



July 15, 2015

**URGENT FIELD SAFETY NOTICE**  
**iChemVELOCITY Automated Urine Chemistry System using iChemVELOCITY Urine**  
**Chemistry Strips REF 800-7204 and 800-7204-001**

To Our iChemVELOCITY Customers:

Iris International is initiating a field safety corrective action for the iChemVELOCITY systems using the strip part numbers 800-7204 and 800-7204-001. This letter contains important information that requires your immediate attention.

<b>ISSUE:</b>	As a result internal investigations following customer complaints, Iris International has determined that the iChemVELOCITY systems do not maintain the on-board strip stability claim of 10 days at 18-28°C at 20-80% relative humidity (RH) as stated in the iChemVELOCITY product labeling.
<b>IMPACT:</b>	The on-board strip stability is affected by temperature and humidity in your laboratory. If your laboratory is operating outside the parameters in Table 1, test results may be affected as indicated below: <ul style="list-style-type: none"><li>• False low or false negative results: Ketone, Blood</li><li>• False high or false positive results: Bilirubin, Urobilinogen, Glucose, Nitrite</li><li>• False high results: Leukocytes</li></ul> Ascorbic Acid, Protein and pH are not affected.
<b>ACTION:</b>	<ul style="list-style-type: none"><li>• Follow the revised on-board strip stability claims per Table 1.</li><li>• Whenever the Strip Provider Module is accessed (<i>i.e.</i>, opened or when loading strips), remove and discard the remaining on-board strips and desiccant before replenishing.</li><li>• Consult with your Laboratory Director to determine whether a retrospective review of results is clinically warranted.</li></ul>
<b>RESOLUTION</b>	Iris International has determined that the Strip Provider Module is not maintaining the humidity levels associated with the original on-board strip stability claim. We are urgently developing a corrective action and will notify you when it is available.

**FSN-15017 -2**

**IRIS International, Inc.**

9172 Eton Avenue  
Chatsworth, CA 91311  
Tel) 818.709.1244  
Tel) 800.776.4747  
Fax) 818.700.9661  
www.proiris.com



The national competent authority has been informed of this field safety corrective action.

Share this information with your laboratory staff and all other relevant personnel. Retain this notification as part of your laboratory Quality System documentation. If you have forwarded any of the affected product(s) listed above to another laboratory, please provide them a copy of this letter.

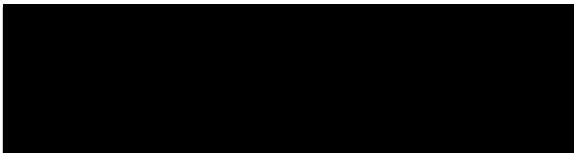
Please complete and return the enclosed Response Form within 10 days so we are assured you have received this important communication.

Beckman Coulter will be managing the logistics of this notice. If you have any questions regarding this notice, please contact:

- From our website: <http://www.beckmancoulter.com>
- Contact your local support Representative.

We apologize for the inconvenience to your laboratory.

Sincerely,



Marwan Fathallah  
Vice President  
Quality and Regulatory Affairs  
Beckman Coulter, Inc.

