



November 8, 2021

*Via Electronic Delivery*

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Mr. Matthew S. Borman

Deputy Assistant Secretary for Export Administration

Bureau of Industry and Security

Office of Technology Evaluation

U.S. Department of Commerce

Docket Number: BIS 2021–0036 or RIN 0694– XC084

Dear Mr. Borman,

FUJIFILM SonoSite, Inc. (SonoSite) appreciates the opportunity to provide comments on the above referenced U.S. Department of Commerce Request for Information (RFI) regarding the ongoing shortages in the semiconductor product supply chain and the adverse impact this shortage is having on the manufacturing of medical imaging devices, specifically portable ultrasound systems.

As a manufacturer of high quality, portable ultrasound systems with its headquarters and manufacturing facility both located in Bothell, Washington, SonoSite’s ultrasound systems provide complete diagnostic ultrasound studies and are optimized for use at the point of care. SonoSite’s products are used across the global in physician offices and hospital inpatient, outpatient, and emergency room settings to provide a wide variety of diagnostic and guidance ultrasound services.

As our Nation and countries all around the world continue their fight against the COVID-19 epidemic, ultrasound used at the point of care has been a critical piece of medical equipment in caring for critically ill COVID-19 patients. The condition of a patient with COVID-19 can deteriorate rapidly. Ultrasound systems that are available at a patient’s bedside allows for the real-time, serial evaluation of lung and cardiac condition of COVID 19 patient allowing for optimal care planning and management. All SonoSite systems have clearance from the Food and Drug Administration (FDA) for an indication of COVID-19.

Use of ultrasound has also been at the forefront of fighting the opioid epidemic as well. Alternatives to the use of opioids and sedation, ultrasound-guided nerve-blocks and injections at the point of care, provide higher quality care through better pain management without the addiction risk that opioid prescriptions have. The increase in demand by healthcare providers for ultrasound systems to address these epidemics, especially the COVID-19 global public health emergency, has created greater need for semiconductor chips at a time when there are also supply chain challenges due to this same epidemic.

Again, SonoSite appreciate the opportunity to provide its perspective as an end users of semiconductor products or integrated circuits on RFI, BIS 2021-0336, and we look forward to working with the Department of Commerce to address the immediate shortages of semiconductors/chips for medical devices, but also the systemic challenges to increase overall chip production for future demand by medical devices manufacturers.

**Our responses to the RFI questions are as follows:**

1. **Identify your type of business and the types of products you sell**

FUJIFILM SonoSite, Inc. (SonoSite) is a medical device company that designs and manufacturers portable ultrasound machines in Bothell, Washington.

SonoSite began when the United States Department of Defense awarded a DARPA1 grant to SonoSite’s parent company, ATL Ultrasound. The mission from the government was clear: Create an ultrasound machine portable and rugged enough to be carried into battle and brought to a trauma patient's side. It took over a decade of expertise in leveraging digital ultrasound and integrated circuit technology to complete the project, but the result was SonoSite’s first[point-of-care ultrasound](https://www.sonosite.com/about/what-pocus-point-care-ultrasound) machine—the SonoSite 180.

1. **What are the (general) applications for the semiconductor products and integrated circuits that you purchase?**

The semiconductor products and integrated circuits that SonoSite purchases are used in the manufacturing of point-of-care ultrasound systems and medical informatics solutions along with [transducers](https://www.sonosite.com/products/transducers)and [accessories](https://www.sonosite.com/products/accessories)that can help healthcare providers improve time-to-diagnosis, patient outcomes, procedural efficiency, and workflow.

1. **For the semiconductor products that your organization purchases, identify those that present the greatest challenge for your organization to acquire. Then for each product, identify the product attributes and purchases in 2019 and 2021, as well as average monthly orders in 2021. Then estimate the quantity of each product your organization would purchase in the next six months barring any production constraints as well as the amount your organization expects to be able to purchase. For each of your organization’s top semiconductor products, estimate each product’s lead times and your organization’s inventory for (a) 2019 and (b) currently (in days). Provide an explanation of any current delays or bottlenecks.**

Lead-times have been growing due to capacity constraints at semiconductor producers. SonoSite has prepared the information requested in Question C. and would be happy to meet with the Department of Commerce to discuss the specifics.

