DODATEK Č. 10

ke Kupní smlouvě spojené se zřízením a provozem konsignačního skladu ev. č. sml. 26/0VZ/11/067-K ze dne 12.5.2011

Smluvní strany

obchodní firma:	**Perfect Distribution a.s.**
sídlo:	Prostějov, U Spalovny 4582/17, PSČ 796 01
jejím jménem:	Tomáš Lyžbicki, předseda představenstva a Mgr. Aleš Rozsypal, člen představenstva
IČ:	476 75 934
DIČ:	CZ47675934
DIČ společného plátce DPH:	CZ699000899

zapsaná v Obchodním rejstříku vedeném Krajským soudem v Brně, oddíl B, vložka 6538

(dále jen jako „**Prodávající**")

A

název:	**Fakultní nemocnice Ostrava**
sídlo:	Ostrava – Poruba, 17. listopadu 1790, PSČ 708 52
jejím jménem:	MUDr. Jiří Havrlant, MHA, ředitel
IČ:	00843998
DIČ:	CZ00843998

Zřizovací listina MZ ČR ze dne 25. Listopadu 1990 č. j. OP-054-25.11.90

(dále jen jako „**Kupující**")

uzavírají tento Dodatek č. 10 (dále jen „**dodatek**"):

Článek I.
Úvodní ustanovení

1.1. Smluvní strany prohlašují, že jsou oprávněny tento dodatek uzavřít a řádně plnit závazky v něm obsažené, a že splňují veškeré podmínky a požadavky stanovené platnými právními předpisy k jeho uzavření.

1.2. Smluvní strany shodně prohlašují, že dne 12.5.2011 mezi sebou uzavřely Kupní smlouvu spojenou se zřízením a provozem konsignačního skladu ev. č. sml. 26/0VZ/11/067-K, jejímž předmětem jsou dodávky kardiostimulační techniky (dále jen „**Smlouva**") ve znění pozdějších dodatků.

[redacted]

Článek II.
Předmět Dodatku

2.1. Vzhledem ke skutečnosti, že výrobci uvedli na trh nové modelové řady stimulačních přístrojů, se smluvní strany dohodly na doplnění tohoto sortimentu nahrazením původní Přílohy č. 1 Smlouvy novou Přílohou č. 1, která je nedílnou součástí tohoto Dodatku. Původní nahrazené produkty zůstávají k dispozici do vyprodání zásob.

2.2. Ostatní ustanovení Smlouvy zůstávají beze změn.

Článek III.
Závěrečná ustanovení

3.1. Tento Dodatek nabývá platnosti a účinnosti dnem jeho podpisu oběma smluvními stranami.

3.2. Dodatek je vyhotoven ve dvou stejnopisech, z nichž každá ze stran obdrží po jednom.

3.3. Smluvní strany prohlašují, že si tento Dodatek přečetly, jeho obsahu porozuměly a prohlašují, že je výrazem jejich pravé a svobodné vůle a není uzavírán v tísni či za nápadně nevýhodných podmínek, což stvrzují svými podpisy.

3.4. Nedílnou součástí tohoto Dodatku je:

Příloha č. 1,

Prohlášení výrobce ke změně sortimentu.

V Prostějově dne .....

[redacted]

Perfect Distribution a.s.
Tomáš Lyžbicki
předseda představenstva

[redacted]

Perfect Distribution a.s.
Mgr. Aleš Rozsypal
člen představenstva

V Ostravě dne 22.11.2021

[redacted]

Fakultní nemocnice Ostrava
MUDr. Jiří Havrlant, MHA
ředitel

39 FAKULTNÍ NEMOCNICE OSTRAVA
17. listopadu 1790, 708 52 Ostrava-Poruba
Tel.: +420 597 371 111, Fax: +420 596 917 340

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Příloha č.1:

