

URGENT FIELD SAFETY NOTICE

CareSens N™ Glucose Meters and associated test strips Field Communication for Awareness

For the Attention of Users and UK Retail suppliers of CareSens N™ Glucose Meters and Strips

Affected products:

| | |
|--|---------------|
| Product Reference CareSens N Strip: 159104-204 | SKU: 345-7546 |
| Product Reference CareSens N Meter: 159363-201 | SKU: 345-7553 |
| Product Reference CareSens N POP Meter: 159465-303 | SKU: 374-9454 |
| Product Reference CareSens N Voice Meter: 159445-302 | SKU: 381-1551 |

CareSens N™ Glucose Meters and test strips

All Lot Numbers of strips and meters supplied after the 1st December 2015

Description of problem:

Spirit Healthcare Ltd, the UK distributor of the CareSens N™ Glucose meters and strips work continuously to ensure that a high quality product is consistently delivered that meets UK market needs.

This included modification of the test strips for the UK Market, in discussion with the UK Competent Authority, in 2012.

Spirit Healthcare have recently become aware that other designs of CareSens N Strips, which do not incorporate these features, are being imported into the UK market, potentially compromising the quality of results from meters distributed by Spirit Healthcare Ltd.

To ensure that the highest standards are maintained for the UK market, Spirit Healthcare Ltd would like to communicate minor design changes to all new test strips and glucose meters distributed to the UK market

All CareSens N™ meters distributed by Spirit Healthcare Ltd will only be compatible with UK livery test strips which incorporate the designs intended for the UK market.

These modified test strips will be backwards compatible with both existing CareSens N™ meters already in use in the market and with new meters distributed by Spirit Healthcare Ltd. Users of existing meters will see no change in the performance of their glucose meters.

The previous design of the glucose test strip will not be compatible with new glucose meters and will not display a result if an incompatible strip is used.

The modified test strips can easily be visually distinguished from other models as illustrated below. In the new strip design a notch has been added to positively engage with the meter.

All packs of the modified strips will contain an image of the red Spirit Healthcare Logo on the pack as demonstrated below

Spirit Healthcare Ltd.

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24/7 NON-AUTOMATED SUPPORT

0800 881 5423

Registered in England & Wales no: 06259954

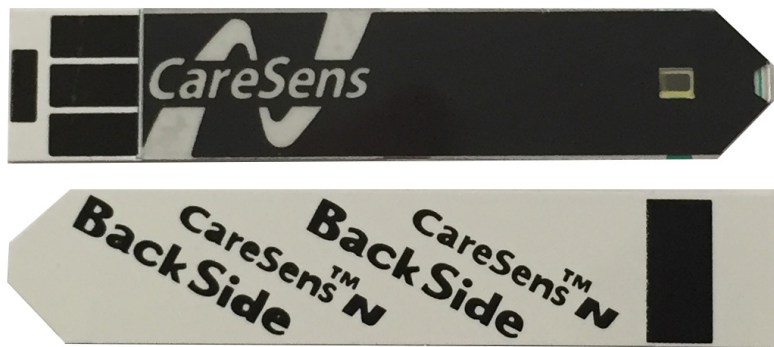


Figure 1: Previous CareSens N™ strip design

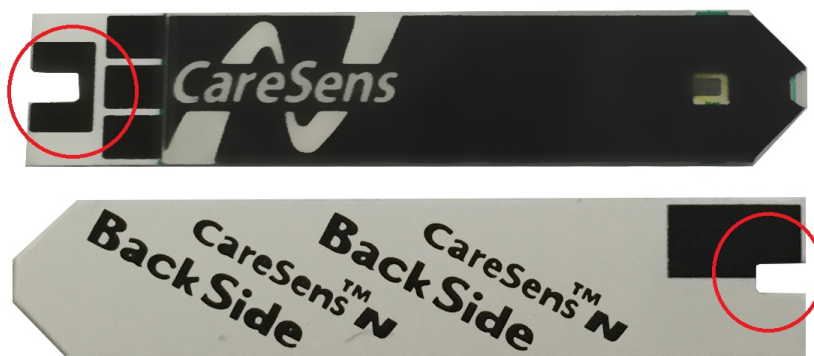


Figure 2. New Modified CareSens N™ Strip design. Note inclusion of engagement notch as described



Figure 3: Strips that are compatible with CareSens N™ glucose meters distributed by Spirit Healthcare Ltd are clearly identified on packaging with the Spirit Healthcare Logo

Action to be taken:

For End Users

All new CareSens N™ Meters distributed in the UK by Spirit Healthcare Ltd, will be accompanied by a notification which will allow the user to identify compatible and incompatible test strips as illustrated in this field notification. This communication will clearly identify incompatible designs of test strips and provide contact details for Spirit Healthcare Ltd Customer Care in case of issues. New design meters will be distributed with a small quantity of compatible test strips in case the responsible pharmacist does not issue the correct strips to accompany the meter

Users and retail distributors of CareSens N™ strips are warned that the strips of unknown provenance will not function with CareSens N™ meters distributed by Spirit Healthcare Ltd from the date shown above and should therefore be disposed of by the user or distributor.

Spirit Healthcare Ltd will directly contact all know product outlets of this market change with a copy of this Field Safety Notice, requesting acknowledgement of communication of this change.



Date: 12th November 2015

Chris Barker
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This Field Safety Notice has been notified to the UK MHRA.

Customer Reply Form (before 20th November 2015)

PLEASE COMPLETE and return to Spirit Healthcare

CUSTOMER CONTACT INFORMATION

| | | | | | |
|----------------|--|-----------|--|--------------|--|
| Pharmacy name | | | | Contact Name | |
| Other Sites | | | | | |
| Street Address | | | | City | |
| County | | Post Code | | Country | |
| Phone | | | | Email | |

Please contact me regarding exchange of non UK Livery Packs (tick here) ☐

By signing below, I acknowledge receipt of the letter and I accept to follow and to apply the safety instructions. Please record below the date on which your facility received this information.

| | |
|----------------|------|
| Name and Title | Date |
| | |
| Signature | |
| | |

Please FAX back to:

+44 (0) 116 271 9901

Or Email to:

cs@spirit-healthcare.co.uk

Or Post to:

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