1. **What are the primary disruptions or bottlenecks that have affected your ability to provide products to customers in the last year?**

SonoSite has experienced several primary disruptions or bottlenecks regarding chips that have impacted timeframe that SonoSite has been able to provide ultrasound systems to hospitals and physician practices. This is distressing given the continued impact of COVID 19 on the healthcare system. The primary disruptions are decommits, cancelations, quantity reductions, allocations and lead-time extensions with no notice causing an inability to plan for the gap in chip supplies for manufacturing.

1. **Is your organization limiting production due to lack of available semiconductors? Please explain.**

SonoSite has had to limit production due to a lack of available semiconductors. SonoSite has been unable to meet productions demands and customer orders in a timely manner. We have a backlog of ultrasound system orders to hospitals due to a lack of semiconductors and chips that we cannot effectively deliver. SonoSite has had to extend its lead-times for ultrasound system deliver from our previous lead-times and have many past-due orders versus our hospital and physician office requirement dates.

1. **What percentage of your current production has your organization had to defer, delay, reject, or suspend in the past year? Explain.**

In SonoSite’s current fiscal year ending March 31, 2022, our production of ultrasound machines is behind customer demand and this delay in order fulfillment is growing. This is growth in delays is due to supply chain shortages, predominately chips.

1. **Is your organization considering or carrying out new investments to mitigate semiconductor sourcing difficulties? Explain.**

SonoSite has spent extra money to secure parts from the “broker market” and we are now also committing additional resources to help our circuit board supplier’s cash flow to allow them to continue to secure parts, including chips. Typically, money we spend with these suppliers for chips and circuit board components would allow them a normalized cash flow to meet our demands. However, due to their lack of supply based on an inability to work due to COVID lockdowns in Malaysia and Taiwan, these companies now lack their normally generated cash flow. Therefore, we are having to provide them with some advanced, “cash flow,” so they can secure parts that they need to meet our demand and stay in business.

SonoSite has also committed three of our supply chain employees to assist our circuit board suppliers in Malaysia in sourcing and securing materials on SonoSite’s behalf and we have invested several engineers and test capabilities to qualify alternative components with the FDA in order to keep production going. Due to COVID restrictions in Malaysia we are having to accomplish all of this remotely versus working on site with these overseas suppliers.

1. **What semiconductor product types are most in short supply and by what estimated percentage relative to your demand? What is your view of the root cause?**

FPGAs and custom logic parts that run on 300mm, 28-30NM nodes have been the biggest issue regarding short supply, as well as older power chips coming from 200MM fabs that are also used in automotive applications. In both cases, it has been a capacity issue. Older 200MM chips have been impacted by huge demand from the automotive space, while the supply of new chips has been gated specifically by output from TSMC for several suppliers in our supply chain.

The root causes of this short supply have been the relative volume of medical products versus larger sectors like automotive, and the supplier of chips reacting to general business laws of supply and demand and how that impacts pricing and revenue. Also, medical imaging devices are regulated by the Food and Drug Administration (FDA) and are subject to the additional time and research required to change components in an FDA approved medical device. This is not the cases for other electronic devices which can change their chips without testing and government approval.

1. **Has your organization changed its material and/or equipment purchasing levels or practices in the past three years?**

Specifically in the last year, SonoSite has extended purchase lead-times for chips and circuit boards and committed with suppliers for component with much longer lead-times. “Just in time” is no longer a supply chain philosophy that can work as the demand for products throughout the COVID-19 Public Health Emergency (PHE) has far exceeded any increased capacity for inventory of ultrasound systems/ safety stock plans SonoSite had available or planned for. We are also having to order from sources that were previously not approved by the FDA (specifically the broker market) at much higher cost to be able to manufacture our ultrasound machines here in the United States.

1. **What single change (and to which portion of the supply chain) would most significantly increase your ability to purchase semiconductors in the next six months?**

The single change needed to significantly increase SonoSite’s ability to purchase chips in the next six months is for the United States to support increases in Fab capacity, both in the United States and with our allied overseas trading partners, specifically in the older technology chip nodes. Current investments being made in places like Arizona (TSMC fabs) are targeting leading edge technology nodes that will not be helpful to general electronics manufacturing or medical device manufacturing for at least 10 years.

SonoSite and the medical device industry in general, needs the Department of Commerce to work on incentives that guarantee cash flow for smaller chip manufacturers and distributors or manage the “gates,” that TSMC is putting in regarding volumes of chips per suppliers to support a more consistent level of chip availability. These actions by the Department of Commerce would help companies such as SonoSite have a more predictable timeline for the supply of chip. This would allow us to plan our manufacturing accordingly to meet our hospital and physician office practice demand in a timely manner.