Kód zboží	Název zboží	Kód VZP	Cena za ks bez DPH	DPH	Cena za ks vč.DPH
BOS-D400	Defibrilátor jednodutinový systém PERCIVA MINI ICD VR, model D400, samostatný přístroj	200578	243 000,00	15%	279 450,00
BOS-D400-BAL	Defibrilátor jednodutinový systém PERCIVA MINI ICD VR, model D400, přístroj vč. 1 elektrody	200579	243 000,00	15%	279 450,00
BOS-D412	Defibrilátor jednodutinový systém PERCIVA MINI ICD VR, model D412, samostatný přístroj	200578	243 000,00	15%	279 450,00
BOS-D412-BAL	Defibrilátor jednodutinový systém PERCIVA MINI ICD VR, model D412, přístroj vč. 1 elektrody	200579	243 000,00	15%	279 450,00
BOS-D401	Defibrilátor dvoudutinový systém PERCIVA MINI ICD DR, model D401, samostatný přístroj	200576	252 000,00	15%	289 800,00
BOS-D401-BAL	Defibrilátor dvoudutinový systém PERCIVA MINI ICD DR, model D401, přístroj vč. 2 elektrod	200577	252 000,00	15%	289 800,00
BOS-D413	Defibrilátor dvoudutinový systém PERCIVA MINI ICD DR, model D413, samostatný přístroj	200576	252 000,00	15%	289 800,00
BOS-D413-BAL	Defibrilátor dvoudutinový systém PERCIVA MINI ICD DR, model D413, přístroj vč. 2 elektrod	200577	252 000,00	15%	289 800,00
BOS-60G324	Defibrilátor biventrik. CHARISMA CRT-D IS1 DF4 IS1 EU model G324, sam. přístroj	200554	270 000,00	15%	310 500,00
BOS-G324-BAL	Defibrilátor biventrik. systém CHARISMA CRT-D IS-1; DF4-LLHH; IS-1, model G324, vč. 3 elektrod	200555	270 000,00	15%	310 500,00
BOS-G325	Defibrilátor biventrik. CHARISMA CRT-D IS1 DF1 IS1 IS1 EU model G325, sam. přístroj	200554	270 000,00	15%	310 500,00
BOS-G325-BAL	Defibrilátor biventrik. systém CHARISMA CRT-D IS1 DF1 IS1 IS1 EU model G325, vč. 3 elektrod	200555	270 000,00	15%	310 500,00
BOS-60G347	Defibrilátor biventrik. CHARISMA CRT-D X4 DF4/IS4, model G347, sam. přístroj	200554	270 000,00	15%	310 500,00
BOS-BUN54-G347	Defibrilátor biventrik. systém CHARISMA CRT-D X4 DF4/IS4, model G347, vč. 3 elektrod	200555	270 000,00	15%	310 500,00

[redacted]

Boston Scientific Česká republika s.r.o.
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Vážený pan
[redacted]
Fakultní nemocnice Ostrava
17. listopadu 1790, 708 00 Ostrava – Poruba

Věc: Vyjádření k technickým specifikacím přístrojů Perciva

Implantabilní defibrilátory (ICD) řady Perciva modelových čísel D412 (jednodutinové ICD) a D413 (dvoudutinové ICD) jsou součástí produktové řady Resonate. Od současně dodávaných přístrojů Autogen a Charisma se liší svými mechanickými parametry, tj. menšími rozměry a z toho vyplývající nižší kapacitou baterie a nižší životností. U modelu D412 (jednodutinové ICD) i u modelu D413 (dvoudutinové ICD) je objem nižší shodně o 3,0 cm^3, při snížení životnosti při specifikovaných podmínkách na 9,3 roků, resp. 8,5 roků. Jiné funkce zůstávají beze změny, jak vyplývá z přiložených produktových listů.

Přístroje Perciva D412 a D413 využívají stejnou platformu Resonate jako současně dodávané přístroje Charisma i stejnou programovou aplikaci.

Dále potvrzujeme, že implantabilní defibrilátory Perciva splňují technické požadavky dané výběrovým řízením a je možno je používat společně s řadami Autogen a Charisma.

V Praze dne.....

