

SUTARTIS Nr. 14-22-00521

Klaipėda,

2022 m. 09 mėn. 08 d.

**1. Sutarties esmė**

VšĮ Klaipėdos universitetinė ligoninė atstovaujama vyriausiojo gydytojo V. Janušonio (toliau vadinama "Pirkėju") ir UAB „Hospitex Diagnostics Kaunas“ atstovaujama direktoriaus A. Bakučio (toliau vadinama "Pardavėju") sudarėme šią sutartį.

"Pardavėjas" įsipareigoja sutartyje numatytais sąlygomis, pristatyti atvirame tarptautiniame konkurse (608410) laimėtą intraoperacinį neuromonitorių NIM Vital, Medtronic, kurio vnt. kaina yra 69.786,75 Eur (šešiasdešimt devyni tūkstančiai septyni šimtai aštuoniasdešimt šeši eurai 75 cent.) ir pateikti "Pirkėjui" pagal šią specifikaciją:

**Intraoperacinis neuromonitorius NIM Vital, Medtronic**

Eil. Nr.	Parametras	Parametro reikšmė	Siūlomo parametro atitikimas, konkreti parametro reikšmė ir atitikimo patvirtinimas (psl. pasiūlyme, puslapyje pabraukiant kiekvienos pozicijos kiekvieną atitikimą, nurodant pozicijos numerį pagal prašomas specifikacijas)
1.	Paskirtis	Sistema skirta nervų lokalizacijoms, stebėjimui, stimuliavimui, EMG atsakų registravimui ir nervų vientisumo nustatymui.	Sistema skirta nervų lokalizacijoms, stebėjimui, stimuliavimui, EMG atsakų registravimui ir nervų vientisumo nustatymui. <b>Katalogas – 2 psl.</b>
2.	Pritaikymo sritys	Intrakranijines, ekstrakranijines, intratemporalines, ekstratemporalines procedūros ir operacijos, susijusios su kaklu - skydliaukė, prieskydinė liauka; stuburu, krūtinės ąšta ir viršutinėmis bei apatinėmis galūnėmis.	Intrakranijines, ekstrakranijines, intratemporalines, ekstratemporalines procedūros ir operacijos, susijusios su kaklu - skydliaukė, prieskydinė liauka; stuburu, krūtinės ąšta ir viršutinėmis bei apatinėmis galūnėmis. <b>Katalogas – 2, 3 psl.</b>
3.	Aparato ekranas	1. Didelio kontrasto, spalvotas, lietimui jautrus ekranas. Ekranas prisitaiko prie lietimo chirurginėmis pirštinėmis. 2. Skiriamoji geba 1920x1080 taškų, ne mažiau 3. Ekranas padėtis gali būti keičiama ir reguliuojama.	1. Didelio kontrasto, spalvotas, lietimui jautrus ekranas. Ekranas prisitaiko prie lietimo chirurginėmis pirštinėmis. 2. Skiriamoji geba 1920x1080 taškų 3. Ekranas padėtis keičiama ir reguliuojama. <b>Katalogas – 4, 5, 6 psl.</b>
4.	Vaizdo projekcija	Konsolė turi turėti galimybę belaidžiu būdu perduoti vaizdą į bet kokį LCD ekraną, taip sudarant galimybę aparatą naudoti skirtingose operacinėse.	Konsolė gali belaidžiu būdu perduoti vaizdą į bet kokį LCD ekraną ir taip sudaro galimybę aparatą naudoti skirtingose operacinėse. <b>Katalogas – 7, 8 psl.</b>
5.	Paciento sąsaja	Belaidė paciento sąsaja	Belaidė paciento sąsaja <b>Katalogas – 9 psl.</b>
6.	Trikdžių šalinimas	Sistema aparato ekrane įspėja naudotoją apie atsiradusį trikdį ir ekrane pateikia trikdžio sprendimo žingsnius.	Sistema aparato ekrane įspėja naudotoją apie atsiradusį trikdį ir ekrane pateikia trikdžio sprendimo žingsnius. <b>Katalogas – 10 psl.</b>
7.	Integruotas garsiakalbis	EMG signalo amplitudės akustiniam atvaizdavimui, aliarmams, balsiniams pranešimams.	Integruotas garsiakalbis skirtas: EMG signalo amplitudės akustiniam atvaizdavimui, aliarmams, balsiniams pranešimams <b>Katalogas – 11, 12, 13, 14 psl.</b>
8.	Garso signalų reguliavimas	Galimybė garsą reguliuoti rankenėle ant aparato korpuso ir ekrane, būtina.	Galimybė garsą reguliuoti rankenėle ant aparato korpuso ir ekrane. <b>Katalogas – 14, 15, 16 psl.</b>
9.	Elektrodų išdėstymas	Ekrane turi būti rodomas galimas	Ekrane rodomas galimas elektrodų

		elektrodų išdėstymas priklausomai nuo pacientui atliekamos procedūros.	išdėstymas priklausomai nuo pacientui atliekamos procedūros. <b>Katalogas – 17 psl.</b>
10.	Garso signalų įjungimas ir išjungimas	Būtina	Garso signalų įjungimas ir išjungimas <b>Katalogas – 13, 18 psl.</b>
11.	EMG kanalų skaičius	Ne mažiau kaip 4 kanalų	4 kanalai <b>Katalogas – 19, 20 psl.</b>
12.	Ne mažiau du nepriklausomi elektriniai stimuliavimo kanalai, skirti nepertraukiamai ir nuolatinei stimuliacijai	Būtina	Du nepriklausomi elektriniai stimuliavimo kanalai, skirti nepertraukiamai ir nuolatinei stimuliacijai <b>Katalogas – 14, 19, 21 psl.</b>
13.	Sistemos garsinis ir vizualinis atsakas stimuliacijos metu	Būtina	Sistemos garsinis ir vizualinis atsakas stimuliacijos metu <b>Katalogas – 22 psl.</b>
14.	Stimuliavimo intensyvumo reguliavimo ribos	Ne siauresnėse ribose kaip 0,01 - 50 mA	0,01 - 50 mA <b>Katalogas – 23 psl.</b>
15.	Pasirenkama stimuliacijos impulso trukmė	Ne siauresniame diapazone kaip 50/100/150/200/250 μs	50/100/150/200/250 μs <b>Katalogas – 14 psl.</b>
16.	Stimuliacijos keitimo žingsnis	Ne didesnis nei 0.05 mA	Stimuliacijos keitimo žingsnis pasirenkamas vartotojo 0.01 arba 0.05 mA <b>Katalogas 14 psl.</b>
17.	Automatinis prijungtų elektrodų patikrinimas	Būtina	Automatinis prijungtų elektrodų patikrinimas <b>Katalogas – 19, 24, 25 psl.</b>
18.	Nuolatinis monitoravimas elektrokoaguliacijos metu	Būtina	Nuolatinis monitoravimas elektrokoaguliacijos metu <b>Katalogas – 19 psl.</b>
19.	Nuolatinis nervo klajoklio monitoravimas	Būtina	Nuolatinis nervo klajoklio monitoravimas <b>Katalogas – 26 psl.</b>
20.	Automatinis artefaktų aptikimas ir nuslopinimas	Būtina	Automatinis artefaktų aptikimas ir nuslopinimas <b>Katalogas – 19 psl.</b>
21.	Galimybė užšaldyti vaizdą ekrane klinikiniam signalų įvertinimui nesustabdant monitoravimo	Būtina	Galima užšaldyti vaizdą ekrane klinikiniam signalų įvertinimui nesustabdant monitoravimo <b>Katalogas – 27 psl.</b>
22.	Duomenų dokumentavimas:	<ol style="list-style-type: none"> <li>1. Informacijos apie pacientą įvedimas</li> <li>2. Ataskaitų saugojimas PDF formate ir USB laikmenoje</li> <li>3. Papildoma galimybė prijungti spausdintuvą, klaviatūrą, monitorių arba kitus duomenų saugojimo įrenginius</li> </ol>	<ol style="list-style-type: none"> <li>1. Informacijos apie pacientą įvedimas</li> <li>2. Ataskaitų saugojimas PDF formate ir USB laikmenoje</li> <li>3. Papildoma galimybė prijungti spausdintuvą, klaviatūrą, monitorių</li> </ol> <b>Katalogas – 28, 29, 30, 31, 32 psl.</b>
	<b>Priedų ir elektrodų rinkiniai sistemos instaliavimui ir paleidimui</b>		
23.	Endotrachėjinis vamzdelis	<ol style="list-style-type: none"> <li>1. Vamzdelis turi turėti ne mažiau tris bipolinius elektrodus abiejų stygų monitoravimui;</li> <li>2. Vamzdelis turi būti komplektuojamas su įrašymo ir įžeminimo elektrodais;</li> <li>3. Ne mažiau 5 skirtingų dydžių vamzdeliai, dydis pasirenkamas užsakymo metu</li> <li>4. Numatyta pozicionavimo žyma;</li> <li>5. Sterilus</li> <li>6. Vienkartinio naudojimo</li> <li>7. Kiekis 100 vnt.</li> </ol>	<ol style="list-style-type: none"> <li>1. Vamzdelis turi keturis bipolinius elektrodus abiejų stygų monitoravimui;</li> <li>2. Vamzdelis komplektuojamas su įrašymo ir įžeminimo elektrodais;</li> <li>3. 5 skirtingų dydžių vamzdeliai, dydis pasirenkamas užsakymo metu</li> <li>4. Numatyta pozicionavimo žyma;</li> <li>5. Sterilus</li> <li>6. Vienkartinio naudojimo</li> <li>7. Kiekis 100 vnt.</li> </ol> <b>Katalogas – 33, 34, 35, 36, 37 psl.</b>
24.	Monopolinis stimulatorius tiesioginei nervų stimuliacijai	<ol style="list-style-type: none"> <li>1. Stimulatorius tiesus;</li> <li>2. Turi būti komplektuojamas su rankena stimulatoriui, komplektai individualiai supakuoti;</li> <li>3. Vienkartinio naudojimo</li> <li>4. Sterilus</li> </ol>	<ol style="list-style-type: none"> <li>1. Stimulatorius tiesus;</li> <li>2. Komplektuojamas su rankena stimulatoriui, komplektai individualiai supakuoti;</li> <li>3. Vienkartinio naudojimo</li> <li>4. Sterilus</li> </ol>

		5. Kiekis 100 vnt.	5. Kiekis 100 vnt. <b>Katalogas – 38 psl.</b>
25.	APS elektrodas	1. Nuolatiniam nervo klajoklio stebėjimui skydliaukės operacijos metu 2. Ne mažiau 2 skirtingų dydžių, dydis pasirenkamas užsakymo metu; 3. Vienkartinio naudojimo 4. Sterilus 5. Kiekis 1 vnt.	1. Nuolatiniam nervo klajoklio stebėjimui skydliaukės operacijos metu 2. 2 skirtingų dydžių, dydis pasirenkamas užsakymo metu; 3. Vienkartinio naudojimo 4. Sterilus 5. Kiekis 1 vnt. <b>Katalogas – 39, 40, 41 psl.</b>
26.	Elektrodai	1. Porinis, poodinis elektrodas, pasirinktinai 2 arba 4 kanalų; 2. Insuliuotos adatos ne daugiau nei 5mm iki adatos galo; 3. Tarpas tarp adatų ne didesnis nei 2.5mm; 4. Ne mažiau dviejų skirtingų ilgių adatos, ilgiai pasirenkami užsakymo metu; 5. Vienkartiniai 6. Sterilūs, individualiai supakuoti.	1. Porinis, poodinis elektrodas, pasirinktinai 2 arba 4 kanalų; 2. Insuliuotos adatos 5mm iki adatos galo; 3. Tarpas tarp adatų 2.5mm; 4. Dviejų skirtingų ilgių adatos, ilgiai pasirenkami užsakymo metu; 5. Vienkartiniai 6. Sterilūs, individualiai supakuoti. <b>Katalogas – 42, 43 psl.</b>
27.	Artefaktų slopinimo jutiklis	1. Tinkamas elektrochirurginiams prietaisams keliantiems trikdžius;	1. Tinkamas elektrochirurginiams prietaisams keliantiems trikdžius; <b>Katalogas – 44 psl.</b>
28.	Garantinis laikotarpis	≥ 12 mėnesių	<b>Garantinis laikotarpis suteikiamas 12 mėnesių.</b>

## 2. Sutarties vertė

Sutarties (1 vnt.) vertė – 69.786,75 Eur (šešiasdešimt devyni tūkstančiai septyni šimtai aštuoniasdešimt šeši eurai 75 cnt.).

Į sutartyje nurodytą kainą įskaityta:

- 2.1. Pervežimo į pirkėjo nurodytą vietą Lietuvos Respublikos teritorijoje išlaidos.
- 2.2. Draudimo pervežant išlaidos.
- 2.3. Garantinio laikotarpio (12 mėnesių) turėtos išlaidos.
- 2.4. Naudojimo instrukcija lietuvių kalba 2 egzemplioriai.
- 2.5. Techninė dokumentacija lietuvių kalba medicinos technikui.
- 2.6. Išlaidos, susijusios su personalo apmokymu, tame tarpe ir medicinos techniko.
- 2.7. Pridėtinės vertės mokestis.
- 2.8. Įvedimas į eksploataciją.
- 2.9. Informacinės sistemos E.sąskaita naudojimo išlaidos.

## 3. Apmokėjimo sąlygos

3.1. „Pirkėjas“ sumoka už pateiktas prekes per 30 (trisdešimt) kalendorinių dienų nuo dienos, kai užsakovas gauna prekes arba paslaugas bei sąskaitą faktūrą arba lygiavertį dokumentą. Mokėjimo terminas gali būti pratęsiamas dar 30 dienų, jeigu vėluojama atsiskaityti ligoinei už suteiktas asmens sveikatos priežiūros paslaugas, tačiau mokėjimo laikotarpis negali viršyti 60 kalendorinių dienų nuo prekių gavimo dienos.

3.2. Jeigu „Pirkėjas“ neatsiskaito per minėtą laiką po prekių pristatymo, „Pardavėjas“ gali reikalauti 0,02% netesybų už kiekvieną uždelstą dieną nuo neapmokėtos sumos.

3.3. Atsiskaitymas vykdomas naudojantis tik informacinės sistemos „E.sąskaita“ priemonėmis.

#### **4. Garantijos**

4.1. "Pardavėjas" garantuoja, kad prekės, nepriklausomai nuo joms būdingos išvaizdos ar pagaminimo būdo yra tikrai naujos ir pagamintos iš reikalingų medžiagų bei pilnai atitinka techniniuose dokumentuose numatytus reikalavimus.

4.2. "Pardavėjas" įsipareigoja pataisyti ar pakeisti defektines prekes (ar jų dalis) per 1 mėnesį, garantinio remonto trukmė iki 1 mėnesio nuo defekto nustatymo. "Pardavėjas", jei tas būtina, atsiunčia savo specialistus pas "Pirkėją", kad išsiaiškintų sutrikimo priežastis, ar pataisytų defektą. Pataisytos arba naujos dalys bus pristatytos "Pirkėjui" nemokamai ir joms bus suteiktas naujas garantinis laikotarpis.

4.3. Jeigu firmos specialistai nustatys, kad gedimo negalima pašalinti "Pardavėjas" įsipareigoja pakeisti visą aparatą.

4.4. Garantinis laikotarpis prasideda nuo įrangos perdavimo – priėmimo akto pasirašymo dienos.

#### **5. Prekių pristatymas**

5.1. "Pardavėjas" pristato "Pirkėjui" nurodytas prekes į jo buveinę laike 30 (trisdešimt) dienų nuo užsakymo pateikimo dienos.

5.2. Pristatyta įranga laikoma nuo to momento, kai yra pasirašyta įrangos priėmimo-perdavimo aktas, sąskaita-faktūra, kai apmokytas personalas, pateikta naudojimo instrukcija lietuvių kalba ir užpildytas įrangos techninis pasas.

5.3. Prekių pervežimą, draudimą, pervežimo metu organizuoja ir apmoka "Pardavėjas".

5.4. Jeigu "Pardavėjas" per minėtą laikotarpį nepateikia prekių, "Pirkėjas" gali reikalauti 0,02% netesybų nuo netiekiamų prekių sumos už kiekvieną uždelstą dieną.

#### **6. Prekių įpakavimas**

6.1. Prekės supakuotos atsižvelgiant į jų pobūdį ir transportavimo saugumo reikalavimus.

6.2. "Pardavėjas" garantuoja, kad prekės nebus pažeistos transportavimo metu.

#### **7. Sutarties nutraukimas**

7.1. Sutartis įsigalioja nuo Sutarties pasirašymo dienos ir galioja 12 mėnesių.

7.1. Sutartis gali būti nutraukta vienu iš šių būdų:

7.1.1. šalių susitarimu;

7.1.2. vienos iš šalių iniciatyva, apie tai raštu informavus kitą šalį ne vėliau kaip prieš 30 (trisdešimt) kalendorinių dienų.

7.2. Pirkėjas turi teisę, įspėjęs Pardavėją prieš 30 (trisdešimt) dienų, vienašališkai nutraukti šią Sutartį dėl esminio jos pažeidimo. Esminiu šios Sutarties pažeidimu bus laikomas bet kurio įsipareigojimo pagal Sutartį neįvykdymas arba netinkamas įvykdymas.

7.3. Pardavėjas turi teisę vienašališkai nutraukti sutartį apie tai prieš 30 (trisdešimt) kalendorinių dienų raštu pranešdama kitai sutarties šaliai.

7.4. Sutarties nutraukimas neatleidžia vienos šalies nuo įsipareigojimų kitai šaliai, kuriuos ji prisiėmė pagal sutartį iki sutarties nutraukimo dienos.

#### **8. Ginčai**

8.1. Ginčo ir nesutarimo atveju, sutarties rėmuose abi pusės stengiasi susitarti taikiu būdu. Nepavykus susitarti derybų keliu, ginčas nagrinėjamas Lietuvos Respublikos įstatymų nustatyta tvarka.



## 9. Baigiamosios nuostatos

9.1. Kiekvieną ginčą, nesutarimą ar reikalavimą, kylantį iš šios Sutarties ar susijusį su šia Sutartimi, jos sudarymu, galiojimu, vykdymu, pažeidimu, nutraukimu, Šalys sprendybomis. Ginčo, nesutarimo ar reikalavimo nepavykus išspręsti derybomis, ginčas bus sprendžiamas teisme pagal Užsakovo buveinės vietą.

9.2. Pirkimo sutartis jos galiojimo laikotarpiu gali būti keičiama neatliekant naujos pirkimo procedūros vadovaujantis Viešųjų pirkimų įstatymo 89 straipsniu.

9.3. Sutartis sudaryta dviem vienodą teisinę galią turinčiais egzemplioriais lietuvių kalba, po vieną kiekvienai Šaliai.

9.4. Bet kokie pranešimai, informacija, dokumentacija ar korespondencija dėl Sutarties nevykdymo ar jos vykdymo turi būti įforminta raštu lietuvių kalba ir išsiųsta registruotu paštu per kurjerį, faksu ar elektroniniu paštu. Jeigu informacija perduodama faksu ar elektroniniu paštu, ji laikoma tinkamai perduota tik tuo atveju, jeigu Šalis, kuriai skirta tokia informacija, faksu arba elektroniniu paštu patvirtina jos gavimo faktą.

9.5. Pasikeitus Šalies buveinės adresui, banko sąskaitos numeriui ar kitiems rekvizitams, Šalis privalo apie tai pranešti kitai Šaliai. Neįvykdžius šių reikalavimų Šalis neturi teisės reikšti pretenzijų ar atsikirtimų, kad kitos Šalies veiksmai, atlikti, vadovaujantis paskutine turima informacija, neatitinka Sutarties sąlygų, arba kad ji negavo pranešimų, siųstų pagal paskutinius turimus rekvizitus.

9.6. Sutarčiai ir iš jos kylantiems Šalių santykiams bei jų aiškinimui taikoma Lietuvos Respublikos teisė.

9.7. Sutarties Šalims yra žinoma, kad ši Sutartis yra vieša, išskyrus joje esančią konfidencialią informaciją. Konfidencialia informacija laikoma tik tokia informacija, kurios atskleidimas prieštarautų teisės aktams. Šalys neskelbia tretiesiems asmenims informacijos apie konfidencialias sutarties sąlygas ir vykdymą, taip pat užtikrina, kad minėta informacija bei visi perduoti duomenys ir dokumentai nepateks tretiesiems asmenims, išskyrus Lietuvos Respublikos įstatymuose nustatytas išimtis.

9.8. Tiekėjas negali perleisti tretiesiems asmenims visų ar dalies savo teisių, susijusių su Sutartimi, įskaitant reikalavimo teisę į Pirkėjo mokėtinas sumas, be išankstinio rašytinio Pirkėjo sutikimo. Be Pirkėjo išankstinio rašytinio sutikimo sudaryti sandoriai dėl teisių ar pareigų pagal šią Sutartį perleidimo laikytini niekiniais ir negaliojančiais nuo jų sudarymo momento.

