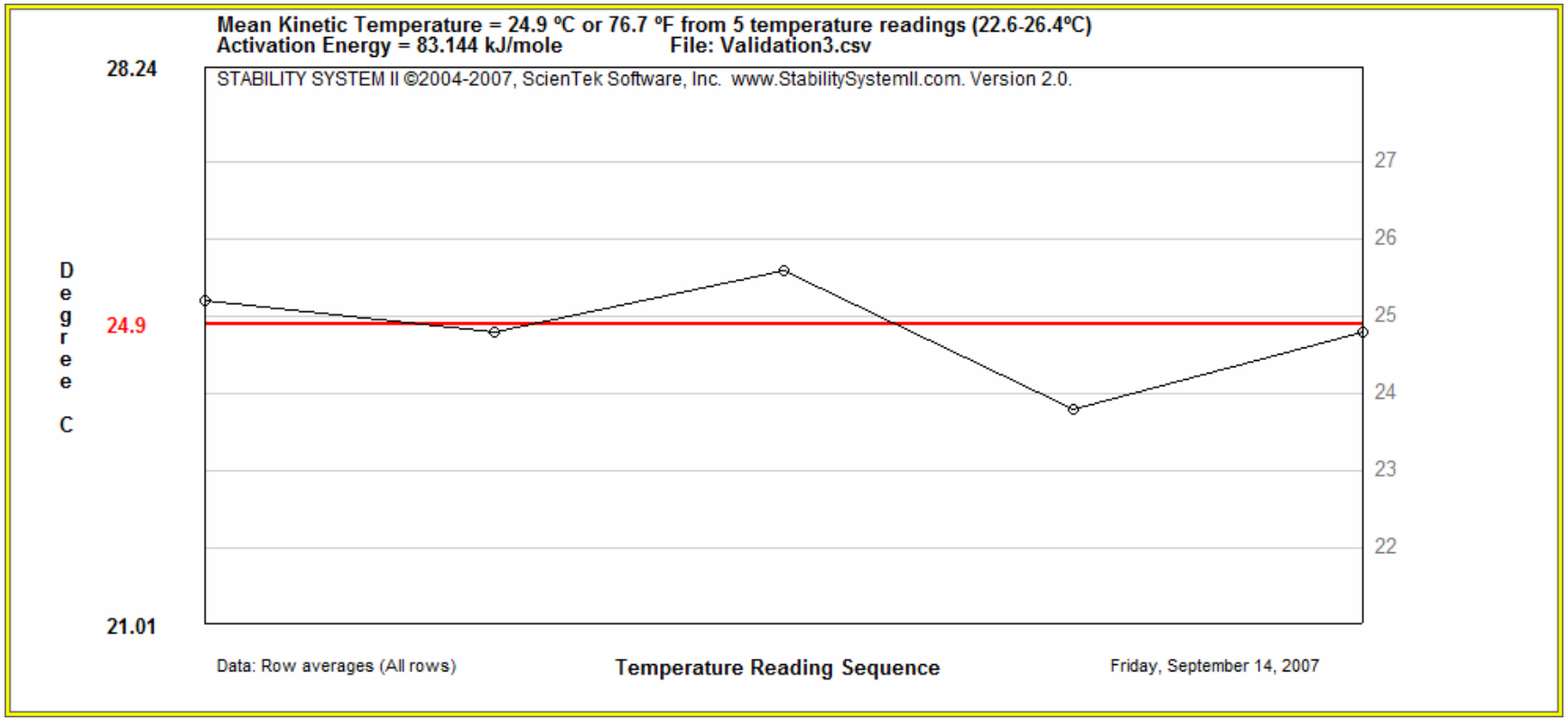
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Conclusion

The arithmetic means for each row in the CSV file are used in the calculation of the mean kinetic temperature. The arithmetic mean for Data Set 3 is exactly the same as that in Data Set 1. Therefore the mean kinetic temperature for Data Set 3 should be the same as that of Data Set 1, which is 24.9 °C.

The mean kinetic temperature for row averages of Data Set 3 computed by **STABILITY SYSTEM II** program is indeed 24.9 °C.

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II. Data set 3 – Low and high temperature reading for each time period from 2 temperature probes

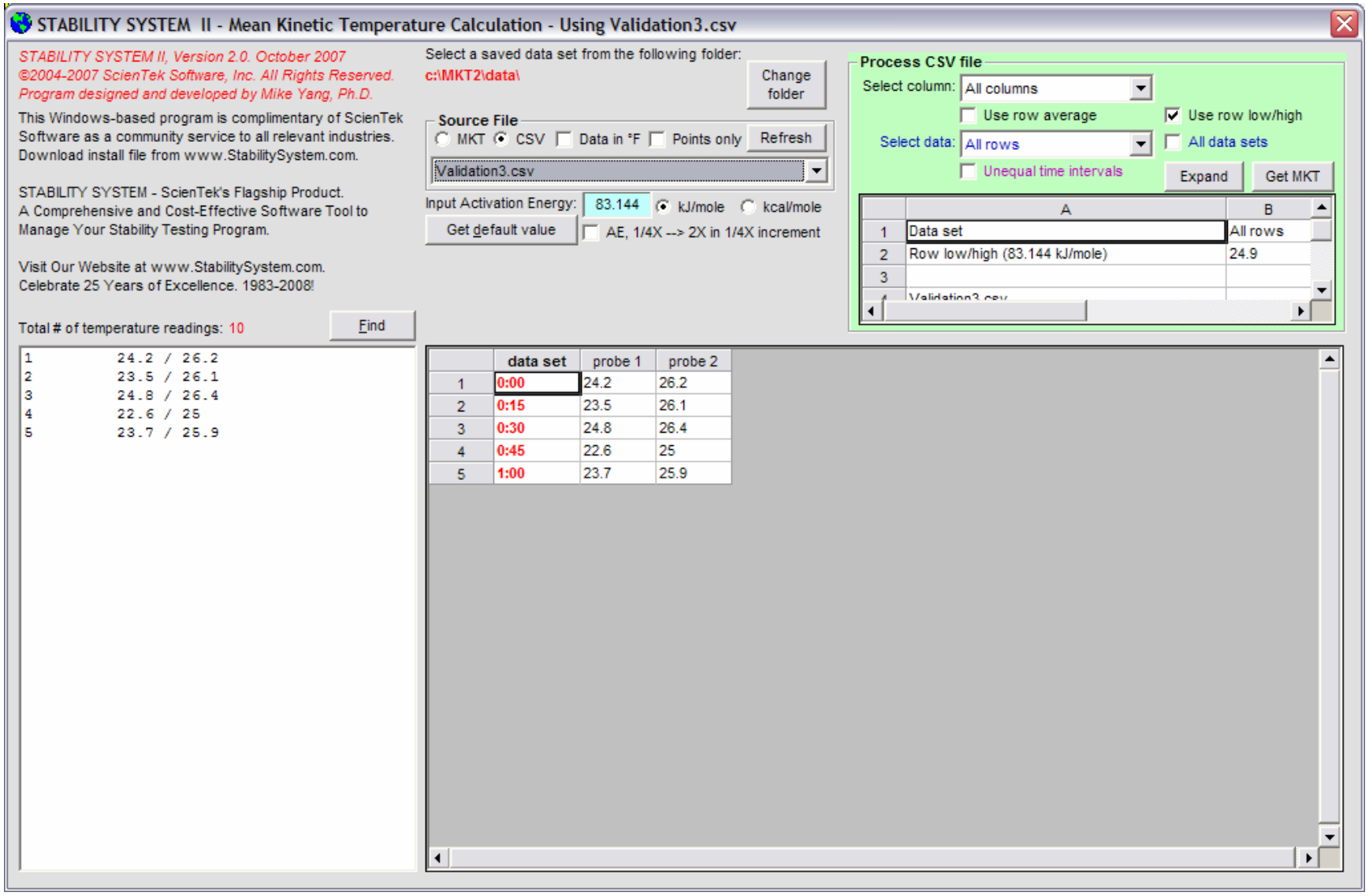
Temperature File – **validation3.CSV**, included in the installation file. (If your Windows Regional Setting is set to one of locals that uses comma as the decimal separator, please use **validation3comma.CSV**.)