[redacted]

[redacted]

Boston Scientific
Advancing science for life™

CHARISMA™ EL (Extended Longevity ICD)

Models D320, D321, D332, D333

- ENDURALIFE™ battery technology projected to last up to 17.5 years for VR devices and 16.0 years for DR devices.*
- This small (29.5 cc) and thin (9.9 mm) high-energy device is designed to enhance patient comfort.
- Heart Failure Sensor Suite provides multi-factorial, physiological, patient-specific data which can enable better informed decisions for treating HF patients.
- IMAGEREADY™ MR Conditional Systems allow patients to safely undergo Full Body MRI scans up to 1.5T.**

ENDURALIFE™ Battery Technology

IMAGEREADY™ MR-Conditional Systems

Mechanical Specifications

Model	Type	Size (cm) (W x H x D)	Mass (g)	Volume (cc)	Connector Type (RA RV)
D320	VR	5.37 x 7.79 x 0.99	70.7	31.5	RV: IS-1/DF–1
D321	DR	5.37 x 7.79 x 0.99	71.0	31.5	RA: IS-1; RV: IS-1/DF–1
D332	VR	5.37 x 7.36 x 0.99	68.9	29.5	RV: DF4
D333	DR	5.37 x 7.68 x 0.99	71.4	31.0	RA: IS-1; RV: DF4

Pulse Generator Longevity (All Models[a,b,c,d,e,f])

ENDURALIFE™ Battery Technology provides industry-leading projected longevity.* The following tables represent sample pulse generator life expectancy estimation (implant to explant) with ENDURALIFE™ battery as provided in product labeling. For specific programmable parameter ranges, refer to product labeling at ***www.bostonscientific.com/manuals***, or contact Boston Scientific technical services or your local representative.

	Type	Pacing Amplitude	Pacing	500 Ω with LATITUDE™[c]	700Ω with LATITUDE™[c]	900Ω with LATITUDE™[c]	700Ω no LATITUDE™, MV/RS, or HFSS[d]
VR							
Typical programmed setting	VR	2.5 V	15%	15.0	15.1	15.2	17.1
Maximum labeled longevity	VR	2.0 V / Off	0%	15.4	15.4	15.4	17.5
DR							
Typical programmed setting	DR	2.5 V	15%	13.6	13.7	13.8	15.4
Maximum labeled longevity	DR	2.0 V	0%	14.2	14.2	14.2	16.0

a. Assumes 60 min^{-1} LRL, 0.4 ms pacing pulse width; sensors On, Heart Failure Sensor Suite On.

b. Projected longevity is calculated assuming 2 maximum energy charging cycles per year, including automatic capacitor re-forms and therapeutic shocks. These calculations also assume 3-channel EGM Onset is on and that the pulse generator spends 3 months in Storage mode during shipping and storage.

c. PaceSafe On for RAAT and RVAT provides an output of 2X the threshold with a minimum output of 2.0 V.

d. Assumes ZIP telemetry use for 1 hour at implant and for 40 minutes annually for in-clinic follow-up checks.

e. Assumes standard use of the LATITUDE™ Communicator as follows: Daily Device Check on, quarterly scheduled remote follow ups, and other typical interrogations.

f. Assumes LATITUDE™ Communicator is not used, Minute Ventilation (MV)/Respiratory Sensor is Off, and Heart Failure Sensor Suite is Off.

Additional Longevity Information

- Boston Scientific devices have corporate warranties at 10 years (VR) and 8 years (DR) in available geographies. Warranty information available at www.bostonscientific.com/warranty.
- Devices use Li/MnO_2 chemistry.
- The Usable Battery Capacity is 1.9 Amp-hours (typical implant to battery capacity depleted).
- Shelf life is 2 years (before use by).

* Assumes: 2.0 V RA, LV-only, 2.0 V LVa, 2.0 V LVb, 700Ω, No LATITUDE™, No Respiratory Rate Sensor, No Heart Failure Sensor Suite.

** When conditions of use are met.

CHARISMA™ EL (Extended Longevity ICD)

Models D320, D321, D332, D333

Pacing Therapy

Brady Modes	Normal: DDD(R), DDI(R), VDD(R), VVI(R), AAI(R), Off Temporary: DDD, DDI, DOO, VDD, VVI, VOO, AAI, AOO, Off
AT/AF Management	ATR Mode Switch, Ventricular Rate Regulation (VRR), Atrial Flutter Response (AFR), PMT Termination, Rate Smoothing
Automaticity	PaceSafe Right Ventricular Automatic Threshold (RVAT), PaceSafe Right Atrium Automatic Threshold (RAAT)
Rate Adaptive Pacing	Accelerometer with sensor trending function
RV Pacing Reduction	AV Search+, RYTHMIQ™, AV Delays to 400 ms, Rate Hysteresis

