

## PRODUCT DATASHEET

Model: PDRNGVIVIX10

Description: **Mobile DR Panel Holder for Vivix 10x12" Panel**

Revision: May 2018

### PRODUCT ATTRIBUTES:

- Holds DR Panel during exams.
- Protects DR Panel during routine handling.
- Provides ergonomic handle and double positive lock to secure DR.
- Made of shock absorbing materials.

### MATERIAL COMPOSITION

**Reina**Imaging



PART	MATERIAL	APPROXIMATE %
Shell	HDP	98
Overlay	Polycarbonate Film	2

### DIMENSIONS AND PERFORMANCE

Product Dimension: 14.6 x 14.3 x 0.934 in. (37.1 x 36.3 x 2.38 cm)

Weight: 1.3 lbs. (0.58 kg)

Weight Tolerance: 400 lbs. (181.4 kg)

*Not designed for weight bearing exams. Not to be used without an image receptor.*

### FLAMMABILITY RATING

The product is non-flammable under the normal operating conditions of the DR Panel.

UL Rating: UL94V-2.

### BIOCOMPATIBILITY

This model is a biocompatible device per ISO 10993.

### STATEMENT OF CONFORMANCE

Reina Imaging hereby states that the data, specifications, and descriptions contained herein this document are accurate and representative of the models being described.

### REGISTRATIONS AND COMPLIANCE

All models listed above are made in the USA and registered to:

**Reina Imaging**

**6107 Lou Ave.**

**Crystal Lake, IL 60014 USA**

### AUTHORIZED EU REPRESENTATIVE

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### DEVICE FAMILY CLASSIFICATION

Country	Class
USA	FDA Class 1, 510(k) exempt
Canada	Class 1
Europe	Class 1, Annex VII, CE
TGA	Class 1