INFORME DE SEGURIDAD

DIRECCIÓN DE DISPOSITIVOS MÉDICOS Y OTRAS TECNOLOGÍAS

El INVIMA informa a los usuarios en general que el Grupo de Tecnovigilancia ha emitido una comunicación relacionada con un Informe de Seguridad asociado a:

NOMBRE DEL DISPOSITIVO MÉDICO	Aberrometro Intraoperatorio de Frente de Onda ORA SYSTEM
NO. IDENTIFICACIÓN RISARH	I1708-392
REFERENCIAS DEL DISPOSITIVO MEDICO	Modelos con VerifEye y VerifEye + Cart, seriales específicos.
REGISTRO SANITARIO	2016DM-0014375
INDICACIONES Y USO ESTABLECIDOS	El ORA SYSTEM está destinado para su uso en la medición y análisis del poder refractivo del ojo es decir, medición de la esfera, cilindro y eje.
NOMBRE DEL FABRICANTE	Alcon Research Ltd Alcon Laboratories Inc
DESCRIPCION DEL PROBLEMA	El fabricante ha identificado que las bases de datos de lentes intraoculares (LIO) en los sistemas anteriores pueden devolver mediciones incorrectas de potencia de la LIO durante la cirugía de cataratas, la condición podría conllevar a que se presenten eventos adversos sobre los pacientes.
FUENTE	ANEXO
FECHA DE NOTIFICACION	31 de Agosto de 2017

RECOMENDACIÓN:

En caso de identificar la existencia del producto mencionado anteriormente comuníquese con su proveedor quien determinara las acciones que se llevaran a cabo.

Es importante mantener un estado de alerta, realizando un seguimiento permanente a los productos que se fabrican y/o comercializan en el país, divulgando la información de seguridad respectiva entre los profesionales de la salud que realizan uso de estos recursos tecnológicos.

Para mayor información comuníquese al teléfono 2948700 extensión 3880 en Bogotá, ó al correo electrónico tecnovigilancia@invima.gov.co

INFORME DE SEGURIDAD

DIRECCIÓN DE DISPOSITIVOS MÉDICOS Y OTRAS TECNOLOGÍAS

ANEXO

[High Priority] - A29100 01 : Alcon—ORA System 2000 Intraoperative Wavefront Aberrometers: May Return Incorrect Intraocular Lens Power Measurements during Cataract Surgery
Medical Device Ongoing Action

Published: Wednesday, August 23, 2017
Last Updated: Wednesday, August 30, 2017

UMDNS Terms:

- Aberrometers [24553]

Product Identifier:

ORA System Aberrometers:	Catalog Nos.:	Serial Nos.:
		C0002, C2006, C2020, C2026, C2054, C3009R, C3010R, C3024, C3036, C3066, C3067, C3085R, C3090, C3093, C3108, C3136, C3153, C4001, C4003, C4005, C4006, C4007, C4009, C4010, C4011, C4012, C4013, C4014, C4015, C4016, C4017, C4019, C4020, C4021, C4022, C4023, C4024, C4025, C4026, C4027, C4028, C4029, C4030, C4031, C4035, C4036, C4037, C4038, C4039, C4040, C4043, C4045, C4046R, C4047R, C4049R, C4050R, C4052R, C4053R, C4054R, C4055R, C4056R, C4057R, C4058R, C4059R, C4060R, C4061R, C4062R, C4065R, C4066R, C4067R, C4068R, C4069R, C4070R, C4071R, C4072R, C4073R, C4074R, C4075R, C4076R, C4077R, C4078R, C4079R, C4080R, C4083R, C4085R, C4086R, C4087R, C4088R, C4089R, C4090R, C4091R, C4092R, C4093R, C4094R, C4095R, C4096R, C4097R, C4098R, C4099R, C4100R, C4101R, C4102R, C4103R, C4104R, C4105R, C4106R, C4107R, C4108R, C4109R, C4110R, C4111R, C4112R, C4113R, C4115R, C4117R, C4118R, C4119R, C4120R, C4121R, C4122R, C4123R, C4124R, C4126R, C4127R, C4128R, C4129R, C4130R, C4132R, C4133R, C4134R, C4135R, C4136R,
With VerifEye	806599 8300	C4138R, C4140, C4142, C4143, C4144, C4145, C4146, C4147, C4148, C4149, C4150, C4151, C4152R, C4153, C4154, C4155, C4156, C4157R, C4158, C4159, C4160R, C4161R, C4162R, C4163R, C4164R, C4165R, C4166R, C4167R, C4168R, C4169R, C4170R, C4173R, C4174R, C4175, C4177R, C4178R, C4179R, C4180R, C4181R, C4182R, C4183R, C4184R, C4185R, C4186R, C4187R, C4188R, C4189R, C4190R, C4191R, C4192R, C4193R, C4195R, C4196R, C4197R, C4198, C4199R, C4200R, C4201, C4202R, C4203R, C4204R, C4205R, C4206R, C4207R, C4208R, C4209R, C4210R, C4211R, C4212R, C4213R, C4214R, C4215R, C4216R, C4217R, C4218R, C4219R, C4220R, C4221R, C4222R, C4223R, C4224R, C4225R, C4226R, C4227R, C4228R, C4229R, C4230R, C4231R, C4232R, C4233R, C4234R, C4235R, C4238R, C4239R, C4240R, C4241R, C4242R, C4243R, C4244R, C4245R, C4246R, C4247R, C4248R, C4249R, C4251R, C4252R, C4253R, C4254R, C4255R, C4256R, C4257R, C4258R, C4259R, C4260R, C4261R, C4262R, C4264R, C4266R, C4267R, C4268R, C4269R, C4271R, C4272R, C4273R, C4274R, C4275R, C4276R, C4278R, C4279R, C4280R, C4283R, C4284R, C4285R,