Patient Diagnostics

Arrhythmia Logbook	Events summary, Stored Electrograms with Annotated Markers, (Intervals and approximately 17 minutes of multichannel EGM, always with 10 seconds Onset and event storage prioritization). Implant activation of all available EGMs. On screen measurement of all stored signal amplitudes and timing
Histograms & Counters	Tachy Events and Brady Counters
Heart Rate Variability (HRV)	SDANN and HRV Footprint (24 hour heart rate collection period)
AT/AF Diagnostics	AT/AF Burden, Daily burden, Average V-rate during ATR Mode Switch Episode
Heart Failure Trends and Diagnostics	Heart Failure Management Report, Weight, Blood Pressure, Events, Activity Level, AT/AF Burden, Respiratory Rate, AP Scan, Heart Rate, SDANN, HRV Footprint, Thoracic Impedance, Night Heart Rate, Sleep Incline ***To note: Weight and Blood Pressure are only available via LATITUDE™.***

Device Testing/Induction Methods

Induction Methods	Vfib Induction, Shock on T Induction, Programmed Electrical Stimulation (PES), 50 Hz/Manual Burst Pacing
Commanded Therapy Methods	Commanded Shock, Commanded ATP

Tachyarrhythmia Therapy

Sensing/Detection	Zones VF only, or VF and VT or VF, VT, VT-1. Lowest Zone can be Monitor Only
Shock Reduction and Appropriate Therapy	AcuShock™ Advanced Technology including Onset/Stability™, RhythmID™ with RhythmMatch™, Dynamic Noise Algorithm (DNA) for sensing, Automatic Gain Control (AGC) with programmable sensing floor, Narrow Band Pass Filter
Antitachycardia Pacing Therapy (ATP) Termination	Quick Convert™ in VF Zone. Two programmable ATP schemes in both VT and VT-1 zones. Quick Convert greater than 250 min^{-1} available, Burst, Ramp, Scan, Ramp-Scan
Shock Energy	41 J stored, 35 J delivered. First two shocks in each zone programmable. VT-1 has 5 shocks. VT has 6 shocks and VF has 8 shocks. Reverse Last Shock Polarity in zone. Programmable RV Coil to RA Coil and Can (TRIAD), RV Coil to Can, RV Coil to RA Coil (COLD CAN)
Nominals	VF Zone (200 min^{-1})–Detection: Rate and Duration, Therapy: Quick Convert, 8 high energy shocks VT Zone (160 min^{-1})–Detection: RhythmID or OBDE, Therapy: ATP x 2, 6 high energy shocks

Implant/In Clinic Follow Up

Implant Communication Mode	Programmable values: Enable use of ZIP™ telemetry (MICS) (Requires initial use of wand for device ID) or use wand for all telemetry Nominal: Enable use of ZIP telemetry (Requires initial use of wand for device ID)
In Clinic Follow-Up	Wireless ECG

Remote Follow-Up

Patient Triggered Monitor (PTM)	Triggers the storage of two minutes onset and one minute post – EGMs, intervals, and annotated marker data during a symptomatic episode–by placing a magnet over the device
Beeper Feature (Patient Alerts)	Beep during capacitor charge, beep when explant is indicated, beep when lead impedance measurement (shock or pace) is out-of-range
Magnet Feature	Magnet Response (Off, Store EGM, Inhibit Therapy)
Remote Monitoring	This device is designed to be LATITUDE™ enabled; LATITUDE™ availability varies by region
Thresholds	Automatic storage of last successful daily PaceSafe threshold test for all active chambers
Wireless	Remote follow-up for all devices (MICS)

IMAGEREADY™ Pulse Generator MR Conditional System

MRI Lead Selection	RELIANCE™ 4-FRONT, RELIANCE™4-SITE defibrillation leads - active and passive fixation, single and dual coil, 59 cm, 64 cm and 70 cm
MRI Conditions	Full body scan, 1.5T, SAR 2 W/Kg, No Scan Time Limitations
MRI Protection Mode	MRI Protection Mode provides protection from MRI, and reactivates original settings following the scan. Programmable Time Out: Off, 3, 6, 9, and 12 hours

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PERCIVA™
Models D400, D412, and D413