## 10. Šalių rekvizitai ir juridiniai adresai

### “Pirkėjas”

VšĮ Klaipėdos universitetinė ligoninė  
Liepojos 41,  
92288 Klaipėda  
A/S LT 827180500000120325  
AB "Šiaulių bankas"  
Banko kodas 71805  
Įmonės kodas 190468035



### “Pardavėjas”

UAB „Hospitex Diagnostics Kaunas“  
Simno g. 4,  
LT-46365 Kaunas  
A/S LT497300010075746862  
AB Swedbank  
Banko kodas 73000  
Įmonės kodas 110747425



LIETUVOS IR ŠVEICARIJOS UAB HOSPITEX DIAGNOSTICS KAUNAS  
I.k. 110747425; PVM kodas LT107474219; adresas Antagynės g. 1, Kaunas; duomenys apie įmonę kaupiami  
registrų centro duomenų bazėje;

VšĮ Klaipėdos universitetinė ligoninė

## PASIŪLYMO FORMA

### DĖL INTRAOPERACINIO NEUROMONITORIAUS PIRKIMO

2022-07-18 Nr. 608410

Kaunas

Tiekėjo pavadinimas <i>/Jeigu dalyvauja ūkio subjektų grupė, surašomi visi dalyvių pavadinimai/</i>	Lietuvos ir Šveicarijos UAB „Hospitex Diagnostics Kaunas”
Tiekėjo adresas	Antagynės g. 1, LT-47164 Kaunas
Įmonės kodas	110747425
Už pasiūlymą atsakingo asmens vardas, pavardė	Direktorius Algis Bakutis
Telefono numeris	8 37 363056
Fakso numeris	-
El. pašto adresas	info@hospitex.lt
Atsiskaitomoji sąskaita, banko rekvizitai	LT767044060003152297, AB SEB bankas, kodas 70440

1. Šiuo pasiūlymu pažymime, kad sutinkame su visomis Konkurso sąlygomis, nustatytomis:

- tarptautinio atviro Konkurso skelbime;
- tarptautinio atviro Konkurso sąlygose;
- kituose pirkimo dokumentuose.

Kartu su pasiūlymu pateikiami šie dokumentai:

Eil. Nr.	Pateiktų dokumentų pavadinimas	Dokumento puslapių skaičius
1.	EBVPD	14
2.	CE sertifikatas	3
3.	Gamintojo įgaliojimas, konfidencialu	4
4.	Katalogas	47
5.	Techninė specifikacija	3
6.	Registrų centro pažyma	2
7.	Registravimo pažymėjimas, įstatai	4

Pasiūlymas galioja iki termino, nustatyto pirkimo dokumentuose.

Eil. Nr.	Pirkimo objekto pavadinimas	Viso pasiūlymo kaina EUR su PVM
1.	Intraoperacinis neuromonitorius NIM Vital, gamintojas Medtronic	69 786,75 Eur.

Ši pasiūlyme nurodyta informacija yra konfidenciali /perkančioji organizacija šios informacijos negali atskleisti tretiesiems asmenims/:

Eil. Nr.	Pateikto dokumento pavadinimas (rekomenduojama pavadinime vartoti žodį „Konfidencialu“)	Dokumentas yra įkeltas šioje CVP IS pasiūlymo lango eilutėje („Prisegti dokumentai“ arba „Kvalifikaciniai klausimai“ prie atsakymo į klausimą)
1.	Gamintojo įgaliojimas, konfidencialu	Gamintojo įgaliojimas, konfidencialu

Pastaba. Tiekėjui nenurodžius, kokia informacija yra konfidenciali, laikoma, kad konfidencialios informacijos pasiūlyme nėra.

Direktorius

\_\_\_\_\_  
(Tiekėjo arba jo įgalioto asmens pareigų pavadinimas\*)

\_\_\_\_\_  
(Parašas\*)

Algis Bakutis

\_\_\_\_\_  
(Vardas ir pavardė\*)

Pasirašoma atskirai elektroniniu parašu tuo atveju, kai dokumente nurodytas kitas nei visą pasiūlymą pasirašantis asmuo.

## Intraoperacinis neuromonitorius

### Bendrieji reikalavimai:

- Žymėjimas CE ženklu - Pateikti CE sertifikatą arba atitikties deklaraciją.

Eil. Nr.	Parametras	Parametro reikšmė	Siūlomo parametro atitikimas, konkreti parametro reikšmė ir atitikimo patvirtinimas (psl. pasiūlyme, puslapyje pabraukiant kiekvienos pozicijos kiekvieną atitikimą, nurodant pozicijos numerį pagal prašomas specifikacijas)
1.	Paskirtis	Sistema skirta nervų lokalizacijoms, stebėjimui, stimuliavimui, EMG atsakų registravimui ir nervų vientisumo nustatymui.	Sistema skirta nervų lokalizacijoms, stebėjimui, stimuliavimui, EMG atsakų registravimui ir nervų vientisumo nustatymui. <b>Katalogas – 2 psl.</b>
2.	Pritaikymo sritys	Intrakranijines, ekstrakranijines, intratemporalines, ekstratemporalines procedūras ir operacijas, susijusias su kaklu - skyd liaukė, prieskydinė liauka; stuburu, krūtinės ląsta ir viršutinėmis bei apatinėmis galūnėmis.	Intrakranijines, ekstrakranijines, intratemporalines, ekstratemporalines procedūras ir operacijas, susijusias su kaklu - skyd liaukė, prieskydinė liauka; stuburu, krūtinės ląsta ir viršutinėmis bei apatinėmis galūnėmis. <b>Katalogas – 2, 3 psl.</b>
3.	Aparato ekranas	1. Didelio kontrasto, spalvotas, lietimui jautrus ekranas. Ekranas prisitaiko prie lietimui chirurginėms pirštinėms. 2. Skiriamoji geba 1920x1080 taškų, ne mažiau 3. Ekranas padėtis gali būti keičiama ir reguliuojama.	1. Didelio kontrasto, spalvotas, lietimui jautrus ekranas. Ekranas prisitaiko prie lietimui chirurginėms pirštinėms. 2. Skiriamoji geba 1920x1080 taškų 3. Ekranas padėtis keičiama ir reguliuojama. <b>Katalogas – 4, 5, 6 psl.</b>
4.	Vaizdo projekcija	Konsolė turi turėti galimybę belaidžiu būdu perduoti vaizdą į bet kokį LCD ekraną, taip sudarant galimybę aparatai naudoti skirtingose operacinėse.	Konsolė gali belaidžiu būdu perduoti vaizdą į bet kokį LCD ekraną ir taip sudaro galimybę aparatai naudoti skirtingose operacinėse. <b>Katalogas – 7, 8 psl.</b>
5.	Paciento sąsaja	Belaidė paciento sąsaja	Belaidė paciento sąsaja <b>Katalogas – 9 psl.</b>
6.	Trikdžių šalinimas	Sistema aparato ekrane įspėja naudotoją apie atsiradusį trikdį ir ekrane pateikia trikdžio sprendimo žingsnius.	Sistema aparato ekrane įspėja naudotoją apie atsiradusį trikdį ir ekrane pateikia trikdžio sprendimo žingsnius. <b>Katalogas – 10 psl.</b>
7.	Integruotas garsiakalbis	EMG signalo amplitudės akustiniams atvaizdavimui, aliarmams, balsiniams pranešimams.	Integruotas garsiakalbis skirtas: EMG signalo amplitudės akustiniams atvaizdavimui, aliarmams, balsiniams pranešimams <b>Katalogas – 11, 12, 13, 14 psl.</b>
8.	Garso signalų reguliavimas	Galimybė garsą reguliuoti rankenėle ant aparato korpuso ir ekrane, būtina.	Galimybė garsą reguliuoti rankenėle ant aparato korpuso ir ekrane. <b>Katalogas – 14, 15, 16 psl.</b>
9.	Elektrodų išdėstymas	Ekrane turi būti rodomas galimas elektrodų išdėstymas priklausomai nuo pacientui atliekamos procedūros.	Ekrane rodomas galimas elektrodų išdėstymas priklausomai nuo pacientui atliekamos procedūros. <b>Katalogas – 17 psl.</b>
10.	Garso signalų įjungimas ir išjungimas	Būtina	Garso signalų įjungimas ir išjungimas <b>Katalogas – 13, 18 psl.</b>

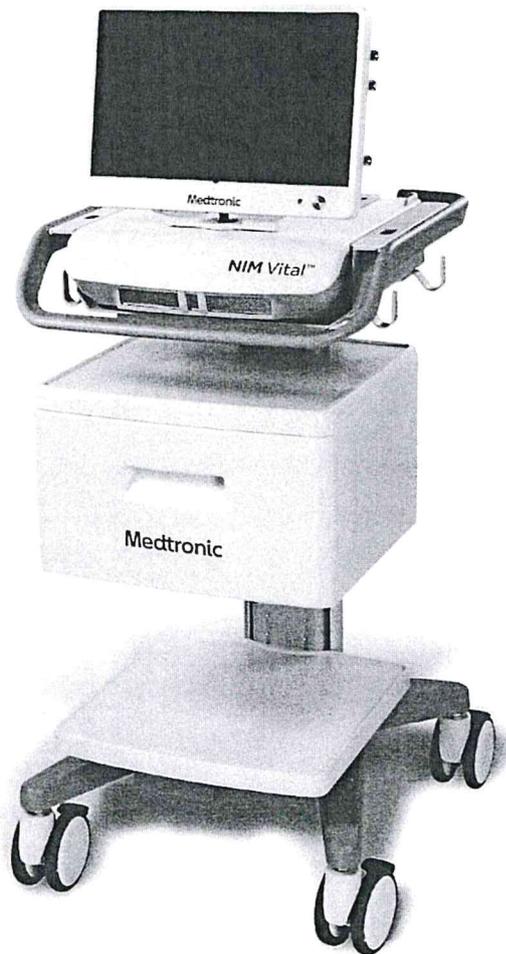
11.	EMG kanalų skaičius	Ne mažiau kaip 4 kanalų	4 kanalai <b>Katalogas – 19, 20 psl.</b>
12.	Ne mažiau du nepriklausomi elektriniai stimuliavimo kanalai, skirti nepertraukiamai ir nuolatinei stimuliacijai	Būtina	Du nepriklausomi elektriniai stimuliavimo kanalai, skirti nepertraukiamai ir nuolatinei stimuliacijai <b>Katalogas – 14, 19, 21 psl.</b>
13.	Sistemos garsinis ir vizualinis atsakas stimuliacijos metu	Būtina	Sistemos garsinis ir vizualinis atsakas stimuliacijos metu <b>Katalogas – 22 psl.</b>
14.	Stimuliavimo intensyvumo reguliavimo ribos	Ne siauresnėse ribose kaip 0,01 - 50 mA	0,01 - 50 mA <b>Katalogas – 23 psl.</b>
15.	Pasirenkama stimuliacijos impulso trukmė	Ne siauresniame diapazone kaip 50/100/150/200/250 μs	50/100/150/200/250 μs <b>Katalogas – 14 psl.</b>
16.	Stimuliacijos keitimo žingsnis	Ne didesnis nei 0.05 mA	Stimuliacijos keitimo žingsnis pasirenkamas vartotojo 0.01 arba 0.05 mA <b>Katalogas 14 psl.</b>
17.	Automatinis prijungtų elektrodų patikrinimas	Būtina	Automatinis prijungtų elektrodų patikrinimas <b>Katalogas – 19, 24, 25 psl.</b>
18.	Nuolatinis monitoravimas elektrokoaguliacijos metu	Būtina	Nuolatinis monitoravimas elektrokoaguliacijos metu <b>Katalogas – 19 psl.</b>
19.	Nuolatinis nervo klajoklio monitoravimas	Būtina	Nuolatinis nervo klajoklio monitoravimas <b>Katalogas – 26 psl.</b>
20.	Automatinis artefaktų aptikimas ir nuslopinimas	Būtina	Automatinis artefaktų aptikimas ir nuslopinimas <b>Katalogas – 19 psl.</b>
21.	Galimybė užšaldyti vaizdą ekrane klinikiniam signalų įvertinimui nesustabdant monitoravimo	Būtina	Galima užšaldyti vaizdą ekrane klinikiniam signalų įvertinimui nesustabdant monitoravimo <b>Katalogas – 27 psl.</b>
22.	Duomenų dokumentavimas:	<ol style="list-style-type: none"> <li>1. Informacijos apie pacientą įvedimas</li> <li>2. Ataskaitų saugojimas PDF formate ir USB laikmenoje</li> <li>3. Papildoma galimybė prijungti spausdintuvą, klaviatūrą, monitorių arba kitus duomenų saugojimo įrenginius</li> </ol>	<ol style="list-style-type: none"> <li>1. Informacijos apie pacientą įvedimas</li> <li>2. Ataskaitų saugojimas PDF formate ir USB laikmenoje</li> <li>3. Papildoma galimybė prijungti spausdintuvą, klaviatūrą, monitorių <b>Katalogas – 28, 29, 30, 31, 32 psl.</b></li> </ol>
	<b>Priedų ir elektrodų rinkiniai sistemos instaliavimui ir paleidimui</b>		
23.	Endotrachėjinis vamzdelis	<ol style="list-style-type: none"> <li>1. Vamzdelis turi turėti ne mažiau tris bipolinius elektrodus abiejų stygų monitoravimui;</li> <li>2. Vamzdelis turi būti komplektuojamas su įrašymo ir įžeminimo elektrodais;</li> <li>3. Ne mažiau 5 skirtingų dydžių vamzdeliai, dydis pasirenkamas užsakymo metu</li> <li>4. Numatyta pozicionavimo žyma;</li> <li>5. Sterilus</li> <li>6. Vienkartinio naudojimo</li> <li>7. Kiekis 100 vnt.</li> </ol>	<ol style="list-style-type: none"> <li>1. Vamzdelis turi keturis bipolinius elektrodus abiejų stygų monitoravimui;</li> <li>2. Vamzdelis komplektuojamas su įrašymo ir įžeminimo elektrodais;</li> <li>3. 5 skirtingų dydžių vamzdeliai, dydis pasirenkamas užsakymo metu</li> <li>4. Numatyta pozicionavimo žyma;</li> <li>5. Sterilus</li> <li>6. Vienkartinio naudojimo</li> <li>7. Kiekis 100 vnt. <b>Katalogas – 33, 34, 35, 36, 37 psl.</b></li> </ol>
24.	Monopolinis stimulatorius tiesioginei nervų stimuliacijai	<ol style="list-style-type: none"> <li>1. Stimulatorius tiesus;</li> <li>2. Turi būti komplektuojamas su</li> </ol>	<ol style="list-style-type: none"> <li>1. Stimulatorius tiesus;</li> <li>2. Komplektuojamas su rankena</li> </ol>

		rankena stimuliatoriui, komplektai individualiai supakuoti; 3. Vienkartinio naudojimo 4. Sterilus 5. Kiekis 100 vnt.	stimuliatoriui, komplektai individualiai supakuoti; 3. Vienkartinio naudojimo 4. Sterilus 5. Kiekis 100 vnt. <b>Katalogas – 38 psl.</b>
25.	APS elektrodas	1. Nuolatiniam nervo klajoklio stebėjimui skydliaukės operacijos metu 2. Ne mažiau 2 skirtingų dydžių, dydis pasirenkamas užsakymo metu; 3. Vienkartinio naudojimo 4. Sterilus 5. Kiekis 1 vnt.	1. Nuolatiniam nervo klajoklio stebėjimui skydliaukės operacijos metu 2. 2 skirtingų dydžių, dydis pasirenkamas užsakymo metu; 3. Vienkartinio naudojimo 4. Sterilus 5. Kiekis 1 vnt. <b>Katalogas – 39, 40, 41 psl.</b>
26.	Elektrodai	1. Porinis, poodinis elektrodas, pasirinktinai 2 arba 4 kanalų; 2. Insuliuotos adatos ne daugiau nei 5mm iki adatos galo; 3. Tarpas tarp adatų ne didesnis nei 2.5mm; 4. Ne mažiau dviejų skirtingų ilgių adatos, ilgiai pasirenkami užsakymo metu; 5. Vienkartiniai 6. Sterilūs, individualiai supakuoti.	1. Porinis, poodinis elektrodas, pasirinktinai 2 arba 4 kanalų; 2. Insuliuotos adatos 5mm iki adatos galo; 3. Tarpas tarp adatų 2.5mm; 4. Dviejų skirtingų ilgių adatos, ilgiai pasirenkami užsakymo metu; 5. Vienkartiniai 6. Sterilūs, individualiai supakuoti. <b>Katalogas – 42, 43 psl.</b>
27.	Artefaktų slopinimo jutiklis	1. Tinkamas elektrochirurginiams prietaisams keliantiems trikdžius;	1. Tinkamas elektrochirurginiams prietaisams keliantiems trikdžius; <b>Katalogas – 44 psl.</b>
28.	Garantinis laikotarpis	≥ 12 mėnesių	<b>Garantinis laikotarpis suteikiamas 12 mėnesių.</b>
29.	Tiekėjas privalo pateikti gamintojo katalogus (prekių aprašymus), kuriuose būtų nurodyta prekių kodai bei visa kita informacija, pagrindžianti prekės atitikimą konkurso specifikacijai. Kataloge turi būti pabrauktas ir pažymėtas atitikimas reikalaujamiems parametrams t. y. pabraukti kiekvienos pozicijos kiekvieną atitikimą, nurodant pozicijos numerį pagal prašomas specifikacijas. Katalogai (prekių aprašymai) turi būti lietuvių arba užsienio kalba. <b><u>Pateikiamos skaitmeninės dokumentų kopijos.</u></b>	Būtina	<b>Pateikiama</b>
30.	Perkamas kiekis	1 vnt.	1 vnt.
31.	PVM tarifas procentais		<b>21%</b>
32.	Kaina Viso Eur su PVM		<b>69 786,75 Eur</b>
33.	Firminis pavadinimas, gamintojas		<b>NIM Vital, gamintojas Medtronic</b>

# Medtronic

## Nerve Integrity Monitor

NIM Vital™



**Instructions for use**

**Rx Only**

## Intended use

The NIM Vital™ is intended for locating and monitoring, including stimulation, of cranial, spinal, peripheral motor and mixed motor-sensory nerves and registering EMG responses during surgery.

## Indications for use

The NIM Vital™ system may be used for EMG monitoring in support of surgical procedures including: intracranial, extracranial, intratemporal, extratemporal and surgeries associated with the neck, spine, thorax, and upper and lower extremities.

## Device description

The NIM Vital™ system is an intraoperative EMG monitor that enables users to locate and confirm the integrity of nerves during surgical procedures.

The system stimulates nerves (propagates an action potential) through a variety of stimulation probes that causes the muscle associated with the nerve to contract. The system then picks up these electric signals from the muscles through a variety of electrodes and converts this information into meaningful graphs and sounds that the system displays on the monitor.

The system also continuously monitors EMG activity from the muscles innervated by the nerve at risk.

## Contraindications

The NIM Vital™ system is contraindicated for use with paralyzing anesthetic agents that will significantly reduce, if not completely eliminate, EMG responses to direct or passive nerve stimulation.

## Warnings and precautions

It is important that the NIM Vital™ system intended operators be familiar with this manual: its warnings, precautions, procedures and safety issues. Disregarding the information on safety is considered abnormal use.

### Warnings

- W1 The NIM Vital™ system does not prevent the surgical severing of nerves. If monitoring is compromised, the surgical practitioner must rely on alternate methods, or surgical skills, experience, and anatomical knowledge to prevent damage to nerves.
- W2 If paralyzing anesthetic agents have been used, patient must regain muscle activity prior to use of the NIM Vital™ EMG Monitor.
  - a. To limit the paralytic effect of anesthetic agents, the anesthesiologist should monitor Train-of-Four (TOF) to prevent diminished EMG activity. Consult anesthesiologist if EMG changes are observed.
- W3 Surgical Identification of exposed nerves is key to their preservation. Failure to use Medtronic's Nerve Stimulation Probe may contribute to unintended surgical nerve damage or resection.
  - a. The user is responsible for ensuring the electrodes are placed, or inserted into the target muscles. The electrode check, or tap test only indicates that the electrodes are making contact with the patient's tissue and does not indicate that the needle is inserted into the correct muscle.
- W4 To avoid the risk of fire or explosion, do not use the Medtronic NIM Vital™ system in the presence of flammable anesthetics and/or oxygen rich environment.
- W5 After each procedure, properly clean and disinfect all reusable system components.
- W6 To avoid alternate site patient burns or lesions when patient interface is connected to the NIM Vital™ console through the patient interface cord:
  - a. Do not activate the electrosurgical instruments (ESU) while stimulator is in contact with tissue.
  - b. Do not leave dissection instruments, stimulating electrodes, or probes in surgical field.
  - c. Do not store dissection instruments, stimulating electrodes, or probes in electrosurgical instrument holder.
  - d. Do not allow a second surgeon (for example, fat harvesting) to use electrosurgical instruments while stimulator is in use.
  - e. Do not activate electrosurgical instrument for prolonged periods while ESU is not in contact with tissue.
  - f. Do not activate electrosurgical instrument near the recording or stimulating electrodes.
  - g. Do not allow patient interfaces or recording / stimulating electrodes sites to be flooded with saline.
  - h. Do not allow excessive stray AC or DC leakage currents from patient connected equipment; Avoid creating an unintended grounding path through applied electrodes.  
Practitioner is responsible for proper use, periodic safety certification of patient connected equipment, and AC power grounding in accordance to the appropriate IEC 60601-1 and/or IEC 60601-1-1 medical safety standard.
- W7 Disconnect power to the console before cleaning the unit to avoid electrical macro shock.
- W8 Achieve electrical grounding reliability with proper connections. Connect the console to hospital grade receptacles only.
- W9 Do not use any parts:
  - a. other than Medtronic components as damage or substandard performance could result.
  - b. that are damaged components or accessories.