1. **What percentage of your orders are fulfilled by distributors versus through direct purchase orders to semiconductor product manufacturers?**

SonoSite procures the majority of its chips through distributors. The reason for this is the inherent lower volume of medical devices being manufactured versus the number of consumer electronics being manufactured. The volume of chips needed for medical devices and for a single company simply aren’t high enough for most chip makers to handle directly.

1. **For the semiconductor products your organization purchases, how long (in months) are the typical purchase commitments? How, if at all, do your organization’s purchase commitments differ for products in short supply?**

Prior to this current chip shortage, lead-times for SonoSite to procure chips for use in manufacturing its ultrasound systems ranged from 2-12 weeks. Today, most of our component suppliers are quoting lead-times of at least 26 weeks or longer. Several key medical device components are now at lead-times of 60 weeks. One of our key ultrasound system components is on “hard allocation” meaning even orders placed out a year in advance are not confirmed that they will happen until the quarter before the shipment of the component.

1. **Has your organization faced ‘‘decommits’’ (defined as a notification from a supplier that expected or committed supply will not be delivered in the agreed-upon time and quantity) in recent months? If this is a significant issue, please explain (e.g., nature of product, supplier, impact).**

For medical devices that use chips, like ultrasound systems, decommits are now a routine part of supply chain and its challenges. For SonoSite, decommits for chips is happening on a weekly basis. We understand for the medical device industry, decommits are now happening and almost daily across the chip supply chain and have been for over 3 months, now.

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SonoSite appreciates the opportunity to respond to this Department of Commerce RFI and we would be happy to meet with you and your staff to discuss the supply shortage issues regarding chips, further. We have also enclosed a copy of a recent article in the Wall Street Journal where SonoSite discussed the current supply chain shortages for chips and its impact. Please do not hesitate to contact me at 1-425-951-1275 or email at [Richard.Fabian@fujifilm.com](mailto:Richard.Fabian@fujifilm.com) with questions or additional information.

Sincerely,



Richard Fabian

President and Chief Operating Officer

**Pacemaker, Ultrasound Companies Seek Priority Amid Chip Shortage**

Medical device makers highlight life-saving products to secure supply: ‘Every single chip you give me gives the gift of breath to a person suffocating’

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An Infineon Technologies computer chip factory. Chips are key components for a range of vital medical devices.

PHOTO: AKOS STILLER/BLOOMBERG NEWS

*By*

Denise Roland

Oct. 3, 2021 7:00 am ET

In the race to secure computer chips amid a global shortage, medical device makers say they have found their ace card: their products save lives.

While only a tiny fraction of the world’s chips end up in medical equipment compared with cars and consumer electronics, the components are key to a range of vital devices like MRI machines, pacemakers and blood-sugar monitors for diabetes. To win priority over larger buyers, medical device makers say their most effective tactic is to raise awareness with executives at chip suppliers.

“Nobody wants to be the person who shuts down critical medical devices in the middle of Covid,” said Mike Arena, vice president of operations for Fujifilm SonoSite, which makes portable ultrasound machines. “When we get to a CEO or senior VP they very much want to help.”

A global [supply crunch for computer chips](https://www.wsj.com/articles/why-the-chip-shortage-is-so-hard-to-overcome-11618844905?mod=article_inline), fueled by soaring demand for electronics as the pandemic expanded home working, has disrupted car production and pushed up the prices of laptops and printers. Medical device makers are also feeling the pinch. In a recent survey of medical technology companies by Deloitte, commissioned by industry group AdvaMed, every respondent reported supply issues. The most commonly cited problems were delays, cutbacks and cancellations.

“Week to week we’re going through different shortages,” said Mr. Arena, adding that his company recently paid a broker $65 apiece for a part that usually costs $1.49 because it was in such short supply, for an order of 3,000 pieces.

For Fujifilm SonoSite, a U.S.-based subsidiary of the Japanese tech giant, chip shortages have been exacerbated by rising demand for its products amid the spread of the Delta variant. Portable ultrasound machines are used in emergency rooms and intensive-care units to diagnose respiratory illnesses. “Right now we have more demand than we can get material to satisfy,” said Mr. Arena.

Medical device makers are desirable customers for chip suppliers. They are resilient during recessions, and because their products are heavily regulated they aren’t updated as frequently as consumer electronics, meaning they generate reliable business. Medical device makers also typically pay a little more than companies in other sectors because of the quality they require.

