
Vigtig produktinformation

KORREKTION nr. 1218959-10-18-2012-006-C

Rettelse til medicinsk enhed

18. oktober 2012

Bemærk: Kunde

Oplysninger om berørt udstyr:

Waters ACQUITY® TQD, ACQUITY® SQD, LCT Premier™ XE, Quattro Premier™, Quattro Premier™ XE, Quattro™ mikro, Xevo® G2 Tof, Xevo® TQ, Xevo® TQD & ZQ 2000 massespektrometre, alle serienumre.

Beskrivelse af problemet:

Waters Corporation iværksætter en frivillig rettelse til medicinske enheder for sine massespektrometre, der henvises til herover. Vores fortegnelser angiver, at De ejer eller lejer et eller flere af disse massespektrometre.

Denne rettelse er nødvendig, fordi der er risiko for, at ionblokkens kildeopvarmer svigter. I nogle tilfælde kan fejlen medføre et kortvarigt tab af eller variation i følsomhed, som efterfølgende kan føre til unøjagtige data. Tabet af eller variationen i følsomhed er mest markant i analyser med kortere holdetider (dvs. mindre end 100 ms) og opdages muligvis ikke altid ved kvalitetskontrol og intern overvågning af standardværdier.

Råd til foranstaltning, der skal træffes af brugeren:

Af hensyn til vores produkters fortsatte sikkerhed og pålidelighed anbefaler Waters, at De straks udskifter ionblokkens kildeopvarmer. Den eller de nødvendige dele følger med denne produktinformation, og Waters vurderer, at udskiftningen tager ca. 30 minutter. Ionblokkens kildeopvarmer kan udskiftes af kunden som beskrevet i betjeningsvejledningens vedligeholdelsesprocedure. Der kan også findes instruktioner affattet på flere forskellige sprog på følgende adresse: www.waters.com/sourceheater. Alternativt kan en lokal servicetekniker udskifte ionblokkens kildeopvarmer omkostningsfrit. Såfremt De foretrækker dette alternativ, bedes De kontakte Deres lokale servicesupportkontor¹ med henblik på at planlægge denne service.

¹ Deres lokale servicetekniker kan uden for USA kontaktes ved at logge på Waters' websted på adressen <http://www.waters.com/waters/home.htm>, vælge Deres land øverst på siden og klikke på About Waters/Contact Waters/Local Country Contacts.



Udfyld venligst den vedlagte svarblanket, og returner den til Waters via e-mail på waters_quality@waters.com eller via fax på nummeret angivet herunder. Denne blanket giver dokumenteret bevis på, at denne meddelelse og erstatningsdelen blev modtaget af Dem.

Afsendelse af denne produktinformation:

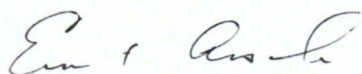
Denne meddelelse skal videregives til alle personer, som skal gøres opmærksom på ovenstående i organisationen, eller til enhver organisation, som de potentielt berørte instrumenter er blevet overdraget til.

Kontaktperson:

Undertegnede bekræfter, at denne meddelelse er videregivet til den relevante myndighed.

Vi undskylder den ulejlighed, som dette måtte medføre. Kontakt mig venligst, hvis De har yderligere spørgsmål.

Venlig hilsen



Ernest Ansah
Quality Assurance Manager, Clinical Quality
Waters Corporation
34 Maple Street
Milford, MA 01757
Telefon: +1 508-482-2811
Fax: +1 508-482-2339



**Rettelse til medicinsk
enhed**

SVARBLANKET

Re.: Waters ACQUITY® TQD, ACQUITY® SQD, LCT Premier™ XE, Quattro Premier™,
Quattro Premier™ XE, Quattro™ mikro, Xevo® G2 Tof, Xevo® TQ, Xevo® TQD & ZQ 2000
massespektrometre, alle serienumre.