INTRODUCTION



## HEAD & NECK SURGERIES

BENIGN DISORDER  
MALIGNANT DISEASE

- Thyroid gland
- Parathyroid gland

- Parotid glands
- Mastoid
- Ear



## NERVES AT RISK

- Recurrent laryngeal nerve (RLN)
- External branch of the superior laryngeal nerve (EBSLN)
- Nonrecurrent laryngeal nerve (NRLN)
- Facial nerve (FN)

2



Nerve Integrity Monitor

# Technical specifications

## Physical dimensions - console

Size: 41 cm W x 45 cm D  
 42.5 cm H (Screen Open)  
 20.5 cm H (Screen Down for storage)  
 Weight: 10.7 Kg

## Physical dimensions - patient interface

Size: 6.5 cm W x 7.5 cm H x 21.5 cm D  
 Weight: 55 Kg

## Physical dimensions - cart (NIM4CC01)

Size: 53 cm W x 101 cm H x 61 cm DP  
 Weight: 45 kg  
 Capacities: Drawer Max. Load - 4.5 kg  
 Shelf Max. Load - 9.0 kg  
 Cart Total Max. Load - 79.5 kg

## Operational environment - console, console back-up battery, patient interface with internal battery

Operating Temperature range: 10 to 33° C (Operating)  
 Humidity: 30-70% RH non-condensing  
 Atmospheric Pressure range: 700 hPa to 1060 hPa

## Transport and storage environment - console, console back-up battery, patient interface with internal battery

Shock and Vibration: Verified to Standard ISTA 2A  
 Ambient Temperature range: -20°C to + 50° C  
 Relative Humidity range: 10 % to 100 %, including condensation  
 Atmospheric Pressure range: 500 hPa to 1060 hPa

## Amplifier

Channels - 1 to 4; Individually and simultaneously selectable  
 Input Sensitivities: 5 – 10,000 µV peak-to-peak AC Coupled ± 5% at 10 mV to ± 30% at 100 mV peak-to-peak AC Coupled  
 Sensitivity Selection: Automatically zeroed  
 Bandpass: 15 Hz - 1.85 kHz (± 3 db @ 500 Hz) EMG Display  
 200 Hz - 1.0 kHz (-6, +3 db @ 500 Hz) Audio EMG Speaker  
 Input Noise: 3-14 µV p-p, < 5 µV RMS @ DC - 2 KHz, inputs shorted  
 Input Impedance: > 10 Meg Ohm  
 DC offset Rejection: ± 0.90 V DC Rejection  
 Common Mode Rejection: >80 dB @ 60 Hz, balanced inputs, >66 dB @ 60 Hz, 1 K Ohm imbalance  
 Channel Enable/Disable Controls: Dedicated function touch pads for independent channel enable/disable.  
 Event Threshold Control and Display: Adjustable Graduated Touch Screen with Voltage threshold displayed.  
 Patient Isolation Wired: 1,000 Vrms 60Hz < 100 µA

## Impedance measurement

Control: Automatic CHECK ELECTRODE feature.  
 Measuring Signal: 6 µA or 24 µA peak-to-peak, 7.8 Hz Square wave  
 Measurement Range: Electrodes:  
 0K to 2K Ohm ± 500 Ohm  
 >2K-175K Ohm ± 20%  
 Ground and Stim Returns < 25K.

## Artifact detection and rejection

Stimulus Artifact: Synchronized and adjustable muting and warning.  
 Bipolar Electrocautery Rejection: Continuous Monitoring During Bipolar Cautery < 40 watts  
 Monopolar Electrocautery (ESU) Interference: Automatic detection and muting in wired or wirefree modes.  
 Muting Detector Input ESU Sensitivity: Monopolar ESU Cut / Coag  
 Contact 5 - 100 Watts  
 Air-Discharge 10-100 Watts  
 Muting Console Input Sensitivity: Muting (0.6 - 2.0 Volts Vrms)  
 Non-Muting (<0.3 Volts Vrms)  
 Muting Detector Input ESU Immunity: ESU < 100 Watts Cut / Coag or  
 (<3.0 Vrms 100-800 KHz Sq. Wave)  
 Electrode Lead Off: Automatic detection with Channel Off Muting and Warning message.

## Display / touch screen

Type: High contrast, digital, graphic color, visible in complete darkness. 3.1  
 Resolution: Display Full HD - 1920H x 1080W pixels 3.2  
 Dedicated Function Event Touch Screen Controls: 3.1  
 Vertical Display: Touch Panel - Capacitive Multi and Glove touch capable 4095H x 4095W 3.1  
 Event Capture: Enable/disable capture mode indicator on touch screen.  
 Time Scale: 25 ms, 50 ms, 100 ms or 20 s display modes.

## Patient Interface

Color Coded Channel Patient Connections: "Touchproof safety connection protected pin 1.5 mm per specification: DIN 42 802"  
 Internal Fuse: Electronic limiting protection circuit and standard fuses. See Stimulator 1 and 2  
 "Internal Fuse".

## Stimulator 1 and 2

Stimulus Type Constant: Constant Current

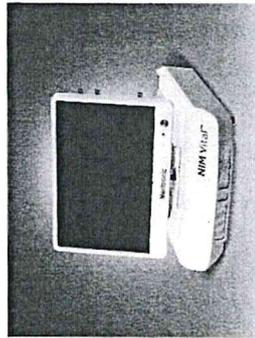
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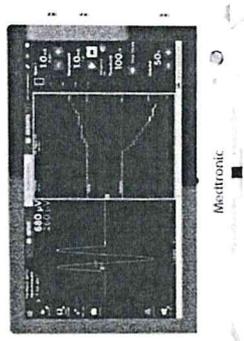
COMPONENTS

# MEDTRONIC'S NERVE INTEGRITY MONITORING (NIM) SYSTEM: NIM VITAL™

NIM Vital™ Mainframe with Touch Screen Display



Real-time Display on NIM Vital™ Monitor



Stimulating Probe allows the stimulation current at the surgical site to be adjusted



APS™ Electrodes



Electrodes



TriVantage™ Tube



## Setting up the NIM Vital™ console

1. Remove the NIM Vital™ console from its shipping box.
2. Place the console on a stable counter or on the NIM Vital™ cart (if purchased). Refer to the “Setting up the NIM Vital™ cart” topic for more information.
3. Install the NIM Vital™ battery that shipped separately from the NIM Vital™ system. Refer to the “Installing the NIM Vital™ battery” topic for more information.
4. While facing the NIM Vital™ console’s front, gently pull the monitor up and toward you until it reaches the desired placement.
5. Rotate the monitor until the monitor screen is facing you.
6. If you are not using the cart, plug the power cord into the socket on the rear of the console.

3.3

## Installing the NIM Vital™ battery

1. Remove the two screws on the information plate located on the back of the console base between the patient interface cradles using a phillips head screwdriver.
2. Insert the battery into the battery compartment with the pull tab on the battery facing up until you feel the battery engage.
3. Replace the information plate by placing the lip on the bottom of the plate into the bottom edge of the battery compartment.
4. Align the two screw holes and replace the phillips head screws using a screwdriver.

## Setting up the NIM Vital™ cart

Refer to the “The NIM Vital™ equipment cart” topic for additional information.

1. Remove the cart from its shipping crate. Refer to the uncrating instructions that ship with the shipping crate.
2. At the top of the cart, remove the tape securing the power cord and move it out of the way.
3. Place the NIM Vital™ console onto the top of the cart making sure to align the two pins on the cart with the holes in the bottom of the console.
4. Reach underneath the console tray and hand-tighten the securing knob.
5. Plug the power cord into the console.
6. Plug the 20 ft Mains power cord into the multi-socket outlet (MSO) located in the lower drawer of the cart.
7. Secure the cord using the cable clamp in the lower drawer using a phillips head screwdriver.

If you plan to add a printer to the bottom shelf of the cart, refer to the “Installing the power isolator” topic. Refer to the “Precautions” topic for additional information.

## Connecting NIM Vital™ accessories

Place the patient interfaces into the cradles to begin charging them.

## First time user interface setup

Refer to the “SETUP tab” topic for more information while performing a basic setup.

1. Connect unit to AC power.
2. Turn power switch On.
3. After the system completes the self-test, press .
4. Select Language (English is default).
5. Press  or  to close Global settings.

## Set the time zone, date, time, and date/time format

1. During setup, press time/date in the lower right corner of the screen.  
The System Date Time Settings dialog box appears.
2. Select the time zone from the Time Zone drop-down menu.
3. Select the date/time format using the Date Time Format drop-down list.
4. Press  and select the correct date from the calendar.
5. Select the time using the Hours/Minutes/Seconds drop-down lists.
6. Do one of the following:
  - Press **[Confirm]** and the system saves the information.
  - Press **[Cancel]** to exit without saving the information.

6

## Nerve Integrity Monitor

### Cleaning

Refer to the "Cleaning and Maintenance" topic.

### Storage

Allow the unit and accessories to thoroughly air-dry before storing in a cool dry place. Refer to the "Technical Specifications" topic for further information.

### Troubleshooting

Should you encounter any difficulty eliciting simulated responses from the NIM Vital™ system patient simulator, check the following:

- Verify that the Stimulus Measured is approximately the same as the Stimulus Intensity.
- Make sure the jumper cables are connected correctly between the SIMULATOR and PATIENT INTERFACE.
- Adjust the EVENT THRESHOLD setting on the NIM Vital™ system.
- Adjust the STIMULUS intensity on the NIM Vital™ system for adequate output.
- Clean the stimulator contacts of debris.
- Check the integrity of the stimulator or stimulus-dissection instrument and its connecting cable.
- Check for a blown fuse in NIM Vital™ system patient interface and replace with a proper valued fuse (shown near fuse box).
- Check for proper closure of fuse holder in the NIM Vital™ system patient interface.

### Customer service information

For further information regarding the use of this product or to report any problems, please contact Medtronic using the appropriate information provided on the blue and white contact information card packaged with each device; or contact your local distributor.

### External display support

The NIM Vital™ system has the following external video ports, but does not have any specific connection settings for a microscope output:

- HDMI
- Display

### Wireless display module

The wireless display module enables users to wirelessly replicate the NIM Vital™ console display onto any monitor with an HDMI input port. Refer to the installation instructions packaged with the wireless display module.

### NIM Vital™ Mute adapter

The NIM Vital™ mute adapter enables the NIM Vital™ console to be connected to an external muting detector.

1. Console Connector (below knobs).
2. Connector to mute probe.
3. Tether.

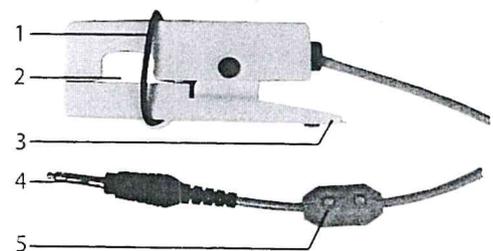


### NIM Muting detector

Refer to the "Precautions" topic for additional information.

The optional Muting Detector Probe is designed to detect the presence of electronic noise from external devices (such as electrocautery/electrosurgical unit) that may cause interference on the EMG monitor. The use of a mute probe could be considered if there is excessive noise from the electrosurgical unit.

1. Anti-slide Ring.
2. Electronic Noise Detection Area.
3. Insulating Sleeve.
4. Cable Connector.
5. Ferrite.



**Medtronic**

**EMEA MARKET SHARE & OVERALL COMPARISON**

**NIM VITAL™ VS NIM 3.0**

**NIM VITAL™ VS COMPETITORS**

**INOMED**

**DR LANGER**

**NEUROSIGN**

**DETAILED COMPARISON TABLE**

# NERVE MONITORING NIM VITAL

## WIRE CABLE OPTION - FREE PROJECTION <sup>4</sup>

### NIM VITAL™

NIM Vital™ console projection onto LCD screens allowing to place the system on any screen in theatres. <sup>4</sup>



NIM Vital™ Wireless Console Projection



**Medtronic**

**EMEA MARKET  
SHARE & OVERALL  
COMPARISON**

**NIM VITAL™  
VS NIM 3.0**

**NIM VITAL™ VS  
COMPETITORS**

**INOMED**

**DR LANGER**

**NEUROSIGN**

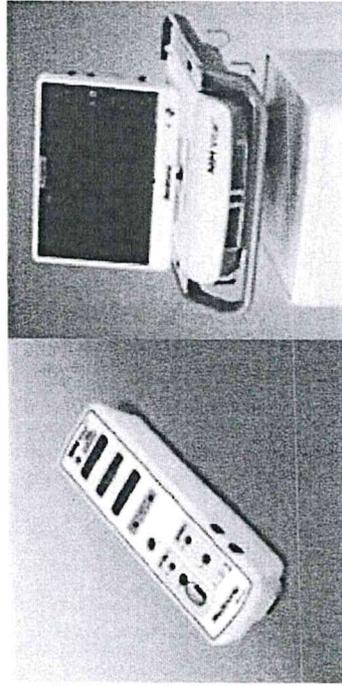
**DETAILED  
COMPARISON  
TABLE**

# NERVE MONITORING NIM VITAL™

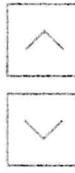
## WIRE-FREE FEATURES

### NIM VITAL™

NIM Vital™ wireless patient interface and wire-free monopolar muting reduce the number of cables to the console, minimizing the risk of tripping over cables in theatres and simplifying set up and dismantling.



NIM Vital™ Wire-free Monopolar Muting



**Medtronic**

**EMEA MARKET SHARE & OVERALL COMPARISON**

**NIM VITAL™ VS NIM 3.0**

**NIM VITAL™ VS COMPETITORS**

**INOMED**

**DR LANGER**

**NEUROSIGN**

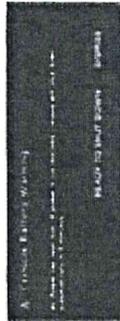
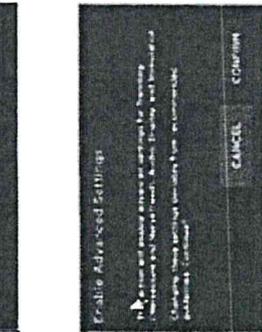
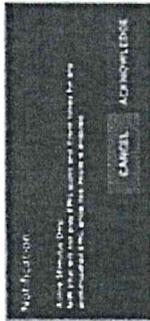
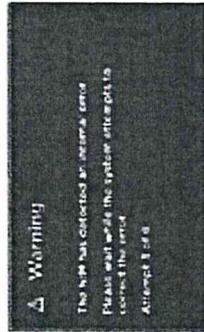
**DETAILED COMPARISON TABLE**

# NERVE MONITORING NIM VITAL™

## TROUBLE SHOOTING

### NIM VITAL™

NIM Vital™ Smart trouble shooting pop ups alert staff to trouble shooting issues and offers resolution protocol.



9. Press , or the MONITORING tab to begin monitoring on the Monitoring screen. The NIM Vital system is ready to monitor with its default settings.
10. After the patient is draped, connect a sterile NIM monopolar stimulator probe to the STIM 1 jack (color-coded black plug and black socket).

## The basics of what you will see and hear during monitoring

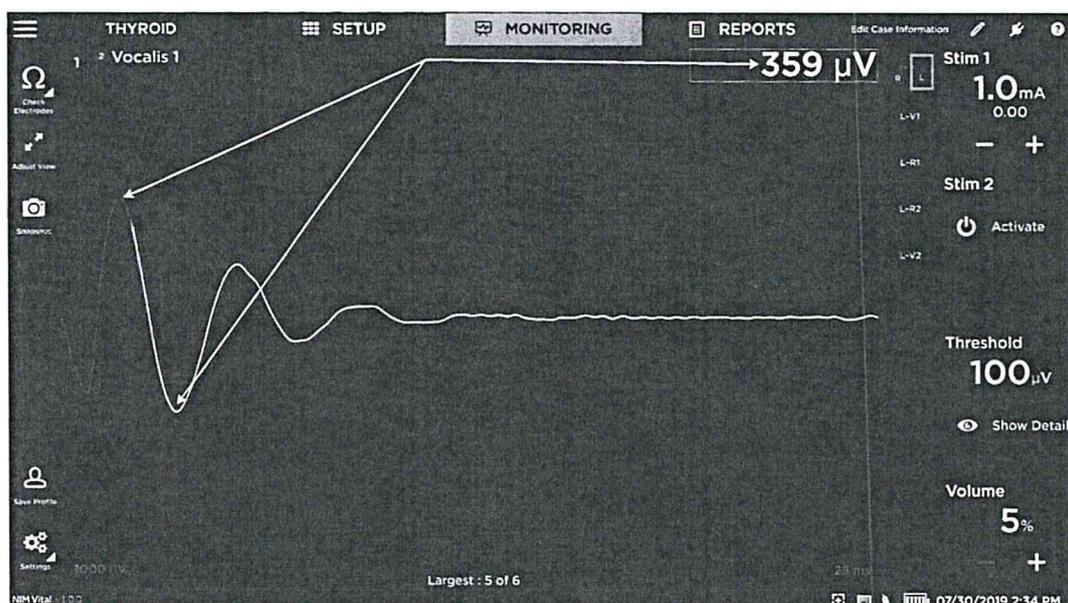
The following procedure is meant to be completed by surgeons and OR staff users. Refer to the "MONITORING tab" topic for more information.

1. The surgeon uses the stimulator probe as the primary means to confirm the location and integrity of the nerves. Refer to warning W3.

One of two events may occur:

- The NIM system sounds a "Current Delivery" tone (a short tweedle sound) when contacting tissue, but not evoking a response. The tone indicates the set current is being delivered.
- Upon stimulation of the nerve, EMG is evoked, and the default audible tone is heard at ~4X/sec and raw EMG (thump, thump, thump). The EMG event is also shown on the monitoring screen as a waveform (figure 1).

Figure 1. Biphasic EMG waveform showing peak-to-peak measurement or amplitude



**Note:** the latency is measured from the stimulus from the left-hand side of the screen to the start of the EMG waveform.

2. Between probe uses the NIM is passively monitoring muscles and you may hear changes in the EMG, or mechanically evoked nerve responses that look and sound similar to stimulator evoked nerve responses. **Note:** The NIM may not alert the surgeon to all types of surgical manipulation of the nerve including sharp, surgical resection.
3. The surgeon confirms the integrity of the nerve using the probe throughout the entire procedure and at the end of the procedure. Refer to the table of contents "Audio - understanding what you hear" topic for more information.

## Unboxing and installing the system

Check off the contents of the box against the packing slip. If incomplete or damaged, notify customer service at +1 800 874 5797.

If the container is damaged or cushioning material shows stress, notify the carrier and customer service. Keep the shipping materials for carrier inspection.

After unpacking, save the cartons and packing material. If the NIM Vital™ system is to be shipped, the shipping package will provide proper protection.

- **Additional Options** - toggle the following options on/off that are available only in Thyroid procedures:
  - Monitoring study group adapted color scheme (2018) – changes the color conditions for alerts.
  - Alarm on best channel – When the user uses the Alarm on Best Channel, the system assigns the status from the individual trended channel with the highest amplitude as the alarm condition. When the user does not use the Alarm on Best Channel, the system assigns the status from the individual trended channel with the lowest status as the alarm condition. Alarm on Best Channel is on by default and cannot be disabled when Single Channel Mode is in use.

Use the advanced alarm settings selections to customize the following alarm settings (**Note:** These settings may behave differently if Alarm on Best Channel is in use):

- Amplitude Only sets the alarm to sound if the EMG response tolerance limit is reached regardless of the latency (default is 50% less than baseline and lower than 2000 $\mu$ V). You can also set an absolute alarm limit in this area.
- Latency Only sets the alarm to sound if the latency tolerance limit is reached regardless of the amplitude (default is latency value plus(+) 10%).
- Absolute alarm limit example: If the baseline amplitude is 3000  $\mu$ V, the amplitude percentage limit is 50% (1500  $\mu$ V), and Amplitude Absolute limit is 1000  $\mu$ V, then a signal of 1400  $\mu$ V would not cause an alarm because although the signal has decreased more than 50%, it is still above the absolute limit.
- Absolute Alarm Adjustment. This is an actual EMG voltage response above which the percentage alarm is disabled.
- Amplitude OR Latency sets the alarm to sound if either the EMG amplitude OR the latency limit is reached.
- Amplitude AND Latency only sets the alarm to sound if BOTH the EMG amplitude AND the latency limits are reached.
- The Latency type button is located to the right of the Increase button and toggles between percent (%) and msec.
  - Percentage – this is the percentage increase in latency from the baseline latency at which an alarm condition occurs (for example, if the setting is 10%, then an alarm occurs when the latency goes above 110% of baseline - a 10% increase).
  - ms – this is the increase in latency (in milliseconds) from the baseline latency at which an alarm condition occurs (for example, if the setting is 1.5 msec and the baseline latency is 8.0 msec, then an alarm occurs when the latency goes above 9.5 msec).