Temperature Readings in Celsius:

data set	probe 1	probe 2
0:00	24.2	26.2
0:15	23.5	26.1
0:30	24.8	26.4
0:45	22.6	25
1:00	23.7	25.9

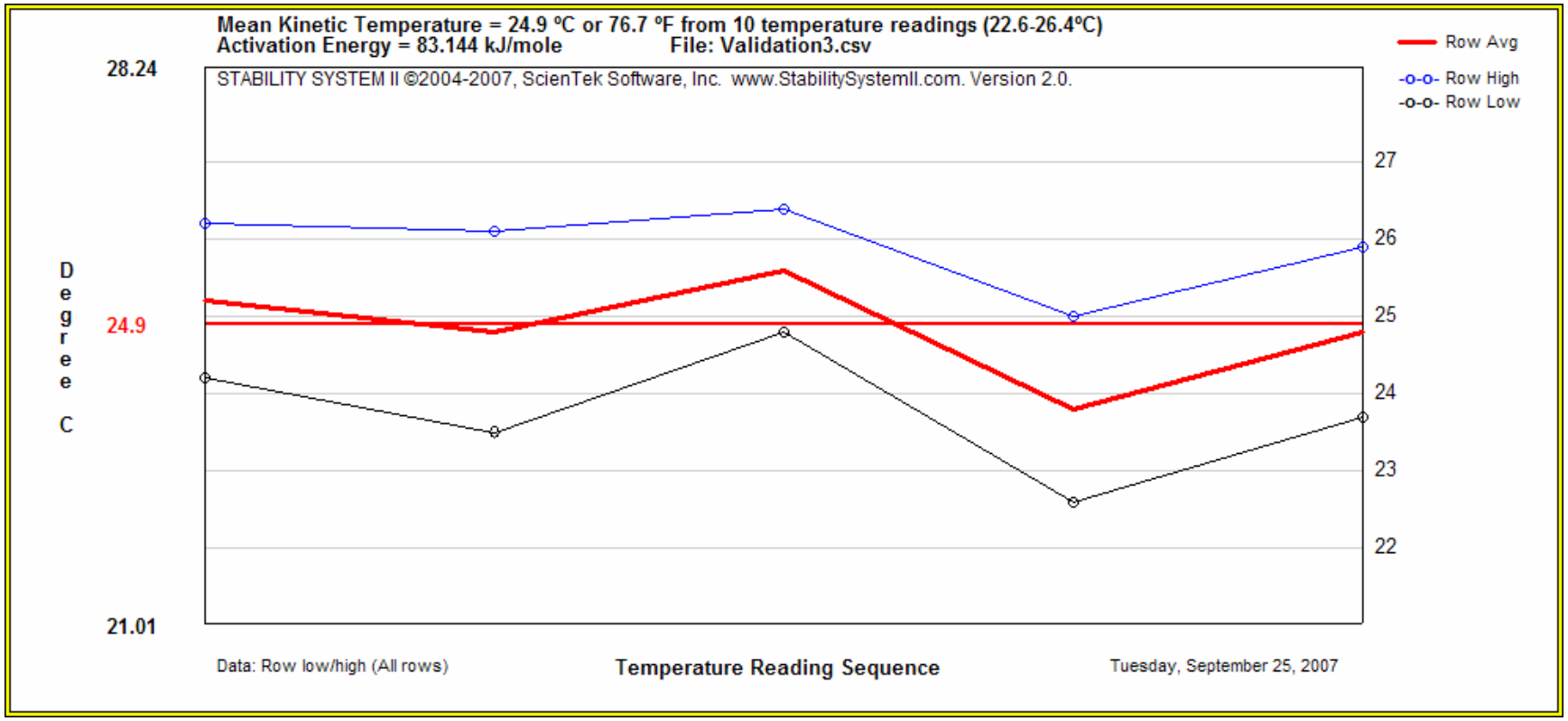
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Conclusion

The low/high values for each row in the CSV file are used in the calculation of the mean kinetic temperature. The row low/high values for Data Set 3 are exactly the same as that in Data Set 2. Therefore the mean kinetic temperature for Data Set 3 should be the same as that of Data Set 2, which is 24.9 °C.

The mean kinetic temperature for row low/high values of Data Set 3 computed by **STABILITY SYSTEM II** program is indeed 24.9 °C.

