IMPORTANT SAFETY NOTICE – IMMEDIATE ACTION REQUIRED

Subject: Varian TV 801 Turbo Pumps on the API 4000™, 4000 QTRAP®, and API 5000™ Mass Spectrometers

For Research Use Only. Not for use in diagnostic procedures

Date: 2017/03/13

Dear Valued Customer,

SCIEX is initiating a field action for the products listed above as a result of a communication received from our pump component supplier, Agilent Technologies. SCIEX has received two customer complaints for the Agilent Technologies' TV 801 turbo pump, which is used in some of SCIEX's API 4000™, 4000 QTRAP®, and API 5000™ systems[1]. This Important Safety Notice contains important information on how to identify if your system is impacted, and what actions you need to take. A copy of the communication from Agilent Technologies is included at the end of this document.

Issue and Impact

The TV 801 turbo pump may experience a rotor fragmentation leading to a sudden separation of the body from the envelope, allowing metal fragments to be ejected from the pump at high speeds, which may result in serious injury or death. To date, there have been no reported injuries.

Actions to be Taken by the User:

CAUTION! Potential System Damage. If the turbo pump is not accessible and the mass spectrometer must be moved, first shut down the system by following the steps outlined in the "How to Shut Down the System" section.

For each API 4000™, 4000 QTRAP®, or API 5000™ system installed at your site, use the steps in the section "How to Determine Whether You Have an Affected Turbo Pump" to determine if

[1] The mass spectrometers were sold under a number of different brand names, including SCIEX, AB SCIEX, MDS SCIEX, and Applied Biosystems.

your system(s) have a TV 801 turbo pump installed. If you do not feel comfortable performing these steps, follow the procedure in "How to Shut Down the System", and then contact your local service representative. If your system(s) does contain this model turbo pump, then:

1. Shut the system down immediately by following the steps in the section "How to Shut Down the System."
2. Complete and submit the "Response Form" found at the end of this document.
3. Contact the Technical Assistance Center (TAC) to schedule a service call:
    - In the United States and Canada, telephone: (877) 740-2129 (toll-free)
    - In other regions, go to SCIEX.com/contact-us to find contact information.
4. Do not resume use of the System until a correction has been installed. (A correction is under development.)

How to Determine Whether You Have an Affected Turbo Pump

CAUTION! Potential System Damage. If the turbo pump is not accessible, and the mass spectrometer must be moved, then first shut down the system, by following the steps in "How to Shut Down the System".

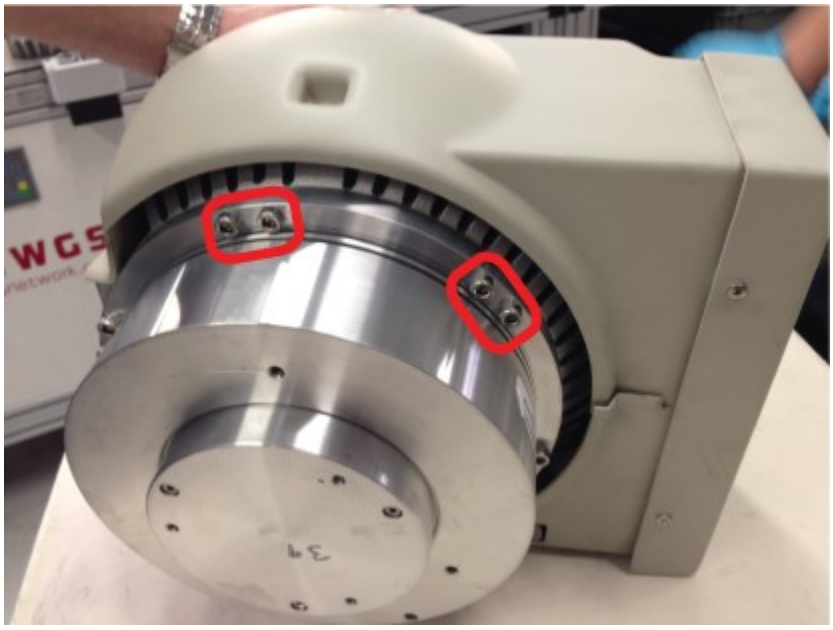
1. Locate the turbo pump. The turbo pump is on the back of the instrument, on the top right, as shown in Figure 1.