INFORME DE SEGURIDAD

DIRECCIÓN DE DISPOSITIVOS MÉDICOS Y OTRAS TECNOLOGÍAS

		C4286R, C4287R, C4288R, C4289R, C4290R, C4291R, C4292R, C4293R, C4294R, C4295R, C4296R, C4297R, C4298R, C4299R, C4300R, C4301R, C4302R, C4303R, C4304R, C4305R, C4306R, C4307R, C4308R, C4309R, C4310R, C4311R, C4312R, C4315R, C4316R, C4317R, C4318R, C4319R, C4320R, C4321R, C4323R, C4324R, C4326R, C4327R, C4328R, C4331R, C4332R, C4334R, C4337R, C4339R, C4340R, C4341R, C4342R, C4343R, C4344R, C4345R, C4346R, C4347R, C4348R, C4349R, C4352R, C4354R, C4355R, C4356R, C4357R, C4358R, C4359R, C4360R, C4361R, C4363R, C4364R, C4365R, C4366R, C4367R, C4368R, C4371R, C4372R, C4373R, C4374R, C4376R, C4377R, C4378R, C4379R, C4380R, C4381R, C4382R, C4383R, C4384R, C4385R, C4387R, C4388R, C4389R, C4394, C4396, C4397, C4399, C4406R, C4407R, C4408R, C4415, C4418, C4420, C4421, C4422, C4423, C4424, C4425, C4426
With VerifEye + Cart	806599 8307	C5013, C5014, C5015, C5016, C5017, C5018, C5019, C5020, C5021, C5023, C5024, C5025, C5026, C5027, C5028, C5029, C5030, C5031, C5032, C5033, C5034, C5035, C5036, C5038, C5039, C5040, C5041, C5042, C5043, C5044, C5045, C5046, C5047, C5048, C5049, C5050, C5051, C5053, C5054, C5055, C5059, C5060, C5061, C5062, C5064, C5065, C5066, C5069, C5071, C5075, C5076, C5077, C5078, C5079, C5080, C5081, C5082, C5083, C5090, C5093, C5094, C5097, C5098, C5101, C5102, C5105, C5106, C5107, C5108, C5109, C5110, C5111, C5112, C5113, C5116, C5117, C5119, C5120, C5121, C5122, C5125, C5126, C5127, C5128, C5129, C5130, C5131, C5132, C5133, C5134, C5136, C5137, C5138, C5139, C5140, C5141, C5142, C5143, C5144, C5146, C5147, C5148, C5149, C5150, C5151, C5152, C5153, C5154, C5155, C5156, C5157, C5158, C5159, C5160, C5161, C5163, C5164, C5165, C5166, C5167, C5168, C5169, C5170, C5171, C5173, C5174, C5175, C5176, C5177, C5178, C5179, C5180, C5181, C5182, C5183, C5184, C5185, C5186, C5187, C5188, C5189, C5190, C5191, C5192, C5193, C5194, C5195, C5196, C5197, C5198, C5199, C5200, C5201, C5202, C5203, C5204, C5205, C5207, C5214, C5215, C5216, C5217, C5218, C5219, C5220, C5221, C5222, C5223, C5224, C5225, C5226, C5227, C5228, C5229, C5230, C5231, C5232, C5233, C5238, C5239, C5240, C5241, C5242, C5243, C5244, C5245, C5246, C5248, C5249, C5250, C5251, C5252, C5253, C5255, C5256, C5257, C5258, C5259, C5260, C5261, C5262, C5263, C5264, C5265, C5266, C5267, C5268, C5269, C5270, C5271, C5272, C5273, C5274, C5276, C5277, C5278, C5279, C5280, C5281, C5282, C5283, C5284, C5285, C5286, C5287, C5288, C5289, C5290, C5291, C5292, C5293, C5294, C5295, C5296, C5297, C5298, C5299, C5300, C5301, C5302, C5303, C5304, C5305, C5306, C5307, C5308, C5309, C5310, C5311, C5312, C5313, C5314, C5315, C5316, C5317, C5318, C5319, C5320, C5321, C5322, C5323, C5326, C5328, C5329, C5330, C5334, C5335, C5336, C5339, C5340, C5341, C5343, C5348, C5349, C5350,