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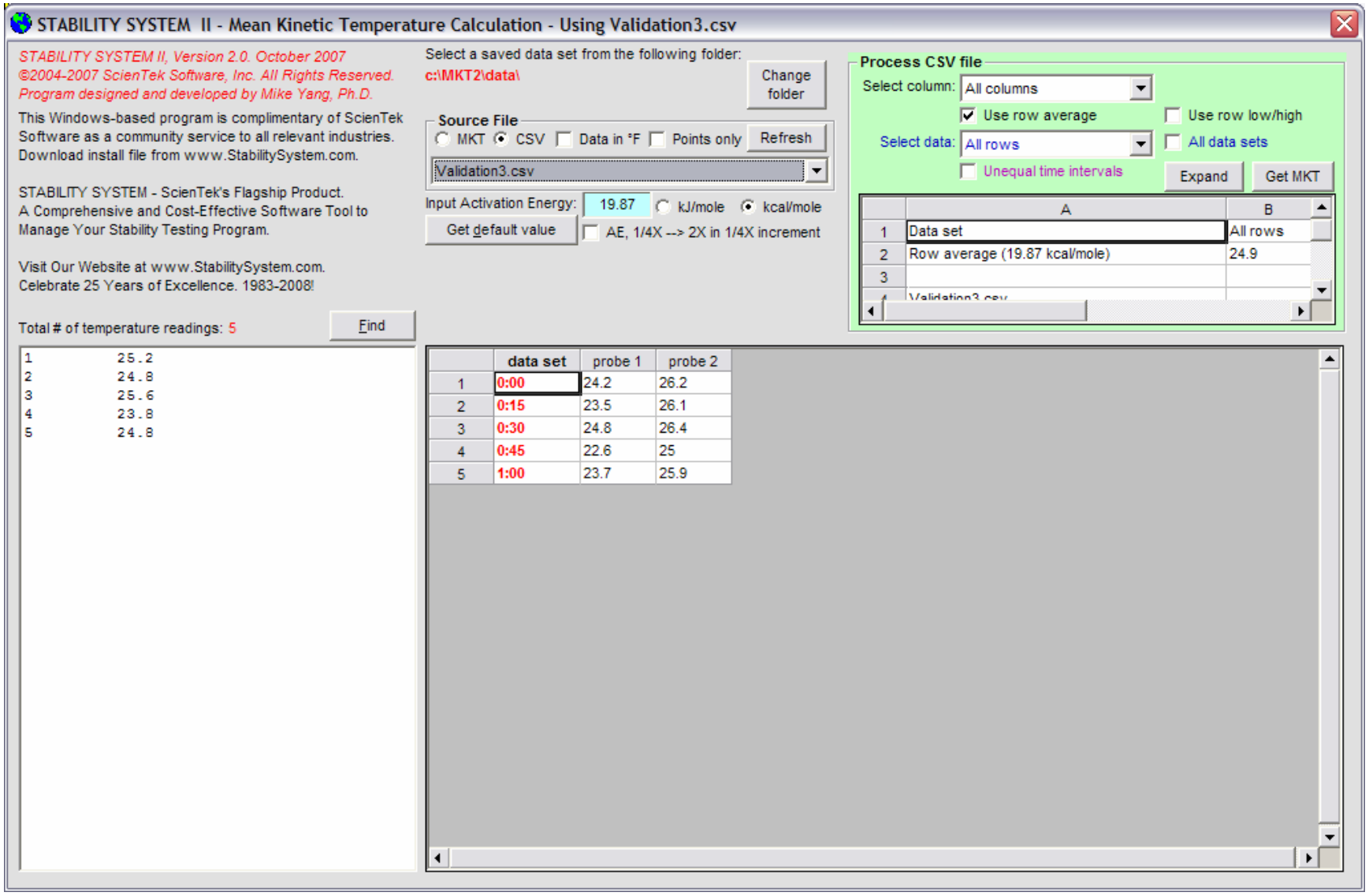
B. Activation Energy in kJ/mole

I. Data set 3 – One temperature reading for each time period from 2 temperature probes

Same as 1.B.I.

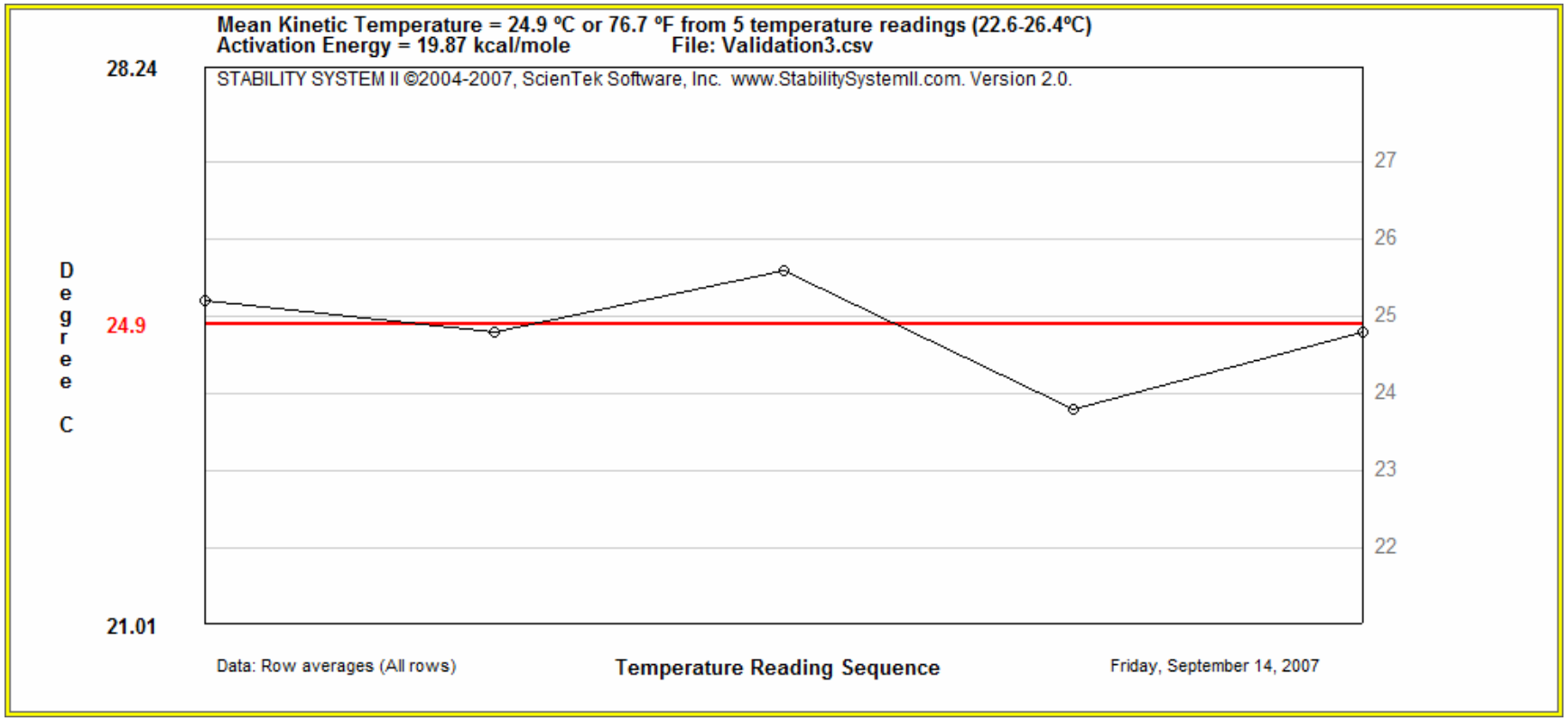
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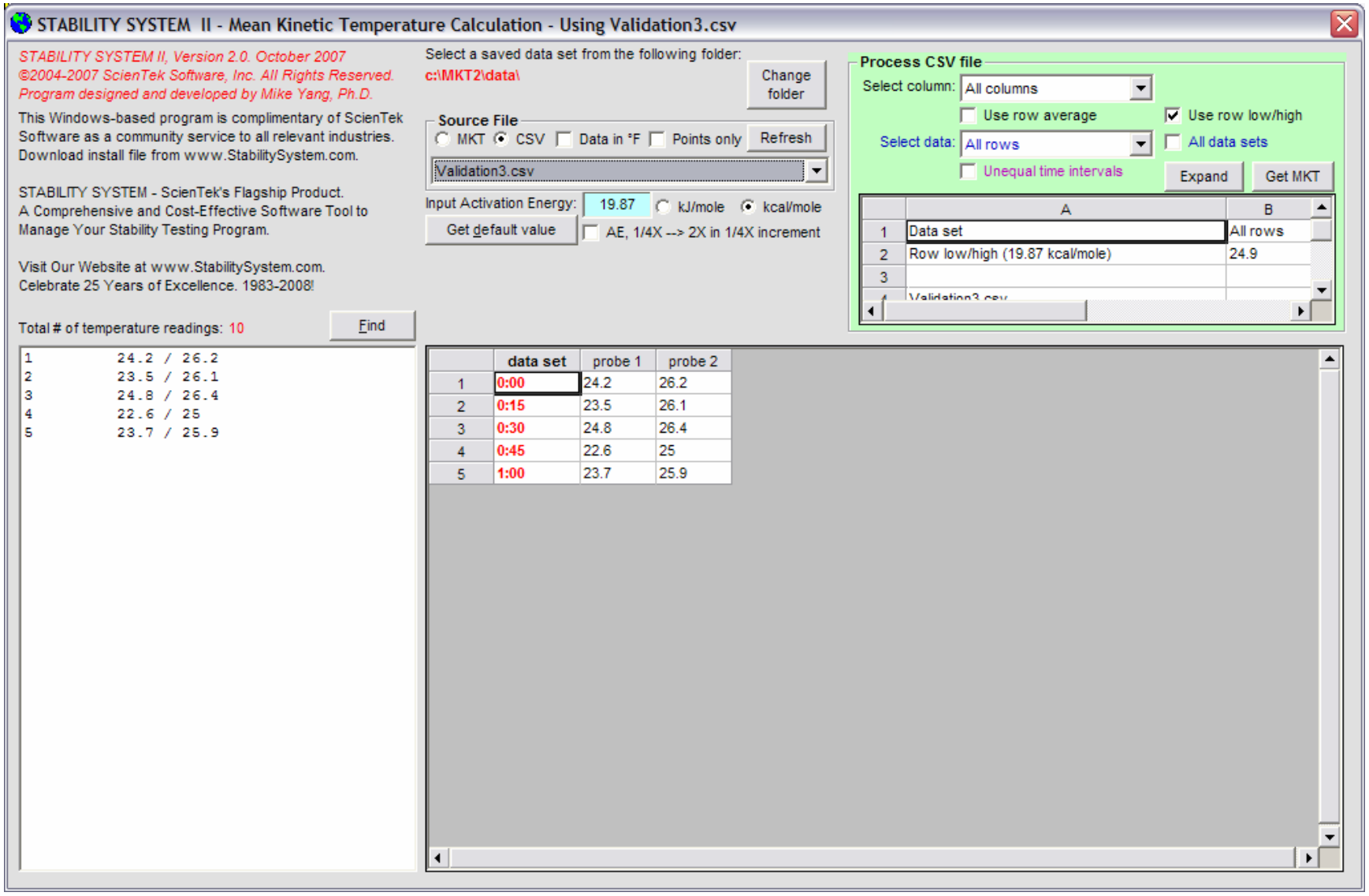
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II. Data set 3 – Low and high temperature reading for each time period from 2 temperature probes