## Audio – understanding what you hear

The NIM Vital™ system Nerve Monitor produces many different sounds throughout the surgical procedure that alert you to various important information. In addition to EMG sounds, the system uses beeps and voices to provide useful information.

### Alarms

The alarms draw attention to any condition which prevents you from properly monitoring the surgical procedure. You should not ignore any of the audible alarms. You must assume that valid monitoring has stopped and determine immediately why the alarm sounded.

There are three distinct alarms:

- BEEP alarm. This is a high-pitched repetitive beep. You will hear the alarm under the following circumstances:
  - Power on.
  - Power off.
  - System failure. Stop using the NIM Vital™ system and contact Medtronic.
- Bleedle alarm. This is a three-note alarm (Blee-Dle Deet) that you cannot disable. You will hear the alarm under the following circumstances:
  - Completion of power up.
  - Check electrode. The alarm repeats if there is an electrode issue until you remedy the responsible condition.
    - As soon as contact with an electrode is lost after removal including lost contact with Nervassure electrodes.
    - The channel shows a lead off message.
    - The system mutes the channel until connection is restored.
  - Muting. As soon as the Muting Detector senses current flow, the dialog box “EMG MONITORING IS DISABLED/Muting from external source” appears and the system becomes mute.
    - For the wired mute probe, after 30 seconds, the bleedle alarm sounds followed by the “Muting” voice. The bleedle alarm repeats every 30 seconds until you remedy the condition.
    - For the ESU filter, after 10 seconds, the bleedle alarm sounds followed by the “Muting” voice. The bleedle alarm repeats every 10 seconds until you remedy the condition.
  - Stimulus tone (warbled).
- Nervassure alarm. The system uses several alarms to notify you when a plotted point is determined to be outside an alarm limit. Refer to the “Muting a Nervassure alarm” topic for more information.
  - Alarm with yellow condition. A single bong alarm sounds every five seconds until the condition is remedied or moves into a different alarm condition.

## Nerve Integrity Monitor

Additional options for the Stimulus Delivery Audio panel (3):

- Brief Tone (default). Delivery of stimulus current is accompanied by a brief warbled tone.
- Continuous Tone. Delivery of stimulus current is accompanied by a continuous, warbled, high-low tone (referred to as "Stimulus Warble Tone").
- Voice - Stimulus. Delivery of current to the surgical field is announced by the word, "STIMULUS".
- Voice - Setting. Delivery of current to the surgical field is announced by the value of the stimulus setting.

**Note:** You will not hear the Stimulus Delivery Audio when an event has occurred.

The following options are located on the Monitoring Audio panel. At least one selection must be active, however you may select all three options.

- EMG audio is the amplified sound of muscle activity that is heard instantaneously as the nerve is stimulated. All EMG activity, regardless of amplitude, is audible when the EMG audio is ON. The EMG activity may sound like a low-pitched "drumbeat", a high-pitched "crackle," or a "growl". When you monitor multiple channels, it is unlikely that you will be able to differentiate the EMG signals as to their channel of origin strictly by the sounds they produce.
- Event Tones are heard when the EMG amplitude is larger than the Event Threshold setting. The Event Tones are easily heard over O. R. noise and are heard at the same time with the EMG audio, previously mentioned.
- "Voice - Stimulated EMG Values" announces the value of the highest channel in the largest event in a sequence if largest is selected in Display settings (approximately one second after the sequence ends). The system rounds the actual value appropriately for annunciation. For example, the NIM Vital™ system would announce 623 as "six hundred twenty."

You can differentiate channels by tone pitch. The tone for channel 1 activity is lower in pitch than channel 2, and so on for channels 3 through 4. When EMG activity exceeding the event threshold occurs at the same time on multiple channels, only the tone of the channel with the highest EMG activity will be produced.

You can mute individual EMG channels by selecting Show Channel Mute Buttons.

Once the user enables a monitoring audio option (EMG Audio, Event Tones, or Voice - Stimulated EMG Values), the system displays a volume balance for the option. All of the balances in this panel default to 50%.

## Audio advanced settings

On the Audio advanced settings panel the user can toggle on/off Audio during Active Stimulus Only. When the user enables the Active Stimulus Only, the system mutes the EMG audio and event tones occurring without stimulation. This mode only works with compatible, connected stimulators.

## Display Settings panel

**Note:** If you adjust the advanced settings, you will change the default characteristics of your NIM Vital™. Only someone with

knowledge of the advanced settings and how they impact your NIM Vital™ should make changes. If the user selects , the system displays a warning. The user must select [Cancel] or [Confirm] to return to settings or move forward to the advanced settings panel.

Stimulus Range:	Stim 1 and Stim 2 0-3 mA, a minimum of $\pm 12$ V compliance (tested into a 4K load)
Load Impedance Range: as long as the load impedance X stimulation current is less than or equal to the compliance voltage.	Stim 1 3.1-50mA a minimum of $\pm 100$ V compliance (tested into a 2K load)
Stimulus Control:	$< 4$ K Ohms (0 - 3 mA): Compliance 12 V $< 2$ K Ohms (3.1 - 50 mA): Compliance 100 V
Stimulus Output Accuracy: Stimulus Adjustment:	Digitally controlled, range - dependent adjustment increments of 0.01, 0.05, 0.1, .5 and 1.0 mA $\pm .01$ mA (or $\pm 10\%$ of reading at 1 K load) over Stimulus Range. Dedicated Side Control knobs and Graduated Touch Screen Control with display of command current and delivered current.
Stimulus Measurement Accuracy: Internal Fuse:	$\pm .02$ mA (or $\pm 10\%$ of reading at 1 K load) over Stimulus Range. 32 mA Type F, 250 V 5 x 20 mm (It must be Xomed #8253075, other similar fuses may not give the same degree of protection). Order 8253075 Fuse Kit for replacements.

**Stimulus 1 and 2 characteristics**

Waveform:	Monophasic, Bi-phasic, Alternating Polarity, or Pulse Train of square pulses
Duration (Width):	Software selectable, 50, 100, 150, 200, 250, or 1000 $\mu$ s (Accuracy: 50uS $\pm$ 15uS, 100uS - 1000uS $\pm$ 10% of setting)
Interpulse Interval:	50uS, 100uS, 500uS, 1-5mSec
Interphase Delay:	50, 100, 500, uS (Accuracy of 0uS $<$ 25uS, 50uS - 100uS = 15uS, 500uS $\pm$ 25uS)
Train Count:	1, 2, 3, 4, and 5
Rise Time to 30 mA:	Less than 10 $\mu$ s
Rate STIM 1 and 2:	Software selectable 1, 4, 7, 10, or 20 Hz ( $\pm 10\%$ of setting)
Rate STIM 2 Nervassure selected:	Nervassure repetition rates 1, 2, 4, 10, 30, 60, and 120 pulses per minute
Stimulus Probe:	Monopolar (standard) or bipolar
Stimulus Trigger Input:	TTL compatible remote input. Not active. For future expansion.

**Audio output**

Volume Adjustment:	Dedicated Side Control knob and Graduated Touch Screen Control with graphic of Volume.
Transducers:	1 x 7.62 x 7.62 cm speaker 4 x 2.5 x 2.5 cm speakers Piezoelectric Sounder
Baseline Audio Sound Level:	58 $\pm$ 4 dBC SPL at (1 ft)
Change in Baseline with added Channels:	$< \pm 4$ dBC SPL at (1 ft)
Change in Baseline due to EMG and Tones:	$> + 20$ dBC SPL at (1 ft)
Max Audio Sound Level:	$> + 88$ dBA SPL at (1 ft)
Min Audio Volume (Tone and Alarm) sounds:	$> 43$ dBA SPL at (1 ft)
EMG & Event Tone Signals:	Continuously processed EMG.
Volume Preset and Limiter:	Volume Power Up Pre-set Default and a Low Volume Limiter.
"Current Delivered" Tone Signals:	Selectable options include continuous and brief warble tone, voice and voice setting. Signal occurs when 80% of set current is delivered over range when greater than (0.05) mA.
Power-Down / Power-up Tone :	Constant Power-up / Decaying Power-down Tone
Touch Screen Key Click:	Selectable ON/OFF
Connection:	3.5mm Mini Audio Female Headphone Jack
Headphone Output:	Line level

**I/O - Video Output/USB Drive Output/Networking**

**Data output**

Connection:	3 x USB-A (3.0) , 2 x USB-C (3.0)
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**Networking**

Ethernet:	Not active. For future expansion.
Connection:	RJ45

**Video Output 1**

Interface:	HD 1920 x 1080 resolution
Connection:	19 pin HDMI

**Video Output 2**

Interface:	HD 1920 x 1080 resolution
Connection:	20 pin Display Port

**Wireless Remote Monitor**

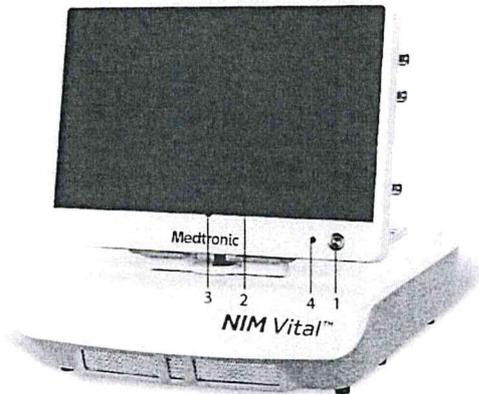
Interface:	HD 1920 x 1080 resolution
Connection:	Display Port or HDMI

**Electrical - Mains**

Input Voltage/Power:	100 - 240VAC, 250VA
Console:	100 - 240VAC, 600VA
Cart:	50 - 60 Hz
Frequency:	50 - 60 Hz
Power consumption:	62 W Nominal; $< 78$ W Peak (Total 72 W [62 W Console, 10 W Wireless HDMI])

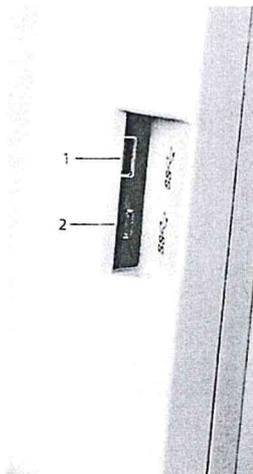
14

## Components



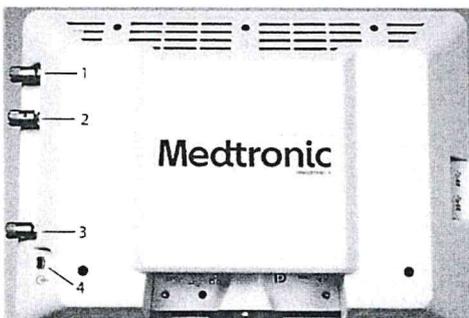
### Console front

- 1 Power button.
- 2 Screen.
- 3 Camera.
- 4 Microphone.



### Console left side

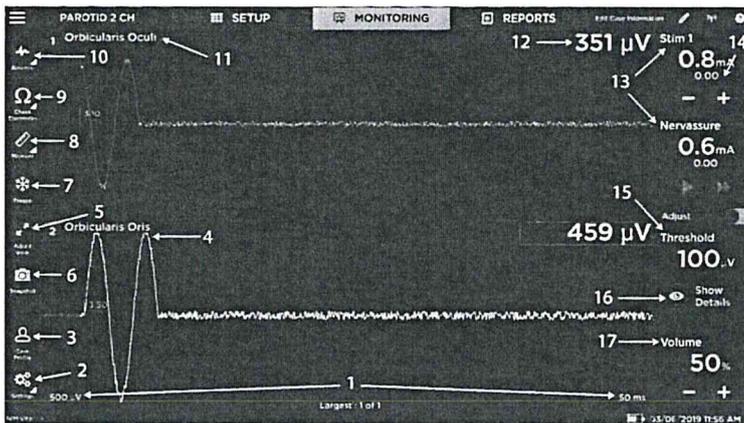
- 1 USB-A (3.0) port.
- 2 USB-C (3.0) port.



### Console right side

- 1 STIM 1 adjustment knob.
- 2 STIM 2 adjustment knob.
- 3 Volume knob. *JD*
- 4 Mute detector adaptor connection.

## Nerve Integrity Monitor



- 1 Scale. Displays screen scale settings.
- 2 Settings button.
- 3 Save Profile button (only when settings have been changed, but not saved into a profile).
- 4 Trace. Display stimulus nerve activity/inactivity.
- 5 Adjust view.
- 6 Snapshot button.
- 7 Freeze button (when activated).
- 8 Measure button (when activated).
- 9 Check Electrodes button.
- 10 Baseline button (only active if the user activates it on the settings panel).
- 11 Channel label. Displays the channel number and nerve being monitored.
- 12 Amplitude.
- 13 Stim panels.
- 14 Stim return value.
- 15 Threshold panel.
- 16 Show details button. Provides access to event capture and adjust threshold.
- 17 Volume panel. Adjust the system volume. P

## EMG display area

The amplitude displays activity level in microvolts on each channel:

- A box encloses the activity level of the highest channel.
- When the STIM probe is removed and "Largest Overall" is selected, a box encloses the channel with the largest event.
- If the system detects a signal (response) outside the range of the system's ability to measure (100,000 µV or higher), the system displays the "Out of Measurement Range" message.
- Absolute Amplitude Limit: The Absolute Amplitude Limit (in µV) and the Amplitude Percentage Limit (in %) are used in conjunction to determine the APS amplitude alarm criteria. The lower of the two limits sets the alarm limit. For example, if the baseline amplitude is 2000 µV, Amplitude Percentage limit is 50%, and Absolute Amplitude limit is 500 µV, then a signal of 800 µV would not cause an alarm because although the signal has decreased more than 50%, it is still above the Absolute Amplitude limit.

## Recognizing stimulus artifacts

Stimulus artifact is a monitoring term for an artifact created by stimulus voltage delivered to the patient, which is picked up as feedback either internally or externally to the monitoring equipment. It is normally small and does not impact monitoring but can, under certain conditions, be displayed and sounded on the monitor. It is important to understand the NIM system's visual and audio feedback so as not to confuse the stimulus artifact with real EMG, or recognize if both the stimulus artifact and real EMG are present at the same time.

The on-screen stimulus artifact, when it appears on the monitoring panel display, is seen as an event (above or below threshold) which starts directly after the stimulus on the left side of the screen and proceeds for a duration into the EMG waveform detection area. The level of the artifact is directly proportional to the stimulus delivery and cannot be EMG because nerve signals need time to propagate.

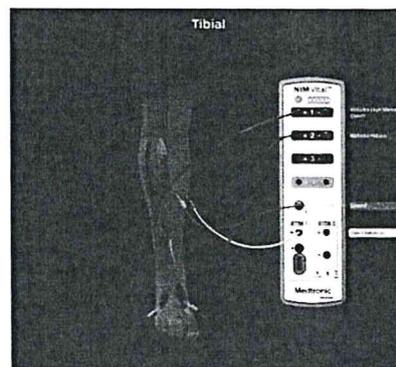
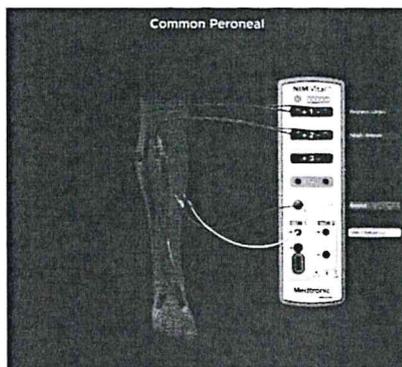
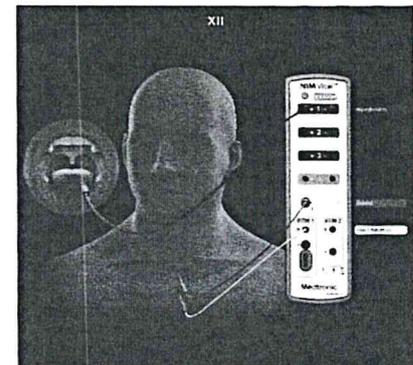
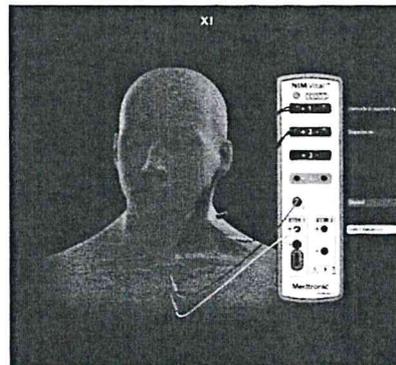
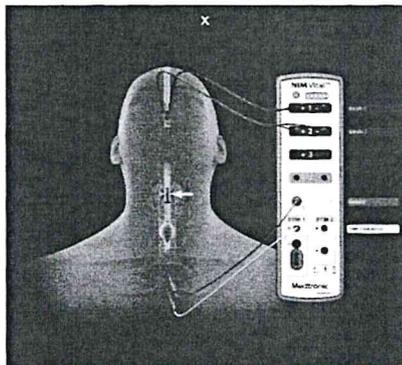
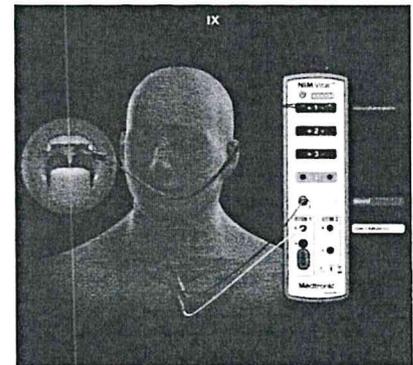
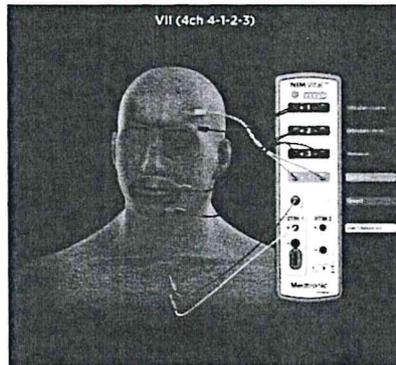
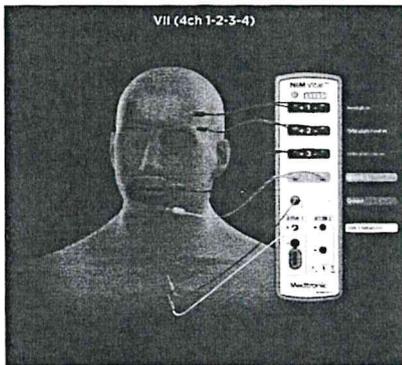
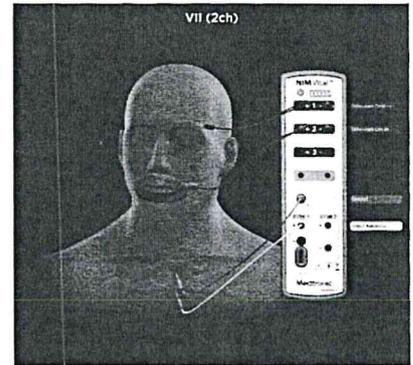
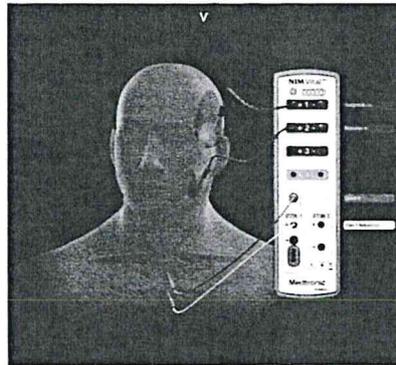
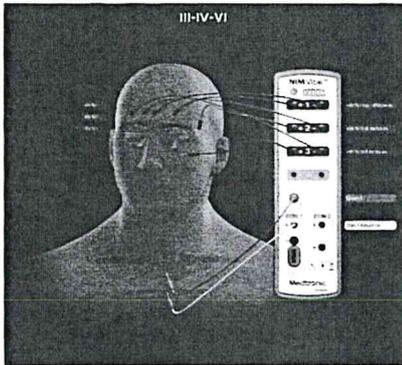
The stimulus artifact sound is the audio representation of stimulus artifact. It is a high frequency sound similar to cymbals and sounds like "ti - - tchi." It is unlike an EMG sound which is similar to a drum sound.

The stimulus rejection period enables you to filter the stimulus artifact (electric noise caused by stimulation) and all other signals in this period.

Nerve Integrity Monitor

The electrode placement guide contains some, but not all, possible electrode placements. Press  on the top right-hand corner of the screen for an additional list of electrode placement guides.

9



17

**MONITORING**

**Nerve Integrity Monitor**



Baseline button.



Electrode check button.



Snapshot button.



Freeze button.



Settings button.



Decrease button.



Increase button.



Activate button.



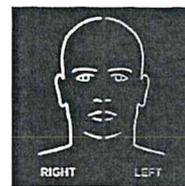
Slow APS Button.



Fast APS button.



Contextual help button.



Operating side buttons (right currently selected, left currently unselected).



Restart/start new baseline button.



Next step button (baseline).



Quick tag buttons (green is selected showing it has been taken). The operating side is shown in a Thyroid procedure and Recall button toggles waveform recall for V1 and R1 snapshots.



