IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS, EASTERN DIVISION

RUSH UNIVERSITY MEDICAL CENTER,	)	
	)	
Plaintiff,	)	
	)	No. _____
v.	)	
	)	JURY DEMANDED
DRAEGER, INC. ,	)	
	)	
Defendant.	)	

COMPLAINT

Plaintiff Rush University Medical Center ("*Rush*") complains against Defendant Draeger, Inc. ("*Draeger*") as follows:

Preliminary Statement

1. Rush is a 664-bed hospital and academic medical center in Chicago, Illinois. Its professionals treat diverse patient population with the full range of medical problems. Monitoring those patients' breathing, vital signs and other physiological conditions is crucial to keeping patients safe and providing effective treatment.

2. In 2011, based on representations Draeger made in response to an RFP and otherwise, Rush purchased a patient monitoring system and associated services ("*Draeger System*") from Draeger. The Draeger System was installed on a rolling basis between January 2012 and January 2016, at a total cost of more than $18 million.

3. As explained in detail below, the Draeger System failed to operate as promised and warranted. The system was marked by inaccurate and unreliable alarming, erratic shifts in alarm settings, and sudden erasures of patient log data. The system also failed to provide key

promised features, including wired-to-wireless monitoring (required for patient transport), and monitoring for de-saturation of neo-natal patients' blood oxygen.

4. These (and other) problems endangered patients, severely disrupted Rush's operations, and caused Rush clinical, technical and engineering professionals to waste thousands of hours of time. But rather than effectively remediating these problems, Draeger largely, and inaccurately, blamed them on Rush. A Draeger software upgrade was insufficient and created new problems. Upgrading was also extraordinarily time-consuming and disruptive, despite Draeger's promises that upgrades could be easily pushed out across the network.

5. By the fall of 2016, Rush concluded it had no choice but to replace the Draeger System; patient safety required it. Although patient monitoring systems typically last for at least ten years from installation, Rush had to replace the Draeger System in five, at a cost of more than $30 million (not including staff disruption and delay).

6. Rush seeks compensation for the substantial losses caused by the Draeger System's failure, which, as alleged in detail below, breached at least two express warranties in Draeger's contract with Rush and amounted to common law fraud and violation of the Illinois Consumer Fraud and Deceptive Trade Practices Act (815 ILCS § 505/1 *et seq.*).

Parties

7. Rush is an Illinois nonprofit corporation with its principal place of business in Chicago, Illinois.

8. Draeger is a Pennsylvania corporation with its principal place of business in Telford, Pennsylvania.

Jurisdiction and Venue

9. This Court has subject matter jurisdiction under 28 U.S.C. § 1332(a) because the amount in controversy exceeds $75,000 and the parties are incorporated and have their principal places of business in different states.

10. This Court has personal jurisdiction over Draeger because Draeger: (a) transacted business in Illinois, including by selling the Draeger System to Rush (735 ILCS § 5/2-209(1)); (b) committed torts in Illinois in connection with that transaction as alleged below (*id.* § 5/2-209(2)); and (c) entered into a contract substantially connected to Illinois (*id.*§ 5/2-209(7)). Draeger also consented to personal jurisdiction in Illinois in its contract with Rush.

11. Venue is proper in this District under 28 U.S.C. § 1391(b)(2) because much of Draeger's complained of conduct occurred in this District and by agreement of the parties.

Background

A. Rush Decides to Buy the Draeger System

12. In 2010, Rush circulated a Request for Proposals ("*RFP*") for a new facility-wide patient monitoring system to numerous vendors, including Draeger. The RFP was in the form of an excel spreadsheet that listed numerous Rush "Technical Requirements." Next to each Technical Requirement were two fields to be completed by vendors, one titled "Comply" and the next titled "Vendor Response."

