

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	Transductores para Ultrasonido
NO. IDENTIFICACIÓN RISARH	I1404-148
REFERENCIAS DEL DISPOSITIVO MEDICO	PA230 - 10852384
REGISTRO SANITARIO	2008DM-0001867
INDICACIONES Y USO ESTABLECIDOS	Sistema de ultrasonido para aplicaciones de: abdomen, intraoperatorio, obstetricia y ginecología, pelvis, mama, ortopedia, urología, pequeñas partes, transcraneal, musculo esquelético, vascular, vascular periférico, cardiología, intracardiaca y transesofagia para pacientes neonatales, pediátricos y adultos.
NOMBRE DEL FABRICANTE	Siemens Medical Solutions Usa, Inc.
DESCRIPCION DEL PROBLEMA	El fabricante informa que el uso del transductor con una configuración definida por el usuario que incluya el ajuste del 100% para la salida de alimentación puede causar que la temperatura de la superficie del transductor supere el máximo límite permisible, incrementando potencialmente el riesgo de quemadura de paciente, conllevando a que se presenten eventos adversos sobre el paciente.
FUENTE	ANEXO 1 (Ver seriales específicos afectados)
FECHA DE NOTIFICACION	15 de Abril de 2014

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

ANEXO 1

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A22090 01 - High Priority Medical Device Alert

Medical Device

Ongoing Action

Updated: April 9, 2014

UMDNS Terms:

- Scanning Systems, Ultrasonic, Obstetric/Gynecologic [15657]
- Transducers, Ultrasonic [14121]

Suggested Distribution:

- Clinical/Biomedical Engineering
- Diagnostic Imaging
- Obstetrics/Gynecology /Labor and Delivery

Geographic Regions:

- Australia
- Austria
- Belgium
- Bhutan
- Bolivia
- Botswana
- Bulgaria
- Canada
- Chile
- Colombia
- Congo
- Croatia
- Denmark
- Ecuador
- France
- Germany
- Greece
- India
- Indonesia
- Ireland
- Israel
- Italy
- Ivory Coast
- Japan
- Korea
- Kuwait
- Malaysia
- Mauritius
- Mongolia
- Morocco
- Mozambique
- Myanmar
- Namibia
- The Netherlands
- Norway
- Peru
- The Philippines
- Poland
- Portugal
- Romania
- Saudi Arabia
- Serbia
- Seychelles
- Singapore
- South Africa
- Spain

Siemens—PA230 Transducers Used with ACUSON P300 Ultrasound Systems: Surface Temperature May Exceed Maximum Allowable Limit

Product Identifier:

PA230 Transducers used with ACUSON P300 Ultrasound Systems [Capital Equipment]