Category item. Clicking will open more settings.



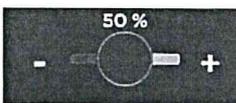
Category title. Clicking will open relevant settings.



Yellow mute when trending.



Toggle slider off/on.



Slider with plus/minus buttons for fine tuning.



Red mute when trending.



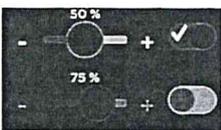
Toggle-enabled drop-down menu.



Drop-down menu.



Measure button.



Toggle-enabled sliders.



Adjust view.



Save profile.



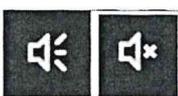
Trend button.



Restart new baseline button.



Next step in baseline.



Channel mute icon.

10

18

Nerve Integrity Monitor

# Technical specifications

## Physical dimensions - console

Size: 41 cm W x 45 cm D  
 42.5 cm H (Screen Open)  
 20.5 cm H (Screen Down for storage)  
 10.7 Kg

Weight:

## Physical dimensions - patient interface

Size: 6.5 cm W x 7.5 cm H x 21.5 cm D  
 Weight: 55 Kg

## Physical dimensions - cart (NIM4CC01)

Size: 53 cm W x 101 cm H x 61 cm DP  
 45 kg  
 Drawer Max. Load - 4.5 kg  
 Shelf Max. Load - 9.0 kg  
 Cart Total Max. Load - 79.5 kg

## Operational environment - console, console back-up battery, patient interface with internal battery

Operating Temperature range: 10 to 33° C (Operating)  
 Humidity: 30-70% RH non-condensing  
 Atmospheric Pressure range: 700 hPa to 1060 hPa

## Transport and storage environment - console, console back-up battery, patient interface with internal battery

Shock and Vibration: Verified to Standard ISTA 2A  
 Ambient Temperature range: -20°C to + 50° C  
 Relative Humidity range: 10 % to 100 %, including condensation  
 Atmospheric Pressure range: 500 hPa to 1060 hPa

## Amplifier

Channels - 1 to 4: Individually and simultaneously selectable  
 Input Sensitivities: 5 - 10,000  $\mu$ V peak-to-peak AC Coupled  $\pm$  5% at 10 mV to  $\pm$  30% at 100 mV peak-to-peak AC Coupled  
 Sensitivity Selection: Automatically zeroed  
 Bandpass: 15 Hz - 1.85 kHz ( $\pm$  3 db @ 500 Hz) EMG Display  
 200 Hz - 1.0 kHz (-6, +3 db @ 500 Hz) Audio EMG Speaker  
 Input Noise: 3-14  $\mu$ V p-p, < 5  $\mu$ V RMS @ DC - 2 KHz, inputs shorted  
 Input Impedance: > 10 Meg Ohm  
 DC offset Rejection:  $\pm$  0.90 V DC Rejection  
 Common Mode Rejection: >80 dB @ 60 Hz, balanced inputs, >66 dB @ 60 Hz, 1 K Ohm imbalance  
 Channel Enable/Disable Controls: Dedicated function touch pads for independent channel enable/disable  
 Event Threshold Control and Display: Adjustable Graduated Touch Screen with Voltage threshold displayed.  
 Patient Isolation Wired: 1,000 Vrms 60Hz < 100  $\mu$ A

## Impedance measurement

Control: Automatic CHECK ELECTRODE feature.  
 Measuring Signal: 6  $\mu$ A or 24  $\mu$ A peak-to-peak, 7.8 Hz Square wave  
 Measurement Range: Electrodes:  
 0K to 2K Ohm  $\pm$  500 Ohm  
 >2K-175K Ohm  $\pm$  20%  
 Ground and Stim Returns < 25K.

## Artifact detection and rejection

Stimulus Artifact: Synchronized and adjustable muting and warning.  
 Bipolar Electrocautery Rejection: Continuous Monitoring During Bipolar Cautery < 40 watts  
 Monopolar Electrocautery (ESU) Interference: Automatic detection and muting in wired or wirefree modes  
 Muting Detector Input ESU Sensitivity: Monopolar ESU Cut / Coag  
 Contact 5 - 100 Watts  
 Air-Discharge 10-100 Watts  
 Muting Console Input Sensitivity: Muting (0.6 - 2.0 Volts Vrms)  
 Non-Muting (<0.3 Volts Vrms)  
 Muting Detector Input ESU Immunity: ESU < 100 Watts Cut / Coag or  
 (<3.0 Vrms 100-800 KHz Sq. Wave)  
 Electrode Lead Off: Automatic detection with Channel Off Muting and Warning message.

## Display / touch screen

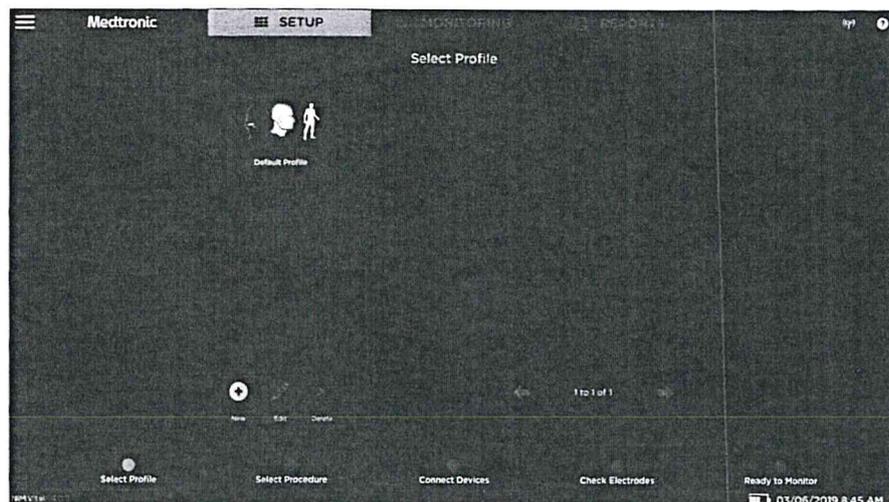
Type: High contrast, digital, graphic color, visible in complete darkness.  
 Resolution: Display Full HD - 1920H x 1080W pixels  
 Dedicated Function Event Touch Screen Controls: Touch Panel - Capacitive Multi and Glove touch capable 4095H x 4095W  
 Vertical Display: 20, 50, 100, 200, 500, 1,000, 2,000 5K, 10K, 20K, 50K, and 100K  $\mu$ V display modes.  
 Event Capture: Enable/disable capture mode indicator on touch screen.  
 Time Scale: 25 ms, 50 ms, 100 ms or 20 s display modes.

## Patient Interface

Color Coded Channel Patient Connections: "Touchproof safety connection protected pin 1.5 mm per specification: DIN 42 802"  
 Internal Fuse: Electronic limiting protection circuit and standard fuses. See Stimulator 1 and 2 "Internal Fuse".

## Stimulator 1 and 2

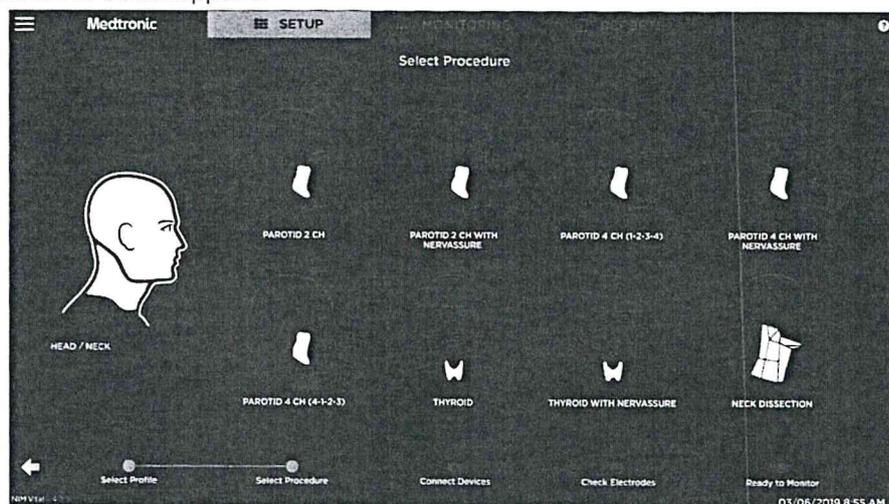
Stimulus Type Constant: Constant Current



You can select any procedure. For this assessment the assumption is that you have setup a custom procedure (refer to the System Setup/Custom Setup for instructions) called "Stimulation Test" and named the channels Ch 1, Ch 2, CH 3, CH 4.

3. Select User Profiles/ Stimulation Test.

The Select Procedure SETUP screen appears.



4. Select a procedure.

The Connect Devices screen appears.

5. Connect the patient interface (wired or wirelessly).

6. Press .

The Check Electrode screen appears.

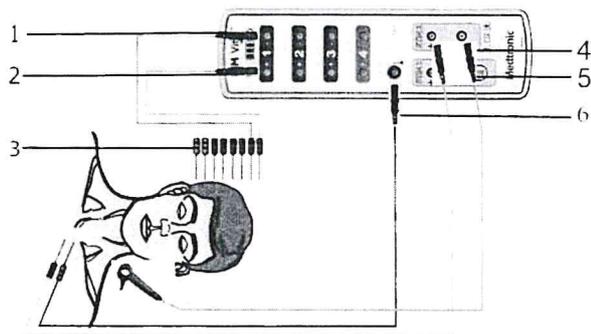
7. Press Show Details.

The Electrodes screen appears. Confirm the following:

- All channels are on.
- All channels have Subdermal selected.
- Positive and negative k $\Omega$  (impedance) for 4 channels is 5.1 k $\Omega$  or 5.6 k $\Omega$   $\pm$  1.0 k $\Omega$  with the Patient Simulator.
- The  $\Delta$  (difference) in their values is 500  $\Omega$   $\pm$  500  $\Omega$ .
- The k $\Omega$  (impedance) of the Ground is 6.5 k $\Omega$   $\pm$  1.0 k $\Omega$ .
- The k $\Omega$  (impedance) of the Stimulus Return is 6.2 k $\Omega$   $\pm$  1.0 k $\Omega$ .

**Note:** If any of these conditions are different, check your setup. If still incorrect, contact Customer service.

Nervassure electrodes stimulator



- 1 Negative Electrode Jacks (electrode plug matches color and wire is black)
- 2 Positive Electrode Jacks (electrodes, plug and wire are the same color)
- 3 Paired Electrodes
- 4 Continuous Monitoring Electrodes Stimulator Output (cathode)
- 5 STIM 2/Nervassure Electrodes Stimulator Return (anode)
- 6 Electrode Ground

The patient interface supports one Nervassure stimulator in the STIM 2 position. The Continuous Monitoring electrodes have a yellow wire and black plug. Insert the black plug into the black (-) jack on the PI (STIM2). The Continuous Monitoring electrodes deliver current to the patient and act as the cathode.

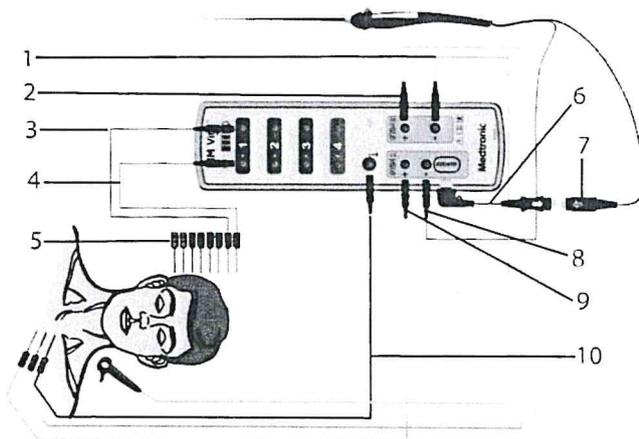
The stimulus return electrode has a white wire and red plug. Insert the red plug into the white jack with a red ring (+). The stimulus return electrode is required for stimulation and is referred to as the stimulus return or anode. Route the white (+) stimulus return wire away from the channel 1- 4 electrode wires.

Patient Interface and stimulator combinations

Note:

- The NIM Vital™ STIM 1 and STIM 2/Nervassure are wired independent of each other with each requiring an output (stimulator) and a return (red electrode with white wire), used for continuous constant stimulation.
- By default STIM 1 is on and STIM 2 is off. STIM 2 must be turned on manually (in Nervassure procedures the system turns on stim 2 when the user presses the baseline or adjust button). Refer to the "MONITORING mode" or "SETUP mode" topics.  
By default STIM 1 and 2 are Monopolar Probes and must be changed manually for Bipolar. Refer to the "Settings" topics.

Monopolar incrementing stimulator and Nervassure electrode stimulator



- 1 Stimulator Output, Continuous Monitoring Electrode (cathode)
- 2 STIM 2/Nervassure Stimulator Return (anode)
- 3 Negative Electrode Jacks (electrode plug matches color and wire is black)
- 4 Positive Electrode Jacks (electrodes, plug and wire are the same color)
- 5 Paired Electrodes
- 6 Incrementing probe adapter
- 7 Remote Control Connector
- 8 Stimulator Output (cathode)
- 9 STIM 1 Stimulator Return (anode)
- 10 Electrode Ground

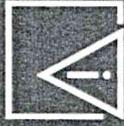
21

TECHNOLOGY OVERVIEW

CLINICAL RATIONALE



**IDENTIFY NERVE FUNCTION** and confirm the integrity of neural structures during head and neck surgery to help reduce the potential risk of nerve damage<sup>17</sup>



When a nerve has been unintentionally or intentionally activated or stimulated, IONM warns the surgeon and operating room staff by **PROVIDING VISUAL ALERTS AND AUDIO FEEDBACK**

13



Help in **EARLY DETECTION OF TRACTION INJURY**<sup>89</sup> by detecting progressive decreases in electromyographic amplitude combined with progressive latency increases



In contrast to intermittent intraoperative neuromonitoring, continuous IONM **PROVIDES CONSTANT MONITORING AND EVALUATION OF NERVE SIGNALS** as the surgeon dissects throughout the procedure



22

## EMEA MARKET SHARE & OVERALL COMPARISON

## NIM VITAL™ VS NIM 3.0

## NIM VITAL™ VS COMPETITORS

## INOMED

## DR LANGER

## NEUROSIGN

## DETAILED COMPARISON TABLE

# DETAILED COMPARISON TABLE

NA

	NIM RESPONSE 3.0 NIM NEURO 3.0		NIM VITAL™		NEUROSIGN 800	NEUROSIGN V4	C2	AVALANCHESI
STIMULUS / MONITORING	0.01 to 30.0 mA	0.01 to 30.0 mA	0.01 to 50.0 mA	0.01 to 50.0 mA	0.05 To 5.0 mA	?	0.01 to 25 mA max 5.0 mA	0.1 to 10 mA
Stimulus Range	0.01 to 30.0 mA	0.01 to 30.0 mA	0.01 to 50.0 mA	0.01 to 50.0 mA	0.05 To 5.0 mA	?	0.01 to 25 mA max 5.0 mA	0.1 to 10 mA
Stimulus security	at 3.0 mA. But possible to go over	at 5.0 mA. But possible to go over	at 5.0 mA. But possible to go over	at 5.0 mA. But possible to go over				
Stimulus Increment	0.01	0.01	0.01	0.01	0.05	?	0.1	?
Stimulus Adjustment	Knob	Knob	Digital	Digital	Peak Button	?	Knob	?
Current Delivered Tone (CDT)	Y	Y	Y	Y	N	?	Y	?
"Stimulus" Voice	?	Y	Y	Y	N	N	N	?
Stimulus Value Voice	Y	Y	Y	Y	N	?	N	?
Constant Current	Y	Y	Y	Y	Y	?	Y	?
Continuous Active Monitoring (APS)	Y	Y	Y	Y	N	N	Y "V3" bipolar Vagus" reusable and "Delta"	Y "Vanessa", S-shaped, "Saxophone"
Stim Rate	1, 4, 7, 10 PER SEC	1, 4, 7, 10 PER SEC	1, 4, 7, 10, 20 PER SEC	1, 4, 7, 10, 20 PER SEC	1, 4 PER SEC	?	1 to 10 Hz	1 to 30 Hz
Stim Pulse Width (µS)	50, 100, 150, 200, 250	50, 100, 150, 200, 250	50, 100, 150, 200, 250, or 1000	50, 100, 150, 200, 250, or 1000	N/A	?	200	?
Current Adjustable Down to 0.01 mA	Y	Y	Y	Y	N	?	Y	?
Incrementing Probe Capability	Y	Y	Y	Y	N	N	N	N
Stim Bur Compatible	Y	Y	N	N	N	N	N	N
Monitor through bipolar cautery	Y	Y	Y	Y	N	N	N	N
Stim connections	2	2	2	2	1	1	2	?
Option to turn raw EMG off	Y	Y	Y	Y	Y	?	Y	?
Muting Detector	In probe, muting range, 1 probe jack input	In probe, muting range, 1 probe jack input	Improved muting range, 2 probe jack input, internal muting	Improved muting range, 2 probe jack input, internal muting	N/A	Y	Y	?
Artifact Detection	Y	Y	Y	Y	N	Y	Y	N
Adjustable Muting	N	N	Y	Y	N	?	Y	?
Muting Indicator	Y	Y	Y	Y	N	?	Y	?



## Nerve Integrity Monitor

### Show details/event capture

The Threshold panel displays the threshold settings and enables you to adjust the setting level (in 5, 10, or 100  $\mu$ V increments depending on the Threshold value). Press  to access the threshold settings and then press  or  to increase or decrease the value as desired. The system displays the setting in micro-Volts. Press  to access the Event Capture toggle button. When event capture is enabled, the system captures any waveform above the event threshold. The event capture stays on the screen until the next waveform above the threshold appears.

### Volume

The Volume panel displays an adjustable volume setting.

You can adjust sound levels using  or  in 5% increments. The default setting is 50.

### MONITORING tab Left panel

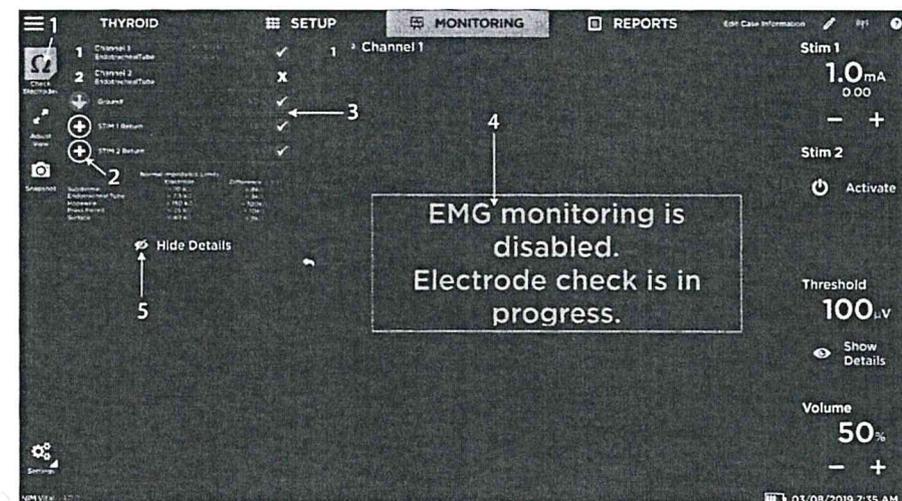
The NIM Vital™ left panel contains the following items you can use to adjust the monitoring screen.

#### Baseline

You can create a baseline and then manually trend future stimulations against the baseline using the trend function. For Nervassure continuous monitoring, select a Nervassure procedure on the Select Procedure screen during initial setup. For non-Nervassure procedures, you can use the NerveTrend function (currently available in thyroid procedures) which works similarly to the trend function.

#### Electrode Check button

The Electrode Check panel checks the integrity of the patient to the patient interface connections.



- 1 Electrode check button. Opens/closes Electrode Check panel.
- 2 STIM 1, STIM 2, and Ground status fields.
- 3 Electrode Show Details status field:
  - Green check marks. Green check marks appear when the electrodes are connected correctly.
  - Spinning icons. Spinning icons appear while the system runs the electrode test.
  - Red X. A red X appears when the electrodes are connected incorrectly or fail.
- 4 The system disables monitoring when the Electrode Check panel is open.
- 5 Show/hide details button.

#### Note:

- There is no STIM status (blank) if you select Bipolar on the Type Panel (located in the Advanced Settings/Stimulation Panel).
- There is no STIM 2 status (blank) if a single stimulator is connected.
- STIM 1, STIM 2, Ground - If a spinning icon a question mark appears after the system has completed the test, no channel electrode or ground was connected, so the system reads that as a no value (impedance). You must connect at least one channel electrode and ground for the system to read STIM 1, STIM 2, and ground impedance.

#### Electrode check

You can perform an electrode check on the MONITORING screen using .