13. In or around May, 2010, Draeger completed a written response to the RFP for its Infinity Omega Monitoring Solution. Draeger's responses included the following:

Technical Requirements	Comply	Vendor Response
System should detect ip addresses and not allow duplicates		Vendor can comply
Describe the process and cost for the software updgrades for the quoted patient monitoring products		Infinity monitors have been designed to be upgradeable in order to protect our customers'

		investment. Typically, upgrades are performed with nothing other than a software upload via a software card. . . . Upgrades can be performed by either DMI or the hospital biomedical team.
Is a separate wired Ethernet network required?	Comply	No.
Is a separate wireless network required?	Comply	No, as long as the existing system meets the product specs
What is the general frequency of software releases? What is required to implement a new release?		. . . Updates on the patient monitoring system can be implemented by trained technical staff of the hospital.

14. Between spring 2010 and June 2011, Draeger and Rush engaged in extensive discussions about Rush's potential purchase of a Draeger monitoring system. During that time, and consistent with the RFP response, Draeger representatives, including Brad Penner, Ed Snauerdt, and Vic Boike, orally told Rush personnel, including Gene Ward, Rush's chief of Clinical Engineering, that software updates could easily be pushed out over Rush's network and implemented by Rush personnel. These representations were also repeated after Rush entered into the Product Purchase Agreement with Draeger (which, as alleged below, was on June 13, 2011).

15. At or around the time Draeger submitted its RFP response, it also gave Rush a document titled "Draeger Medical Value," which stated: "The RFP envisions an advanced IT solution for your hospital, allowing you to leverage both your current and future IT investments. DMI has shown a commitment to open standards, attempts to be nonproprietary in nature and is committed to investment in R&D. All of this translates into a product designed to have a High Degree of Flexibility and the Lowest Cost of Ownership in the industry."

16. The "Draeger Medical Value" document also stated: "Most monitoring companies require hospitals to own their own separate network in order to provide life critical security and performance. The infinity OneNet architecture supports seamless wired and wireless real-time patient monitoring, often on your hospital's existing network architecture."

17. Consistent with that representation, Draeger employees, including Penner, Boike, and Snauerdt (whose title was "Technical Implementation Specialist"), orally told Rush employees, including Gene Ward, that Draeger's monitoring systems had the capability to provide full wired-to-wireless monitoring, meaning the system could continuously monitor a patient who was taken off of a bedside monitor and placed on a portable, battery-operated monitor during transport. These representations were made after Rush had provided Draeger with detailed specifications of its wireless network. In fact, Snauerdt told Ward that Rush's wireless network was well-designed and provided ample access points for the Draeger System's wired-to-wireless capabilities.

18. Also during this same time period (spring 2010 through June 2011), Snauerdt, Boike and Penner orally told Rush employees, including Ward, that Draeger's systems could be configured by Rush to provide accurate and clinically useful patient monitoring and alarming.

19. In reliance on these and other representations, Rush selected Draeger in the RFP process. Instead of the Omega Monitoring Solution, however, Draeger recommended that Rush buy a related system called the Infinity Acute Care Monitoring System or "IACS," and Rush followed that suggestion. Draeger made clear to Rush that the core promises about its system (made in relation to the Omega Monitoring Solution) would also apply to the IACS. Draeger also stated (in a document titled "The DMI Infinity Monitoring System offers a different approach")

that the IACS would "NEVER compromise the level of patient monitoring or lose patient information." (Capitalization in original.)

20. The IACS system (together with associated services, the "*Draeger System*" as defined above) had four main components, each of which were to be fully networked with the others: (a) bedside monitors, known as C500s; (b) larger monitors that were placed at each hospital unit's central nursing stations ("*Central Stations*"), at which data from multiple bedside monitors could be viewed; (c) small monitors, known as M540s, that ran on rechargeable batteries and could be docked for use on Rush's wired network but then removed and run on the wireless network during patient transport; and (d) wireless, patient-worn monitors, known as M300s, that monitor ECG and, if selected, pulse oximetry.

B. The Product Purchase Agreement and Product Documentation

21. Rush and Draeger executed a Product Purchase Agreement ("*Product Agreement*") dated June 13, 2011, a copy of which is attached as Exhibit A. The Product Agreement did not require purchase of any set amount of Draeger System components. Instead, it provided the terms on which any purchases would take place during the agreement's five-year term (June 13, 2011 through June 12, 2016).