- Projected to last up to 9.3 years for VR devices and 8.5 years for DR devices.*
- This small (28.5 cc) and thin (9.9 mm) high-energy device is designed to enhance patient comfort.
- Heart Failure Sensor Suite provides multi-factorial, physiological, patient-specific data which can enable better informed decisions for treating HF patients.
- IMAGEREADY™ MR Conditional Systems allow patients to safely undergo Full Body MRI scans up to 1.5T.**

IMAGEREADY™
MR-Conditional Systems

Mechanical Specifications

Model	Type	Size (cm) (W x H x D)	Mass (g)	Volume (cc)	Connector Type (RA RV)
D400	VR	5.23 x 7.14 x 0.99	61.9	28.5	RV: IS-1/DF-1
D401	DR	5.23 x 7.14 x 0.99	62.3	28.5	RA: IS-1; RV: IS-1/DF-1
D412	VR	5.23 x 6.71 x 0.99	60.0	26.5	RV: DF4
D413	DR	5.23 x 7.03 x 0.99	62.5	28.0	RA: IS-1; RV: DF4

Pulse Generator Longevity (All Models[a,b,c,d,e,f])

The following tables represent example pulse generator life expectancy estimation (implant to explant) as provided in product labeling. For specific programmable parameter ranges, refer to product labeling at ***www.bostonscientific.com/manuals***, or contact Boston Scientific technical services or your local representative.

	Type	Pacing Amplitude	Pacing	500 Ω with LATITUDE™[c]	700Ω with LATITUDE™[c]	900Ω with LATITUDE™[c]	700Ω no LATITUDE™, MV/RS, or HFSS[d]
VR							
Typical programmed setting	VR	2.5 V	15%	8.0	8.0	8.1	9.1
Maximum labeled longevity	VR	2.0 V / Off	0%	8.2	8.2	8.2	9.3
DR							
Typical programmed setting	DR	2.5V	15%	7.2	7.3	7.3	8.1
Maximum labeled longevity	DR	2.0V	0%	7.5	7.5	7.6	8.5

a. Assumes 60 min^{-1} LRL, 0.4 ms pacing pulse width; sensors On, Heart Failure Sensor Suite On.

b. Projected longevity is calculated assuming 2 maximum energy charging cycles per year, including automatic capacitor re-forms and therapeutic shocks. These calculations also assume 3-channel EGM Onset is on and that the pulse generator spends 3 months in Storage mode during shipping and storage.

c. PaceSafe On for RAAT and RVAT provides an output of 2X the threshold with a minimum output of 2.0 V.

d. Assumes ZIP telemetry use for 1 hour at implant and for 40 minutes annually for in-clinic follow-up checks.

e. Assumes standard use of the LATITUDE™ Communicator as follows: Daily Device Check on, quarterly scheduled remote follow ups, and other typical interrogations.

f. Assumes LATITUDE™ Communicator is not used, Minute Ventilation (MV)/Respiratory Sensor is Off, and Heart Failure Sensor Suite is Off.

Additional Longevity Information

- Boston Scientific devices have corporate warranties at 5 years in available geographies. Warranty information available at www.bostonscientific.com/warranty.
- Devices use Li/MnO_2 chemistry.
- The Usable Battery Capacity is 1.0 Amp-hours (typical implant to battery capacity depleted).
- Shelf life is 2 years (before use by).

* Assumes: 2.0 V pacing amplitude, 0% pacing, 700 Ohms, No LATITUDE™, No Respiratory Rate Sensor, No Heart Failure Sensor Suite.

** When conditions of use are met.

PERCIVA™
Models D400, D412, and D413

Pacing Therapy

Brady Modes	Normal: DDD(R), DDI(R), VDD(R), VVI(R), AAI(R), Off Temporary: DDD, DDI, DOO, VDD, VVI, VOO, AAI, AOO, Off
AT/AF Management	ATR Mode Switch, Ventricular Rate Regulation (VRR), Atrial Flutter Response (AFR), PMT Termination, Rate Smoothing
Automaticity	PaceSafe Right Ventricular Automatic Threshold (RVAT), PaceSafe Right Atrium Automatic Threshold (RAAT)
Rate Adaptive Pacing	Accelerometer, RightRate™ (Minute Ventilation) or blended sensors with sensor trending function
RV Pacing Reduction	AV Search+, RYTHMIQ™, AV Delays to 400 ms, Rate Hysteresis