## Nerve Integrity Monitor

- P5 Avoid accidental contact between 'PATIENT APPLIED PARTS' and other conductive parts including those connected to protective earth.
- P6 The NIM Vital™ is only compatible with the metal Muting Probe (Ref - 8220325). Earlier model Muting Probes are not compatible.
- P7 The muting detector is susceptible to damage from dropping. Visually inspect inner jaw surfaces for cracking, chipping or damage prior to use. Insufficient muting may result.
- P8 The patient interface is susceptible to damage from dropping. Visually inspect for damage prior to use. Inability to monitor may result.
- P9 The Ethernet connection of the NIM Vital™ Console, if activated, is intended to be connected to the hospital network. Do not connect it to other equipment.
- P10 At the end of their life cycle, all NIM Vital™ System electronic components must be sent to a WEEE recycling center or disposed of according to local regulations.
- P11 The NIM Vital™ console contains a Li-Ion battery pack that the user installs/replaces. Failure to follow the instructions for proper installation/replacement of the Li-Ion battery pack may could result in a hazard.
- P12 The Patient Interface contains a Li-Ion battery pack that must be replaced by trained service personnel only. The replacement of Li-Ion batteries by inadequately trained personnel could result in a hazard.
- P13 The multiple socket outlet (MSO) inside the locked drawer of the NIM Vital™ Cart is only intended to power the NIM Vital™ Console and NIM Vital™ Power Isolator for Printer. Connecting both NIM Vital™ Console and NIM Vital™ Power Isolator for Printer into the MSO effectively leads to create a Medical Electrical system. The system has been tested and met the applicable portions of the IEC 60601-1 standard.
  - a. Do not plug any device into the MSO other than the NIM Vital™ Console and NIM Vital™ Power Isolator for Printer.
  - b. Do not overload the MSO by using it for multiple systems. The MSO shall be only used for supplying power to one NIM Vital™ Console and one NIM Vital™ Power Isolator for Printer.
  - c. Printer shall be always powered through the NIM Vital™ Power Isolator for Printer.
  - d. Do not plug the power cord of the NIM Vital™ Cart into an extension cord or an additional MSO.
- P14 The battery inside the NIM Vital™ Console can only power the system for a short period of time. NIM Vital™ system shall be always connected to mains power for extended use and loss of power source would result in risk of loss of monitoring.
- P15 To avoid the risk of electric shock, this equipment must only be connected to a supply main with protective earth.
- P16 A baseline EMG response should be obtained with a stimulating probe once the nerve(s) of interest are identified. Nerve integrity should be checked with a stimulating probe then compared to the baseline throughout the procedure.

## NIM quick monitoring set-up

The following procedure for OR staff users is not meant to replace a complete understanding of this user's guide but may serve as a quick reminder of basic NIM setup, monitoring screens, and monitoring sounds. Refer to the "MONITORING tab" topic for more information.

1. Place the NIM Vital™ system within the surgeon's view and plug the NIM power cord into the dedicated outlet.
2. Press  on the bottom right of the console display.
3. The system automatically runs the self-test until you hear the bleedle tone.
4. On the NIM Vital™ Setup screen, select the default profile followed by a surgical specialty and specific procedure to be monitored.
5. After selecting a procedure, the Connect Devices screen appears on the NIM Vital™ Setup screen. Undock the patient interface from the console base. Wait for the solid blue paired wireless symbol to appear on the patient interface which indicates a wireless connection.

**Note:** If the wireless is not available, plug in the PI cord between the console and the PI. The console connector is located on the back-left side and is marked by a PI box symbol (refer to the "Buttons and indicators" and "Symbols" topics for more information).

**Anesthesia Note:** Do not use long-term paralyzing anesthetics to ensure proper EMG monitoring.

6. After the patient interface connects to the NIM Vital™ system, press  to progress to the Check Electrode screen. The Electrode placement guide appears indicating how to connect the system.
7. Ensure the date and time are synchronized with the OR clock. **Optional:** Enter case information using the Edit Case information button located on the top right of the screen.
8. Following the illustration on the screen, connect all color-coded cables (subdermal electrodes or EMG tube, ground, and STIM 1 return [red with white wire]) to the corresponding patient interface.

**Note:** The automatic electrode check shows one of the following for each connection: green bars with white checkmarks confirm the integrity of the connections. Red bars with white Xs indicate a bad connection. White, spinning icons indicate the system is checking the connection.

Electrode Ground (green with green wire) and Electrode Stimulus Return (red with white wire).



Hookwire Electrode. Two small wires attached to the end of a hypodermic needle. Injected intramuscularly (then the hypodermic needle is removed). The wires are insulated to within 3 mm of the end and are designed to obtain a more specific response.

**NIM Vital™ continuous monitoring electrodes and tools**

APS (Automatic Periodic Stimulation) Probe.

Continuous, real-time monitoring of vagus nerve through low-level stimulation.

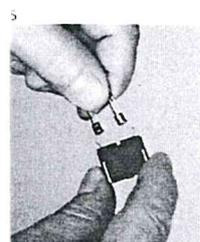
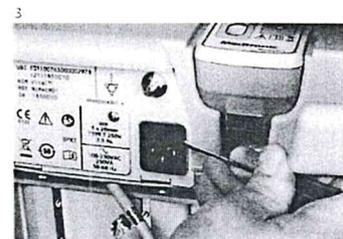
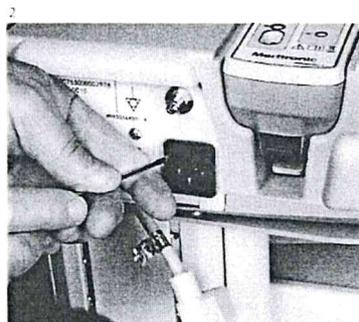
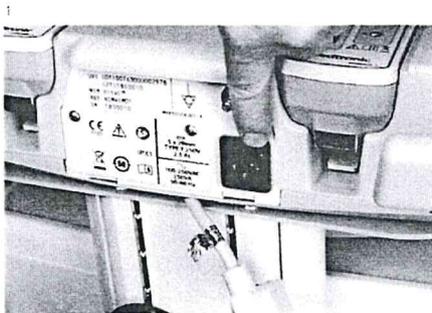
19

Single-use.



**Fuses**

Console Replacement: the console AC power is fuse protected. Have a Biomedical Engineer check the fuse if a problem is suspected. It is very important that the correct replacement fuse is used (5 x 20 mm, 2.5 Amp, time-lag, Low breaking capacity, Xomed Fuse Kit # NIM4CFU1).



### Electrode Check panel pass/fail

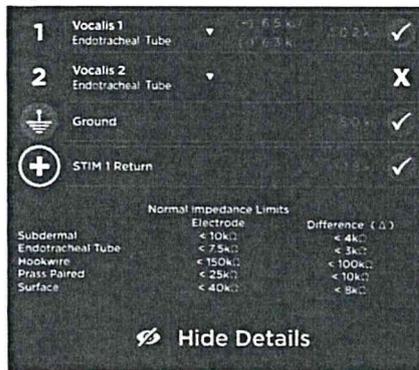
The system measures impedance values of the electrodes to the patient to confirm the integrity of the connection. The electrode check only indicates that the electrodes are making contact with the patient's tissue. The system does not confirm that the needle is inserted into the correct muscle. The user is responsible for ensuring the electrodes are placed, or inserted into the target muscles.



The above graphic illustrates that all channels have passed the electrode check. A red bar with a white X will replace the green bar with a white checkmark if a channel(s) fails.

### Electrode Check Show Details button

Press the Show Details button to see the actual impedance values. Refer to the "Troubleshooting" topic for more information.



**Note:** When you select , the system displays the normal electrode impedance limits if the number of channels is less than six.

### Measure

When activated, press  to enable and adjust the measurement cursor. Refer to the "Display settings" topic for additional information.

1. Enable the Measurement cursor on the main screen.
2. Select the cursor type. This determines where the cursor is initially displayed.
3. Adjust the cursor position.

### Freeze

When activated, press  to freeze the current waveform on the screen. The main screen shows "Display is Frozen" during this time. Press  again to end the freeze. Monitoring continues in the background when enabled and monitoring sounds still play.

21

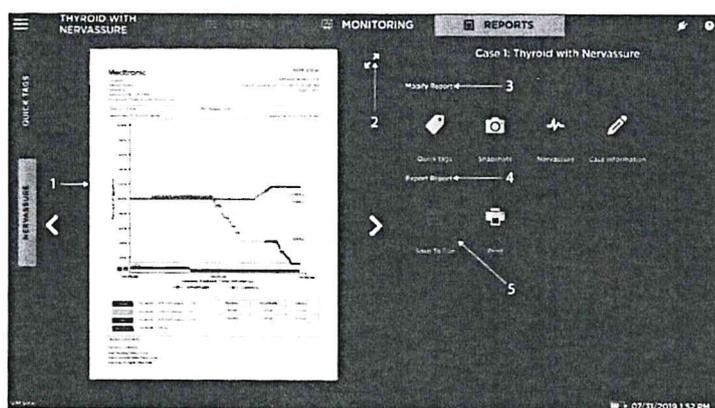
- Use the increase (plus)/decrease (minus) positions to move through the bottom control buttons and select **[Continue]**.  
The second baseline screen appears showing the operative side selection panels.
- Use the plus/minus positions to select the right/left operative side, then press the select button.  
Once the user has selected the operative side using the probe, the system focuses on the bottom control buttons.
- Use the increase (plus)/decrease (minus) positions to move through the bottom control buttons and select **[Accept]**.

## REPORTS tab

**Note:** All stored case data (snapshots, log files, Nervassure data, and reports) is lost when unit is powered off.

The REPORTS mode enables you to quickly compose and print/save reports using a report builder. The system provides report templates to simplify report creation.

The REPORTS mode can be active while audio monitoring continues in the background. The system saves all work performed in REPORTS mode if you exit REPORTS and return to MONITORING. For example, you can start a report midway through a monitoring session. When you return to MONITORING to complete the session, all previous work is available when you return to the REPORTS mode. When you turn the system off, you lose all monitoring session data.



- Live Preview window: Displays auto-generated report. Use the tabs to jump to bookmarks within the report.
- Live Preview expand: Expands the report to a two-page at a time view.
- Modify Report Panel: Options to edit Quick Tags, Snapshots, and baseline sessions in the case.
- Export Report Panel: Options to save a .pdf version of the report to a USB (if the system detects a mounted, approved USB) and to print the report with a connected printer. 22
- Save To File button: Saves a copy of the case to a USB (if the system detects a mounted, approved USB). 23

## Include quick tags on a report

By default, the system includes all quick tags the user creates during monitoring on the report. Once the user makes all quick tag changes to the snapshots (the user can change multiple quick tags at once), the user can create a report.

- Select **[Edit Quick Tags]**.  
The Modify Quick Tags screen appears.
- Select a quick tag from the left side panel.
- Select a snapshot from the center of the screen.
- Press **[Include in Report]**.  
The system adds the quick tag to the report.
- Do one of the following:
  - Select **[CONFIRM]** to save your changes.
  - Select **[RESET]** to revert snapshots back to their last saved state prior to the editing session.

## Delete quick tags from the report

- Select **[Edit Quick Tags]**.  
The Modify Quick Tags screen appears.
- Select a quick tag from the left side panel.
- Press **[Include in Report]** twice to toggle it off.  
The system removes the quick tag from the report.

Nerve Integrity Monitor



Print button.



Save Database button.



Save to .pdf button.

22.2

REPORTS

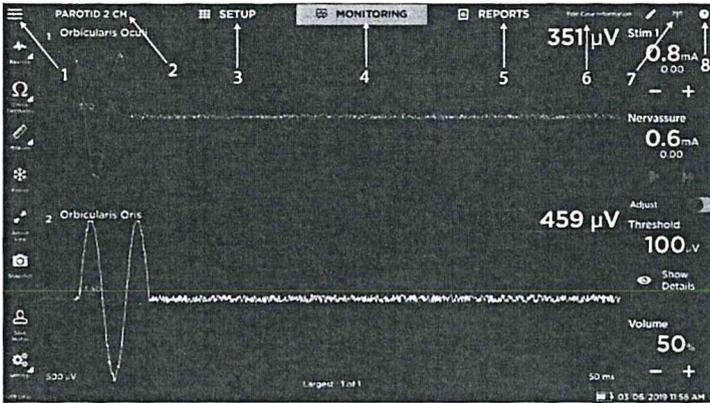


Quick Tags report button.

Nerve Integrity Monitor

**NIM Vital™ top panel**

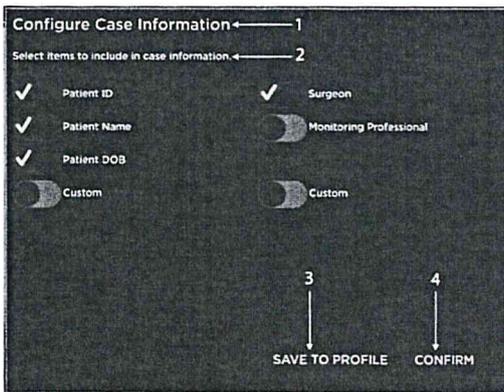
You can view, add, and update patient information using the Edit case information button located on the top panel of the NIM Vital™. You can also access the NIM Vital™ Help screen and view the connected devices.



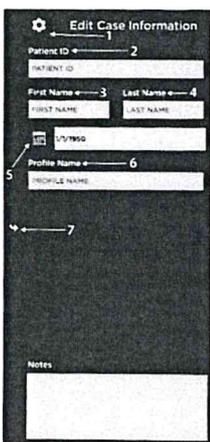
- 1 Global settings.
- 2 Current procedure.
- 3 SETUP tab.
- 4 MONITORING tab.
- 5 REPORTS tab.
- 6 Edit case information button.
- 7 Type of patient interface connection.
- 8 Help button.

**Edit/configure case information button**

The Configure case information setting enables the user to choose which fields appear on the Edit case information panel. The Edit case information panel opens when you press the Edit Case Information button. Use this screen to enter data into preselected data fields. The user can modify the Data fields displayed by selecting the icon on the top left of the Edit case information panel. In the Configure Case Information window, the user can turn on/off each data field for display in the Edit case information panel. Select **[Save to Profile]** to keep the changes in a surgeon profile, or **[Confirm]** to save the changes for the current case.



- 1 Configure Case Information setting.
- 2 Select Items to Include in Case Information.
- 3 SAVE TO PROFILE.
- 4 CONFIRM.



- 1 Edit Case Information. Press any of the information fields to open the keyboard for data entry. Changes are saved automatically.
- 2 Patient ID.
- 3 First Name.
- 4 Last Name.
- 5 Date of Birth.
- 6 Profile Name.
- 7 Close the Edit Case Information screen.

**Nerve Integrity Monitor**

Cart Auxiliary AC output Power Isolator (See Printers listed in NIM Vital™ Compatible Accessories):

NIM4CC02 100-127VAC, 50-60 Hz - 200VA  
 NIM4CC03 220-240VAC, 50-60 Hz - 200VA

- Continuous duty cycle – 200VA  
 - 25% Intermittent duty cycle (Up to 5 minutes on at maximum 2X rated load then 15 minutes off)  
 NIM Printer Power Supply (# 8253025) 150 VA Max.

Auxiliary AC output: (For Use With Approved NIM Accessories Only):

4000 V Peak-to-Peak 60Hz dielectric withstand from Line Connections to Signal Ground

Line Isolation:  
 Internal Fuse:  
 Potential Equalization Connection:

5 x 20mm, 5Amp, 250V, Quick-acting, Low breaking capacity, POAG Equipotential Earthing Connection for supplemental grounding or convenient electrical safety test connection point  
 All patient probes and electrodes are Type BF applied parts  
 100 pF +/- 30% @ 1kHz (All patient probes and electrodes combined to Safety GND)

Patient Connections:  
 Patient Connection Capacitance:

**Electrical - Batteries**

Console Back-up Battery - Li-ion - Secondary:  
 Console Real Time Clock (RTC) - Primary Lithium Cell:  
 Patient Interface Battery - Li-ion - Secondary:

14.4V / 4750 mAH / 72Wh (user replaceable)  
 3.0V / 0.600mAH / 1.8Wh (non-user replaceable)  
 7.2V / 3400mAH / 24.4Wh (non-user replaceable)

**Classification**

Type of Protection against electrical shock:  
 Degree of protection against electrical shock:  
 Ingress of water, dust, or solids IEC 60529:  
 Use with flammable anesthetic mixtures, with air, oxygen, and nitrous oxide:  
 Transportation of Batteries UN/DOT 38.3 2015:

Class I Medical Device per IEC/EN60601-1  
 Type BF applied parts  
 Console IPX1, Patient Interface IPX2  
 Not suitable for use in the presence of flammable anesthetic mixtures.

Battery Safety

Recommendations of the Transport of Dangerous Goods: Manual of Tests and Criteria - Lithium Metal and Lithium Ion Batteries  
 Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirement for portable sealed secondary cells, and for batteries made from them, for use in portable application.

IEC 62123-2012:

Audible notification (tone, buzzer, voice) to the user if monitoring of one or more active channels is halted

NIM Vital™ System Essential Performance as defined by IEC 60601-1:

AND

Audible notification (event tone, stim delivery tone) that nerve stimulus has been delivered.

**NIM Vital Compatible Accessories**

**Audio Accessories Verified Compatible**

Wireless Video Output 22.3

Wireless HDMI:  
 Interface:  
 Connection:

C2G 29329  
 HD 1920 x 1080 resolution  
 Display Port or HDMI through C2G

Printers Verified Compatible 22.3

Printer 1:

Samsung Xpress m2020w Wireless Black-and-White laser printer  
 - 25% Intermittent duty cycle (Up to 5 minutes on- Printing followed by 15 minutes off or Standby)  
 HP officejet 200 Mobile Printer Wireless Color Inkjet printer  
 Samsung Xpress C430W  
 - 25% Intermittent duty cycle (Up to 5 minutes on- Printing followed by 15 minutes off or Standby)

Printer 2:  
 Printer 3:

USB Drive Data Output 22.2

USB Compact Flash Memory:

SanDisk Brand, Cruzer Mini SanDisk Brand, Cruzer Micro, Apricorn Aegis Secure Key ASK-256-26GB

**The NIM Vital™ equipment cart**

The equipment cart serves as a convenient means to operate the NIM Vital™ in the operating room as well as store the console and accessories when not in use.

3. Do any of the following:
  - Select **[New]** to create a custom title/comment. Use the on-screen or attached keyboard to type a title or comment.
  - Select a title, press **[Edit]** and then edit the existing title.
  - Select a title, press selected item is a Quick Tag title toggle. See the "Quick Tags" topic for more information.
  - Select a title, press **[Delete]**. The system deletes the title. This option is not available if the title is a quick tag that has already been used during the procedure.
4. Press  to close the settings panel.

## Optional features in monitoring

### Quick tags

You can use the Enable Quick Tags toggle slider to display the abbreviation of the title that appears on a quick tag button on the tool bar at the right of the screen during the Monitoring phase. You can activate a quick tag by selecting a title and then select "Selected item is a Quick Tag title" toggle. Type an abbreviation for the title of the button using the pop-up that appears.

1. Select the Enable Quick Tags toggle slider.
2. Select the Selected item is a Quick Tag title toggle slider.  
The Edit Title/Comment Abbreviation pop up appears with the title/comment name in the Title/Comment box.
3. Press the Abbreviation box.

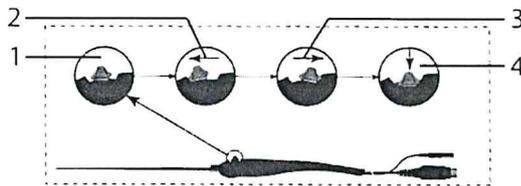
The Abbreviation pop up appears with the choice to use an on screen keyboard, or use your attached keyboard. *22-3*

4. Type the abbreviation you want to use for your quick tag and press **[CONFIRM]**.

**Note:** the system adds new titles to the end of the quick tag list.

### Probe-based functions

The (single use) Incrementing Probe provides the surgeon with the means to adjust the stimulation current at surgical site.



- 1 - Toggle button normal or at rest.
- 2 - Increase (plus).
- 3 - Decrease (minus).
- 4 - The user can perform the following functions with the toggle button:
  - Momentary press saves a snapshot of the current screen to memory (for reports) and to a selected peripheral device (printer and/or USB flash drive) if the user selected that option in the settings area.
  - Press and hold opens a menu on the user interface with more options.

### Control stimulation and volume using the probe

By default, the increase (plus)/decrease (minus) positions control stimulation values and announce the newly set stimulation current. There are two methods the user can use to toggle between stimulation and volume controls.

#### Method 1

1. Press the increase (plus) position for two seconds.  
The probe's increase (plus)/decrease (minus) positions now control volume and provides audio feedback of the volume level.
2. When in the volume mode, press the increase (plus) position for an additional two seconds.  
The probe's increase (plus)/decrease (minus) positions now control stimulation. If the probe is in volume mode, after 30 seconds of no use it defaults back to stimulation control.

#### Method 2

1. Press the toggle button for two seconds.  
A menu appears.
2. Use the increase (plus)/decrease (minus) positions to navigate through the menu options and select **[Volume]**.  
The probe's increase (plus)/decrease (minus) positions now control volume and provide audio feedback of the volume level.
3. Press the toggle button for two seconds.  
A menu appears.

# EMG Endotracheal Tubes

The NIM® EMG endotracheal tube monitors electromyography (EMG) activity during surgery and functions as a normal endotracheal tube, except that it contains bipolar contact electrodes for continuously monitoring both vocal cords during surgery.