22. Rush and Draeger also entered into a "Service Agreement" (for Draeger to provide certain services in connection with the System) and a "Draeger Insight Agreement." The latter memorialized Rush's participation in Draeger's "Customer Insight Program," which would give Rush favorable pricing and create marketing and research partnership.

23. The Product Agreement contains several distinct warranties, including one titled "Computer Viruses" ("*Software Warranty*") and another titled "Compliance with Documentation" ("*Documentation Warranty*"). The Software Warranty states:

> This Section applies to any software ("Software") which is a Product(s) or which is provided or sold by Seller and is necessary for the proper use of a Product(s). Seller represents and warrants that the Software does not contain any virus, timer, clock, counter, or other limiting design, instruction, or routine that would erase data or programming or cause the Software or any other programs, equipment, or data to become inoperable or otherwise incapable of being used in the full manner for which it was designed and created (a "Software Limitation"). . . .

Ex. A at 10 (§ II(3)(C(3)).

24. The Documentation Warranty states:

> Seller represents and warrants that the Product(s) shall comply with "Documentation." For purposes of this Agreement, "Documentation" includes, but is not limited to, complete operator guides, operating procedures, including year-end procedures, user manuals, training aids, installation guides, and technical documents as would be sufficient to enable a staff consisting of a reasonable number of individuals with ordinary skills and experience to fully utilize the Product(s) for all purposes for which they are being acquired.

Ex. A at 10 (§ II(3)(C(4)).

25. Such "Documentation" included Draeger's "Instructions for Use Infinity Acute Care System" ("*IACS Instructions*") (attached as Exhibit B). Among other things, the IACS Instructions state that the Draeger System is "fully networked" (at p. 36) and otherwise provide that the System allowed wired-to-wireless monitoring *See, e.g.,* Ex. B at 20, 24, 38, 40, 97. The IACS Instructions also provide that users could configure all alarms as necessary to make them clinically meaningful or useful, and that all life-threatening alarms were coded as red. *See id.* 98, 115-18. The IACS Instructions further state that "if an alarm condition no longer exists, associated alarms will" either stop automatically for non-latching (typically less perilous) alarms or continue until stopped for latching (typically more perilous) alarms. *Id*. at 99.

26. "Documentation" also included Draeger's "Instructions for Use, Infinity Central Station" ("*Central Station Instructions*"; attached as Exhibit C). The Central Station Instructions contain many of the same representations as the IACS Instructions and repeatedly provide that

the Central Stations will retain reliable patient data, including "full disclosure" (complete, beat-to-beat waveforms of key patient physiological measurements (e.g., ECG) covering 72 hours) and event logs, which list notable physiological events.

27. Another item of Draeger's Documentation was a brochure titled "Infinity M540 Monitor." (Attached as Exhibit D). Among other things, this brochure provides that the Draeger System offers "continuous monitoring throughout the hospital."

C. Installation, Operation and Failure of the Draeger System

28. Draeger installed its System one unit or section of the hospital at a time, beginning with Rush's then-new five-story tower, where the System went live in January 2012, and ending with the Endoscopy Unit, which went live in January 2016.

29. As the Draeger System went live, Rush experienced serious problems with wire-to-wireless monitoring. When M540s were moved from the wired to the wireless network, they stopped collecting patient full disclosure data, which is essential for keeping track of patient health. Then, instead of assigning themselves to an open IP address – of which there were plenty – the M540s would frequently grab an IP address that was already in use by a bedside monitor, knocking that monitor off of the Central Station. This created a major safety hazard, since unless a nurse happened to be in the patient room that was knocked off the Central Station, that patient would be completely unmonitored.

30. Rush technical staff spent hundreds of hours trying to remedy these problems, and Rush clinical staff spent extensive time trying to work around them, such as by deploying extra nurses to patient rooms. In the course of these efforts – and, as noted above, prior to purchase and installation of the Draeger System – Draeger Technical Implementation Specialist Ed Snauerdt repeatedly confirmed to Rush that its wireless network was well-designed and provided

ample access points for the Draeger System's wired-to-wireless capabilities to fully function. But when it finally became clear that the Draeger System could not safely provide wired-to-wireless monitoring, Rush was forced to abandon that critical capability and never ended up receiving it.