Patient Diagnostics

Arrhythmia Logbook	Events summary, Stored Electrograms with Annotated Markers, (Intervals and approximately 17 minutes of multichannel EGM, always with 10 seconds Onset and event storage prioritization). Implant activation of all available EGMs. On screen measurement of all stored signal amplitudes and timing
Histograms & Counters	Tachy Events and Brady Counters
Heart Rate Variability (HRV)	SDANN and HRV Footprint (24 hour heart rate collection period)
AT/AF Diagnostics	Atrial Arrhythmia Report, AT/AF Burden, Daily burden, Average V-rate during ATR Mode Switch Episode
Heart Failure Trends and Diagnostics	Heart Failure Management Report, Weight, Blood Pressure, Events, Activity Level, AT/AF Burden, Respiratory Rate, AP Scan, Heart Rate, SDANN, HRV Footprint, Thoracic Impedance, Night Heart Rate, Sleep Incline ***To note: Weight and Blood Pressure are only available via LATITUDE™.***

Device Testing/Induction Methods

Induction Methods	Vfib Induction, Shock on T Induction, Programmed Electrical Stimulation (PES), 50 Hz/Manual Burst Pacing
Commanded Therapy Methods	Commanded Shock, Commanded ATP

Tachyarrhythmia Therapy

Sensing/Detection	Zones VF only, or VF and VT or VF, VT, VT-1. Lowest Zone can be Monitor Only
Shock Reduction and Appropriate Therapy	AcuShock™ Advanced Technology including Onset/Stability™, RhythmID™ with RhythmMatch™, Dynamic Noise Algorithm (DNA) for sensing, Automatic Gain Control (AGC) with programmable sensing floor, Narrow Band Pass Filter
Antitachycardia Pacing Therapy (ATP) Termination	Quick Convert™ in VF Zone. Two programmable ATP schemes in both VT and VT-1 zones. Quick Convert greater than 250 min^{-1} available, Burst, Ramp, Scan, Ramp-Scan
Shock Energy	41 J stored, 35 J delivered. First two shocks in each zone programmable. VT-1 has 5 shocks. VT has 6 shocks and VF has 8 shocks. Reverse Last Shock Polarity in zone. Programmable RV Coil to RA Coil and Can (TRIAD), RV Coil to Can, RV Coil to RA Coil (COLD CAN)
Nominals	VF Zone (200 min^{-1})–Detection: Rate and Duration, Therapy: Quick Convert, 8 high energy shocks VT Zone (160 min^{-1})–Detection: RhythmID or Onset/Stability, Therapy: ATP x 2, 6 high energy shocks

Implant/In Clinic Follow Up

Implant Communication Mode	Programmable values: Enable use of ZIP™ telemetry (MICS) (Requires initial use of wand for device ID) or use wand for all telemetry Nominal: Enable use of ZIP telemetry (Requires initial use of wand for device ID)
In Clinic Follow-Up	Wireless ECG

Remote Follow-Up

Patient Triggered Monitor (PTM)	Triggers the storage of two minutes onset and one minute post – EGMs, intervals, and annotated marker data during a symptomatic episode–by placing a magnet over the device
Beeper Feature (Patient Alerts)	Beep during capacitor charge, beep when explant is indicated, beep when lead impedance measurement (shock or pace) is out-of-range
Magnet Feature	Magnet Response (Off, Store EGM, Inhibit Therapy)
Remote Monitoring	This device is designed to be LATITUDE™ enabled; LATITUDE™ availability varies by region
Thresholds	Automatic storage of last successful daily PaceSafe threshold test for all active chambers
Wireless	Remote follow-up for all devices (MICS)

IMAGEREADY™ Pulse Generator MR Conditional System

MRI Lead Selection	RELIANCE™ 4-FRONT, RELIANCE™ 4-SITE defibrillation leads - active and passive fixation, single and dual coil, 59 cm, 64 cm and 70 cm INGEVITY™ and FINELINE™ II pacing leads – active and passive fixation, straight and J, 45 cm, 52 cm, 58 cm, and 59 cm
MRI Conditions	Full body scan, 1.5T, SAR 2 W/Kg, No Scan Time Limitations
MRI Protection Mode	MRI Protection Mode provides protection from MRI, and reactivates original settings following the scan. Programmable Time Out: Off, 3, 6, 9, and 12 hours

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DINCRM0941EA