23.1

A properly positioned NIM EMG Tube can reduce the risk of patient injury by helping to:

- Identify the recurrent laryngeal or vagus nerves
- Control manipulation during dissection
- Verify nerve integrity prior to surgical closure

Only NIM EMG Tubes are clinically proven and validated for use with NIM® Systems.

## NIM TRIVANTAGE® EMG ENDOTRACHEAL TUBE

A standard-sized DEHP-free PVC non-reinforced tube with an inflatable high-volume, low-pressure cuff. Each tube is imprinted with two pairs of bipolar conductive silver ink electrodes. Its innovative low profile and smooth surface design allows for enhanced EMG recordings and helps optimize contact with the vocal cords, even upon tube rotation and movement.

23.1

Product	ID	OD	Qty
8229705	5 MM	.6.5 MM	1
8229706	6 MM	.8.2 MM	1
8229707	7 MM	.9.5 MM	1
8229708	8 MM	.10.7 MM	1
8229709	9 MM	.12 MM	1
8229735	5 MM	.6.5 MM	3
8229736	6 MM	.8.2 MM	3
8229737	7 MM	.9.5 MM	3
8229738	8 MM	.10.7 MM	3
8229739	9 MM	.12 MM	3

23.3

## NIM CONTACT® REINFORCED EMG ENDOTRACHEAL TUBE

Vocal cords are easily visible against the white band. Recording electrode leads are twisted pair. Packaged sterile with one green and one white subdermal needle. Single use.

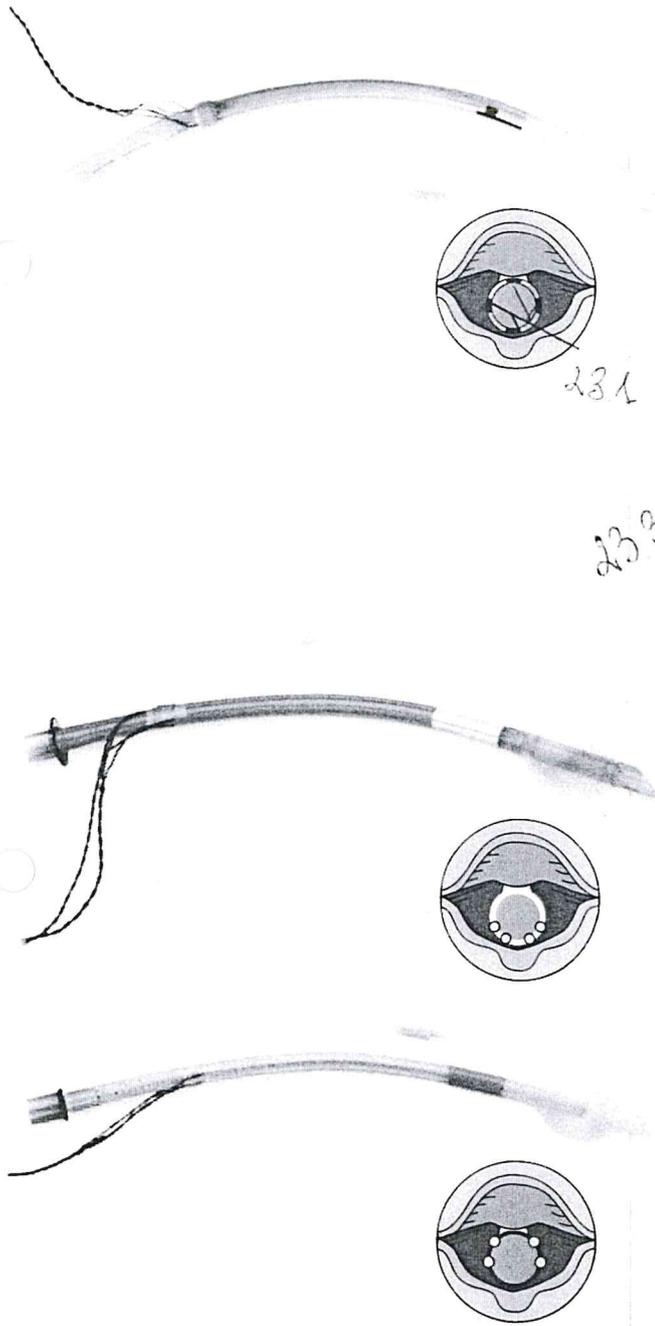
Product	ID	OD	Qty
8229506	6 MM	.9 MM	1
8229507	7 MM	.10.5 MM	1
8229508	8 MM	.11.5 MM	1

## NIM® STANDARD REINFORCED EMG ENDOTRACHEAL TUBE

Recording electrode leads are twisted pair. Packaged sterile with one green and one white subdermal needle. Single use.

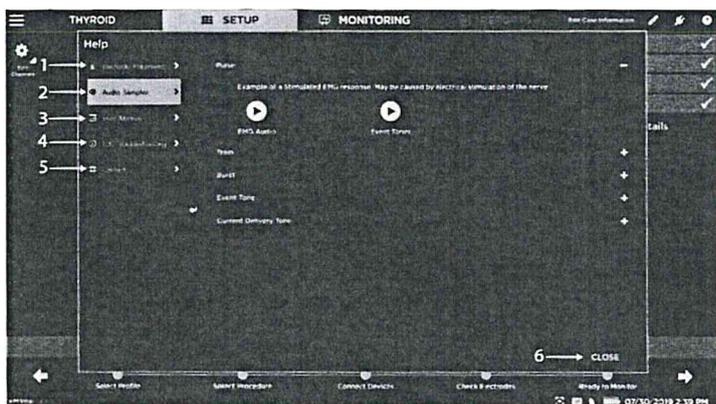
Product	ID	OD	Qty
8229306	6 MM	.8.8 MM	1
8229307	7 MM	.10.2 MM	1
8229308	8 MM	.11.3 MM	1

ID = INNER DIAMETER, OD = OUTER DIAMETER



1. From the MONITORING screen, press the Edit Case Information button.  
The Case Information screen appears.
2. Press the Surgeon box and type the surgeon information using the on screen or attached keyboard.
3. Repeat step 2 and 3 for the following information depending on configuration:
  - Patient ID
  - Patient Name
  - Patient DOB
  - Notes
4. Press the reverse arrow button on the right side panel.  
The system returns you to the previous screen.

**Help**



- 1 Electrode Placement.
- 2 Audio Samples.
- 3 User Manual.
- 4 LOS Troubleshooting.
- 5 Contact.
- 6 Close Button.

The Help screen displays help graphics for locating electrodes, sample audio sounds, an electronic version of the IFU, LOS troubleshooting, and contact information.

You can use the Help screen to view electrode placement graphics which aids in the electrode placement and sample audio sounds.

**View Electrode placement using the Help screen**

You can use the Electrode Placement tab on the Help screen to view electrode placement graphics.

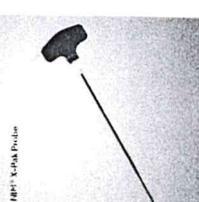
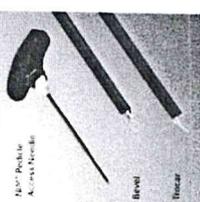
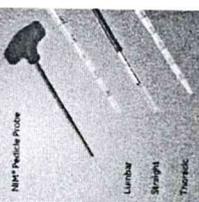
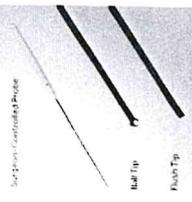
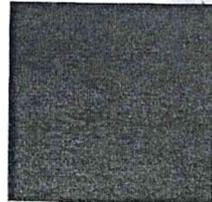
1. In the top right-hand corner of the screen, press .  
The Help screen appears.
2. Press [**Electrode Placement**]
3. Place electrodes according to the appropriate help graphic.
4. Press [**Close**] to return to the current screen.

**Note:** When the user accesses the Help screen from the MONITORING screen, the system disables monitoring.

**Electrode placement**

The surgeon should insert the electrodes into the appropriate muscle location innervated by the monitored nerve. The surgeon should then insert the ground electrode (green) and the stim return (white) as shown in the electrode placement diagram. Once the surgeon places the electrodes on the patient, the surgeon needs to insert the other end of the electrodes into the patient interface to complete the electrode setup. NIM Vital™ systems include nerve and electrode placement guides that are color-coded to help reduce confusion.

13.2



**PROBES**

**SURGEON-CONTROLLED PROBE KIT**

- Kit includes one Straight 100 mm Flush-Tip Probe, one 1.75 mm Straight Probe, and one 250 mm Angled Ball-Tip Probe

PRODUCT	DESCRIPTION	QTY
SPK1004	Surgeon-Controlled Probe Kit	1

**PEDICLE PROBE**

- NIM\* Pedicle Probes facilitate open pedicle screw placement
- Available with straight, thoracic, and lumbar tips
- Pre-sterilized, single-patient use only

PRODUCT	DESCRIPTION	QTY
8225715	NIM* Pedicle Probe, Flush Tip	1
8225747	NIM* Pedicle Probe, Lumbar	1
8225755	NIM* Pedicle Probe, Straight	1

**PEDICLE ACCESS NEEDLES**

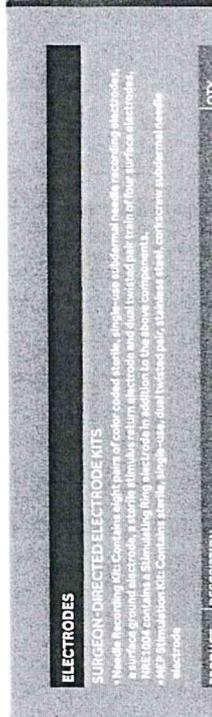
- NIM\* Pedicle Access Needles enable percutaneous screw placement
- Each has a bevel or Hepar tip style
- Pre-sterilized, single-patient use only

PRODUCT	DESCRIPTION	QTY
8225720	NIM* Pedicle Access Needle, Bevel	1
8225769	NIM* Pedicle Access Needle, Hepar	1

**X-PAK PROBE**

- NIM\* X-PAK Probe aids monitoring in the direct lateral approach
- Pre-sterilized, single-patient use only

PRODUCT	DESCRIPTION	QTY
8225766	NIM* X-PAK Probe	1



**ELECTRODES**

**SURGEON-DIRECTED ELECTRODE KITS**

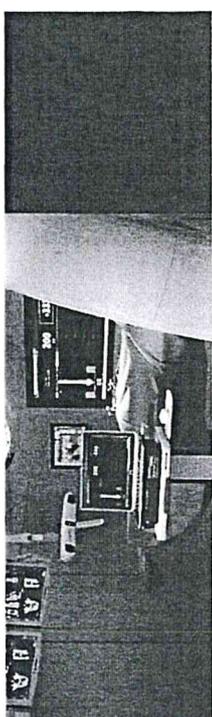
- Needle Recording Kit: Contains eight pairs of color-coded sterile, single-use subdural needles recording electrodes, a surface ground electrode, a sterile stimulus return electrode and dual twisted pair train of four surface electrodes. NIM1004 contains a Stimulating Ring Electrode in addition to the above components.
- NIM\* Stimulation Kit: Contains sterile, single-use, dual twisted pair, stainless steel, conforming subdural needle electrode

PRODUCT	DESCRIPTION	QTY
NIM1003	Needle Recording Electrode Kit (4-Channel)	1
NIM1004	Needle Recording Electrode Kit (4-Channel) with Stimulating Ring Electrode	1
MFP1001	MFP Stimulation Electrode Kit, contains 2 conforming electrodes with 2m paired cable	1
SHE1002	Surface Recording Electrode Kit (4-Channel)	1
RSE1000	Stimulating Ring Electrode Kit, sterile, single-use, dual twisted pair, stainless steel, conforming subdural needle electrode. Features colored pair labeled leads for fused, long-pole connections.	1



**KIT COMPONENTS**

- Needle Recording Electrode (Close-Up)
- Stimulating Ring Electrode
- Surface Snag Electrode
- Stimuli Stimuli Electrode
- Conformer Electrode
- Needle Recording Electrode
- Stimulating Ring Electrode
- Surface Snag Electrode
- Stimuli Stimuli Electrode
- Conformer Electrode



**ENDOTRACHEAL TUBES**

- Monitor's vocal cords and recurrent laryngeal nerves of EMG activity during surgery
- Recording electrode leads are twisted pair
- Various electrode designs to meet your needs
- Packaged sterile with one green and one white subdural needle electrode

PRODUCT	DESCRIPTION	QTY
8225960	NIM FLEX EMG Endotracheal Tube	1
8225965	NIM FLEX EMG Endotracheal Tube	1
8225970	NIM FLEX EMG Endotracheal Tube	1
8225975	NIM FLEX EMG Endotracheal Tube	1
8225980	NIM FLEX EMG Endotracheal Tube	1
8225985	NIM FLEX EMG Endotracheal Tube	1



**IRVINGTAGE™ EMG ENDOTRACHEAL TUBES**

PRODUCT	DESCRIPTION	QTY
8225905	IRVINGTAGE™ EMG Endotracheal Tube	1
8225906	IRVINGTAGE™ EMG Endotracheal Tube	1
8225907	IRVINGTAGE™ EMG Endotracheal Tube	1
8225908	IRVINGTAGE™ EMG Endotracheal Tube	1
8225909	IRVINGTAGE™ EMG Endotracheal Tube	1

**STANDARD EMG REINFORCED ENDOTRACHEAL TUBES**

PRODUCT	DESCRIPTION	QTY
8225906	STANDARD EMG Reinforced Endotracheal Tube	1
8225907	STANDARD EMG Reinforced Endotracheal Tube	1
8225908	STANDARD EMG Reinforced Endotracheal Tube	1

# NECK SURGERIES NERVASSURE™

THYROID WITH  
NERVASSURE™

SET UP

MONITORING

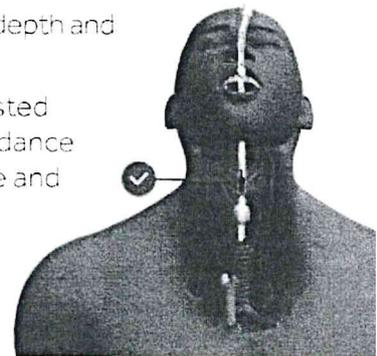
USING THE  
INCREMENTING PROBE

## POSITIONING THE EMG TUBE EXAMPLE OF THE NIM TRIVANTAGE™ TUBE

These instructions do not replace or supersede the instructions for use. It should not be considered the exclusive source of information and should be used in conjunction with the device manual.

- Determine the proper size tube for the individual patient prior to intubation. A tube that is one size larger than standard selection is recommended to improve electrode contact with vocal cords.
- Lubricate cuff with an aqueous lubricant for intubation. Use only non-anesthetic lubricants. Avoid local anesthetic gas and solutions which may impair monitoring.
- 234 ■ Place the tube so that the marking is anterior, with red wire on the right and blue wire on the left.
- Visualize electrode contact with the true vocal cords. A blue cross-hair is printed, anteriorly, on the tube to aid placement. The tube is optimally placed with the vocal folds in contact with the wide blue cross-hair section.
- Confirm the depth of intubation per the procedure for non-reinforced endotracheal tubes. The EMG Endotracheal tube has depth markings on the surface of the tube. Electrode depth and location should be checked against preoperative inspection using these markings.
- Use the EMG monitor to measure electrode impedance and imbalance. Suggested impedance values for the EMG Endotracheal tube are less than 5 kOhms. Impedance imbalance values of less than 2 kOhms are recommended between the positive and negative electrodes of a channel. Reposition if necessary.
- Secure the tube once positioned properly in the trachea.

**Note:** A bite block is recommended for use with the EMG Endotracheal tube to prevent damage to the tube.



## PROPER POSITIONING

### TRIVANTAGE

- 234 ■ Blue cross at the vocal cords
  - 4 Silver ink electrodes
  - Black numbers and cuff anterior (12h), median
- Unique reference for Superior Laryngeal Nerve monitoring**

### FLEX TUBE

- Use of a stylet often required
- Symmetric electrodes (double black bands) against
- vocal cords – 2/3 behind VF/ 1/3 before
- Cuff anterior (12h), median



## NIM Tr Vantage™ EMG Endotracheal Tube

35

- Recording electrode leads are twisted pair
- Packaged sterile with one green and one white subdermal needle
- Single use

23.6

Product	ID	OD	Qty
8229705	5.0 mm	6.5 mm	1
8229706	6.0 mm	8.2 mm	1
8229707	7.0 mm	9.5 mm	1
8229708	8.0 mm	10.7 mm	1
8229709	9.0 mm	12.0 mm	1
8229735	5.0 mm	6.5 mm	3
8229736	6.0 mm	8.2 mm	3
8229737	7.0 mm	9.5 mm	3
8229738	8.0 mm	10.7 mm	3
8229739	9.0 mm	12.0 mm	3



## NIM Contact™ EMG Reinforced Endotracheal Tube

- Recording electrode leads are twisted pair
- Packaged sterile with one green and one white subdermal needle
- Single use

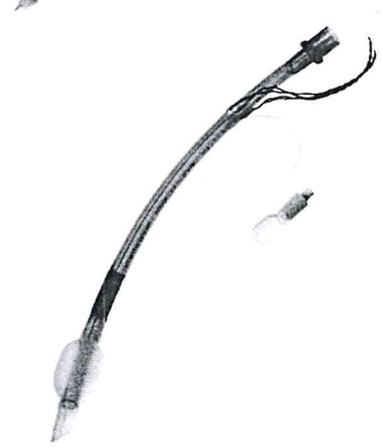
Product	ID	OD	Qty
8229506	6.0 mm	9.0 mm	1
8229507	7.0 mm	10.5 mm	1
8229508	8.0 mm	11.5 mm	1



## NIM™ EMG Reinforced Endotracheal Tube

- Recording electrode leads are twisted pair
- Packaged sterile with one green and one white subdermal needle
- Single use

Product	ID	OD	Qty
8229306	6.0 mm	8.8 mm	1
8229307	7.0 mm	10.2 mm	1
8229308	8.0 mm	11.3 mm	1



Nerve Monitoring Equipment

All measurements in millimeters  
ID = Inner Diameter, OD = Outer Diameter

37

# Monopolar probes

## STANDARD PRASS FLUSH-TIP MONOPOLAR STIMULATOR PROBE

24.9 The single-use Standard Prass Monopolar Stimulating Probe is used for locating and mapping cranial nerves in the surgical field. It features a flush 0.5 mm tip and is insulated to the tip to prevent current shunting. Individually sterile packaged.

Product	Description	Qty
8225101	TIPS AND HANDLES	5
8225110	TIPS ONLY	10

## BALL-TIP MONOPOLAR STIMULATOR PROBE

With a flexible tip and shaft, the single-use Ball-Tip Monopolar Stimulating Probe enables greater access to neural structures. The 1 mm tip diameter allows atraumatic contact to larger neural structures. To prevent current shunting, the probe is insulated to the tip. Individually sterile packaged.

Product	Description	Qty
8225275	TIP AND HANDLE, 1 MM	1
8225277	TIPS ONLY, 1 MM	10
8225276	TIP AND HANDLE, 2.3 MM	1
8225278	TIPS ONLY, 2.3 MM	10

## YINGLING FLEX TIP MONOPOLAR STIMULATOR PROBE

The highly flexible, single-use Yingling Monopolar Stimulating Probe allows stimulation in areas outside the surgeon's field of view. The platinum-iridium wire of the probe is fully insulated to the ball tip to prevent current shunting. Individually sterile packaged with one green subdermal electrode.

Product	Description	Qty
8225251	TIPS AND HANDLES	5

## INCREMENTING PROBE\*

The Incrementing Probe allows you to easily adjust the stimulus level from within the surgical field and to print or save the screen display.

Product	Description	Qty
8225825	PRASS STANDARD TIP	3
8225490	BALL TIP, 1 MM	3

\*For use with NIM-Response® and NIM-Neuro® models 2.0 and later.

## MONOPOLAR PROBE HANDLES, STERILE

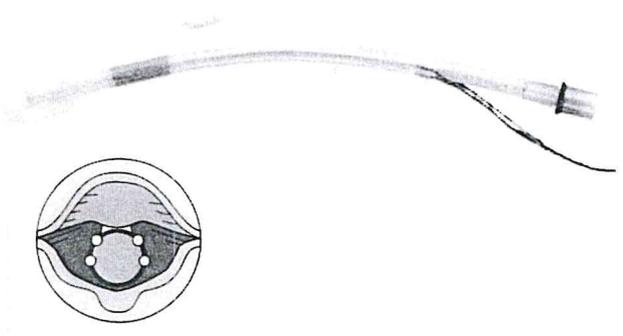
Product	Description	Qty
8225051	HANDLES	10



**NIM® STANDARD REINFORCED EMG ENDOTRACHEAL TUBE**

Recording electrode leads are twisted pair. Packaged sterile with one green and one white subdermal needle. Single use.

Product	ID	OD	Qty
8229306	6 MM	8.8 MM	1
8229307	7 MM	10.2 MM	1
8229308	8 MM	11.3 MM	1



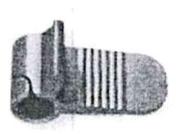
**Specialty**

**APS® (AUTOMATIC PERIODIC STIMULATION) ELECTRODE\***

25.1 The APS® Electrode enables continuous, real-time monitoring of the vagus nerve. The electrode is placed on the nerve and delivers continuous low-level stimulation. A baseline of nerve function is obtained and subsequent EMG responses are monitored to provide real-time feedback about nerve function.