Figure 1: Turbo Pump (Shown Inside the Red Circle)

2. Inspect the pump to determine the number of securing bolts. Refer to Figure 2 and Figure 3.

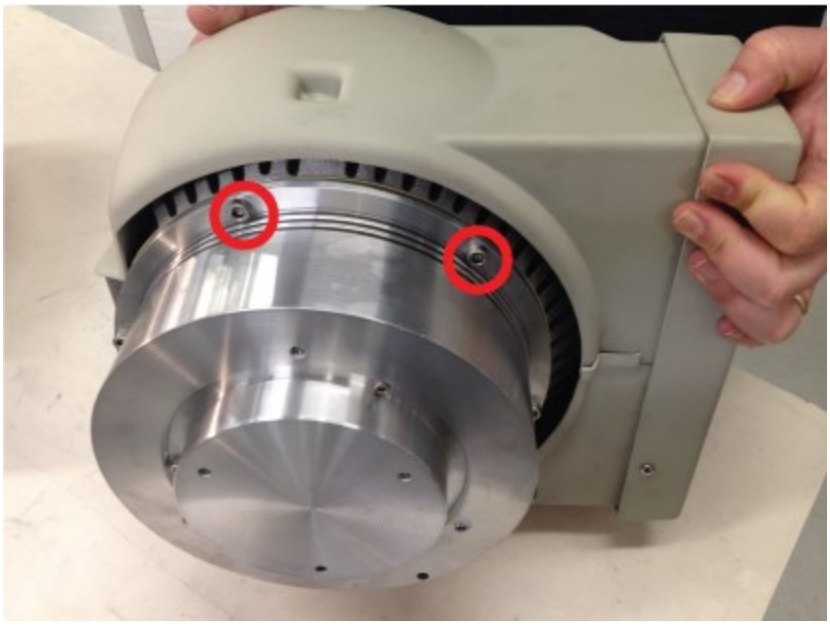
   <u>If the pump has double bolts, then it is NOT a TV 801 pump. No further action is required.</u>

Figure 2: TV 902 Pump with Double Bolts <u>(No Action Required)</u>



<u>If the pump has single bolts, then it is a TV 801 pump. Immediate action is required.</u>

Figure 3: TV 801 Pump with Single Bolts (Action Required - Shut Down the System Immediately by following the "<u>How to Shut Down the System</u>" section below.)



2. If the turbo pump is a TV 801 pump, then:

    a. Record the serial number of the mass spectrometer on the "Response Form". The serial number is located on the back of the mass spectrometer, in the bottom left corner, as shown in Figure 4.

    b. Record the serial number of the turbo pump on the "Response Form". The serial number is located on the turbo pump label. The label is visible from underneath the turbo pump, as shown in Figure 5.

Figure 4: Mass Spectrometer Serial Number Location

Figure 5: Turbo Pump Model & Serial Number Location

How to Shut Down the System

CAUTION! Potential System Damage. Turn off sample flow before shutting down the mass spectrometer.

CAUTION! Potential System Damage. Leave the roughing pump running for at least 15 minutes after turning off the mass spectrometer, to allow the turbo pumps to spin down gradually, and to prevent pressure buildup in the vacuum lines.

CAUTION! Do not resume use of the System until a correction has been installed. (A correction is under development.)

1. In the Analyst® software, complete or stop any ongoing scans.
2. Turn off sample flow to the instrument.
3. Deactivate the hardware profile, and then close the Analyst® software. Refer to the Analyst® software documentation.
4. Stop the AnalystService in the Windows Control Panel. Refer to the Analyst® software documentation.
5. Turn off the main power switch on the mass spectrometer. The switch is located on the bulkhead beside the serial number label.
6. Wait for 15 minutes.
7. Turn off the roughing pump. The power switch is located above the power supply input attachment.

   Note: The API 5000™ has two roughing pumps. Turn both of them off.

   Note: The roughing pump has its own power switch and must be turned off manually.
8. Wait 10 minutes for the mass spectrometer to vent naturally.
9. Disconnect the mains power cable for the mass spectrometer from the mains supply outlet.
10. Disconnect the mains power cable for the roughing pump from the mains supply outlet.

Please share this information with your laboratory staff, and retain this notification as part of your laboratory Quality System documentation. If the affected product listed above has been relocated to another location, please provide the appropriate personnel at the location with a copy of this letter and provide us with the updated contact information.