But for all those strengths, the medical technology sector is tiny compared with the giant automotive and consumer electronics industries. In 2020, total medical semiconductor revenue was $5 billion, just 1.1% of the overall chip market, according to Omdia, a technology data company.A picture containing person, hospital room, room

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Tending to a patient on a ventilator. In a recent survey of medical technology companies, every respondent reported supply issues.

PHOTO: JON CHERRY/GETTY IMAGES

“We’re competing for parts against companies that are doing hundreds of millions of dollars worth of revenue,” said Fujifilm SonoSite’s Mr. Arena. “Here we are somebody who represents $50,000-$100,000 a year. It’s very hard to get on their radar.”

To secure supplies, medical device makers are appealing to suppliers’ sense of higher duty. When a supplier recently told Fujifilm SonoSite that an order of 9,000 chips would arrive more than 60 days later than planned, Mr. Arena quickly tracked down the chief executive officer using LinkedIn. Guessing their email address, he wrote the CEO to let them know that the chips were intended for medical equipment. In response, the supplier reallocated chips from other customers, and 9,000 semiconductors arrived in three separate shipments over the following two weeks.

“What I’m asking them is to take some components from your higher-revenue customers and give some to me so you can do something good for the world,” said Mr. Arena. It helps that the volume of chips he is asking for would barely make a dent in an auto maker’s allocation, he added.

[Boston Scientific](https://www.wsj.com/market-data/quotes/BSX) Corp. , one of the world’s biggest medical technology companies, has also persuaded suppliers to give it priority on the basis that its products improve people’s health, according to Brad Sorenson, its senior vice president of supply chain.

“One of the biggest levers we have is that relationship,” he said. “What we do for patients and to make sure they understand that.”

That message has helped Boston Scientific secure supply as typical lead times for components quintupled from three to 15 months. The company has also embedded its own manufacturing engineers at some key suppliers to speed production and keep lines of communication open. So far it has kept up with demand for its products, which include pacemakers and brain implants for treating Parkinson’s disease, but only just. “There are times when we’re flying closer to the sun than we’d like to,” Mr. Sorenson said.

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ResMed, which makes ventilators and other products like this sleep monitor, expects production to be constrained until at least the end of spring next year.

PHOTO: CHRIS RATCLIFFE/BLOOMBERG NEWS

Mick Farrell, chief executive of [ResMed](https://www.wsj.com/market-data/quotes/RMD) Inc., which makes ventilators and other breathing aids, is using the same tactic with suppliers. “I lead with the human element,” he said. “People are very much listening to that.”

His pitch: “Every single chip you give me gives the gift of breath to a person suffocating.” That argument helped ResMed keep on top of orders until recently, when [a huge recall](https://www.wsj.com/articles/sleep-apnea-sufferers-scramble-after-philips-recall-of-critical-machine-11629019801?mod=article_inline) by its top competitor Royal Philips NV triggered a surge in demand for the devices it makes to treat sleep apnea.

Mr. Farrell said that under normal conditions the company would have been able to meet that new demand within six to nine months. With the supply crunch he expects ResMed’s production to be constrained until the end of spring next year, at the earliest.

One chip maker that has publicly backed medical device makers is Germany’s [Infineon Technologies](https://www.wsj.com/market-data/quotes/IFNNY) AG . Last year it provided millions of chips to help ResMed increase ventilator production at the outset of the pandemic. A spokesman said Infineon has since given medical device makers priority in some cases when supplies are tight.

Some hospitals are experiencing long order delays because of the semiconductor shortage, according to Mike Schiller, senior director for supply chains at the Association for Health Care Resource and Materials Management, an industry group. He said some members have reported monthslong delays for new CT scanners, defibrillators and telemetry monitors, machines that track patients’ vital signs.

But the medical device makers’ efforts to woo suppliers seem to have prevented widespread shortages. Ed Hisscock, senior vice president of supply chain management at Trinity Health, which operates 90 hospitals across 22 states, said his team has been on “high alert” for shortages of thousands of items containing semiconductors for the past six months, but that none have yet materialized.

“We’re in a decent position,” said Boston Scientific’s Mr. Sorenson. “But the repercussions here could be really significant.”

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*Appeared in the October 4, 2021, print edition as 'Medical-Device Makers Want Front of the Line for Chips.'*