31. The Draeger System was also plagued with recurrent and/or chronic alarming problems. By way of example only:

(a) The Draeger System was supposed to alarm for desaturation of neo-natal patients' blood oxygen ("*Desat Alarm*"). This alarm, however, could not be configured by system users. Instead, Draeger had pre-set or fixed the alarm parameters in its code, and the fixed value consistently produced nuisance alarms and otherwise failed to provide clinically meaningful results. Rush clinical professionals were forced to spend hundreds of hours trying to work around this problem and repeatedly brought it to Draeger's attention. Draeger was never able to resolve it, and in approximately June 2015, told Rush that re-writing the Desat Alarm code to make the parameters configurable would be impossible without FDA approval.

(b) Monitoring for heart arrhythmia in patients with pacemakers (which the Documentation confirmed would be provided) was frequently inaccurate. The System would falsely alarm for a pause in the heartbeat, or even for bradycardia and asystole (life-threatening, high-priority alarms), when the pacemaker was working properly. This led to alarm fatigue and major staff disruption, as nurses had to waste substantial time responding to false alarms, reassuring patients, and providing one-on-one care to manage

patient monitors, all of which limited clinicians' ability to respond to truly serious alarms for other patients.

(c) Separately, the Draeger System's full disclosure data for patients with pacemakers did not consistently capture pacer spikes (instances where the pacemaker fired), and event-level records known as "arrhythmia strips" did not clearly annotate pacer spikes, creating inaccurate patient records.

(d) The Draeger System's arrhythmia alarm setting would periodically shift from "advanced" to "basic" without any apparent reason or explanation. This would sharply reduce the number of conditions being monitored and deprive clinicians of necessary patient data. Rush complained about this problem for more than two years, and Draeger personnel consistently blamed Rush clinicians, accusing them of inadvertently changing the alarm settings. It turned out the problem resulted from a Draeger software glitch (Thor app memory leak), but Draeger never sent Rush a "Field Safety Notice" (which other medical device makers typically send customers as soon as they discover any significant malfunction) or otherwise directly told Rush about it.

(e) Rush required apnea monitoring – which captures stoppages in respiration and is especially critical for patients on opioids – for all patients. Although Draeger's RFP response and the M540 Brochure (Ex. D at 3) indicated apnea monitoring was immediately available, the capability did not exist until March 2015. Separately, Draeger's impedance-based apnea monitoring was unreliable, particularly for non-standard patients, like

infants or the obese. Finally, the IACS treated apnea alarms as a "yellow," when they should have been treated as "red."

(f) Rush also required EtCO2 monitoring of all patients, whether they were on a ventilator (*i.e.*, intubated) or not, and the IACS Instructions indicated such monitoring was provided. *See* Ex. B at 317-22. The 2012 Report of The Joint Commission Sentinel Event Alert also made clear that such monitoring was industry standard, for both intubated and non-intubated patients. The Draeger System, however, did not provide EtCO2 monitoring for non-ventilated/intubated patients (which would typically be done through a nasal cannula). This forced Rush to spend more than $400,000 on separate machines solely to provide that monitoring.

32. In addition to the wired-to-wireless and alarming problems discussed above, the cords and cables for the Draeger system – particularly, the 3-lead ECG cables used in the Neo-Natal Intensive Care Unit ("*NICU*") – were inexplicably fragile and required frequent replacement. These cable failures endangered patients, particularly if and when they failed at critical times. Draeger eventually replaced all 72 cables in the NICU, but they continued failing at an unacceptable rate.

33. Rush repeatedly complained to Draeger about the problems discussed above (and others). While Draeger improved limited aspects of the System, it ultimately failed to resolve at least the problems identified above. In some instances, such as with the shifting arrhythmia alarm settings described above and the erasure of patient log data, which is described below, Draeger incorrectly blamed the problem on Rush.

34. In January 2015, Draeger began implementing a major System software upgrade, to a program known as VG3. As noted above, Draeger's RFP response repeatedly indicated that software upgrades could be pushed out over the network and implemented by Rush staff, and Draeger personnel repeated that representation to Rush after entry into the Product Agreement (but well before Rush had bought substantial portions of equipment). Those representations were untrue; in fact, Draeger personnel had to install the upgrade one machine at a time, taking each piece of equipment out of use while the upgrade was installed.