Same as 1.B.II.

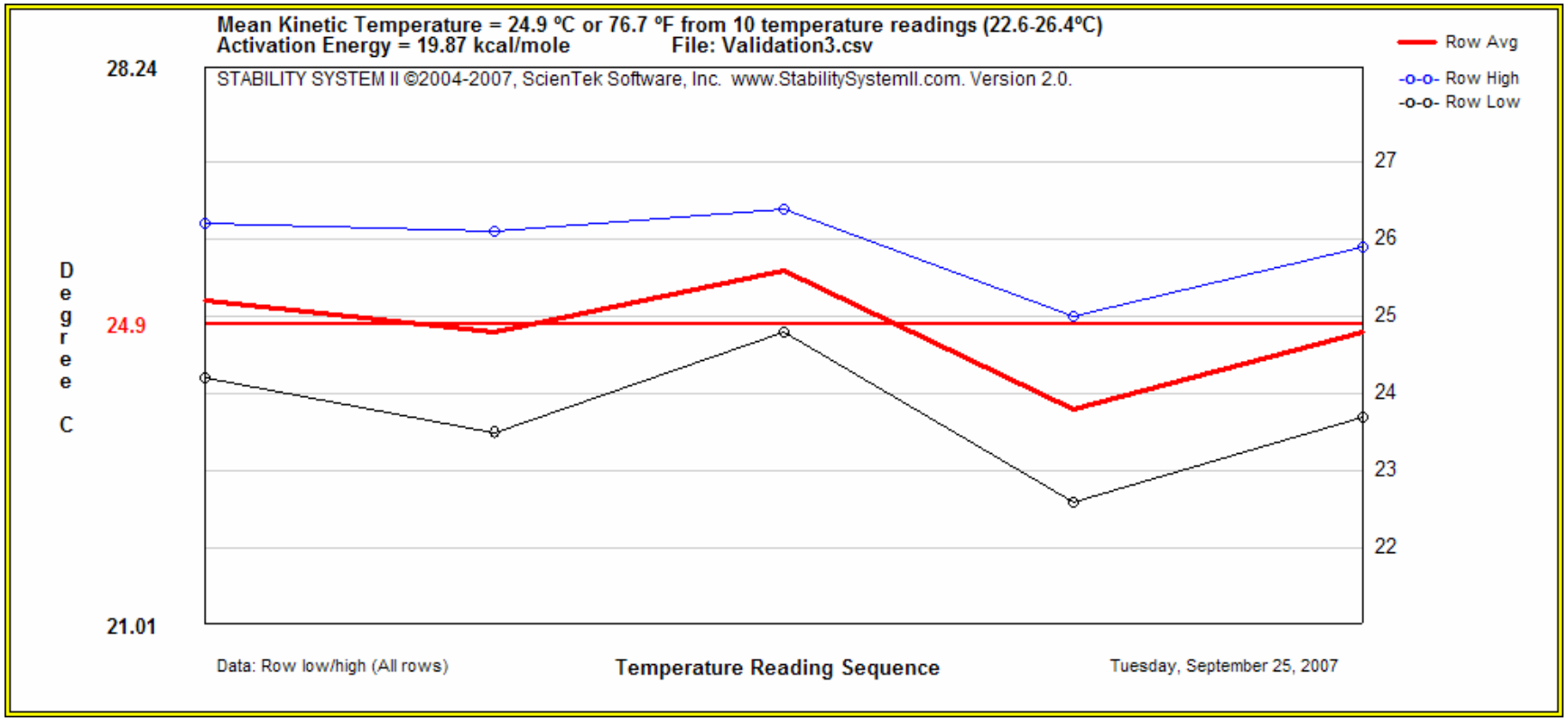
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3. CSV file with Reduced Data Sets