Enclosure: Response Form

**FSN-15017 -2**



**Table 1**

**On-board Strip Stability at Various Temperature and Humidity Levels**

Temperature °C	Relative Humidity												
	20%	21 - 25%	26 - 30%	31 - 35%	36 - 40%	41 - 45%	46 - 50%	51 - 55%	56 - 60%	61 - 65%	66 - 70%	71 - 75%	76 - 80%
18°	2.5 Days	2.0 Days	2.0 Days	1.5 Days	1.0 Days	1.0 Days	22 Hrs	18 Hrs	15 Hrs	12 Hrs	10 Hrs	10 Hrs	10 Hrs
19°	2.5 Days	2.0 Days	2.0 Days	1.5 Days	1.0 Days	1.0 Days	22 Hrs	17 Hrs	14 Hrs	11 Hrs	10 Hrs	9 Hrs	9 Hrs
20°	2.5 Days	2.0 Days	1.5 Days	1.5 Days	1.0 Days	1.0 Days	21 Hrs	17 Hrs	13 Hrs	11 Hrs	9 Hrs	8 Hrs	8 Hrs
21°	2.5 Days	2.0 Days	1.5 Days	1.5 Days	1.0 Days	1.0 Days	20 Hrs	16 Hrs	13 Hrs	10 Hrs	8 Hrs	8 Hrs	8 Hrs
22°	2.5 Days	2.0 Days	1.5 Days	1.5 Days	1.0 Days	1.0 Days	20 Hrs	15 Hrs	12 Hrs	9 Hrs	8 Hrs	7 Hrs	7 Hrs
23°	2.5 Days	2.0 Days	1.5 Days	1.5 Days	1.0 Days	1.0 Days	19 Hrs	15 Hrs	11 Hrs	9 Hrs	7 Hrs	6 Hrs	6 Hrs
24°	2.5 Days	2.0 Days	1.5 Days	1.5 Days	1.0 Days	1.0 Days	18 Hrs	14 Hrs	11 Hrs	8 Hrs	6 Hrs	6 Hrs	5 Hrs
25°	2.5 Days	2.0 Days	1.5 Days	1.5 Days	1.0 Days	1.0 Days	17 Hrs	13 Hrs	10 Hrs	7 Hrs	6 Hrs	5 Hrs	5 Hrs
26°	2.5 Days	2.0 Days	1.5 Days	1.0 Days	1.0 Days	22 Hrs	17 Hrs	13 Hrs	9 Hrs	7 Hrs	5 Hrs	4 Hrs	4 Hrs
27°	2.5 Days	2.0 Days	1.5 Days	1.0 Days	1.0 Days	21 Hrs	16 Hrs	12 Hrs	9 Hrs	6 Hrs	4 Hrs	4 Hrs	3 Hrs
28°	2.0 Days	2.0 Days	1.5 Days	1.0 Days	1.0 Days	20 Hrs	15 Hrs	11 Hrs	8 Hrs	5 Hrs	4 Hrs	3 Hrs	3 Hrs

Equivalent to 12 Hours

stability claim. To find the on-board strip stability for your laboratory under the specified conditions, follow the steps below:

- Determine the temperature and relative humidity in your laboratory.
- Find the segment or range of segments corresponding to your laboratory's environmental conditions.
- This represents your revised on-board strip stability claim.

As an example, the on-board strip stability for a laboratory operating at 25°C and 35% RH is 1.5 days.



July 15, 2015

**URGENT MEDICAL DEVICE RECALL**  
**iChemVELOCITY Automated Urine Chemistry System using**  
**iChemVELOCITY Urine Chemistry Strips REF 800-7212 and 800-7212-001**

To Our iChemVELOCITY Customers:

Iris International is initiating a field action for the iChemVELOCITY, using strips PN 800-7212 and 800-7212-001. This letter contains important information that requires your immediate attention.

<b>ISSUE:</b>	As a result of internal investigations following customer complaints, Iris International has determined that the iChemVELOCITY systems do not maintain the on-board strip stability claim of 5 days at 18-28°C at 20-80% relative humidity (RH) as stated in the iChemVELOCITY product labeling.
<b>IMPACT:</b>	<p>The on-board strip stability is affected by temperature and humidity in your laboratory. If your laboratory is operating outside the parameters in Table 1, test results may be affected as indicated below:</p> <ul style="list-style-type: none"> <li>• False low or false negative results: Ketone, Blood</li> <li>• False high or false positive results: Bilirubin, Glucose, Leukocytes</li> <li>• False high results: Urobilinogen</li> </ul> <p>Ascorbic Acid, Protein, pH, and Nitrite are not affected.</p>
<b>ACTION:</b>	<ul style="list-style-type: none"> <li>• Follow the revised on-board strip stability claims per Table 1.</li> <li>• Whenever the Strip Provider Module is accessed (<i>i.e.</i>, opened or when loading strips), remove and discard the remaining on-board strips and desiccant before replenishing.</li> <li>• Consult with your Laboratory Director to determine whether a retrospective review of results is clinically warranted.</li> </ul>
<b>RESOLUTION</b>	Iris International has determined that the Strip Provider Module is not maintaining the humidity levels associated with the original on-board strip stability claim. We are urgently developing a corrective action and will notify you when it is available.

**FA-15017-1**

*IRIS International, Inc.*

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[www.proiris.com](http://www.proiris.com)



Share this information with your laboratory staff. Retain this notification as part of your laboratory Quality System documentation. If you have forwarded any of the affected product(s) listed above to another laboratory, please provide them a copy of this letter.