35. The VG3 upgrade took three months and was enormously disruptive. While the upgrade resolved some issues (including the shifts in alarm settings, which turned out to have been caused by a software glitch, not Rush staff, as Draeger had wrongly insisted), it did not resolve any of the other issues identified above. The upgrade also created at least one major new problem: random periodic erasure of patient event log data at the Central Stations, eliminating critical patient records. Draeger must have known this was at least a potential problem at the time it installed VG3 at Rush. That is because the next generation of software (VG4) was in fairly advanced development by that time, and Draeger claims that VG4 resolves the patient log erasure issue. Draeger, however, failed to warn Rush that installation of VG3 might lead to erasure of patient event log data at the Central Stations, and Rush expended substantial resources trying to understand and resolve the problem on its own. Rush did not learn that Draeger had identified the problem until June 2016, when a Draeger technician suggested VG4 might fix it.

36. In addition to failing to timely disclose this problem with VG3, Draeger consistently failed to timely provide Rush with software release notes, the detailed technical descriptions of software version features that vendors customarily share with their customers.

Only after Rush personnel repeatedly requested these notes, over a course of months, did Draeger provide them.

37. By the summer of 2016, Rush determined that it had no choice but to replace the Draeger System. Not only had the problems identified above (and others) persisted, but Draeger's consistent failure to take responsibility for them, and its failure to forthrightly disclose new problems (like the erasure of patient event log data), had broken Rush's trust. Rush began installing a replacement system in early 2017, at a total cost of more than $30 million, excluding staff disruption and delay.

Count I
Breach of Contract

38. Rush incorporates paragraphs 1 through 37 as if fully set forth in this Count I.

39. The Product Agreement constituted a valid, legally enforceable contract.

40. Rush performed all of its obligations under the Product Agreement.

41. At least the following failures of the Draeger System described above constitute and/or reflect "Software Limitations" that prevented the System from being used in the full manner for which it was designed and created, and thereby violated the Product Agreement's Software Warranty: (a) the failure to provide wired to wireless monitoring; (b) the failure to provide proper Desat Alarm capability for neo-natal patients; (c) the failure to provide reliable arrhythmia monitoring for paced patients; (d) the failure to accurately record pacer spikes in full disclosure and arrhythmia strips; (e) the Thor app memory leak that led to erratic shifts in alarm settings; and (f) the erasure of patient event log data following installation of VG3.

42. At least the following Draeger System problems violated the Product Agreement's Documentation Warranty because they reflected or constituted a failure to comply with "Documentation" as defined in the Product Agreement and prevented the System from

being fully utilized for the purpose for which it was acquired: (a) the failure to provide wired to wireless monitoring; (b) the failure to provide proper Desat Alarm capability for neo-natal patients; (c) the failure to provide reliable arrhythmia alarming for paced patients; (d) the failure to accurately record pacer spikes in full disclosure and arrhythmia strips; (e) erratic shifts in alarm settings; (f) the delay in providing apnea monitoring; (g) the failure to provide accurate and reliable impedance-based apnea monitoring; (h) the failure to provide EtCO2 monitoring for non-intubated patients; (i) the chronic breakage and failure of 3-lead ECG cables in the NICU; and (j) the sudden erasure of patient event log data following installation of VG3.

43. Draeger's breaches of the Product Agreement caused Rush to suffer extensive damages, including, not limited to: (a) the cost of thousands of hours of staff time required to diagnose and otherwise deal with the failures of the Draeger System; (b) the cost of paying for a monitoring system (the Draeger System) that should have lasted at least ten years but had to be replaced in only five; and (c) the cost of replacing the Draeger System at least five years before it should have had to be replaced.

Count II
Unjust Enrichment

44. Rush incorporates paragraphs 1-20 and 28-37 as if fully set forth in this Count II.

45. This Count is asserted in the alternative to Count I above.

46. Rush paid Draeger, and Draeger has retained, more than $18 million in exchange for the Draeger System.

47. As alleged above, the Draeger System was grossly deficient. It endangered Rush's patients, failed to perform essential functions, caused Rush staff to waste thousands of hours of staff time (which Rush had to pay for), and ultimately, required Rush to spend more than $30

million on a replacement system, at least five years before such replacement should have been required.