A. Every 2nd Row

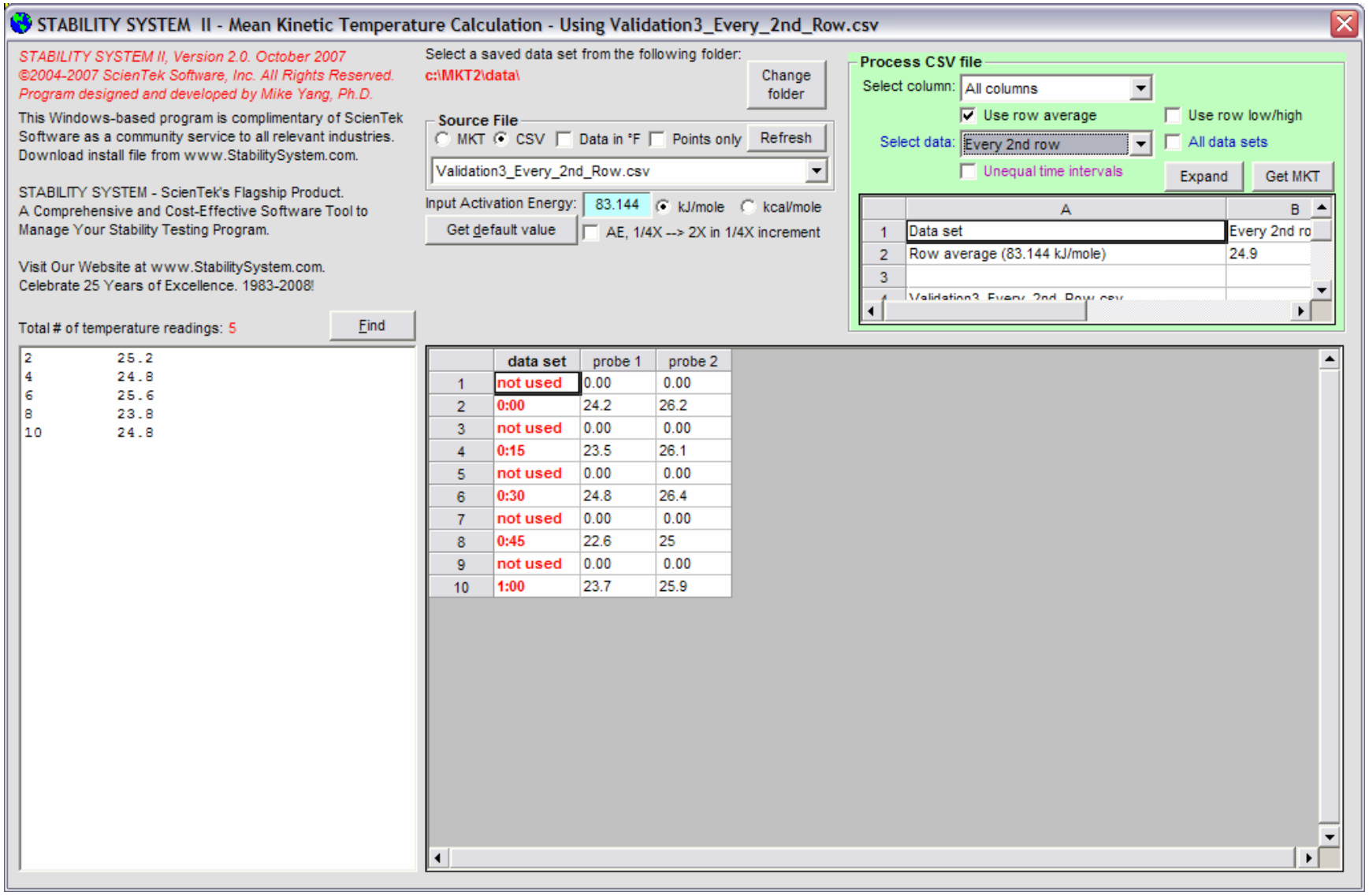
Source Data:

data set	probe 1	probe 2
not used	0	0
0:00	24.2	26.2
not used	0	0
0:15	23.5	26.1
not used	0	0
0:30	24.8	26.4
not used	0	0
0:45	22.6	25
not used	0	0
1:00	23.7	25.9

The computed Mean Kinetic Temperature is the same as 2.A.I.