ACUSON Model No. 10433816; Transducer Model No. 10852384; Transducer Serial Nos.: 105, 106, 114, 116, 117, 118, 119, 120, 121, 122, 123, 124, 125, 126, 127, 128, 129, 130, 131, 132, 133, 134, 135, 136, 137, 138, 139, 140, 141, 142, 143, 144, 145, 146, 148, 149, 150, 152, 153, 154, 155, 156, 157, 158, 159, 160, 161, 162, 163, 164, 165, 166, 167, 168, 169, 170, 171, 172, 173, 174, 175, 176, 178, 186, 187, 188, 189, 193, 194, 197, 198, 199, 200, 201, 202, 203, 204, 205, 206, 207, 208, 209, 210, 211, 212, 213, 214, 215, 216, 217, 218, 219, 220, 221, 222, 223, 224, 225, 226, 227, 229, 230, 231, 232, 233, 234, 235, 236, 237, 238, 239, 240, 241, 242, 243, 244, 245, 246, 247, 248, 249, 250, 251, 252, 253, 254, 257, 258, 259, 260, 262, 263, 264, 265, 266, 267, 268, 269, 270, 271, 272, 273, 274, 275, 276, 277, 278, 279, 280, 281, 282, 283, 284, 285, 286, 287, 288, 289, 290, 291, 292, 293, 294, 295, 296, 297, 298, 299, 300, 301, 302, 303, 304, 305, 306, 307, 308, 309, 310, 311, 312, 313, 314, 315, 316, 317, 318, 319, 320, 321, 322, 323, 324, 325, 330, 331, 334, 336, 337, 339, 340, 341, 342, 343, 344, 345, 347, 348, 349, 350, 351, 352, 353, 354, 355, 356, 357, 358, 359, 360, 361, 362, 363, 364, 365, 366, 367, 368, 369, 371, 373, 374, 375, 377, 378, 379, 380, 382, 383, 384, 385, 386, 387, 388, 389, 390, 391, 392, 393, 394, 395, 396, 400, 401, 402, 403, 404, 405, 406, 407, 408, 409, 410, 411, 412, 413, 414, 415, 416, 417, 418, 421, 422, 423, 424, 425, 426, 427, 428, 429, 430, 431, 432, 433, 434, 435, 436, 437, 438, 439, 440, 441, 442, 443, 444, 445, 446, 447, 448, 449, 450, 451, 452, 453, 454, 455, 456, 457, 458, 459, 460, 461, 462, 463, 464, 465, 466, 467, 468, 469, 470, 471, 472, 475, 476, 477, 478, 479, 480, 481, 482, 483, 484, 485, 486, 487, 488, 489, 490, 491, 492, 493, 494, 495, 496, 497, 498, 501, 506, 507, 508, 509, 510, 511, 512, 513, 515, 516, 518, 519, 520, 521, 522, 526, 527, 529, 530, 535, 536, 537, 538, 539, 540, 541, 542, 544, 545, 546, 547, 548, 549, 550, 551, 552, 553, 554, 555, 556, 557, 558, 559, 560, 561, 562, 563, 564, 565, 566, 567, 568, 569, 596, 597, 598, 601, 602, 603, 604, 605, 606, 607, 608, 610, 614, 615, 616, 617, 618, 619, 620, 621, 622, 624, 627, 628, 629, 630, 633, 634, 635, 636, 637, 638, 639, 640, 641, 642, 643, 644, 646, 647, 648, 650, 651, 652, 653, 654, 655, 656, 657, 659, 660, 661, 662, 663, 664, 665, 666, 667, 668, 669, 670, 671, 672, 674, 675, 676, 678, 679, 680, 681, 682, 683, 684, 685, 686, 687, 689, 693, 694, 696, 697, 698, 699, 704, 706, 707, 709, 710, 711, 712, 713, 718, 719, 720, 721, 722, 723, 724, 725, 727, 728, 729, 730, 731, 732, 733, 734, 737, 739, 743, 745, 746, 747, 748, 749, 750, 751, 752, 753, 754, 755, 757, 758, 759, 760, 761, 762, 763, 764, 765, 766, 767, 768, 769, 770, 771, 772, 773, 775, 776, 777, 778, 779, 782, 783, 784, 785, 791, 792, 793, 794, 795, 796, 797, 798, 800, 801, 806, 807, 808, 810, 811, 812, 814, 815, 816, 817, 818, 819, 821, 822, 823, 824, 825, 826, 827, 828, 829, 830, 832, 834, 835, 836, 837, 838, 839, 840, 841, 842, 843, 845, 847, 848, 853, 854, 855, 856, 857, 858, 860, 861, 862, 863, 864, 865, 866, 872, 879, 881, 890, 892, 893, 894, 895, 896, 897, 898, 900, 901, 902, 903, 904, 909, 910, 911, 912, 913, 914, 919, 920, 929, 933, 934, 935, 936, 937, 938, 939, 940, 941, 942, 943, 944, 945, 946, 947, 948, 949, 950, 951, 952, 957, 958, 959, 960, 961, 962, 963, 964, 965, 967, 969, 970, 972, 973, 974, 975, 976, 977, 979, 980, 981, 985, 986

Manufacturer:

- Siemens Medical Solutions USA Inc1230 Shorebird Way, Mountain View, CA 94043-7393, United States

Summary:

This Alert provides additional information based on FDA Center for Devices and Radiological Health (CDRH) source material regarding [Alert Accession No. A22090](#). FDA's CDRH states that the manufacturer initiated a recall by Customer Safety Advisory Notification on March 7, 2014. Additional information is provided in the following fields:

- Product Identifier (see bolded information)
- Geographic Regions (see bolded regions)

- Switzerland
- Taiwan
- Trinidad and Tobago
- Turkey
- U.K.
- United Arab Emirates
- U.S.

Problem:

[April 2, 2014]

In a Customer Safety Advisory Notification letter posted by the U.K. Medicines and Healthcare Products Regulatory Agency (MHRA), Siemens states that using the above transducer with a user-defined preset that includes the 100% setting for output power may cause the transducer surface temperature to exceed the maximum allowable limit, potentially increasing the risk of patient burn. The manufacturer has not confirmed the information in the source material.

Action Needed:

The following actions are those listed in Alert Accession No. A22090. Identify any affected product in your inventory. If you have affected product, verify that you have received the Customer Safety Advisory Notification letter from Siemens. Siemens recommends that you only utilize the factory-defined presets for imaging with the above transducers. A Siemens service engineer will contact your facility to schedule for product repairs and software upgrade. Notify all relevant personnel at your facility of the information in the letter.

For Further Information:

Siemens

Website: [Click here](#)

References:

- Great Britain. Medicines and Healthcare Products Regulatory Agency. Siemens Medical Solutions Inc (Ultrasound division). Ultrasound, imaging ultrasound unit. ACUSON P300™ ultrasound system. 10852646 [online]. London: Department of Health; 2014 Mar 31 [cited 2014 Apr 1]. (Field safety notice; reference no. 2014/003/026/081/010). Available from Internet: [Click here](#).
- United States. Food and Drug Administration. Center for Devices and Radiological Health. Class 2 device recall ACUSON P300 ultrasound system with P300 PA 230E cardiac probe [online]. 2014 Apr 3 [cited 2014 Apr 4]. Available from Internet: [Click here](#).

Comment:

- 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):

- 2014 Apr 4. FDA CDRH Database. Class II. Z-1331-2014
- 2014 Apr 2. MHRA FSN. 2014/003/026/081/010
- 2014 Apr 22. MHRA FSN.