48. Given these facts and circumstances, Draeger has retained the $18 million that Rush paid it to Rush's detriment, and that retention violates the fundamental principles of justice, equity, and good conscience.

Count III
Fraudulent Inducement

49. Rush incorporates paragraphs 1-37 as if fully set forth in this Count III.

50. Draeger made false statements of material fact to Rush by telling its personnel that the Draeger System had the following capabilities: (a) to provide wired-to-wireless monitoring at Rush (including the subsidiary representations in the RFP response that the System would "detect IP addresses and not allow duplicates"); (b) to accept system upgrades through Rush's network and did not require touching each piece of equipment; and (c) to be configured by Rush so as to make alarms reliable and clinically meaningful. As alleged above, Draeger made these false statements in its RFP response and orally to Rush employees.

51. Draeger knew or believed those statements to be false and made them to induce Rush to purchase the Draeger System.

52. Rush reasonably relied on Draeger's statements in deciding to purchase the Draeger System.

53. Rush was damaged as a result of its purchase of the Draeger System because it paid more than $18 million for a patient monitoring system that did not work and had to be replaced at a cost of more than $30 million at least five years before any replacement should have been required. Rush was also damaged because it had to spend substantial time and resources trying to diagnose and ameliorate the failures of the Draeger System.

Count IV
Violation of Illinois Consumer Fraud and Deceptive Business Practices Act
815 ILCS § 505/1 *et seq.*

54. Rush incorporates paragraphs 1-37 as if fully set forth in this Count IV.

55. Draeger engaged in deceptive acts or practices in the course of conducting trade or commerce by falsely and/or misleadingly telling Rush that the Draeger System had the following capabilities: (a) to provide wired-to-wireless monitoring at Rush (including the subsidiary representations in the RFP response that the System would "detect IP addresses and not allow duplicates"); (b) to accept system upgrades through Rush's network and did not require touching each piece of equipment; and (c) to be configured by Rush so as to make alarms reliable and clinically meaningful.

56. Draeger intended Rush to rely on these deceptions in deciding to purchase and continue installation of the Draeger System.

57. Rush was deceived by Draeger's false and misleading statements, and as a proximate result of that deception, purchased and approved installation of the Draeger System. This damaged Rush by causing it pay more than $18 million for a patient monitoring system that did not work and had to be replaced at a cost of more than $30 million at least five years before any replacement should have been required. Rush was also damaged because it had to spend substantial time and resources trying to diagnose and ameliorate the failures of the Draeger System, including those linked to the deceptions summarized above.

58. Draeger also engaged in deceptive acts or practices in the course of conducting trade or commerce by falsely telling Rush that two defects in the Draeger System were being caused by Rush personnel: (a) the erasure of patient event log data; and (b) the sudden shifting of arrhythmia alarm settings from "advanced" to "basic."

59. Draeger intended Rush to rely on these deceptions.

60. Rush was deceived by these false statements and as proximate result of that deception, spent hundreds of hours of staff time and other resources trying to correct problems that Draeger knew had been caused by defects in the Draeger System.

WHEREFORE, Rush prays that this Court enter an Order:

(a) For judgment in favor of Rush and against Draeger;

(b) Awarding Rush all damages it is entitled to under the law in an amount to be proven at trial;

(c) Awarding Rush pre- and post-judgment interest as appropriate at the maximum rate permitted by law;

(d) Awarding Rush punitive damages (Counts III and IV only);

(e) Awarding Rush reimbursement of reasonable attorneys' fees (Count IV only);

(d) Granting Rush all other relief the Court finds just and proper.

Respectfully submitted,

Rush University Medical Center

/s/Robert Michaels
One of its Attorneys

Robert Michaels (6203462)
Daniel C. Curth (6229090)
GOLDSTEIN & McCLINTOCK LLLP
111 W. Washington St., Suite 1221
Chicago, Illinois 60602
(312) 337-7700
robm@goldmclaw.com
dcurth@goldmclaw.com