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B. Every 5th Row

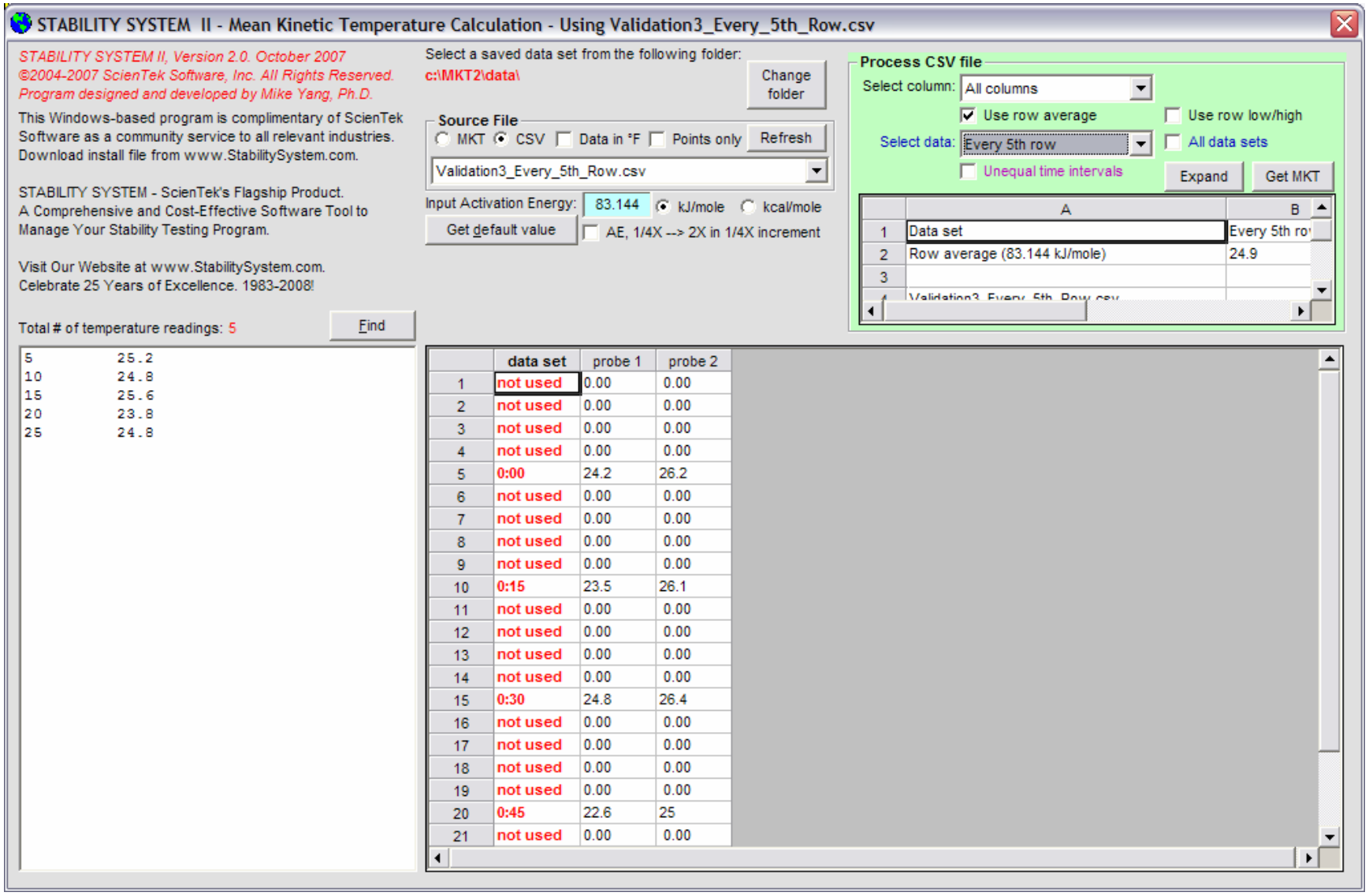
Source Data:

data set	probe 1	probe 2
not used	0	0
not used	0	0
not used	0	0
not used	0	0
0:00	24.2	26.2
not used	0	0
not used	0	0
not used	0	0
not used	0	0
0:15	23.5	26.1
not used	0	0
not used	0	0
not used	0	0
not used	0	0
0:30	24.8	26.4
not used	0	0
not used	0	0
not used	0	0
not used	0	0
0:45	22.6	25
not used	0	0
not used	0	0
not used	0	0
not used	0	0
1:00	23.7	25.9

The computed Mean Kinetic Temperature is the same as 2.A.I.

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C. Every 10th Row

Source Data:

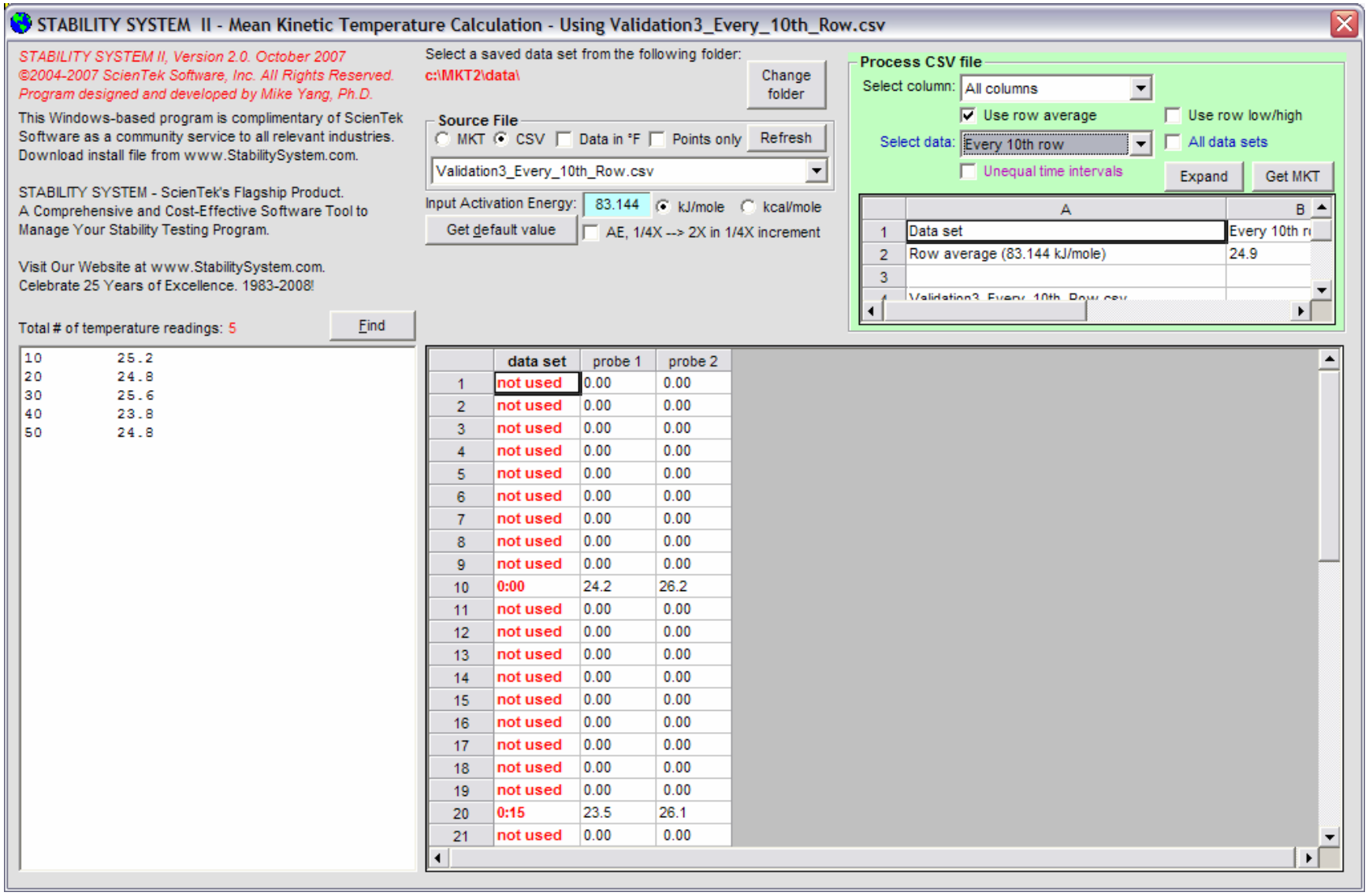
data set	probe 1	probe 2
not used	0	0
not used	0	0
not used	0	0
not used	0	0
not used	0	0
not used	0	0
not used	0	0
not used	0	0
not used	0	0
0:00	24.2	26.2
not used	0	0
not used	0	0
not used	0	0
not used	0	0
not used	0	0
not used	0	0
not used	0	0
not used	0	0
not used	0	0
0:15	23.5	26.1
not used	0	0
not used	0	0
not used	0	0
not used	0	0
not used	0	0

data set (continued)	probe 1	probe 2
not used	0	0
not used	0	0
not used	0	0
not used	0	0
0:30	24.8	26.4
not used	0	0
not used	0	0
not used	0	0
not used	0	0
not used	0	0
not used	0	0
not used	0	0
not used	0	0
not used	0	0
not used	0	0
0:45	22.6	25
not used	0	0
not used	0	0
not used	0	0
not used	0	0
not used	0	0
not used	0	0
not used	0	0
not used	0	0
not used	0	0
not used	0	0
1:00	23.7	25.9

The computed Mean Kinetic Temperature is the same as 2.A.I.