Please complete and return the enclosed Response Form within 10 days so we are assured you have received this important communication.

Beckman Coulter will be managing the logistics of this notice. If you have any questions or concerns regarding this notice, please contact Customer Support:

- Via our website, at <http://www.beckmancoulter.com>
- By phone, call 800-526-7694 in the United States and Canada
- Outside the United States and Canada,

We apologize for the inconvenience to your laboratory.

Sincerely,

[Redacted signature]

[Redacted name]

Enclosure: Response Form

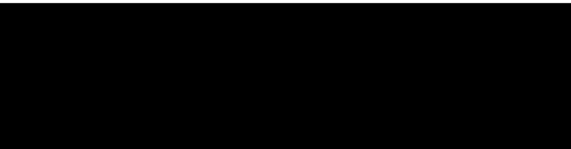
FA 15017-1



**Table 1**

**On-board Strip Stability at Various Temperature and Humidity Levels**

Temperature °C	Relative Humidity												
	20%	21 - 25%	26 - 30%	31 - 35%	36 - 40%	41 - 45%	46 - 50%	51 - 55%	56 - 60%	61 - 65%	66 - 70%	71 - 75%	76 - 80%
18°	5.0 Days	4.0 Days	3.0 Days	2.5 Days	2.5 Days	2.0 Days	2.0 Days	2.0 Days	1.5 Days	1.5 Days	1.5 Days	1.5 Days	1.5 Days
19°	5.0 Days	4.0 Days	3.0 Days	2.5 Days	2.0 Days	2.0 Days	2.0 Days	1.5 Days	1.5 Days	1.5 Days	1.5 Days	1.5 Days	1.5 Days
20°	5.0 Days	4.0 Days	3.0 Days	2.5 Days	2.0 Days	2.0 Days	1.5 Days	1.5 Days	1.5 Days	1.5 Days	1.5 Days	1.0 Days	1.0 Days
21°	5.0 Days	3.5 Days	3.0 Days	2.5 Days	2.0 Days	1.5 Days	1.5 Days	1.5 Days	1.5 Days	1.0 Days	1.0 Days	1.0 Days	1.0 Days
22°	5.0 Days	3.5 Days	2.5 Days	2.0 Days	2.0 Days	1.5 Days	1.5 Days	1.5 Days	1.0 Days	1.0 Days	1.0 Days	1.0 Days	1.0 Days
23°	5.0 Days	3.5 Days	2.5 Days	2.0 Days	2.0 Days	1.5 Days	1.5 Days	1.0 Days	1.0 Days	1.0 Days	1.0 Days	1.0 Days	1.0 Days
24°	5.0 Days	3.5 Days	2.5 Days	2.0 Days	1.5 Days	1.5 Days	1.5 Days	1.0 Days	1.0 Days	1.0 Days	1.0 Days	1.0 Days	1.0 Days
25°	5.0 Days	3.5 Days	2.5 Days	2.0 Days	1.5 Days	1.5 Days	1.0 Days	1.0 Days	1.0 Days	1.0 Days	1.0 Days	1.0 Days	1.0 Days
26°	5.0 Days	3.5 Days	2.5 Days	2.0 Days	1.5 Days	1.5 Days	1.0 Days	1.0 Days	1.0 Days	1.0 Days	1.0 Days	20 Hrs	20 Hrs
27°	4.5 Days	3.0 Days	2.5 Days	2.0 Days	1.5 Days	1.5 Days	1.0 Days	1.0 Days	1.0 Days	1.0 Days	20 Hrs	20 Hrs	20 Hrs
28°	4.5 Days	3.0 Days	2.5 Days	2.0 Days	1.5 Days	1.5 Days	1.0 Days	1.0 Days	1.0 Days	1.0 Days	20 Hrs	20 Hrs	20 Hrs



equivalent to 12 Hours

stability claim. To find the on-board strip stability for your laboratory, follow the steps below:

- Determine the temperature and relative humidity in your laboratory.
- Find the segment or range of segments corresponding to your laboratory's environmental conditions.
- This represents your revised on-board strip stability claim.

As an example, the on-board strip stability for a laboratory operating at 25°C and 35% RH is 2 days.

**FA-15017-1**