

87654321

REV

DESCRIPTION

CN

BY

APPR

DATE

02

UPDATE LABEL FOR UDI COMPLIANCE.

21217

MPK

SEE

AGILE

03

REWORD LABEL NOTES FOR CLARIFICATION

21694

JJM

SEE

AGILE

04

Up rev for traceability of Update IFU.

27635

MPK

See

Agile

LAST 3 REVS

Y RoHS Compliant to 2011/65/EU

Y Latex Free

Y BPA Free

Y DEHP <0.1% by Weight

Affix the label such that the tick marks straddle the intersection of the top and bottom sections of the box.

60mm (REF)

90mm (REF)

Eras Bold ITC 11pt font, Regular

14 x 0.38mm  
Stainless Steel Needle  
DIN 42802 connector

Disposable 12 Color  
Natus Ultra Subdermal  
Needle Electrode

Length: 1.5m

Qty: 24

REF

019-476900

LOT

XXXXXXXX

XXXX-XX-XX

Use By

Distributed by:  
Natus Neurology Incorporated  
3150 Pleasant View Road  
Middleton, WI, USA 53562  
Made in Indonesia

USA Only  
Rx Only

0086

EC REP

Natus Manufacturing Limited  
IDA Business Park  
Gort, Co. Galway, Ireland

(01)GTIN(11)(10)LOT NUMBER (EXAMPLE ONLY) 04

COMPONENT NOTE:

Pin Socket material/ design: Tin plated brass no ridges

Overmold material: PVC 85A

Guide pin size: 1.50mm +/- 0.01

Wire Specs: Tin plated copper19/0.10/1.2mm TC with PVC insulation

UNLESS OTHERWISE SPECIFIED DIMENSIONS ARE IN INCHES. TOLERANCES ARE:

.X± 0.1

.XX± 0.02

.XXX± 0.015

∠ ± 1°

√ SURFACE FINISH

REMOVE ALL BURRS, BREAK SHARP EDGES  
DRAWING PER ANSI Y14.5  
WELDING SYMBOLS PER AWS A2.0

DO NOT SCALE DRAWING

MATERIAL

SEE NOTES

FINISH

SEE NOTES

DESIGN BY  
Matthew Keller

DATE  
03-JUL-2014

APPROVED BY

DATE

natus  
neurology

Natus Neurology Incorporated  
3150 Pleasant View Road  
Middleton, WI 53562

TITLE  
ELC/DISP 12COLOR/ULTRASUB,1.5M

SIZE  
B

DRAWING/PART NO.  
019-476900

REV  
04

SCALE: NTS

E-FILE:  
019-476900.ai

SHEET 1 OF 1

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LABEL NOTES:

1. Text and graphics, indelible black.

2. Barcode format for **non-UDI** barcoding is USS 128 auto compressed.  
Barcode position shown for reference only.  
Barcode to be printed by manufacturer.  
LINEAR BARCODE HEIGHT: MINIMUM: 0.2" / OPTIMAL: 0.5" / MAXIMUM 1.25"  
MINIMUM FONT SIZE FOR HUMAN-READABLE PORTION OF BARCODE AND REF, LOT, EXP. DATE TEXT: 6 POINT (8 POINT RECOMMENDED)  
Manufacturing date and use before date format **not** contained in UDI: **YYYY-MM-DD**

3. Barcode format for 2D UDI barcoding is GS1- DataMatrix:  
Barcode position shown for reference only.  
2D Barcode Size: MINIMUM 0.10" x 0.10" / OPTIMAL: 0.40" x 0.40 / MAXIMUM: 0.75" x 0.75"  
Barcode to be printed by manufacturer.  
Computer readable portion should include GTIN, serial, lot and/or expiration date (as required) and shall **not** contain brackets ( ) surrounding the application identifier.  
Human readable portion shall include brackets ( ) around application identifier:  
(01) **00382830040013** Natus GTIN number for this item only  
(10) Batch/Lot Number (If Applicable)  
(11) Production Date (If Applicable)  
(17) Expiration date (If Applicable)  
(21) Serial Number (If Applicable)  
**GTIN** = GLOBAL TRADE IDENTIFICATION NUMBER PROVIDED BY NATUS.  
**LOT** = LOT NUMBER OF PRODUCT. (IF APPLICABLE)  
**PRODUCTION DATE** = TO CONTAIN THE PRODUCTION DATE OF PRODUCT. (IF APPLICABLE)  
**EXPIRATION DATE** = TO CONTAIN THE EXPIRATION DATE OF PRODUCT. (IF APPLICABLE)  
**SERIAL NUMBER** = SERIAL NUMBER LOCATED ON THE PRODUCT. (IF APPLICABLE)  
All UDI barcode (human readable and machine readable) date formats: **YYMMDD**

4. FINISHED PARTS TO COMPLY TO EU ROHS DIRECTIVE 2011/65/EU.

FRM-0250 REV 04  
DCO# 9892