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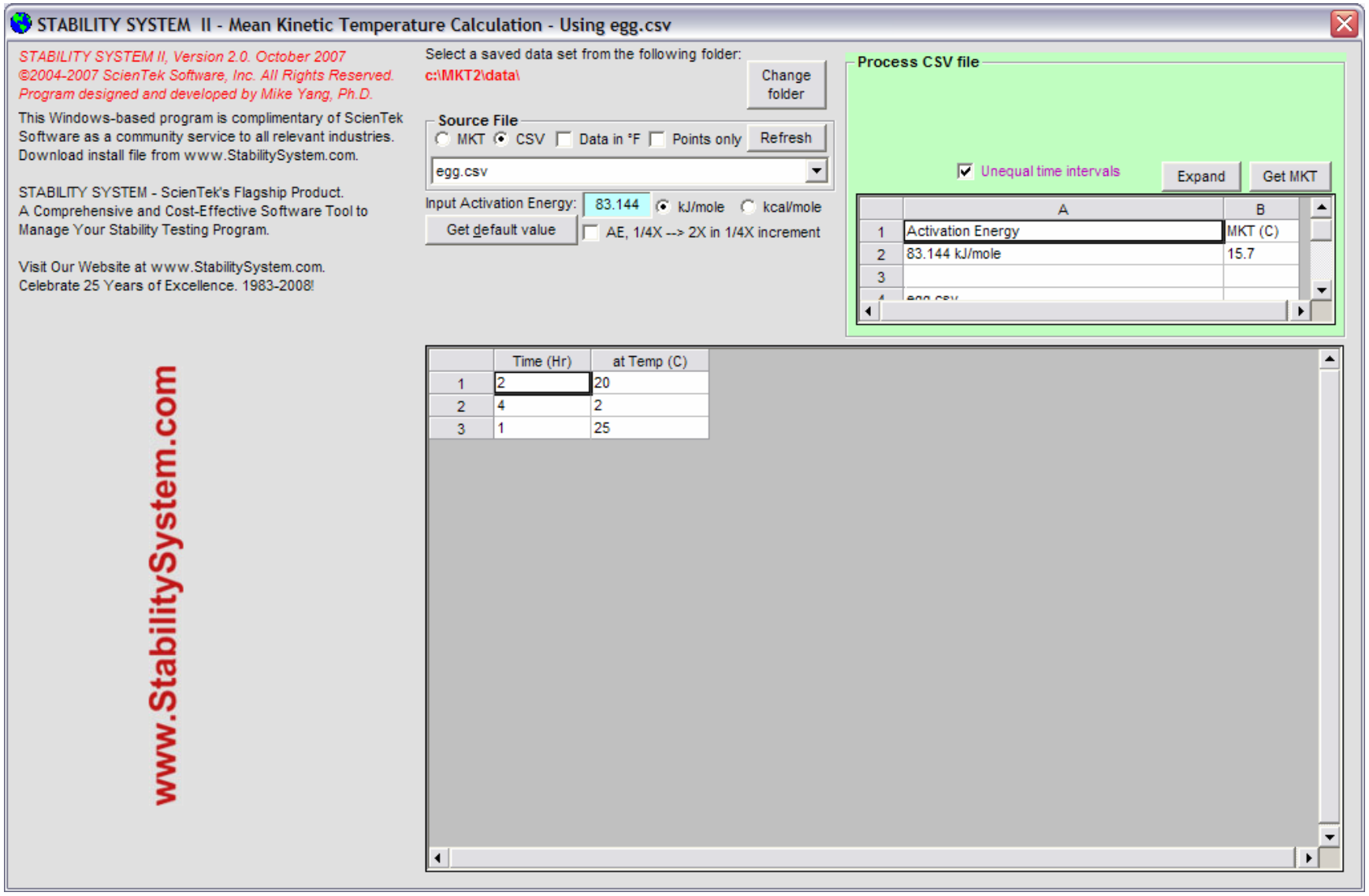
4. What is the mean kinetic temperature if eggs are stored at 20°C for 2 hours, 4 hours at 2°C and 1 hour at 25°C?

Source data:

Time (Hr)	at Temp (C)
2	20
4	2
1	25

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Conclusion

The computed mean kinetic temperature of 15.7 C is the same as documented in the following reference:

"What Is Mean Kinetic Temperature?" by MONARCH INSTRUMENT
Web address: http://www.monarchserver.com/Mean%20Kinetic%20Temp.pdf

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5. Source data in degree F

Temperature File – **validation4_F.MKT**, included in the installation file. (If your Windows Regional Setting is set to one of locals that uses comma as the decimal separator, please use **validation4_F_comma.MKT**.)

Temperature Readings in Fahrenheit:

