

*Title*

# Extravasation Detection Accessory: Clinical Evaluation in 500 Patients

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## SUMMARY

A study was conducted at the above institutions to evaluate an accessory to detect extravasation of contrast media during CT power injection. The study concluded that E-Z-EM's contrast injector with EDA™ is *“easy to use, safe, and accurate in the monitoring of intravenous injections for extravasation, which could prove especially useful in high-flow-rate CT applications.”*

### Purpose of the Study

To assess the ability of a device (E-Z-EM's CT contrast injector with EDA – Extravasation Detection Accessory) to detect clinically important (10 mL or greater) extravascular injection of iodinated contrast material delivered with an automated CT power injector.

### Method of the Study

The study evaluated the effectiveness of the EDA device in identifying and interrupting any CT power injection associated with an extravasation of contrast media of 10 mL or greater. Five hundred patients were evaluated in four leading medical institutions. The actual presence or absence of extravasation was carefully delineated by helical CT of the arm at every injection site and quantified by using the trace function software of the scanner.

### Parameters

#### Scanners

CT HiSpeed Advantage, GE Medical Systems  
CTI, GE Medical Systems  
Somatom Plus 4, Siemens Medical Systems

#### Cannulas

20 gauge, 1.0 inch length (86%)  
22 gauge, 1.25 inch length (14%)

#### Contrast

Nonionic, low-osmolality (70%)  
Ionic, high-osmolality (30%)

#### Injection Sites

Antecubital fossa (78%)  
Forearm (10%)  
Back of the hand (7%)  
Wrist (5%)

#### Flow Rates

20 gauge cannulas – 5.0 mL/sec  
22 gauge cannulas – 3.5 mL/sec

#### Patient Set-Up Time

Less than 20 seconds



## Definitions and Results

- (96.8%) True-negative case:** No interruption of injection, and CT demonstrated no extravasation or extravasation of less than 10 mL.
- (0%) False-negative case:** No interruption of injection, and CT demonstrated clinically important extravasation.
- (0.8%) True-positive case:** EDA interrupted the injection, and CT demonstrated clinically important extravasation.
- (2.4%)\* False-positive case:** EDA interrupted the injection, and CT demonstrated no extravasation or extravasation of less than 10 mL.

*\*Nine (75%) of the 12 false-positive cases were believed to have resulted from inadvertent manipulation of the EDA electrode patch during infusion of contrast material. This occurred when nursing personnel vigorously palpated the sensor patch within seconds of bolus initiation in four patients and while monitoring the course of the injection in five. Motion at the percutaneous injection site may have contributed to a 10<sup>th</sup> false-positive case in which a patient experienced multiple tremors during the injection.*

## Discussion

Although most radiologists exercise diligence and follow recommended guidelines, extravasation of radiologic contrast material continues to be an event that occurs on the order of three to four times per month during contrast-enhanced CT. Moreover, automated power injection of contrast material may result in large-volume (50-150 mL) extravasation because the mechanical injector will continue to infuse the contrast material at a fixed pressure regardless of whether the injection is intra- or extravasacular.

## Conclusions

*“We found the EDA to be easy to use, safe, and accurate for monitoring intravenous injections for extravasation. The prevalence of clinically important extravasation in this study was 0.8% (four of 500 cases), which is comparable to extravasation rates recently reported in the literature.”*

*“...the EDA evaluated in this study demonstrated a sensitivity of 100%...and a specificity of 98%...in the detection of clinically important extravasation.”*

*“We believe that this device represents a technological breakthrough in dynamic contrast-enhanced CT and has the potential to eliminate nearly all clinically important contrast material extravasation events, whether with ionic or non-ionic contrast media. The device should prove especially useful for high-flow-rate CT applications because the EDA algorithm is configured to suspend extravasated injections at a threshold of 10 mL, regardless of injection rate. Its use may be particularly efficacious in patients who are at increased risk for extravasations and severe sequelae, including patients with preexisting intravenous catheters.”*



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