Product	Description	Qty
8228052	2 MM, SIZE RANGE 2 MM TO 3 MM	1
8228053	3 MM, SIZE RANGE 3 MM TO 4 MM	1

\* For use with NIM-Response® 3.0 and NIM-Neuro® 3.0 models only.

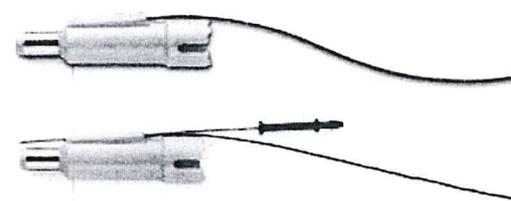


**STIM BUR GUARD\*\***

The Stim Bur Guard provides warning of the bur's proximity to the facial nerve during otologic surgery. Stimulating the nerve while the bur is in use can offer approximately 1-3 mm of advance warning.

Product	Description	Qty
3318601	WITH IRRIGATION	1
3318602	WITHOUT IRRIGATION	1

\*\* For use with NIM® models 2.0 and later, Visao® High-Speed Otologic Drill and the Integrated Power Console (IPC®) System.

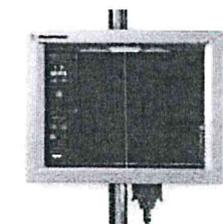


**SURGEON MINI-SCREEN†**

For easier viewing within the surgical field, the Mini-Screen can be mounted to any I.V. pole to display monitoring information from the NIM® System.

Product	Description	Qty
8253010	MINI-SCREEN AND CABLE	1

† For use with NIM-Response® 3.0 and NIM-Neuro® 3.0 models only.



**NIM® EQUIPMENT CART**

The NIM Cart provides a stable, mobile base for the NIM® system. Convenient and portable, it allows for cord management and storage of the printer, mini-screen, accessories and supplies. The cart also has two locking castors.

Product	Description	Qty
8253020	EQUIPMENT CART	1



APS™ (Automatic Periodic Stimulation) Electrode\*

- Sterile, single use

29.3 u 25.74



Product	Description	Qty
8228052	2 mm, Size Range 2 mm to 3 mm	1
8228053	3 mm, Size Range 3 mm to 4 mm	1

Stim Bur Guard\*\*

- Sterile, single use

Product	Description	Qty
3318601	With Irrigation	1 each
3318602	Without Irrigation	1 each



\*For use with NIM-Response™ 3.0 and NIM-Neuro™ 3.0 models only.

\*\*For use with NIM™ models 2.0 and later, the Visio™ High-Speed Otologic Drill and Integrated Power Console (IPC™) System.

# NECK SURGERIES NERVASSURE™

THYROID WITH  
NERVASSURE™

SET UP

MONITORING

USING THE  
INCREMENTING PROBE

## MAIN PROCEDURES

- Thyroidectomy
- Parathyroidectomy
- Neck dissection

25-1

## REQUIRED DISPOSABLES



**EMG ENDOTRACHEAL TUBE**  
8229xx.....

**ELECTRODE APS 2MM OR 3 MM**  
(with 1 stim return needle in the package)  
8228052..... 2mm, Size range 2 to 3mm  
8228053..... 2mm, Size range 2 to 3mm

### SIMULATOR PROBE

#### STANDARD MONOPOLAR STIMULATOR PROBES

- 8225101..... Prass Flush-Tip  
(tip and handle)
- 8225275..... Ball Tip (tip and handle)

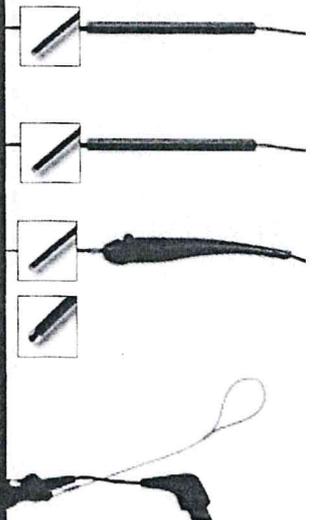
#### INCREMENTING PROBE

- 8225825..... Prass Standard Tip
- 8225490..... Ball Tip

#### NIM VITAL™ INCREMENTING PROBE ADAPTOR

NIMCAD 400

*\*Required if legacy incrementing probe  
is used.*



41

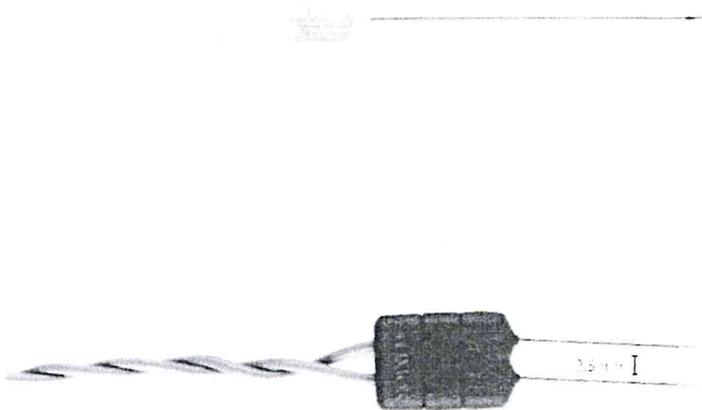


# Electrodes

## EMG HOOKWIRE ELECTRODES

Hookwire Electrodes may be ordered individually or in pairs. Each is silicone-coated to within 3 mm of the tip. The electrodes are designed for intramuscular placement to obtain a more specific response. Each electrode is 25 mm long with a 1 m wire. Packaged sterile with one green and one white subdermal needle. Single use.

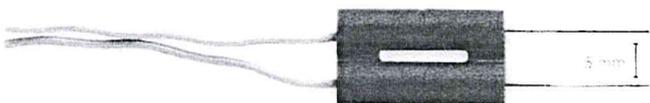
Product	Description	Qty
8226326	PAIRED ELECTRODES	1 SET
8226626	SINGLE ELECTRODES	6



## PAIRED SUBDERMAL ELECTRODES

Designed for optimal performance, the Paired Subdermal Electrodes are color-coded for easy patient setup. They feature twisted wires to provide noise shielding. These electrodes are available for 2-channel, 4-channel, and 8-channel monitoring procedures. Sterile packaged with one green and one white subdermal electrode. Single use.

Product	Description	Qty
8227410	2-CHANNEL, 12 MM	1 SET
8227411	4-CHANNEL, 12 MM	1 SET
8227412	8-CHANNEL, 12 MM	1 SET
8227465	MIX 1: RED, BLUE, ORANGE, VIOLET, GRAY	25
8227466	MIX 2: YELLOW, GREEN, TAN, BLACK, WHITE	25



## PRASS PAIRED ELECTRODES

Muscle-specific and single-use, the Prass Paired Electrodes are insulated to within 5 mm of the tip with 5 mm spacing between electrodes. The color-coded cables are twisted pair. Individually sterile packaged.

Product	Description	Qty
8227304	2-CHANNEL, 18 MM, 1 M	5 SETS
8227301	2-CHANNEL, 25 MM, 1 M	5 SETS
8227307	2-CHANNEL, 38 MM, 1 M	5 SETS
8227500	4-CHANNEL, 18 MM, 2 M	1 SET
8227505	4-CHANNEL, 25 MM, 2 M	1 SET
8227510	2-CHANNEL, 18 MM, 2 M	5 SETS
8227515	2-CHANNEL, 25 MM, 2 M	5 SETS



## PRASS PAIRED ELECTRODES WITH SMALL HUB

Muscle-specific and single-use, the Prass Paired Electrodes are insulated to within 5 mm of the tip with 2.5 mm spacing between electrodes.

These electrodes feature a longer needle length for deeper access to the targeted muscle. Individually sterile packaged.

Product	Description	Qty
8227414	2-CHANNEL, 12 MM	5
8227415	4-CHANNEL, 12 MM	5
8227418	2-CHANNEL, 18 MM	5
8227419	4-CHANNEL, 18 MM	5

26.2

26.5  
26.3

26.6

26.5

26.4

\* For use with NIM-Response\* 3.0 and NIM-Neuro\* 3.0 models only.

\*\* For use with NIM\* models 2.0 and later, Visao\* High-Speed Otologic Drill and the Integrated Power Console (IPC\*) System.

42

# PAROTID INTERMITTENT MONITORING

PAROTID 4 CH  
(1-2-3-4)

SET UP

MONITORING

USING THE  
INCREMENTING PROBE

## REQUIRED DISPOSABLES

	<p><b>SUBDERMAL ELECTRODES 2 OR 4 CHANNELS</b></p> <p><b>PAIRED SUBDERMAL ELECTRODES</b>              8227410.....2-channel, 12 mm              8227411.....4-channel, 12 mm</p> <p><b>PRASS PAIRED ELECTRODES</b>              8227304.....2-channel, 18 mm, 1 m              8227301.....2-channel, 25 mm, 1 m              8227307.....2-channel, 38 mm, 1 m              8227500.....4-channel, 18 mm, 2 m</p> <p><b>PRASS PAIRED ELECTRODES WITH SMALL HUB</b>              8227414.....2-channel, 12 mm              8227415.....4-channel, 12 mm              8227418.....2-channel, 18 mm              8227419.....4-channel, 18 mm</p> <p><b>SIMULATOR PROBE</b></p> <p><b>STANDARD MONOPOLAR STIMULATOR PROBES</b>              8225101..... Prass Flush-Tip (tip and handle)              8225275..... Ball Tip (tip and handle)</p> <p><b>INCREMENTING PROBE</b>              8225825..... Prass Standard Tip              8225490..... Ball Tip</p> <p><b>NIM VITAL™ INCREMENTING PROBE ADAPTOR</b>              NIMCAD 400  <i>*Required if legacy incrementing probe is used.</i></p>	
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43



### Cleaning

Refer to the "Cleaning and Maintenance" topic.

### Storage

Allow the unit and accessories to thoroughly air-dry before storing in a cool dry place. Refer to the "Technical Specifications" topic for further information.

### Troubleshooting

Should you encounter any difficulty eliciting simulated responses from the NIM Vital™ system patient simulator, check the following:

- Verify that the Stimulus Measured is approximately the same as the Stimulus Intensity.
- Make sure the jumper cables are connected correctly between the SIMULATOR and PATIENT INTERFACE.
- Adjust the EVENT THRESHOLD setting on the NIM Vital™ system.
- Adjust the STIMULUS intensity on the NIM Vital™ system for adequate output.
- Clean the stimulator contacts of debris.
- Check the integrity of the stimulator or stimulus-dissection instrument and its connecting cable.
- Check for a blown fuse in NIM Vital™ system patient interface and replace with a proper valued fuse (shown near fuse box).
- Check for proper closure of fuse holder in the NIM Vital™ system patient interface.

### Customer service information

For further information regarding the use of this product or to report any problems, please contact Medtronic using the appropriate information provided on the blue and white contact information card packaged with each device; or contact your local distributor.

### External display support

The NIM Vital™ system has the following external video ports, but does not have any specific connection settings for a microscope output:

- HDMI
- Display

### Wireless display module

The wireless display module enables users to wirelessly replicate the NIM Vital™ console display onto any monitor with an HDMI input port. Refer to the installation instructions packaged with the wireless display module.

### NIM Vital™ Mute adapter

The NIM Vital™ mute adapter enables the NIM Vital™ console to be connected to an external muting detector.

1. Console Connector (below knobs).
2. Connector to mute probe.
3. Tether.

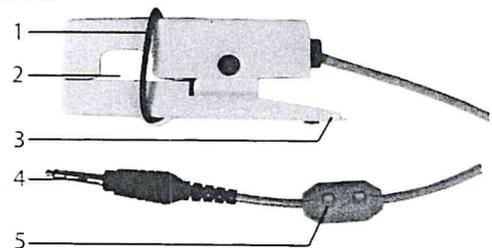


### NIM Muting detector

Refer to the "Precautions" topic for additional information.

The optional Muting Detector Probe is designed to detect the presence of electronic noise from external devices (such as electrocautery/electrosurgical unit) that may cause interference on the EMG monitor. The use of a mute probe could be considered if there is excessive noise from the electrosurgical unit.

1. Anti-slide Ring.
2. Electronic Noise Detection Area.
3. Insulating Sleeve.
4. Cable Connector.
5. Ferrite.



**2 psl.**

1. NIM Vital sistema skirta nervų lokalizacijoms ir stebėjimui, įskaitant stimuliavimą, kranialinėje, stuburo, periferinių ar maišytų motosensorinių nervų srityse, bei EMG registravimui operacijų metu.

1. NIM Vital sistema yra intraoperacinis EMG monitorius kuris leidžia rasti, patvirtinti nervų vietą ir užtikrinti jų vientisumą.

2. NIM Vital sistema naudojama EMG monitoravimui ir pagalbai chirurginių procedūrų metu:

Intrakranijines, ekstrakranijines, intratemporalines, ekstratemporalines procedūras ir operacijas, susijusias su kaklu - skyd liaukė, prieskydinė liauka: stuburu, krūtinės lasta ir viršutinėmis bei apatinėmis galūnėmis.

**3 psl.**

2. Procedūros susijusios su kaklu: skyd liaukės ir prieskydinės liaukos operacijos.

**4 psl.**

3.1. Didelio kontrasto, spalvotas, lietimui jautrus (touch screen) ekranas, prisitaikantis prie lietimo chirurginėmis pirštinėmis.

3.2. Ekranu skiriamoji geba 1920x1080 taškai.

**5 psl.**

3.1. Liečiamas ekranas

**6 psl.**

3.3. Ekranu padėtis keičiama ir reguliuojama: lengvai patraukite konsolės monitorių į viršų ar arčiau savęs, veiksma tęskite kol ekranas bus jums tinkamoje padėtyje. Sukite monitorių, kol jis bus atsuktas į jus.

**7 psl.**

4. Konsolė turi belaidę sąsają, kurios deka galima replikuoti konsolės vaizdą į bet kokį ekraną.

**8 psl.**

4. NIM Vital konsolės perduodamas vaizdas į LCD ekraną, taip sudarant galimybes konsolę naudoti skirtingose operacinėse.

**9 psl.**

5. Konsolės belaidė paciento sąsaja.

**10 psl.**

6. NIM Vital ekrane įspėja naudotojus apie atsiradusį trikdį ir pateikia galimus trikdžio sprendimo žingsnius.

**11 psl.**

7. Nervo stimuliacijos metu, išsukiamas EMG signalas su amplitude ir girdimas garsinis tonas/signalas.

**12 psl.**

7. NIM Vital konsolė skleidžia daug skirtingų garsų chirurginės procedūros metu, kurie įspėja vartotoją apie svarbią informaciją ir procedūros eigą. Greta EMG skleidžiamo signalas, konsolė skleidžia pypsėjimo garsus ir balsinius pranešimus, kad pateiktų vartotojui svarbią informaciją.

7. Konsolė turi aliarmo garsą, kuris girdimas visais atvejais kuomet susidaro situacija dėl kurios negalimas tinkamas atliekamos procedūros monitoravimas.

**13 psl.**

7. Balsiniai pranešimai girdimi stimuliacijos metu, girdima STIMULUS komanda. Balsiniai pranešimai girdimi nustatymų atveju, balsas informuoja apie nustatytas stimuliacijos vertes.

10. Garso signalai gali būti įjungiami/išjungiami.

**14 psl.**

12. Du nepriklausomi stimuliaciniai kanalai:

16. Stimuliacijos kontrolės keitimo žingsniai valdomi. Pasirenkami žingsniai: 0.01; 0.05; 0.1; 0.5 ir 1.0 mA

15. Stimuliacijos impulso trukmė pasirenkama diapazone: 50; 100; 150; 200; 250 arba 1000  $\mu$ s.
8. Garsą galima reguliuoti tiek rankenėle ant aparato korpuso, tiek ir konsolės ekrane.
7. Integruotas garsiakalbis
- 15 psl.**
8. Garso rankenėlė ant konsolės korpuso.
- 16 psl.**
8. Garso valdymas konsolės ekrane.
- 17 psl.**
9. Elektrodo išdėstymo "gidas": matomas galimas elektrodo išdėstymas priklausomai nuo pacientui būsimos atliekamos procedūros.
- 18 psl.**
10. Garsinių signalų užtildymas/išjungimas ekrane.
- 19 psl.**
11. 4 EMG kanalai
17. Automatinė elektrodo tikrinimo funkcija
20. Artefaktų aptikimas: automatinis artefaktų aptikimas ir nutildymas tiek laidiniuose konsolės režimuose tiek belaidžiuose.
18. Nuolatinis monitoravimas elektrokoaguliacijos metu
12. Du nepriklausomi kanalai, kurie skirti nepertraukiamai ir nuolatinei stimuliacijai
- 20 psl.**
11. Teigiamo ir neigiamo impedanso reikšmė visuose **4 kanaluose**.
- 21 psl.**
12. STIM1 ir STIM2 elektriniai stimuliacijos kanalai yra nepriklausomi nuo vienas kito ir naudojami nepertraukiamai ir nuolatinei stimuliacijai.
- 22 psl.**
13. Sistema pateikia vizualinį ir garsinį atsaką į bet kokią tyčinę ar netyčinę nervo stimuliaciją ir taip įspėja naudotojus operaciniėje.
- 23 psl.**
14. Stimuliacijos intensyvumo ribos 0.01 iki 50.0 mA
- 24 psl.**
17. Elektrodo patikros metu konsolė pateikia automatinį atsaką į prijungtus elektrodus: žalia varnelė indikuoja, jog elektrodai prijungti teisingai; besisukanti ikona indikuoja, kad vykdomas elektrodo testavimas; raudonas X indikuoja, jog elektrodas netinkamas arba blogai prijungtas.
- 25 psl.**
17. Automatinė elektrodo patikra nurodo būklę apie kiekvieną prijungtą elektrodą.
- 26 psl.**
19. Elektrodo atliekamas nuolatinis nervo klajoklio monitoravimas realiu laiku, itin žemos stimuliacijos būdu
- 27 psl.**
21. Konsolė suteikia galimybę sustabdyti arba „užšaldyti“ ekrane matomą vaizdą signalo įvertinimui, nesustabdant monitoravimo ir garsų fone.
- 28 psl.**
- 22.2. Ataskaitos gali būti saugomos .pdf formatu, bei galimos eksportuoti į prijungtą USB laikmeną
- 29 psl.**
- 22.2 Saugoti .pdf klavišas
- 30 psl.**

22.1. Informacijos apie pacientą įvedimas: paciento ID; vardas; pavardė; gimimo data; profilio pavadinimas (dažniausiai nurodoma atliekama procedūra)

**31 psl.**

22.3. Galimybė prijungti monitorių: spaudintuvą; USB laikmeną

**32 psl.**

22.3. Galima naudoti prijungtą klaviatūrą

**33 psl.**

23.1. Endotrachėjinis vamzdelis turi kontaktinius elektrodus abiejų stygų monitoravimui operacijos metu. Visi vamzdeliai turi po dvi poras bipolinių elektrodų (iš viso 4 elektrodai).

23.3. Pasirenkama iš 5 dydžių

**34 psl.**

23.2. Vamzdelis komplektuojamas su įžeminimo elektrodu (žalias) ir stimulo grįžimo elektrodu (baltas).

**35 psl.**

23.2. Vamzdeliai turi suporuotą įrašymo elektrodą (komplekte/pritaisyti prie vamzdelio)

23.2. Steriliai supakuota komplektacijoje subderminiai žalias ir baltas elektrodai (stim grįžimo ir įžeminimo)

**36 psl.**

23.4. Įstatykite vamzdelį taip, kad žymė būtų priekinėje padėtyje (pozicionavimo žymė). Pozicionavimo žymė – mėlynas kryželis prie balso stygų.

23.1. 4 elektrodai

**37 psl.**

23.5. ir 23.6. Sterilu ir vienkartinio naudojimo.

**38 psl.**

24.1. Standartinis monopolinis nervu stimulatorius, tiesus

24.3. Vienkartinis

24.4. Sterilu

24.2. Komplektuojama su rankenomis (5 stimulatoriai ir 5 rankenos), viskas supakuota individualiai.

**39 psl.**

25.1. APS elektrodai skirti nuolatinei nervo klajoklio stimuliacijai

25.2. Pasirenkama iš 2 dydžių

**40 psl.**

25.3. ir 25.4. Sterilu, vienkartinio naudojimo

**41 psl.**

25.1. APS elektrodas naudojamas nuolatinei nervo klajokio stimuliacijai ir stebėjimui skydliaukės, prieskydinės liaukos ir kaklo operacijų metu.

**42 psl.**

26.5. Vienkartiniai elektrodai

26.2. Elektrodai insuliuoti 5mm iki adatos galo

26.3. 2.5mm tarpas tarp adatų

26.6. Individualiai supakuotos, sterilios

26.1. 2 arba 4 kanalų

26.4. Dviejų ilgių

**43 psl.**

26.1. Elektrodai subderminiai (poodiniai) poriniai

**44 psl.**

27.1. Artefaktų slopinimo jutiklis skirtas aptikti ir trikdžiams iš kitų prietaisų