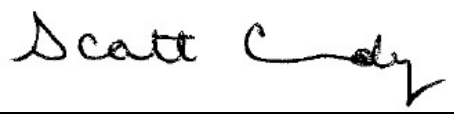
We apologize for the potential disruption this notification can have on your operation. We are working diligently together with the manufacturer of the TV 801 turbo pump to complete the failure mode investigation and to develop, validate, and manufacture potential remediation solutions that would allow you to resume safe use and operation of the affected systems. We will work closely with your organization to discuss these and other possible actions. If you have any questions, please contact your local SCIEX sales or service representative or visit the web site below for further information.

https://SCIEX.com/tv801safetynotice

Sincerely,

Scott Cundy, SCIEX VP RA/QA

Name, Title (Print)



Signature

2017/03/13

Date (yyyy/mm/dd)

RESPONSE FORM

Electronic “Response Form” may be found at https://SCIEX.com/tv801safetynotice

Check the appropriate box below:

☐ We have a SCIEX API 4000™, 4000 QTRAP®, or API 5000™ system with an affected TV 801 turbo pump. I have read and understood the information within the accompanying SCIEX Notification, dated March 13, 2017. All relevant personnel have been informed of its contents, any necessary actions have been taken, and records have been retained as part of our Laboratory Quality System documentation.

or:

☐ We own a SCIEX API 4000™, 4000 QTRAP®, or API 5000™ system, but it does not have an affected TV 801 turbo pump.

or:

☐ We do not own a SCIEX API 4000™, 4000 QTRAP®, or API 5000™ system.

Please fill in the following table with the information about the affected products at your site. Attach additional pages, if necessary.

ON-SITE AFFECTED PRODUCT INFORMATION	
Mass Spectrometer Serial Number	**Turbo Pump Serial Number**

Please sign the section below, indicating your acknowledgement of this communication.

Contact Person Name and Title (Please Print)

Company Name

Company Address (Street)	
Company Address (City)	Company Address (Country, Zip/Postal Code)
Signature	Date
Telephone	Email

Please complete and return this form to:

SCIEX
Attention: Quality Assurance Department
71 Four Valley Drive
Concord, Ontario
L4K 4V8, Canada

Or

Attention: Quality Assurance Department
Fax: 905-660-2629

Or

quality@SCIEX.com

Agilent Technologies, Inc.
121 Hartwell Avenue
Lexington, MA 02124

781 860 5441 telephone
tom.branchaud@agilent.com
www.agilent.com

Agilent Technologies

March 8, 2017

Tri Lu
SCIEX
71 Four Valley Dr, Concord ON
Canada

Subject: Potential Hazard to Users of the Varian TV-801 Turbo Pump

Due to the recent field failures of two Varian TV-801 Turbo Pumps, Agilent Technologies has performed a preliminary investigation of TV-801 pumps manufactured by Varian between 2002 and 2009. Although the investigation is not complete, given the age of the TV-801 field population and the potential severity of this failure mode, Agilent recommends SCIEX take immediate action.

Hazard Description: Based on our preliminary investigation, the TV-801 Turbo Pump may experience a rotor fragmentation leading to a sudden separation of the body from the envelope, allowing metal fragments to be ejected from the pump at high speeds, which may result in serious injury or death.

Affected Models, Serial Numbers & Dates: All TV-801 Turbo Pumps, including exchange models, are affected. Agilent Part Numbers:

SQ336	(Obsoleted 2004)
EXSQ336 (refurbished pump)	(Obsoleted 2004)
8698933	(Obsoleted 2009)
EX8698933 (refurbished pump)	

No other Turbo Pump models, such as the TV-902 or TV-903, are affected by this notification.

Action Required: We recommend SCIEX take the necessary steps to ensure that its customers immediately cease use of the existing TV-801's, including sending a copy of this letter to your customers.

Agilent Technologies is committed to a high standard of Quality and Safety. We are making this recommendation because we are committed to the safety of our customers and desire to eliminate this hazard where it may exist. We remain available to you to collaborate on potential solutions to immediately address your affected installed base.

Sincerely,

Thomas Branchaud

Thomas Branchaud
Quality Manager, Spectroscopy & Vacuum Division