ANVISNINGER I AT UDFYLDE DENNE SVARBLANKET:

Denne udfyldte blanket er nødvendig af hensyn til spring. **Afkryds de relevante bokse, angiv de påkrævede oplysninger, og returner denne blanket** via fax eller e-mail til:

(f) Faxnummer: (508) 482-2339 eller
(e) E-mail-adresse: waters_quality@waters.com

AFSNIT, DER SKAL UDFYLDES AF KUNDEN

- Vi har modtaget meddelelsen og den nye kildeopvarmer til ionblokken
 Ionblokkens kildeopvarmer blev udskiftet

Virksomhedsnavn _____

Adresse _____

Navn på kontaktperson: _____ Andet: _____

Kontaktpersons titel: _____

Afdeling: _____ Telefonnummer: _____

Underskrift (obligatorisk): _____ Dato: _____

E-mail-adresse: _____

Serienummer: _____

Identifikationsnummer 1218959-10-18-2012-006-C



Urgent Field Safety Notice

CORRECTION # 1218959-10-18-2012-006-C

Medical Device Correction

October 18, 2012

Attention: Customer

Details on affected devices:

Waters ACQUITY® TQD, ACQUITY® SQD, LCT Premier™ XE, Quattro Premier™, Quattro Premier™ XE, Quattro™ micro, Xevo® G2 Tof, Xevo® TQ, Xevo® TQD & ZQ 2000 Mass Spectrometers, all serial numbers.

Description of the problem:

Waters Corporation is initiating a voluntary medical device correction for its mass spectrometers referenced above. Our records indicate that you own or lease one or more of these mass spectrometers.

This correction is necessary because there is a possibility that the ion block source heater may fail. In some instances, the failure could cause a short term loss of or variation in sensitivity that may subsequently lead to inaccurate data. The loss of or variation in sensitivity is most pronounced in assays with shorter dwell times (i.e. less than 100 ms) and may not always be detected by quality control and internal standard value monitoring.

Advise on action to be taken by the user:

To ensure the continued safety and reliability of our products Waters recommends that you replace the ion block source heater immediately. The necessary part(s) are included with this Field Safety Notice and Waters estimates the replacement should take approximately 30 minutes. The ion block source heater is customer replaceable as detailed in the maintenance procedure of the operators guide. Instructions can be also be found in several languages at the following address: www.waters.com/sourceheater. Alternatively, a local field service engineer can replace the ion block source heater at no cost. If you prefer this alternative, please contact your local field service support office¹ to schedule this service.

Please complete the attached Reply Verification Tracking Form and return it to Waters via e-mail at waters_quality@waters.com, or via fax at the number provided below. This form provides documented evidence that this notification and the replacement part were received at your site.

¹ To contact your local field service engineer outside of the United States, log onto the Waters Website at <http://www.waters.com/waters/home.htm>; choose your country at the top of the page, click on About Waters/Contact Waters/Local Country Contacts.



Transmission of this Field Safety Notice:

This notice needs to be passed on to all those who need to be aware within your organisation or to any organisation where the potentially affected instruments have been transferred.

Contact reference person:

The undersigned confirms that this notice has been provided to the appropriate Regulatory Agency.

We regret any inconvenience that this action may cause. Please do not hesitate to contact me if you have any questions.

Thank you,

Ernest Ansah
Quality Assurance Manager, Clinical Quality
Waters Corporation
34 Maple Street
Milford, MA 01757
Telephone: +1 508-482-2811
Fax: +1 508-482-2339

**Medical Device
Correction**

REPLY VERIFICATION TRACKING FORM

Re: Waters ACQUITY® TQD, ACQUITY® SQD, LCT Premier™ XE, Quattro Premier™, Quattro Premier™ XE, Quattro™ micro, Xevo® G2 Tof, Xevo® TQ, Xevo® TQD & ZQ 2000 Mass Spectrometers, all serial numbers.

INSTRUCTIONS FOR COMPLETING THIS REPLY VERIFICATION TRACKING FORM:

This completed form is required for tracking purposes. **Please check the applicable boxes, provide the required information and return this form** via Fax or email to:

- (f) Fax Number: (508) 482-2339 or
- (e) E-mail address: waters_quality@waters.com

SECTION TO BE COMPLETED BY CUSTOMER

- We received the notification and the replacement ion block source heater
- The ion block source heater was replaced

Company Name _____

Company Address _____

Contact name: _____ Other: _____

Contact Title: _____

Department: _____ Telephone Number: _____

Signature (required): _____ Date: _____

Email address: _____

Reply Verification Tracking Form Serial Number: _____

Field Action Identification Number 1218959-10-18-2012-006-C



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