INFORME DE SEGURIDAD
DIRECCIÓN DE DISPOSITIVOS MÉDICOS Y OTRAS TECNOLOGÍAS

C5352, C5353, C5354, C5355, C5356,
C5357, C5358, C5359, C5360, C5361,
C5362, C5363, C5364, C5365, C5366,
C5368, C5369, C5370, C5371, C5372,
C5373, C5374, C5375, C5376, C5377,
C5378, C5379, C5380, C5381, C5382,
C5383, C5384, C5385, C5386, C5387,
C5388, C5389, C5390, C5391, C5392,
C5393, C5394, C5395, C5396, C5397,
C5398, C5399, C5400, C5401, C5402,
C5403, C5404, C5405, C5406, C5407,
C5408, C5409, C5410, C5411, C5412,
C5413, C5414, C5415, C5416, C5417,
C5418, C5434, C5435, C5436, C5437,
C5438, C5439, C5440, C5441, C5442,
C5443, C5444, C5446, C5448, C5449,
C5451, C5452, C5453, C5454, C5456,
C5458, C5462, C5463, C5464, C5465,
C5466, C5467, C5469, C5471, C5473,
C5475, C5476, C5477, C5478, C5479,
C5484, C5485, C5486, C5487, C5488,
C5489, C5490, C5493, C5494, C5495,
C5496, C5497, C5499, C5500, C5501,
C5502, C5503, C5507, C5508, C5509,
C5510, C5511, C5512, C5515, C5516,
C5517, C5518, C5519, C5520, C5521,
C5522, C5524, C5525, C5526, C5527,
C5528, C5529, C5530, C5532, C5533,
C5534, C5535, C5536, C5537, C5538,
C5539, C5544, C5545, C5546, C5547,
C5549, C5550, C5553, C5555

[Capital Equipment]
Previous Product Listing: Alert A29100

Geographic Regions: (Impact in additional regions has not been identified or ruled out at the time of this posting), Argentina, Australia, Belgium, Brazil, Canada, China, Colombia, France, India, Japan, Mexico, The Netherlands, Panama, Portugal, Romania, Spain, Thailand, United Arab Emirates, U.K., U.S.

Manufacturer(s): Alcon Laboratories Inc6201 South Frwy, Fort Worth, TX 76134-2099, United States

Suggested Distribution: Clinical/Biomedical Engineering, OR/Surgery, Information Technology, Ophthalmology

Summary:
This Alert provides new information based on FDA Center for Devices and Radiological Health (CDRH) source material regarding Alert A29100 . FDA's CDRH states that the manufacturer initiated action by telephone call on June 30, 2017. New information is provided in the Product Identifier and Geographic Regions fields.
Problem: Health Canada states that the intraocular lens (IOL) databases in the above systems may return incorrect IOL power measurements during cataract surgery. Health Canada also states that the manufacturer initiated a recall on July 14, 2017. The manufacturer has not confirmed the information provided in the source material.

Action Needed:
Identify any affected systems in your inventory. If you have affected systems, verify that you have been contacted by Alcon.
For Further Information:
Alcon
Website: Click here

References:
Health Canada. Recalls and safety alerts. Ora System 2000 intraopertive [*sic*] wavefront aberrometer [online]. 2017 Aug 14 [cited 2017 Aug 17]. Available from Internet: Click here .
United States:

- Food and Drug Administration. Center for Devices and Radiological Health. Class 2 device recall ORA System with VerifEye [online]. 2017 Aug 21 [cited 2017 Aug 22]. Available from Internet: Click here .
- Food and Drug Administration. Center for Devices and Radiological Health. Class 2 device recall ORA System with VerifEye [online]. 2017 Aug 21 [cited 2017 Aug 22]. Available from Internet: Click here .

Comments:

- This alert is a living document and may be updated when ECRI Institute receives additional information. In circumstances in which we determine that it is appropriate for customers to repeat their review of an issue (e.g., when additional affected product has been identified), we will post a separate update alert. In other cases, we may add information, such as additional commentary, recommendations, and/or source documents, to the original alert. For additional information regarding the format of this alert, refer to our HDA Format Guide .

Source(s):

- 2017 Aug 23. FDA CDRH Database. Class II. Z-3049-2017, Z-3050-2017 Download
- 2017 Aug 28. BfArM (Germany). 07532/17 Download