77.36
76.64
78.08
74.84
76.64

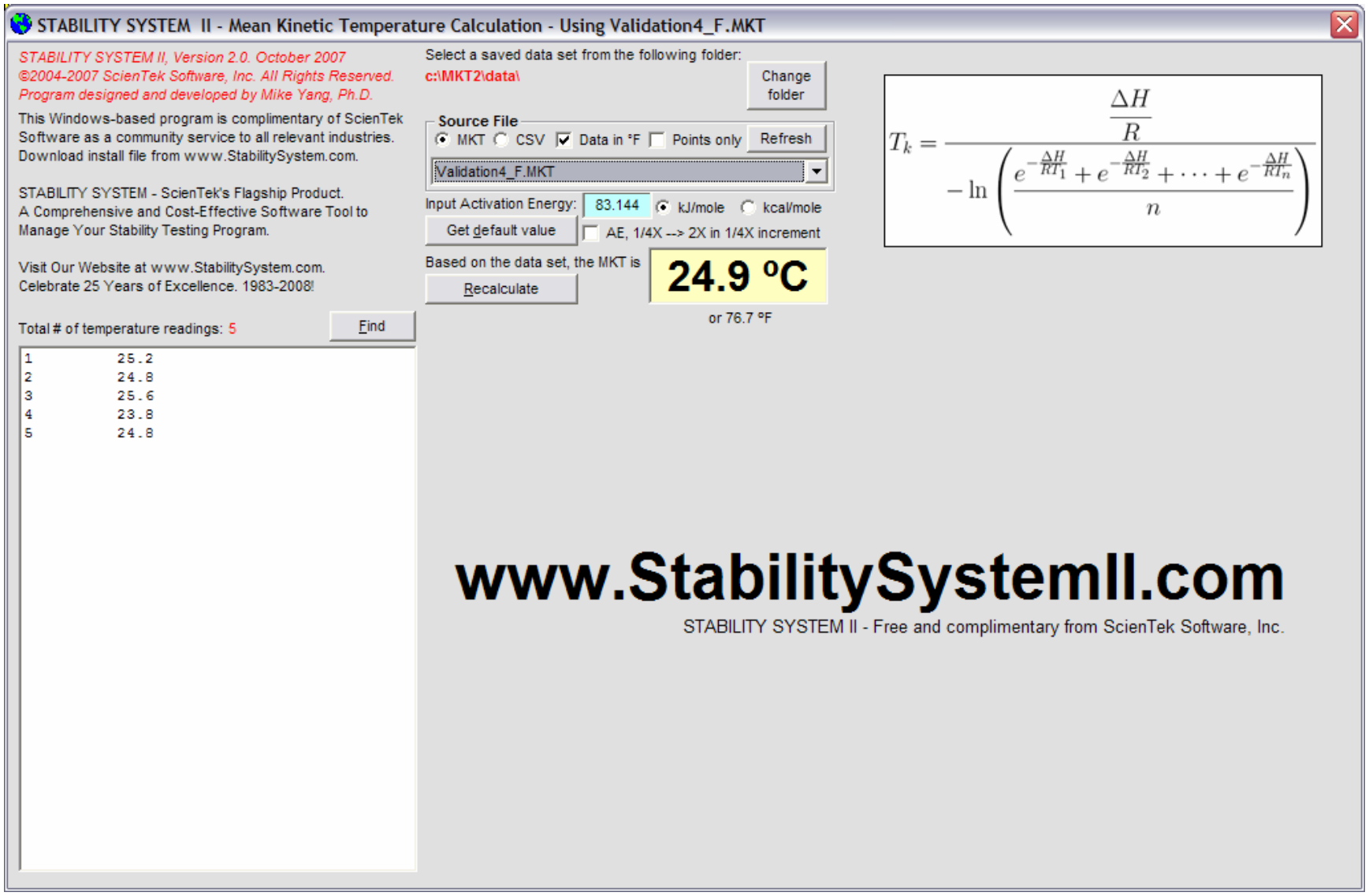
Manual Calculation

Temperature probe	Low Temperature °F	High Temperature °C
Period 1	77.36	25.2
Period 2	76.64	24.8
Period 3	78.08	25.6
Period 4	74.84	23.8
Period 5	76.64	24.8

The above table shows that the temperature in degree C in **validation4_F.MKT** is exactly the same as that in Data Set 1 (see Section 1.A.I). Therefore the manual calculation produces the same mean kinetic Temperature of 24.9 °C.

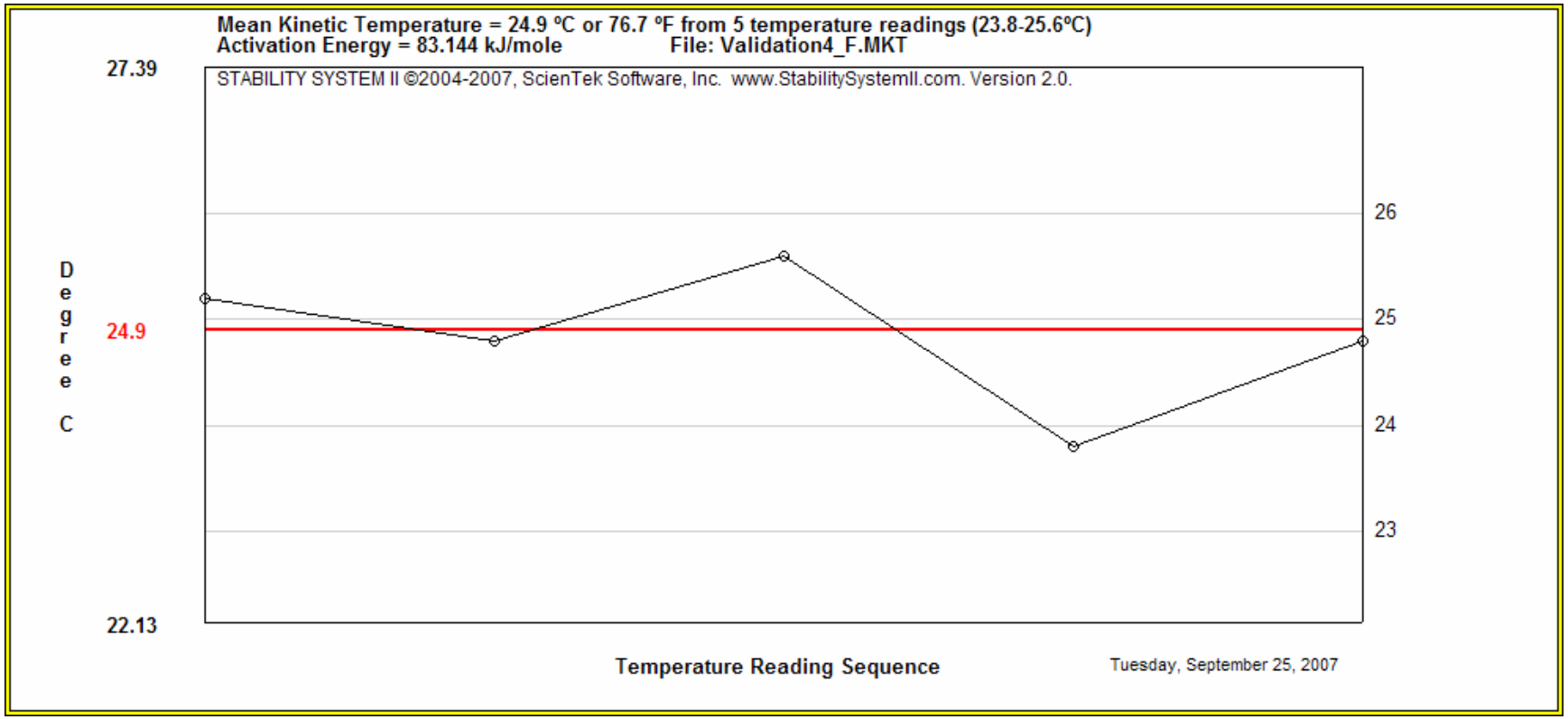
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STABILITY SYSTEM II *Calculation*



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